| | |
|---|---|
| Description of document: | National Institutes of Health (NIH) Transition Briefing for the Incoming Biden Administration, 2020 |
| Requested date: | 01-January-2021 |
| Release date: | 20-October-2023 |
| Posted date: | 20-May-2024 |
| Source of document: | FOIA Request<br>NIH FOIA Office<br>Building 1, Room 344<br>1 Center Drive, MSC 0188<br>Bethesda, Maryland 20892-0188<br>Fax: (301) 402-4541<br>FOIA Request Portal |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 1, Room 344
1 Center Drive, MSC 0188
Bethesda, Maryland 20892-0188
phone: (301) 496-5633
fax: (301) 402-4541

October 20, 2023

Email

Re: FOIA Case No. 55694

This responds to your January 1, 2021, Freedom of Information Act (FOIA) request addressed to the FOIA Office, National Institutes of Health (NIH). Department of Health and Human Services' (HHS) policy calls for the fullest possible disclosure provided by the FOIA, 5 U.S.C. §552, consistent with the protections contained therein. The implementing HHS Regulations establish the criteria pursuant to which the FOIA is administered, *see* 45 C.F.R. Part 5. Copies of the FOIA and the HHS FOIA Regulations are located at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm.

You requested a digital/electronic copy of the transition briefing document(s) (late 2020) prepared by NIH for the incoming Biden Administration.

NIH searched their files and found 490 pages of responsive records. I have determined to withhold portions of the enclosed pages under FOIA exemptions 5, 6, and 7a and 7e, as well as the corresponding exemptions embodies in the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 5 permits the withholding of internal government records which are predecisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy. Exemption 7(A) protects from release information that, if released, would interfere with a pending law enforcement proceeding. Exemption (7)(E) would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law. Releasing such information would show the investigative technique performed by NIH that could reasonably be expected to risk circumvention of the law.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart C of the HHS FOIA

Regulations http://www.nih.gov/icd/od/foia/cfr45.htm) to the Assistant Secretary for Public Affairs, at: https://requests.publiclink.hhs.gov/App/Index.aspx.

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Denean Standing-Ojo
Public Affairs Specialist
Office of Communications and Public Liaison
Building 31, Room 5B52S
31 Center Drive
Bethesda, MD 20814
301-496-5077 (phone)
301-496-0818 (fax)
nihfoia@od.nih.gov (email)

OGIS
National Archives and Records Admin
8601 Adelphi Rd - OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: 490 pages

U.S. Department of Health and Human Services

National Institutes of Heath

OM

November 2020

# NATIONAL INSTITUTES OF HEALTH

# OWNER'S MANUAL

NOVEMBER 2020

## Table of Contents

# ORGANIZATIONAL OVERVIEW

**NIH MISSION**

The National Institutes of Health (NIH) is the steward of medical and behavioral research for the Nation. The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The agency's goals in pursuit of this mission are to:

- Foster fundamental creative discoveries and innovative research strategies, and promote their applications as a basis to advance significantly the Nation's capacity to protect and improve health;
- Develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
- Expand the knowledge base in medical and associated sciences to enhance the Nation's economic well-being and ensure a continued high return on public investment in research; and
- Exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

As the largest source of funding for biomedical and behavioral research in the world, NIH plays a unique role in turning basic scientific discovery into improved health. NIH's significant and enduring investment in basic research today assures breakthroughs in the health care of tomorrow, and NIH's translational research aims to enhance the health of each individual. This robust research enterprise depends on NIH's ability to recruit and retain a highly creative, diverse, and well-trained workforce. With continued support, NIH contributes significantly to the economic engine that drives American competitiveness in science and technology. The resulting advances will lead to a future where all Americans can enjoy long, healthy lives.

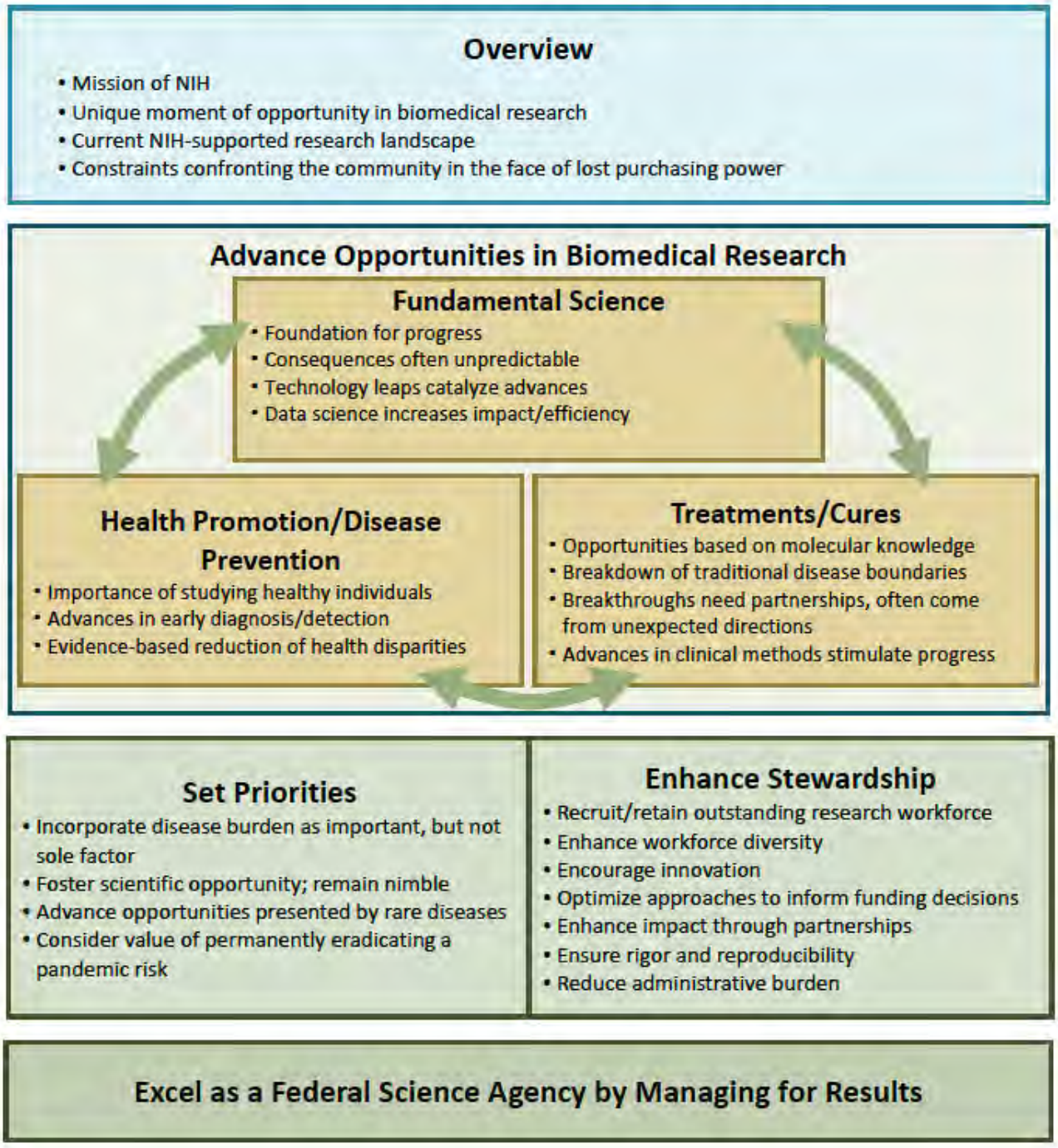
NIH is comprised of 27 different components termed Institutes and Centers (ICs). Each IC is led by a director (ICD), and develops its own specific mission and research agenda, often focusing on particular diseases/conditions. All but three ICs receive their funding directly from Congress and all 27 administer their own budgets.

**NIH STRATEGIC PLAN**

The purpose of the NIH-Wide Strategic Plan is to communicate how NIH will advance its mission to support research in pursuit of fundamental knowledge about the nature and behavior of living systems, and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

The current NIH-Wide Strategic Plan, covering FYs 2016-2020, was submitted to Congress on December 15, 2015. The strategic plan focuses on four interdependent objectives to establish a framework for carrying out its mission and optimize return on public investment. These objectives are to advance opportunities in biomedical research, foster innovation by setting NIH priorities, enhance scientific stewardship, and excel as a federal science agency by managing for results. The strategic plans of each IC are being linked to this overarching strategic plan to ensure a cohesive priority-setting process. Recent advances in portfolio analysis methods will aid efforts to prioritize NIH investments by helping NIH identify emerging scientific opportunities and optimize future scientific investments.

## NIH-Wide Strategic Plan Framework




As part of implementing the 21st Century Cures Act (P.L. 114–255), NIH will update its Strategic Plan every five years. The agency is currently developing an updated NIH-Wide Strategic Plan, for FYs 2021-2025 and is anticipating its release in early 2021. The FY 2021-2025 NIH-Wide Strategic Plan highlights NIH's approach towards the achievement of its mission while ensuring good stewardship of taxpayer funds.

The Framework for the FY 2021-2025 NIH-Wide Strategic Plan articulates NIH's priorities with three key objectives and four cross-cutting themes:

- Objective 1: Advancing Biomedical and Behavioral Sciences
- Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity
- Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

**Cross-Cutting Themes**:

- Increasing, Enhancing, and Supporting Diversity
- Improving Women's Health and Minority Health, and Reducing Health Disparities
- Optimizing Data Science and the Development of Technologies and Tools
- Promoting Collaborative Science
- Addressing Public Health Challenges Across the Lifespan

**NIH PRIORITIES**

(b) (5)

(b) (5)

[redacted]

(b) (5)

**NIH GRANTS PROCESS**

**Extramural:** NIH currently devotes approximately 83 percent of its budget to grants and contracts supporting more than 300,000 members of the research workforce, including 35,000 principal investigators (PIs), in the extramural biomedical and behavioral/social sciences research communities. NIH supports researchers at all career stages, located at many kinds of institutions, organizations, and small businesses in all 50 states. Decisions about NIH grant awards are informed by a highly competitive, two-stage peer-review process. An initial evaluation is conducted by peer reviewers from the scientific community. The second-level review is conducted by NIH ICOs' (Institute/Center/Office) national advisory council members, who take into account each ICOs' research priorities. Ultimately, ICO Directors are responsible for approving funding. As detailed in the NIH-Wide Strategic Plan, they take into account scientific merit, public health needs, alignment with the ICO strategic plan, the scientific opportunity, and the existing portfolio of supported work.

**Intramural:** Approximately 11 percent of NIH's budget supports about 7,400 researchers at NIH intramural research facilities. Scientists in the NIH Intramural Research Program include approximately 1,100 PIs, 1,800 staff clinicians and staff scientists, and 4,500 trainees. The Intramural Research Program facilitates high-impact science in a variety of important ways. For example, the program serves as a testbed for unique approaches to difficult research challenges, with the resulting solutions often being adopted by the extramural scientific community. The progress and quality of the intramural program research is evaluated by a highly rigorous process overseen by the IC Board of Scientific Councils which conducts quadrennial reviews of each PI's research accomplishments and plans for future work. These reviews are then presented to the IC national advisory councils.

## STATUTORY REQUIREMENTS AND ENABLING LEGISLATION

NIH and its component research ICs are established pursuant to Title IV of the Public Health Service (PHS) Act 42 U.S.C. §§ 281 *et seq*. The statutory provisions in Title IV of the PHS Act enumerate the authorities of the NIH Director and the Directors of the national research ICs, as well as the NIH's and the research ICs' missions. NIH is subject to federal statutes of general applicability to federal agencies, including laws governing appropriations, procurement, government information and records, federal employment, and intellectual property.

# NATIONAL INSTITUTES OF HEALTH ORGANIZATIONAL CHART

## OFFICE OF THE DIRECTOR

**Director**
Francis S. Collins MD PhD

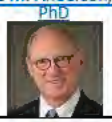
**Principal Deputy Director**
Lawrence Tabak DDS PhD

**Deputy Director for Management**
Alfred C. Johnson PhD

**Deputy Director for Extramural Research**
Michael S. Lauer MD

**Deputy Director for Intramural Research**
Michael M. Gottesman MD

**Deputy Director for Program Coordination, Planning, and Strategic Initiatives**
James M. Anderson, MD, PhD



**Chief of Staff**
Carrie D. Wolinetz PhD (Acting)

**Associate Deputy Director**
Tara A. Schwetz PhD

**National Cancer Institute**
Norman E. Sharpless MD

**National Eye Institute**
Michael F. Chiang, MD

**National Heart, Lung, and Blood Institute**
Gary H. Gibbons MD

**National Human Genome Research Institute**
Eric D. Green MD PhD

**National Institute on Aging**
Richard J. Hodes, MD

**National Institute on Alcohol Abuse and Alcoholism**
George F. Koob PhD

**National Institute of Allergy and Infectious Diseases**
Anthony S. Fauci MD

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**
Robert Carter MD (Acting*)

**National Institute of Biomedical Imaging and Bioengineering**
Bruce J. Tromberg PhD

**Eunice Kennedy Shriver National Institute of Child Health and Human Development**
Diana W. Bianchi MD

**National Institute on Deafness and Other Communication Disorders**
Debara L. Tucci MD MS MBA

**National Institute of Dental and Craniofacial Research**
Rena D'Souza, DDS., MS, PhD

**National Institute of Diabetes and Digestive and Kidney Diseases**
Griffin P. Rodgers MD MACP

**National Institute on Drug Abuse**
Nora D. Volkow, MD

**National Institute of Environmental Health Sciences**
Rick Woychik, PhD

**National Institute of General Medical Sciences**
Jon R. Lorsch, PhD

**National Institute of Mental Health**
Joshua A. Gordon, MD, PhD

**National Institute on Minority Health and Health Disparities**
Eliseo J. Pérez-Stable, MD

**Center for Information Technology**
Andrea T. Norris MBA

**Center for Scientific Review**
Noni H. Byrnes PhD

**National Library of Medicine**
Patricia Flatley Brennan, RN, PhD

**John E. Fogarty International Center for Advanced Study in the Health Sciences**
Roger I. Glass MD PhD

**National Center for Advancing Translational Sciences**
Christopher P. Austin, MD

**National Center for Complementary and Integrative Health**
Helene Langevin MD

**National Institute of Neurological Disorders and Stroke**
Walter Koroshetz MD

**National Institute of Nursing Research**
Shannon N. Zenk PhD MPH, RN, FAAN

**Clinical Center**
James Gilman MD

*Lindsay A. Criswell MD MPH DSc. has been selected as the next NIAMS Director and will start in January 2021

**Color-Coding for Personnel Categories**

- Senior Executive Position
- Schedule C Position
- Individual in Position (acting)
- Key Subject Matter Expert
- Vacant Position

## NIH HISTORY

**Offices Created or Re-Engineered** (chronologically)

**NIH Anti-Sexual Harassment Steering Committee, Office of the Director (OD)**. In Fall 2018, NIH announced development of an anti-sexual harassment website to outline agency policies, practices, and initiatives not only at NIH, but at the institutions supported by the NIH and "anywhere where NIH research activities take place." NIH launched a number of initiatives under the guidance of an NIH Anti-Sexual Harassment Steering the NIH Principal Deputy Director (DEPD) and Deputy Director for Management (DDM) co-chair this Committee. For more: https://www.nih.gov/anti-sexual-harassment and https://www.nih.gov/about-nih/who-we-are/nih-director/statements/changing-culture-science-end-sexual-harassment.

**NIH Helping to End Addiction Long-term (HEAL) Initiative**. NIH awarded $945 million in total FY 2019 funding for grants, contracts and cooperative agreements across 41 states through the HEAL Initiative to reverse the opioid crisis. This trans-NIH research effort, launched in September 2019, aims to improve treatments for chronic pain, curb the rates of opioid use disorder (OUD) and overdose, and achieve long-term recovery from opioid addiction. NIH's investments in HEAL will augment ongoing NIH efforts related to pain and opioid addiction research and provide a framework for future strategic research investments. The NIH HEAL Initiative is administered out of the OD and directed by Rebecca G. Baker, Ph.D. For more: https://heal.nih.gov/

**Executive Appointments**

**Immediate Office of the Director**

- Francis S. Collins, M.D., Ph.D., 16th NIH Director (August 17, 2009)
- Lawrence A. Tabak, D.D.S., Ph.D., NIH Principal Deputy Director (August 2010)
- Carrie Wolinetz, Ph.D., Chief of Staff (acting) (May 2017)
- Tara A. Schwetz, Ph.D., Associate Deputy Director (January 2019)

**Key Leadership Appointments (chronologically by announcement date)**

- Major General James K. Gilman, M.D., Chief Executive Officer, NIH Clinical Center (January 2017)
- David R. Wilson, Ph.D. (Diné, Born for Tódích'íi'nii and born to Honágháahnii), Director, NIH Tribal Health Research Office (February 2017)
- Alfred C. Johnson, Ph.D., Deputy Director for Management (May 2017)
- Julie Broussard Berko, M.P.A. Director, Office of Human Resources (July 2018)
- Bruce J. Tromberg, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering (September 2018)
- Helene Langevin, M.D., Director, National Center for Complementary and Integrative Health (November 2018)
- Tara A. Schwetz, Ph.D., Associate Deputy Director (January 2019)
- Colleen McGowan, Director of the Office of Research Services (February 2019)
- Noni H. Byrnes, Ph.D., Director, Center for Scientific Review (February 2019)
- Debara L. Tucci, M.D., M.S., M.B.A., Director, National Institute on Deafness and Other Communication Disorders (September 3, 2019)
- Susan K. Gregurick, Ph.D., Associate Director for Data Science and Director, NIH Office of Data Science Strategy (September 16, 2019)
- Norman E. Sharpless, M.D., Director, National Cancer Institute (November 2019; originally appointed in June 2017; served as Acting FDA Commissioner from April 2019 to November 2019)

- Joshua Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program (December 2019)
- Darla Hayes, Associate Director for Management, Office of the Director (March 2020)
- Richard Woychik, Ph.D., Director, National Institute of Environmental Health Sciences (June 2020)
- Shannon N. Zenk, Ph.D., M.P.H., R.N., F.A.A.N., Director, National Institute of Nursing Research (September 13, 2020)
- Rena N. D'Souza, D.D.S., M.S., Ph.D., Director, National Institute of Dental and Craniofacial Research (October 2020)
- Michael F. Chiang, M.D., Director, National Eye Institute (selected July 2020, expected start date November/December 2020)
- Lindsey A. Criswell, M.D., M.P.H., D.Sc., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (selected August 2020, expected start date January 2021)

**Highlighted Program Changes** (chronologically)
**Strengthened Governance and Leadership, NIH Clinical Center (CC)**. To emphasize a focus on patient safety and regulatory compliance, NIH launched a series of reforms designed to make the "House of Hope," the nation's largest hospital devoted to clinical research, even more outstanding. The measures include centralized approaches to facilities safety, governance and reporting lines, and establishment of a hotline. To oversee these reforms, NIH appointed Major General James K. Gilman, M.D., U.S. Army (Retired) to be the inaugural Chief Executive Officer (CEO) of the CC, effective January 2017. For more: https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-clinical-center-improvement-plan

***All of Us* Research Program**. In 2015, NIH formed a special working group to develop a framework for a new program called *All of Us*, stemming from NIH's ambitious Precision Medicine Initiative (PMI). *All of Us* is designed to usher in a new era where researchers, health care providers, technology experts, community partners, and the public work together to develop individualized health care. In 2016, NIH made its first awards in support of a nationwide consortium of partners to implement the program. After an initial period of infrastructure development and beta testing, the program opened enrollment nationwide in May 2018. *All of Us* is designed to inform thousands of studies on a variety of health conditions. The program is directed by CEO Josh Denny, M.D., M.S. For more: https://allofus.nih.gov/

**Optimize NIH**. As part of a "strategic shift" to make HHS a more innovative and responsive organization, NIH leadership across the agency has been considering how NIH can optimize operations in support of the NIH mission while maintaining support of its highly valued workforce. Since the program launched in 2018 Optimize NIH has made a number of innovations to improve operations:

- Committee Management: Full implementation of the USA Staffing Onboarding System for Special Government Employees and the elimination of Committee Management courier services to HHS resulted in cost savings of $11,000 per year
- FOIA: Adoption of a single, unified FOIA system and launch of a public-facing portal streamlined FOIA request processing by 79%, enabling staff to focus on decreasing backlog and increasing compliance with the law (20-day mandate)
- Property: Coordination and implementation of the NIH Property Management Portal (NPMP) across all ICs at NIH improved accuracy of personal accountability for property records; 20,000 NIH Employees have verified over 180,000 accountable assets
- IT Security: Launched an award-winning IT Security awareness campaign to enhance cyber safe practices across the NIH with defined roles and responsibilities

**Modernization of Human Gene Therapy Oversight**. Decades of research have begun to yield products for the benefit of human health. Several products have received approval from the U.S. Food and Drug Administration (FDA) as treatments for lymphoblastic leukemia, lymphoma, and vision loss. This evolution prompted the NIH Director and FDA Commissioner to institute streamlining efforts, chiefly the elimination of duplicative reporting requirements. In 1974, NIH created the Recombinant DNA Advisory Committee (RAC) to address scientific, safety, and ethical issues surrounding gene therapy. With the changes introduced by both agencies, the RAC's role at NIH will focus on the scientific, safety, and ethical issues associated with emerging biotechnologies, as well as other responsibilities. The measure is expected to ease some of FDA's regulatory burdens in this area. For more information: https://www.federalregister.gov/documents/2018/08/17/2018-17760/national-institutes-of-health-nih-office-of-science-policy-osp-recombinant-or-synthetic-nucleic-acid

## KEY MISSION DELIVERY PERFORMANCE MEASURES

**HHS Agency Priority Goals (APGs) Supported by NIH.** The Government Performance and Results Act (GPRA) Modernization Act of 2010 requires federal executive departments and independent federal agencies to identify a limited number of Agency Priority Goals (APGs) with specific targets that reflect a near-term result or achievement that agency leadership wants to accomplish within approximately 24 months. For FYs 2020-2021, HHS has three APGs that were developed with input from OPDIVS/STAFFDIVS. NIH co-leads one of the APGs and contributes to the other two.

**Reducing Opioid Morbidity and Mortality (M&M)**: NIH's National Institute on Drug Abuse (NIDA) co-leads this APG with the HHS Office of the Assistant Secretary for Health and the Substance Abuse and Mental Health Services Administration. NIH-funded research, including numerous projects funded under the HEAL Initiative, is making progress in multiple areas that support this APG: the development of new non-addictive pain medications, more flexible medication options and behavioral interventions for treating OUD, the comparison of different treatments for neonatal abstinence syndrome, and implementation science to develop and test pain and OUD treatment models.

**Ending the HIV Epidemic**: NIH's National Institute of Allergy and Infectious Diseases (NIAID) and Office of AIDS Research (OAR) contribute to this APG by funding HIV implementation science research and working with community-based organizations and HHS partners to develop locally relevant plans for diagnosing, treating, and preventing HIV in areas with high rates of new HIV cases.

**Kidney Care**: NIH's National Institute of Diabetes and Digestive and Kidney Disease NIDDK) contributes to this APG by supporting the development of innovative approaches to renal replacement therapy and addressing critical accompanying challenges such as vascular access and fluid management during dialysis.

## HISTORICAL PERFORMANCE OUTCOMES

**Annual Performance Reporting.** NIH reports its performance in the agency's budget request and through HHS for purposes of the GPRA Modernization Act. NIH's performance measures are categorized into four functional areas: Scientific Research Outcomes, Capacity Building and Research Resources, Communication and Transfer of Results, and Management and Program Oversight. In FY 2019, NIH had 73 active performance measures. Of the 73 measures, NIH met the annual targets for 71 measures (97 percent), and 11 of the 73 measures were completed in FY 2019. Six of the 73 measures were featured in the HHS Annual Performance Plan and Report. (b) (5)

## ORDER OF SUCCESSION

As stipulated in Executive Order 12656 the following positions, in order listed, are designated to succeed the NIH Director in case of absence, illness, resignation, death, or unavailability during times of national emergencies or significant local emergencies (more information can be found in the Appendix):

- Principal Deputy Director
- Deputy Director for Extramural Research
- Deputy Director for Intramural Research
- Deputy Director of the Division of Program Coordination, Planning, and Strategic Initiatives
- Deputy Director for Management
- Director, National Institute of Environmental Health Sciences

## WORKFORCE DATA AND TRENDS

**Hiring authorities**: Delegated Examining, Merit Promotion, Schedule A, Schedule C, Schedule D, Veterans Recruitment Appointment (VRA), The Veterans Employment Opportunities (VEOA), Commissioned Corps, Direct-Hire Authority, 30% or more Disabled Vet, Noncompetitive for Military Spouses, Movement between civil service systems, Appointment for Scientific and Professional Positions, Reinstatement, Transfer, ACTION volunteer appointment, Title 42 (g), Title 42 (f), Title 42 authority for various council, committee, and advisory positions, Title 42 for Kirschstein National Research Awards, Pathways Conversion, Term reinstatement, Designation of provisional appointments, Appointment from Reemployment Priority List, Interagency transfer, Direct Hire Authority (COVID-19), Competitive reassignment/promotion authority.

**Size of workforce**: As of September 30, 2020, NIH has an approved workforce size of 18,105 Full-time Equivalents (FTEs).

**Workforce by Pay Plan:**

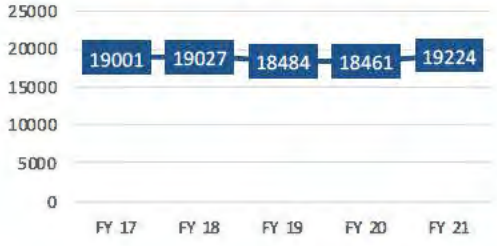
| Pay Plan | # of Employees (Headcount) |
|---|---|
| **General Schedule** | 13,936 |
| **Title 42** | 3,823 |
| **Federal Wage System** | 370 |
| **Commission Corp** | 227 |
| **Senior Executive Service** | 73 |
| **Total** | **18,429** |

The above table was generated via an nVision report based on headcount of onboard federal staff as of September 30, 2020. It excludes those staff on the EI (Members, Committees, Advisory Council, Board or Scientific Counselors) and ZZ (Non-applicable Code is for use only with pay basis WC (without compensation) when other pay plan codes are not applicable) pay plans.

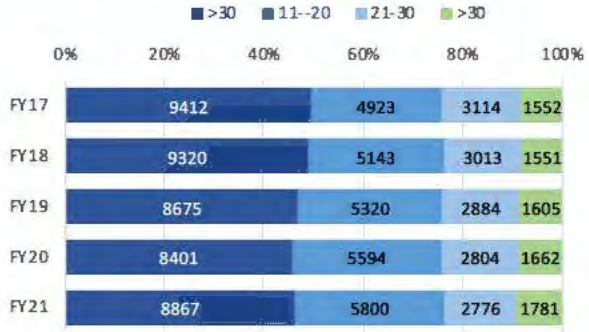
National Institutes of Health
*Turning Discovery Into Health*

# NIH WORKFORCE SNAPSHOT[1]

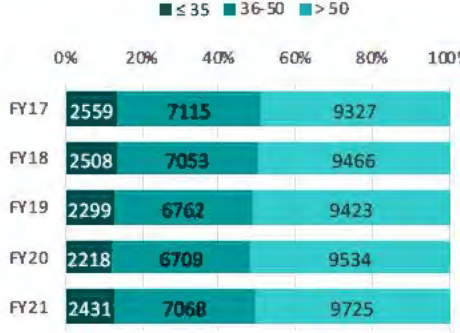
## Federal Employee Onboard (Headcount) Trending



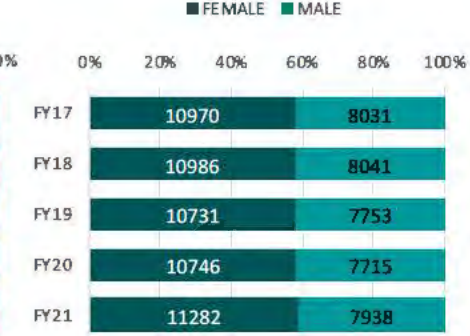

## Federal Length of Service (Yr.) Trending



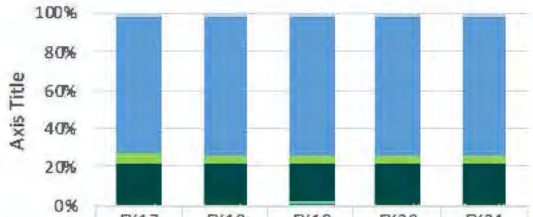

## Age Trending




## Gender Trending

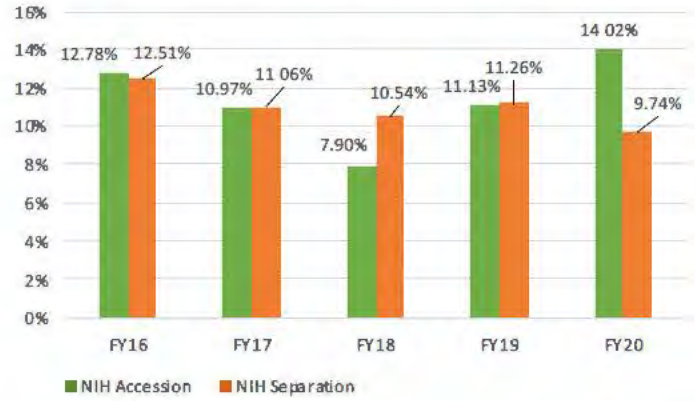



## Pay Plan Trending[2]

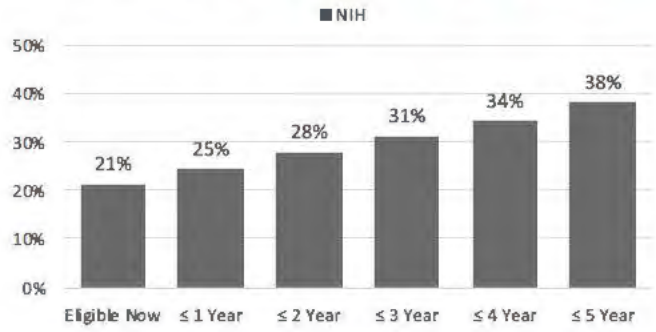



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 377 | 381 | 377 | 360 | 369 |
| GS | 13486 | 13607 | 13275 | 13305 | 13919 |
| EI | 827 | 832 | 814 | 835 | 820 |
| T42 | 3946 | 3852 | 3656 | 3624 | 3815 |
| SES | 101 | 98 | 89 | 78 | 73 |
| CC | 263 | 257 | 273 | 258 | 227 |

## NIH Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

## NIH DETAILEES ON THE HILL AND AT OTHER AGENCIES

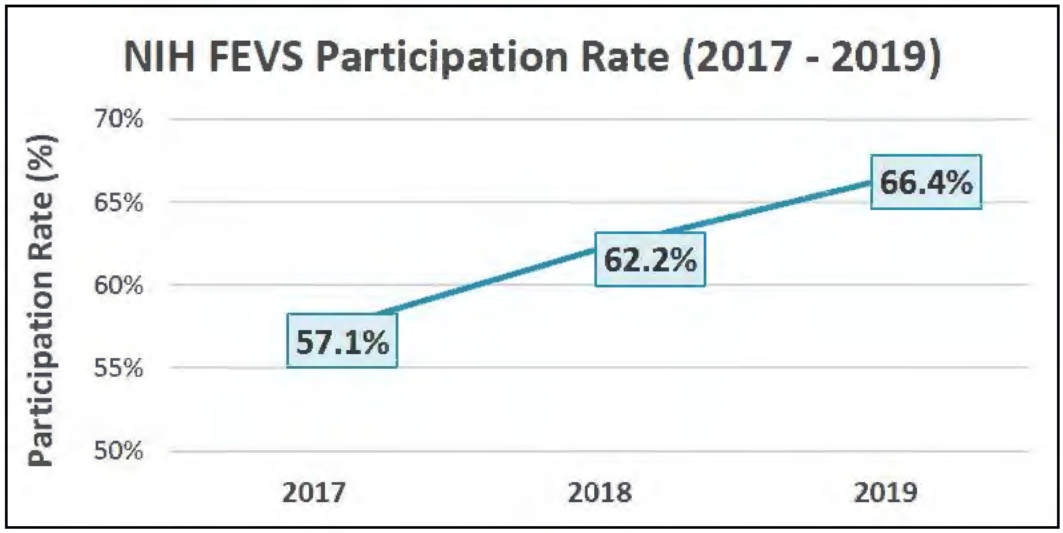
| NIH ICO | Employee Name | Employee Type | Series and Grade | Position | Detail Start | Detail End | Detailed Agency |
|---|---|---|---|---|---|---|---|
| NIDCR | Doug Sheeley, Sc.D. | Title 42 | 601 | Deputy Director, NIDCR | 3/23/2020 | 9/23/2020 | OSTP |

## OFFICE OF PERSONNEL MANAGEMENT (OPM) LIMITS ON SCHEDULE C/NON-CAREER SES POSITIONS AND HIRING RULES

Other than the NIH Director and the NCI Director, who are presidential appointees (PAS and PA, respectively), NIH has no non-career or Schedule C employees.

## CULTURE OVERVIEW

**Federal Employee Viewpoint Survey (FEVS):** The FEVS is an annual survey administered by OPM that measures Federal Government employees' perceptions about their work experiences, organizations, and leaders. The NIH participation rate on the FEVS increased over the past several years. In 2014, the response rate at NIH was just 39.2%, whereas it was 66.4% in 2019.




NIH steadily increased in six FEVS categories (my work experience, my work unit, my agency, my supervisor/team leader, leadership, my satisfaction) over the past three years, as well as in the OPM's FEVS major indices. The work/life category was changed in 2018 to include all respondents regardless of participation so there is not an accurate comparison for that section.

| Measured Variable | 2017 | 2018 | 2019 |
|---|---|---|---|
| Satisfaction Index | 74% | 74% | 75% |
| Employee Engagement Index | 77% | 78% | 78% |
| New Inclusion Quotient (New IQ) | 71% | 72% | 72% |
| Partnership for Public Service's *Best Places to Work Ranking* | 72 out of 339 | 61 out of 415 | 62 out of 420 |

**NIH FEVS Index Comparison**

The HHS Secretary identified two key areas of interest: 1) Performance Feedback and Evaluation Processes, and 2) Communication and Engagement.

| | HHS Secretary's Areas of Interest | 2017 | 2018 | 2019 |
|---|---|---|---|---|
| **Performance Feedback and Evaluation Processes** | 23. In my work unit, steps are taken to deal with a poor performer who cannot or will not improve. | 43.1% | 46.1% | 46.0% |
| **Communication and Engagement with the HHS Workforce** | 24. In my work unit, differences in performance are recognized in a meaningful way. | 49.1% | 50.8% | 52.1% |
| | 33. Pay raises depend on how well employees perform their jobs. | 42.2% | 45.2% | 44.8% |
| | 53. In my organization, senior leaders generate high levels of motivation and commitment in the workforce. | 61.0% | 64.0% | 64.2% |
| | 54. My organization's senior leaders maintain high standards of honesty and integrity. | 70.9% | 72.9% | 73.6% |
| | 58. Managers promote communication among different work units (for example, about projects, goals, needed resources). | 66.0% | 67.7% | 67.7% |
| | 60. Overall, how good a job do you feel is being done by the manager directly above? | 72.7% | 73.8% | 74.0% |
| | 61. I have a high level of respect for my organization's senior leaders. | 71.9% | 75.1% | 74.7% |

## IMPORTANT RELATIONSHIPS WITH OTHER FEDERAL AGENCIES AND ORGANIZATIONS

| Agency | NIH Representative |
|---|---|
| **Inter-HHS** | |
| **Agency for Healthcare Research and Quality (AHRQ)** | Dr. Carrie Wolinetz, OD/OSP |
| **Assistant Secretary for Health (OS/ASH)** | Dr. Lawrence A. Tabak, Principal Deputy Director, NIH<br>Dr. Carrie Wolinetz, OD/OSP |
| **Assistant Secretary for Preparedness and Response (OS/ASPR)** | Dr. Anthony Fauci, NIAID<br>Dr. Carrie Wolinetz, OD/OSP |
| **Center for Medicare & Medicaid Services (CMS)** | Dr. Richard Hodes, NIA<br>Dr. Carrie Wolinetz, OD/OSP |
| **Commissioned Corps (Cco)Advisory Board** | Dr. Richard Wyatt, OD/OIR |
| **U.S. Food and Drug Administration (FDA)** | Dr. Carrie Wolinetz, OD/OSP |
| **U.S. Food and Drug Administration (FDA) – Center for Tobacco Products** | Dr. Helen Meissner, OD/DPCPSI/ODP |
| **HHS National Coordinator for Health Care Information Technology (ONC-HIT)** | Dr. Susan Gregurick, NIGMS/OD/BBTCB |
| **Indian Health Service (I)** | Dr. David Wilson, OD/DPCPSI/THRO |
| **Office of Civil Rights (HHS)** | Dr. Carrie Wolinetz, OD/OSP |
| **Office of Global Affairs (OS/OGA)** | Dr. Roger Glass, FIC<br>Dr. Jessica Tucker, OD/OSP |
| **Office for Human Research Protections (OHRP)** | Dr. Carrie Wolinetz, OD/OSP |
| **Office of the Surgeon General (OSG) (NIH CCo)** | RADM Helena O. Mishoe, NHLBI<br>(CDR Doris Ravenell-Brown, OM/HRC) |
| **Inter-Departmental** | |
| **Department of Defense (DOD)** | Dr. Jim Anderson, OD/DPCPSI |
| **Department of Energy (DOE)** | Dr. Bruce Tromberg, NIBIB |
| **Department of Veterans Affairs (VA)** | Dr. Joshua Gordon, NIMH |
| **Environmental Protection Agency (EPA)**<br>***Federal Radon Summit*** | Dr. Rick Woychik, NIEHS<br>*Dr. Christopher Weis, NIEHS* |
| **National Aeronautics and Space Administration (NASA)** | Dr. Christopher Austin, NCATS |
| **National Institute of Standards and Technology (NIST)** | Dr. Bruce Tromberg, NIBIB |
| **National Science Foundation** | Dr. Jon Lorsch, NIGMS |
| **Office of Management and Budget OMB)** | Neil Shapiro, OD/OB |
| **Office of Science and Technology Policy (OSTP)** | Dr. Francis Collins, Director, NIH<br>Dr. Lawrence A. Tabak, Principal Deputy Director, NIH |
| **Social Security Administration (SSA)** | Dr. Leighton Chan, CC/RMD |
| **U.S. Patent and Trademark Office (PTO) Department of Commerce** | Dr. Mark Rohrbaugh, OD/OSP |

# TOP ISSUES FOR NEW LEADERSHIP

## ADDICTION AND OVERDOSE CRISIS

### EXECUTIVE SUMMARY

Scientific solutions are needed to stop the public health crisis of opioid misuse, addiction, and overdose. More than 67,300 people died from drug overdose in the United States in 2018, and deaths involving synthetic opioids, cocaine, and methamphetamine, and combinations of these drugs, have continued to increase sharply. In addition, over 10 million Americans misuse opioids, and more than 50 million Americans experience chronic pain, putting them at risk of opioid misuse and addiction. The COVID-19 pandemic is exacerbating these trends, highlighting the need for innovative and data-driven approaches to address the crisis.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

The Helping to End Addiction Long-term℠ Initiative, launched in 2018, is a trans-agency plan spanning basic, translational, and clinical research on opioid misuse, addiction, and pain. Through the NIH HEAL Initiative, NIH has awarded over $1.5 billion in research representing more than 500 research projects.

- To develop new medications for opioid use disorder (OUD) and overdose, HEAL supports 63 targeted studies and a consortium to develop immunotherapies. Eight projects submitted and were authorized to proceed on Investigational New Drug applications.
- To evaluate integration of evidence-based interventions for treating OUD into practice, HEAL supports 110 research studies, including the HEALing Communities Study (HCS) which is testing a coordinated set of interventions within 67 communities across 4 states. The Justice Community Opioid Innovation Network (JCOIN) is testing strategies to expand effective substance use disorder (SUD) treatment in justice settings.
- To determine the most effective therapies for specific pain conditions, 55 HEAL studies are testing non-addictive pain treatments to advance evidence and guidelines for treatment of pain.
- To accelerate development of non-addictive analgesics and reduce reliance on opioids, 90 HEAL preclinical studies will validate therapeutic targets for acute and chronic pain conditions, develop accurate research models to predict how drugs will affect patients, and advance innovative device-based treatments.
- To develop new or improved prevention and treatment strategies for opioid addiction, 125 HEAL projects, including 46 small business innovation awards, will test new approaches such as a collaborative care model for treating OUD and mental illness in primary care settings.
- To improve care for infants born with neonatal opioid withdrawal syndrome, the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT-NOW) program will determine how to safely reduce or eliminate opioid treatment among neonates with opioid withdrawal symptoms and understand the long-term outcomes of infants exposed to opioids in utero.

## KEY CHALLENGES TO DATE

- Most people who could benefit from medications for SUD do not get them: access to medications is limited by regulations and inequitable across population subgroups. There are no FDA-approved pharmacotherapies for stimulant use disorders, and opioid overdose reversal agents are less effective against synthetic opioids or opioids together with stimulants.
- People with SUD are more susceptible to COVID-19 and its complications. Social distancing, plus increasing stress, have challenged access to SUD treatment and recovery supports.
- Need for development of safe and effective pain management therapies.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Rebecca Baker, Ph.D.** | Director, HEAL Initiative, Office of the Director | rebecca.baker@nih.gov | Coordinates HEAL activities across ICs, manages HEAL budget, governance groups |
| **Walter Koroshetz, M.D. and Nora Volkow, M.D.** | Directors, NINDS and NIDA | koroshetzw@ninds.nih.gov<br>nvolkow@nida.nih.gov | Directors of ICs where HEAL funds are appropriated |
| **NIH HEAL Initiative Executive Committee** | NIH Institute and Center Directors with equities in HEAL | Committee Members | Advise the NIH Director to make final decisions regarding NIH HEAL Initiative research |
| **Wilson Compton, M.D., M.P.E.** | NIDA Deputy Director | wcompton@nida.nih.gov | Chair Behavioral Health Coordinating Committee Opioids and Controlled Substances Subcommittee |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **ADM Brett Giroir, M.D.** | Assistant Secretary for Health | Brett.Giroir@hhs.gov | Serves as Senior Adviser to the Secretary for Opioid Policy |
| **Elinore McCance-Katz, M.D., Ph.D.** | Assistant Secretary for Mental Health and Substance Use | Elinore.Mccance-katz@samhsa.hhs.gov | Partner in HEALing Communities Study; regulates opioid treatment programs |
| **HEAL Multidisciplinary Working Group** | n/a | Working Group | Council members and experts in pain and addiction research |

## *ALL OF US* RESEARCH PROGRAM

### EXECUTIVE SUMMARY

*All of Us* is a momentous effort to collect and study data from one million or more people living in the United States. The study is building one of the largest and most diverse datasets to advance health research, including being one of the largest genomic sequencing activities in the world. This resource will inform thousands of studies, and NIH Institutes and Centers may leverage it to support their own research portfolios. Top issues have been identified by NIH Leadership and include:

- **Participant retention:** The program is developing multi-year relationships with its participants and needs to demonstrate value to participants to ensure they remain active with the program.
- **COVID-19:** The program paused all in-person activity, including enrollment and engagement activities, in response to COVID-19 and is developing plans to recover from setbacks. The program also launched scientific efforts to help understand the current pandemic.
- **Congressional support and interest:** The program receives strong bicameral, bipartisan congressional support. Congress has repeatedly asked about participant privacy and the timeline to enroll children.
- **Key leadership vacancies:** The program has opened four national searches to fill leadership positions in four divisions. The program is seeking to identify diverse candidates with expertise and experience to lead critical aspects of the program.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

- As of mid-September, the program has more than 357,000 participants, including more than 271,000 who have completed the protocol's initial steps. More than 80 percent of these participants are from communities that have been historically underrepresented in biomedical research, and more than 50 percent are from racial and ethnic minority groups.
- Since making initial awards in July 2016, the program launched national enrollment in May 2018 and started beta testing the data platform in May 2020. More than 200 researchers have signed up to use the beta researcher platform in the first three months. This is the first, broadly accessible, fully cloud-based researcher platform, and pioneers a new data access model.
- In September 2020, the NIH Council of Councils (COC) approved the Nutrition for Precision Health proposal, powered by the *All of Us* Research Program concept.

### KEY CHALLENGES TO DATE

- Scale: No other study has attempted to develop a resource of its size; diversity including geography, racial/ethnic minorities, and individuals who have been underrepresented in biomedical research; and data types, including EHRs, survey, biospecimens, Mobile Health: Technology and Outcomes in LMICs program (mHealth), and genomic sequencing.
- COVID-19 Pandemic: *All of Us* was affected by the pandemic and had to pause its in-person enrollment activities. These are still limited; however, the program is working on expanding digital participation activities and planning for the resumption of in-person activities.

- Genomics: The program had to develop the infrastructure necessary to return genetic results responsibly to participants who wish to have them. The program worked closely with the FDA to obtain regulatory approval to permit the return of health-related genomics results.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Josh Denny, M.D., M.S.** | CEO, *All of Us* Research Program | joshua.denny@nih.gov | Dr. Denny leads NIH's *All of Us* Research Program |
| **Stephanie Devaney, Ph.D.** | COO, *All of Us* Research Program | stephanie.devaney@nih.gov | Co-chair of *All of Us* Trans-NIH Liaisons Coordinating Team to facilitate two-way dialogue with ICs |

## CYBERSECURITY

### EXECUTIVE SUMMARY

NIH follows a risk-based approach to balance the needs for a collaborative and open research environment and protect NIH's key assets while focusing cybersecurity efforts on areas of greatest potential risk. NIH moves roughly 200 terabytes of data through the internet and over 1.5 petabytes of data across NIH labs and facilities daily. NIH has almost 3,000 public facing systems and web sites, and almost 100,000 different devices routinely connected to the NIH network. NIH has a comprehensive security program to protect information and assets and comply with Federal laws and policies. (b) (5)

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

NIH established a new Capital Investment Cybersecurity Fund to allow up to $70 million annually in FY 2020-2022 to support investments in cybersecurity improvements in 4 strategic areas--improving network re-architecture and security, tools rationalization, maturing cyber detection and response, and streamlining risk management (RM). The fund also supports remediation efforts of recent audit findings. NIH has implemented automatic protections and preventions from unauthorized access, theft, or loss preventing 90,000 intrusion attempts and 37 million malicious emails daily. NIH has had more than a dozen cybersecurity-related audits open since January 2019. The range of topics have included the agency's network protections, compliance with Federal information security standards, the agency's high-value asset information systems, and capabilities to manage and report cybersecurity incidents and vulnerabilities. When an audit is completed, the entity typically issues recommendations which are tracked and managed until the issues are resolved.

### KEY CHALLENGES TO DATE

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### NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Andrea Norris, M.B.A.** | NIH Chief Information Officer (CIO) | andrea.norris@nih.gov | n/a |
| **Dennis Papula** | Acting OCIO Deputy Director | dennis.papula@nih.gov | n/a |
| **Amber Simco** | Acting Chief Information Security Officer (CISO) | amber.simco@nih.gov | n/a |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Janet Vogel** | HHS CISO | janet.vogel@hhs.gov | n/a |

## DATA SCIENCE AND MANAGEMENT: ARTIFICIAL INTELLIGENCE (AI), MACHINE LEARNING (ML), AND RELATED INNOVATIONS

### EXECUTIVE SUMMARY

Artificial intelligence and machine learning are sub-categories in the larger and growing data science landscape at NIH. NIH is also actively building data science infrastructure, support, community, and workforce. (b) (5) . The Office of Data Science Strategy (ODSS) leads and coordinates data science-related activities across NIH. These efforts also are being augmented and leveraged to use data to combat the ongoing COVID-19 pandemic serves as a roadmap for goals and activities.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

The ODSS is leading efforts to build a trans-NIH data ecosystem. Under the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative, agreements between NIH and commercial cloud providers support large scale computation and data storage. For example, NIH moved 40 petabytes of sequence data to two commercial cloud providers. A trans-NIH team is implementing single sign-on to manage user identity and access to sensitive datasets uniformly, and another tans-NIH team is exploring use of generalist repositories for sharing data that are findable, accessible, interoperable, and reusable (FAIR). NIH established a Common Data Elements (CDE) Repository and is promoting the use of Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) standard for exchange of health data across clinical systems.

To advance use of AI in biomedicine and leverage the ongoing data ecosystem efforts, the NIH Common Fund plans to launch a new AI program in FY 2021. The overall goal of this program is to generate new biomedically relevant datasets amenable to machine learning analysis at scale. The program will support data, standards, and tools, that will be of lasting broad value to biomedical research.

### KEY CHALLENGES TO DATE

- Recruitment: NIH has had difficulty recruiting and retaining Artificial Intelligence/Machine Learning (AI/ML) and other data/computer science experts. Technical expertise in these fields does not require doctoral degrees, yet NIH's current pay scale cannot compensate these experts with bachelor's and master's degrees. ODSS seeks to address this issue through workforce programs like the Data and Technology Advancement Scholars and the Civic Digital Fellowship. NIH needs new Federal hiring authorities to accommodate selection of non-Ph.D. technical staff at competitive salaries. It is expected that the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service also assist with this recruitment by allowing NIH to

recruit and retain individuals outstanding in the fields of biomedical research, clinical research evaluation, and biomedical product assessment without regard to the provisions of Title 5 of the U.S. Code concerning appointments.

- Lack of Cloud Use: NIH has begun to adopt more CLOUD supported technology, such as the STRIDES Initiative and eRA. However, the lack of broad cloud use by researchers and the need for support infrastructure for cloud use at less-resourced institutions still represents a significant challenge. Additionally, the diversity of data standards across fields has limited the efficiency of research.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Susan Gregurick, Ph.D.** | Associate Director for Data Science | Susan.gregurick@nih.gov | ODSS Director, NIH leader on Data Science and AI |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Staff directors/clerks** | House and Senate Labor HHS Appropriations | Contact through NIH Office of Legislative Policy and Analysis | The clerks have great interest in data science and AI/ML and are supportive of these activities at NIH |

## DIVERSITY, INCLUSION, EQUITY AND CULTURE

### EXECUTIVE SUMMARY

Equity, diversity, and inclusion are critical, scientific imperatives that allow NIH to achieve its goal of turning discovery into health. NIH is deeply committed to advancing diversity and inclusion and promoting the experiences and contributions of all members of the biomedical community. NIH's anti-harassment program supports a culture of civility and respect to create a safe NIH work environment.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

The Advisory Committee of the Director (ACD) Working Group on Changing the Culture to End Sexual Harassment and Working Group on Diversity have developed recommendations to address diversity, inclusion, equity, and culture across the biomedical research enterprise. In 2018, NIH issued the Anti-Harassment Policy and established a formal mechanism outside of the Equal Employment Opportunity (EEO) for reporting allegations of harassment. In 2019, NIH administered its inaugural NIH Workplace Climate and Harassment Survey to better understand NIH staff experiences, assess workplace influences, and establish a baseline for evaluating effects of policies and programs. Women, sexual and gender minorities (SGM), younger individuals (18–24 years), trainees (including students and fellows), and individuals with a disability were more likely to experience harassment. The NIH Anti-Harassment Steering Committee provides trans-NIH leadership in creating a workplace free of harassment that is diverse, inclusive, and equitable.

### KEY CHALLENGES TO DATE

- Modification of nondiscrimination protections at HHS removed requirements for grant recipients to enforce nondiscrimination protections that prohibit discrimination on several bases including race, national origin, age, disability status, sex, sexual orientation, and gender identity.
- Guidance limiting training on topics to address racial, ethnic, and SGM disparities.
- Survey fatigue and the ability to create a representative sample of the NIH population.
- Lack of SGM data prevents NIH from assessing if disparities exist in the employee life cycle.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lawrence A. Tabak, D.D.S., Ph.D.** | NIH Principal Deputy Director | Lawrence.Tabak@nih.gov | Chair, NIH Anti-Harassment Steering Committee |
| **Alfred C. Johnson, Ph.D.** | Deputy Director for Management | JohnsoA1@mail.nih.gov | Chair, NIH Anti-Harassment Steering Committee |
| **Marie A. Bernard, M.D.** | Acting Chief Officer for Scientific Workforce Diversity | mbernard@nia.nih.gov | Office leads NIH's effort to diversify the national scientific workforce and expand recruitment and retention |
| **Treava S. Hopkins-Laboy** | Acting Director, Office of Equity, Diversity and Inclusion | treava.hopkins-laboy@nih.gov | Cultivate a culture of inclusion where diverse talent is leveraged to advance health discovery |
| **Jessica Hawkins** | Civil Coordinator, Human Resources | hawkinj@od.nih.gov | Partners with stakeholders across the NIH to administer the NIH Anti-Harassment program and Workplace Violence Prevention program. |
| **Carrie D. Wolinetz, Ph.D.** | Acting Chief of Staff, Associate Director for Science Policy | carrie.wolinetz@nih.gov | Co-Chair ACD WG on Changing the Culture to End Sexual Harassment |

**External**

None Identified

## DUAL USE RESEARCH OF CONCERN (DURC) AND GAIN-OF-FUNCTION (GOF) RESEARCH

### EXECUTIVE SUMMARY

Dual Use Research of Concern (DURC) is a small subset of research that is *reasonably anticipated* to provide information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agriculture, the environment, or other aspects of national security. In recent years, certain studies with the potential to generate potential pandemic pathogens with enhanced pathogenicity and/or transmissibility (enhanced PPPs)—so-called gain-of-function (GOF) studies—have raised biosafety and biosecurity concerns, including potential dual use risks associated with the misuse of the information or products resulting from such research.

Concerns have been raised that review process and NIH funding decisions on enhanced PPP research lack adequate consideration of transparency, and that the scope of the DURC policies is too narrow to capture all possible DURC. Modifications to the scope of policies would have significant effects on Federal research programs and grant administration and could unduly burden the community.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

- The *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) formalized a multidisciplinary Department-level review of individual, proposed research that is reasonably anticipated to create, transfer, or use enhanced PPPs to guide agency funding decisions and oversight.
- In accordance with the HHS P3CO Framework, NIH/National Institute of Allergy and Infectious Diseases (NIAID) has referred three extramural research proposals to the HHS P3CO review group after deeming them scientifically meritorious and being considered for funding. The HHS P3CO review group has completed review of two proposals and, in both cases, determined that the research was acceptable for HHS funding. NIAID incorporated suggestions from the HHS review group into the awards before allowing the projects to proceed.
- In March 2019, NIH reaffirmed its commitment to transparency and HHS posted information about the reviews on the Science, Safety, Security website with links to NIH RePORTER.
- In January 2020, the National Science Advisory Board for Biosecurity (NSABB) publicly convened to discuss balancing considerations regarding security and public transparency when sharing information about enhanced PPP research.
- The (United States Government) USG renewed the NSABB's charter in 2020, an indication of the continued value of the Board.

### KEY CHALLENGES TO DATE

- Enhanced PPP research remains sensitive and debate about necessity and risks/benefits persist.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie D. Wolinetz, Ph.D.** | Acting Chief of Staff and Associate Director for Science Policy (NIH/OD) | carrie.wolinetz@nih.gov | NIH lead for DURC and P3CO policy issues |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **David Christian Hassell, Ph.D.** | Senior Science Advisor, Assistant Secretary for Preparedness and Response (HHS/ASPR) | david.hassell@hhs.gov | Chairs the HHS P3CO Review Group |
| **CAPT Michael Schmoyer, Ph.D.** | Assistant Director for Health Security Threats (EOP/OSTP) | Michael.W.Schmoyer@ostp.eop.gov | Coordinates interagency biosecurity efforts |
| **Tom Inglesby, M.D.** | Director, Center for Health Security, John Hopkins University | tinglesby@jhu.edu | Long-term involvement in P3CO discussions |
| **Yoshihiro Kawaoka, Ph.D.** | Professor, University of Wisconsin-Madison | yoshihiro.kawaoka@wisc.edu | Influenza researcher |

## ETHICAL, LEGAL, AND SOCIETAL ISSUES IN EMERGING GENETIC TECHNOLOGIES

### EXECUTIVE SUMMARY

Biotechnologies have rapidly advanced and hold immense promise for improving human health. Genetic and genomic biotechnologies are poised to be translated into medical and public health practices. These technologies are associated with significant and unique ethical, legal, and societal implications (ELSI). A significant quantity of research and policy development is being carried out in this area focused on ensuring that emerging biotechnologies can advance responsibly, safely, efficiently, and benefit all.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

Genetic and genomic technologies have advanced to the point that it is relatively inexpensive to determine the entire sequence of a human genome, i.e., *read the genome*. Related technologies have made it easier to manipulate the genomic sequence of plants, animals and potentially, humans, *editing the genome*. Lastly, rapid advances are being made in synthetic biology, *writing the genome*. ELSI issues related to genomic medicine and gene editing depend largely on the specific application, but some examples include the ability to predict disease susceptibility years in advance, treat genetic diseases by correcting gene variants in human tissues, and changing the human genome in such a way that would allow those changes to be passed on to future generations.

### KEY CHALLENGES TO DATE

- Identifying appropriate mechanisms for broad public input.
- Ensuring that both risks and benefits of emerging biotechnologies are considered.
- Ensuring that perspectives of the research and public health agencies are included in policy discussions that primarily impact those agencies.
- Developing and implementing a regulatory environment that allows for innovation and technological advancement along with ensuring safety, quality, efficacy and clinical utility.
- Ensuring that ELSI research issues informs policy discussions and practices that impact genomics and biomedicine more broadly.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lawrence Brody, Ph.D.** | Director, NHGRI Division of Genomics and Society | lbrody@mail.nih.gov | NHGRI POC |
| **Adam Berger, Ph.D.** | Director, OSP Clinical and Healthcare Research Policy Division | adam.berger@nih.gov | NHGRI POC |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Mildred Cho, Ph.D.** | Stanford Professor of Pediatrics and of Medicine | micho@stanford.edu | Leads the Stanford Center for ELSI Resources and Analysis |
| **Debra Mathews, Ph.D.** | Assistant Director for Science Programs, Berman Institute of Bioethics, Johns Hopkins University School of Medicine | dmathews@jhu.edu | Oversees Berman Institute Stem Cell Policy and Ethics program and the Program in Ethics and Brain Sciences |

## GENE-BASED CURES FOR SICKLE CELL DISEASE AND HIV: A COLLABORATION BETWEEN NIH AND THE BILL AND MELINDA GATES FOUNDATION

### EXECUTIVE SUMMARY

In October 2019, NIH Director Dr. Francis S. Collins and the Bill & Melinda Gates Foundation (BMGF) President of Global Health Dr. Trevor Mundel announced a new collaboration to develop safe, effective, and durable gene-based cures that could be implemented in low resource settings where Sickle-Cell Disease (SCD) and HIV are major burdens on health. The NIH-BMGF Collaboration aims to align aggressive, high-reward research efforts to accelerate progress on shared gene-based strategies to cure SCD and HIV. Each organization is committing $100 million and applying other assets and strengths toward achievement of this goal. NIH and BMGF have mapped out a scientific strategy for the Collaboration, as reflected in a set of scientific milestones to be accomplished within a three-year timeframe and informed by expert consultations and a scientific roundtable.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

NIH and BMGF have collaborated on the development of a research blueprint that sets strategic scientific goals for the endeavor and guides future funding. The blueprint includes milestones for targeting cells of interest, gene editing and expression, safety, target product profiles, public-private partnerships (PPPs), and capacity building.

In May 2020, NIH and BMGF organized a pivotal scientific workshop on *Safe and Effective In Vivo Targeting and Gene Editing in Hematopoietic Stem Cells: Strategies for Accelerating Development* to understand the state of the science and to foster conversations about key opportunities and challenges among leading scientists. That event is informing the future directions of the Collaboration, and a proceedings document will be disseminated widely to the scientific community to inform the field at large.

### KEY CHALLENGES TO DATE

There are several scientific and practical challenges to overcome before the goal of fully accessible, single-shot therapies will be realizable.

- Scientific and technical: Many gene delivery systems are inefficient in their ability to transduce cells. Ensuring efficient, precise, and durable gene expression is vitally important.
- Ethical: Populations in low resources settings are particularly vulnerable. Sickle cell patients are disproportionately pediatric, and research with children raises special concerns for their welfare and voluntary participation.
- Limited resources and health care capacity in resource-poor regions: Healthcare and research facilities are extremely limited in many regions of Africa where these diseases are endemic.
- Global access: At present, gene therapies are extremely expensive and only accessible by individuals in resource-rich environments. Developing a product that is financially accessible in low-resources regions is both critically important and very difficult.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Amy Patterson, M.D.**<br><br>**W. Keith Hoots, M.D.** | Chief Science Advisor<br><br>Director, Division of Blood Diseases and Resources | amy.patterson@nih.gpv<br><br>keith.hoots@nih.gov | NHLBI assigned to lead strategic management of the Collaboration |
| **Jessica Tucker, Ph.D.** | Director, Biosafety, Biosecurity, and Emerging Biotechnology, Office of Science Policy | Jessica.tucker@nih.gov | NIH-BMGF Executive Committee |
| **James Anderson, M.D., Ph.D.** | Director, NIH Division of Program Coordination, Planning, and Strategic Initiatives | James.anderson2@nih.gov | Somatic Cell and Genome Editing Program Common Fund |

### External

| Name | POC | Contact Information | Critical Role |
|---|---|---|---|
| **Betsy Foss-Campbell, M.A.** | American Society for Gene and Cell Therapy Director of Policy and Advocacy | BFoss@asgct.org | Professional and scientific society; expressed an interest in finding ways to work with the Collaboration |
| **Mike McCune, M.D., Ph.D.** | Head, HIV Frontiers, Global Health Innovative Technology Solutions, BMGF | Mike.McCune@gatesfoundation.org | Informs development of HIV cures to maximize uptake & implementation |

## HEALTH DISPARITIES RESEARCH IN THE BIOMEDICAL ENTERPRISE

### EXECUTIVE SUMMARY

In the United States, disparities in health outcomes have been persistent, and progress to eliminate them has been slow. Populations with health disparities are defined as racial/ethnic minorities, less privileged socio-economic status, underserved rural residents, and sexual and gender minorities, all of whom are subjected to discrimination, have experienced higher incidence or prevalence of disease, premature or excessive mortality, greater global burden of disease, and poorer health behaviors and clinical outcomes, often as a result of being socially disadvantaged and underserved in health care.

Health disparities are multifactorial and are influenced by health determinants at multiple levels, including behavioral, social, economic, environmental, biological, and health care. Examples of health determinants include education, health insurance, community environment, discrimination, racism, biological vulnerability, and health care access. In particular, social determinants of health, the conditions and environments where people are born, live, learn, work, play, worship, and age, are key contributors to health and health disparities. Addressing health disparities requires a concerted effort from multi-sectoral partners to address the broad array of health determinants, including the social determinants of health, in order to reduce health disparities.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

- Established clear definitions for minority health and health disparities (MH/HD), and defined health disparity outcomes – Novel Approaches to Advance Minority Health and Health Disparities Research.
- Developed the Minority Health and Health Disparities Research Framework that depicts health determinants that can impact health at multiple levels across the life course.
- Designated U.S. populations with health disparities as: racial and ethnic minorities; socioeconomically disadvantaged populations; underserved rural populations: and sexual and gender minorities.
- Prioritized building research capacity at institutions supporting research training and career development among racial and ethnic minorities underrepresented in the biomedical workforce.
- Identified Community-engaged participatory research as an important scientific approach to understand and intervene amongst populations with health disparities.
- Published New Perspectives to Advance Minority Health and Health Disparities Research, an NIH-wide collaboration with scientists from across the United States to identify research strategies to monitor and reduce health disparities.

### KEY CHALLENGES TO DATE

- Limited evidence that applies a multifactorial approach to characterize the health status and research priorities of populations with health disparities.
- Lack of standard methods and measurements to monitor and address MH/HD in research.

- Limited effective and targeted multi-level interventions that incorporate multiple levels of health determinants that contribute to reducing health disparities and promoting health equity.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eliseo J. Pérez-Stable, M.D.** | Director, NIMHD | Eliseo.perez-stable@nih.gov | Leads scientific research to improve minority health and reduce health disparities |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H., F.A.A.P.** | Deputy Assistant Secretary for Minority Health, OMH | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations |

## HUMAN FETAL TISSUE RESEARCH

### EXECUTIVE SUMMARY

NIH conducts and funds basic, preclinical, and clinical research involving the analysis or use of human fetal tissue (HFT) for a wide range of diseases and conditions. In FY 2019, NIH supported 200 grants and projects that involve research with HFT.

In 2019, HHS announced that it would convene an Ethics Advisory Board (EAB) in FY 2020 to advise, consult with, and make recommendations to the HHS Secretary on the ethics of research involving HFT from elective abortions (as authorized in the Public Health Service Act) proposed in grant applications and contract proposals recommended for funding. HHS also announced that no new research would be conducted within the NIH Intramural Research Program that required acquisition of HFT from elective abortions. The FY 2020 EAB was established, met in July 2020, and was disbanded (per the statute) in September 2020. (b) (5)

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

To implement the HHS policy position, NIH issued guidance for potential applicants alerting them of the newly required information for applications using HFT and the associated evaluation criteria. HHS published a Federal Register Notice soliciting nominations of individuals for appointment to the EAB. The FY 2020 EAB met in July 2020, reviewed 14 research proposals, and recommended that the HHS Secretary withhold funds for 13 out of the 14 proposals for ethical reasons. A report outlining these recommendations was delivered to Congress, as required by statute, and is publicly available.

### KEY CHALLENGES TO DATE

- The statute establishing the EAB requires a new Board be constituted for each review. This requirement has proven challenging to match NIH funding cycles and meet Federal Advisory Committee Act (FACA) requirements.
- Different stakeholders have strongly held views on the use of HFT in research funded by NIH, which were reflected in the reactions to the EAB's report. Some religious organizations oppose the use of HFT and supported the EAB's report. Numerous scientific organizations support research with HFT and oppose the policy changes announced in 2019 and the EAB's report.
- Several senior members of Congress wrote to the Secretary in September 2020, asking that he halt efforts to withhold funding for HFT research.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie D. Wolinetz, Ph.D.** | Associate Director for Science Policy | Carrie.Wolinetz@nih.gov | HFT policy lead |
| **Michael Lauer, M.D.** | Deputy Director for Extramural Research | Michael.Lauer@nih.gov | HFT extramural research lead |
| **Tara A. Schwetz, Ph.D.** | Associate Deputy Director | Tara.Schwetz@nih.gov | NIH liaison to HHS |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eric Anthony** | Director of Policy, International Society for Stem Cell Research | eanthony@isscr.org | Key scientific organization |
| **David Prentice, Ph.D.** | Vice President, Charlotte Lozier Institute | DPrentice@lozierinstitute.org | Key pro-life advocacy organization; EAB member |
| **Kevin Wilson** | Director of Public Policy, American Society for Cell Biology | kwilson@ascb.org | Key scientific organization |

## IMPACT OF COVID-19 ON THE WORKFORCE

### EXECUTIVE SUMMARY

The COVID-19 pandemic had unprecedented disruptive effects on the NIH and external biomedical research workforce. NIH extended a variety of accommodations and flexibilities to support the extramural community. Internally, NIH expanded a variety of workforce flexibilities as it returns staff gradually and safely to its worksites, in accordance with the NIH Framework for Return to Physical Workspaces.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

In close coordination with OMB, NIH allowed for a number of accommodations and flexibilities, including allowances for continued salary support, extended deadlines for applications and reports, delayed audits, and extensions for NIH funded research and training grants. Some of these accommodations and flexibilities expired in late FY 2020. NIH issued a survey of NIH funded researchers and institutional leaders in October 2020 to learn more about how the pandemic has affected their workforce.

Within NIH, staff that meet the Framework principles of Group 0 remained onsite throughout the pandemic. Staff in Group A began returning on June 22 and Group B on July 20. As NIH has facilities in seven counties in Maryland, Montana, North Carolina, Massachusetts, and Arizona, not every group began on the same day at every worksite. The NIH Response Team reviews the conditions at each location before approving staff to begin returning. The earliest that Group C is projected to begin is in November (where conditions allow).

### KEY CHALLENGES TO DATE

- Bringing back staff gradually and safely to NIH physical workspaces, prioritizing staff whose work can only be completed onsite.
- Uncertainty about the course of the pandemic and the ability of external research institutions to restart bench and clinical research operations.
- Concerns about effects on women who are disproportionately burdened with childcare responsibilities in the setting of widespread school closures.
- Limitations in monitoring and coordinating daily staffing levels in individual and multi-IC buildings and facilities.
- Ensuring sufficient PPE and cleaning supplies for the NIH workforce.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lawrence A. Tabak, D.D.S., PhD** | Principal Deputy Director | (b) (6) | NIH Coronavirus Response Team |
| **Alfred C. Johnson, Ph.D.** | Deputy Director for Management | johnsoA1@mail.nih.gov | NIH Coronavirus Response Team |
| **Michael Lauer, M.D.** | Deputy Director for Extramural Research | michael.lauer@nih.gov | NIH Coronavirus Response Team; oversees external workforce matters |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **J. Blair Duncan, M.P.A.** | HHS Chief Human Capital Officer; Deputy Assistant Secretary for Human Resources | James.Duncan@hhs.gov | HHS HR POC for COVID-19 policy and guidance updates |
| **Bahar Niakan** | HHS Deputy Chief Human Capital Officer; Director, Strategic Initiatives | Bahar.Niakan@hhs.gov | HHS HR POC for COVID-19 policy and guidance updates |

## INCLUSION OF UNDERREPRESENTED POPULATIONS IN RESEARCH

### EXECUTIVE SUMMARY

Over the past 30 years, NIH has instituted policies to ensure that participants in clinical research are representative of affected patient populations. NIH-funded clinical research has achieved that goal. Yet, some populations remain underrepresented in non-NIH clinical research studies, particularly clinical trials. These populations include racial and ethnic minorities, children, and older populations. Limited evidence exists on the participation of sexual and gender minorities (SGM). To generate the best evidence possible and to ensure that all communities benefit equally from advances in prevention, treatment, or management of disease, it is important for clinical research and trials to include participants who adequately represent those with the disease or condition under study.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

- Redefinition of minority health and health disparities (MH/HD), designation of SGMs as an HD population, and establishment of the Research Framework for MH/HD.
- Development of the All of Us Research Program database of diverse participants that can inform thousands of studies on a variety of health conditions.
- Inclusion Across the Lifespan policy and workshops focused on including individuals of all ages such as older adults and children.
- Establishment of the Tribal Health Research Office (THRO) in 2015, which formed the NIH Tribal Advisory Committee and released the NIH Strategic Plan for Tribal Research.
- Established the Sexual and Gender Minority Research Office (SGMRO) in 2015, the SGM Research Working Group of the COC in 2016, and the first NIH SGM Research Strategic Plan.
- Clinical Trials Transformation Initiative (CTTI), a PPP to identify practices to increase the quality and efficiency of clinical trials.
- Funding opportunities to promote the inclusion of, understudied, underreported and underrepresented women (NOT-OD-20-048).

### CHALLENGES TO DATE

- Issues surrounding data sharing, informed consent, and medical community distrust.
- Exclusion criteria that disproportionately affect racial and ethnic minorities, children under age 3 years, and older adult populations, such as presence of comorbidities.
- Discrimination and racism in healthcare. Final ruling of Section 1557 of the Affordable Care Act (ACA) interprets sex discrimination as determined by biology, and gender identity is not an ACA protected category. The law also prohibits discrimination on the basis of race, color, national origin, age, sex, and disability.

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eliseo J. Pérez-Stable, M.D.** | NIMHD Director | eliseo.perez-stable@nih.gov | Leads efforts to improve MH and reduce HD |
| **Richard Hodes, M.D.** | NIA Director | hodesr@31.nia.nih.gov | Leads effort to understand the nature of aging and extend the healthy, active years of life |
| **David Wilson, Ph.D.** | THRO Director | Dave.wilson2@nih.gov | Leads efforts to gather input from and collaborate with Tribal Nations |
| **Karen L. Parker, Ph.D., M.S.W.** | SGMRO Director | klparker@mail.nih.gov | Leads SGM-related research and activities |
| **Janine Clayton, M.D.** | ORWH Director | Janine.clayton@nih.gov | Leads efforts to coordinate women's health research |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H., F.A.A.P.** | Director, HHS Office of Minority Health | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations |

## INTELLECTUAL AND DEVELOPMENTAL DISABILITIES (IDDS)

### EXECUTIVE SUMMARY

As many as seven percent of children are affected by intellectual and developmental disabilities (IDDs), such as Down syndrome, autism, and Fragile X syndrome. Individuals with IDDs often have cognitive limitations and other functional difficulties, and many IDDs are associated with increased risk of serious comorbid conditions, including cardiac problems, gastrointestinal disorders, Alzheimer's disease (AD), and psychiatric disorders. Clinical studies have made it clear that individuals with IDDs benefit greatly from early detection and evidence-based interventions. However, policy, regulatory, funding, and logistical challenges require attention. Inclusion of individuals with IDDs in research has proven challenging, and the COVID-19 pandemic has disrupted research and crucial services for the IDD community.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

Research infrastructure provide resources for sustained research and enable rapid responses to emerging health threats, including COVID-19. NIH supports centers of excellence and research networks focused on IDDs, including the NICHD's Intellectual and Developmental Disabilities Research Centers (IDDRCs); the Autism Centers of Excellence (ACE); and the Centers for Collaborative Research in Fragile X and *FMR-1* Associated conditions. NICHD's Pediatric Trials Network is currently working to develop resources to promote inclusion of children with Down syndrome (DS) in clinical research. The INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) project is a multi-Institute initiative focused on DS, and conditions that affect both individuals with DS and the general population. The *DS Connect®* Down Syndrome Registry is a unique online resource to engage individuals with DS and their families, as well as researchers and clinicians.

### KEY CHALLENGES TO DATE

- The cognitive effects of IDDs present challenges for participation in research. Some individuals may need special procedures to provide informed consent, and/or consent may also be needed from caretakers or parents. Some individuals with IDDs may find it difficult to consistently follow research protocols or may need additional assistance to provide information on the effects of treatment which also make it difficult to evaluate the effect of interventions.
- Individuals with IDDs are often excluded from the research that tests interventions they will use to manage co-morbid conditions.
- The COVID-19 pandemic has disproportionately affected people with IDDs, with higher rates of severe complications and hospitalizations. Many children with IDDs receive in-person, school-based interventions, and interruption of these services has been disruptive to the children and in some cases to research.

### NEXT STEPS

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- Award new IDDRC research center grants to advance the diagnosis, prevention, treatment, and amelioration of IDDs through multidisciplinary research and provision of infrastructure and core services to the field (RFA-HD-21-009).
- Issue the next edition of the NIH INCLUDE Down Syndrome Research Plan with stakeholder input.

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lisa Gilotty, Ph.D.** | Chair; NIH Autism Coordinating Committee | gilottyl@mail.nih.gov | Committee coordinates activities related to autism spectrum disorders (ASD) across the NIH |
| **Diana Bianchi, M.D.**<br>**Gary Gibbons, M.D.** | Co-Chairs; NIH-wide Steering Committee for INCLUDE project | diana.bianchi@nih.gov<br>Gary.Gibbons@nih.gov | This committee coordinates activities related to the NIH-wide INCLUDE project |
| **Melissa Parisi, M.D., Ph.D.** | Down syndrome Consortium POC | parisima@mail.nih.gov | The Consortium is a public-private partnership to exchange information and promote the DS Connect® registry |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **John Tschida, M.P.P.** | CEO, Association of University Centers on Disabilities | jtschida@aucd.org | The Association addresses multiple IDD issues, interacts with larger disabilities community |

## MATERNAL MORBIDITY AND MORTALITY (MMM)

### EXECUTIVE SUMMARY

The maternal mortality rate is higher in the United States than in other industrialized countries, and more than 50,000 women in the United States experience severe maternal morbidity. An estimated 60% of maternal deaths –- disproportionately occurring in minority women – are preventable. Rigorous, multi-faceted research is essential to inform effective, evidence-based clinical and population-based interventions. However, policy, regulatory, funding, and logistical challenges require attention. NIH has worked across organizational lines to advance maternal health research. Additional effort and resources are needed to promote inclusion of pregnant women in research, develop, and rigorously test community-based interventions, and link large-scale health systems data to make it useful and available to researchers.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

NIH supports a robust research infrastructure that enables scientists to conduct rigorous basic and clinical research studies to advance research on maternal morbidity and mortality (MMM). To coordinate NIH-wide efforts, NIH developed its Maternal Morbidity and Mortality Task Force and has begun implementing a new NIH initiative, Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE). The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's (NICHD) Maternal and Fetal Medicine Units (MFMU) Network conducts clinical research to develop the evidence base for safe and effective obstetric practice to reduce maternal morbidity. In addition, the new Maternal and Pediatric Precision in Therapeutics Hub will provide pharmacology expertise, basic science research, and technology platforms for pharmacology research. The National Institute on Minority Health and Health Disparities (NIMHD) issued a collaborative funding opportunity focused on social determinants of health in addressing racial disparities in MMM, and the National Heart, Lung, and Blood Institute (NHLBI) has sponsored research on the long-term cardiovascular effects of preeclampsia and other threats to maternal health. The congressionally mandated Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC) convened stakeholders to address the significant gaps in research on safety, efficacy, and dosing of medications in pregnant and lactating women. The Task Force converted its 15 recommendations of 2018 into multiple, concrete implementation steps for action.

### KEY CHALLENGES TO DATE

- Inclusion in Research: Achieving scientifically validated safe and effective interventions for pregnant women and lactating women is difficult because many researchers routinely exclude these women from clinical research, without adequately considering potential risks of untreated maternal disorders to both the mother or the fetus.
- Community-specific interventions: At a NIH-supported Community Engagement Forum, participants emphasized reducing disparities by: building the healthcare infrastructure so more women can receive quality healthcare near where they live; developing provider education on respectful care for all patients; providing education on treating women with disabilities and

chronic conditions; improving care coordination among providers; and ensuring that best practices in maternal care.

- Health records systems: The lack of connectivity among health records systems in the United States and lack of linkages between maternal and child health records makes it more difficult for scientists to use real-world evidence to study maternal and newborn conditions.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Diana Bianchi, M.D.**<br>**Janine Clayton, M.D**<br>**Tara A. Schwetz, Ph.D.** | Trans-NIH Task Force on MMM | Diana.Bianchi@nih.gov<br>Janine.Clayton@nih.gov<br>tara.schwetz@nih.gov | Co-chairs, Trans-NIH Task Force on MMM |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Katie Schubert, M.P.P. (CEO)** | Society for Women's Health Research | kschubert@shr.org | Key policy resource |
| **Rachel Tetlow (Director, Federal Affairs)** | American College of Obstetrics and Gynecology | rtetlow@acog.org | Key policy resource |
| **Rebecca Abbott (Director, Federal Affairs)** | Society for Maternal and Fetal Medicine | rabbott@smfm.org | Key policy resource |

## PANDEMIC PREPAREDNESS

### EXECUTIVE SUMMARY

The continual emergence and re-emergence of infectious diseases, accelerated by globalization and rapidly evolving microbes, threatens the health of people worldwide. A critical component of preparedness is biomedical research to develop medical countermeasures that could be rapidly deployed in response to a naturally occurring or deliberately introduced infectious disease outbreak. NIH conducts and supports biomedical research that informs future approaches to responding to an emerging pandemic.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

When a large Ebola virus disease (EVD) outbreak began in the Democratic Republic of Congo (DRC) in 2018, NIH swiftly mobilized its flexible infrastructure and extensive experience establishing collaborative research partnerships to advance several promising agents for treating EVD. The Ebola outbreak was occurring in an area of armed conflict and tenuous security, hindering response efforts. Despite these challenges, a randomized, controlled clinical trial evaluating four investigational agents (ZMapp, remdesivir, REGN-EB3, and mAb114) was launched in the DRC. Preliminary data suggested the superiority of both mAb114 or REGN-EB3 in increasing survivorship, leading to a halt of the trial and the results being made public to help save lives and stem the latest outbreak. This experience demonstrated the efficacy of promising therapeutics to treat EVD and serves as a potential guide for conducting future clinical trials in outbreak settings.

### KEY CHALLENGES TO DATE

- Relevant animal models provide valuable insight into the potential safety and effectiveness of candidate therapeutics and vaccines prior to clinical testing in humans. Challenge studies, which often cannot be conducted in humans, provide key evidence that a specific medical countermeasure will be a viable solution to halting a pandemic. The limited availability of non-human primates (NHP) has created bottlenecks in medical countermeasures research and a coordinated effort across the government has been integral to prioritize their use and advance potential candidate countermeasures into clinical trials.

### NEXT STEPS

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and monoclonal antibodies (MAbs) for prevention and treatment will be launched with an emphasis on under-represented populations that carry a higher burden of disease.

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Hilary Marston, M.D., PhD** | Medical Officer and Policy Advisor for Pandemic Preparedness | Hilary.marston@nih.gov | Coordinate research across NIAID, NIH, and other Federal agencies during outbreaks |
| **Nicholas Bushar, Ph.D.** | Section Chief, Policy, Planning, and Reporting | Nicholas.bushar@nih.gov | NIAID Preparedness SWAT Team: Coordinate research across NIAID during outbreaks |
| **Cliff Lane, M.D.** | Director, Division of Clinical Research | clane@niaid.nih.gov | Rapid deployment of clinical trials in endemic areas |

**External**

None Identified

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## RARE DISEASES

### EXECUTIVE SUMMARY

Rare diseases are an important but underserved public health consideration. Advances in science have rendered a substantial number of rare diseases potentially treatable in the near term with available technologies. Greater access to early genetic/genomic testing and investments in rare disease networks, diagnostic strategies, gene therapies, precision medicine approaches, and many-diseases-at-a-time approaches could meaningfully advance rare diseases research and accelerate rare diseases therapeutics development for the approximately 30 million Americans afflicted with these disorders.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

The NIH-Wide Strategic Plan for FY 2016-2020 includes a priority to "advance opportunities presented by rare diseases" and highlights how public funding enables researchers to pursue scientific questions, such as those posed by rare diseases, on the basis of opportunity, not just perceived market value.

The Rare Diseases Clinical Research Network (RDCRN), which advances medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment and data sharing. Genetic and Rare Diseases Information Center (GARD) provides comprehensive information about rare and genetic diseases to patients, their families, health care providers, researchers and the public. The Platform Vector Gene Therapy (PaVe-GT) pilot project, which seeks to increase the efficiency of clinical trial startup by using the same gene delivery system and manufacturing methods for multiple rare disease gene therapies. The Therapeutics for Rare and Neglected Diseases Program, which supports preclinical development of therapeutic candidates intended to treat rare or neglected disorders, with the goal of enabling an IND application.

### KEY CHALLENGES TO DATE

- The rare disease space is that rare diseases are under resourced relative to their health and societal impacts. The use and expansion of research networks, collective disease approaches, gene banks, and registry studies could dramatically accelerate rare diseases therapeutics development in the near-term, for the thousands of rare diseases that currently considered potentially treatable.
- Many rare diseases' therapeutics and research needs could be readily addressed by focusing on the 3 major challenges of: 1) Rare diseases awareness and diagnosis; 2) Many-disease-at-time, many-therapies-at-a-time approaches; and 3) Expansion of the rare disease knowledge base to inform research priorities.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Anne Pariser, M.D.** | Director, Office of Rare Diseases Research, NCATS | Anne.Pariser@nih.gov | Leads NIH's efforts on rare diseases, in coordination with all NIH ICs |
| **Donald Lo, Ph.D.** | Director, Therapeutic Development Branch, NCATS | Donald.Lo@nih.gov | Leads NCATS' efforts on rare diseases preclinical drug development |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Rare Disease Congressional Caucus** | n/a | https://rareadvocates.org/rarecaucus/ | Appropriators, authorizers, and the Rare Disease Congressional Caucus |

## RIGOR, REPRODUCIBILITY AND TRANSPARENCY

### EXECUTIVE SUMMARY

Science has long been regarded as 'self-correcting' and advances arise from reproducing prior work. However, interrelated factors can affect the checks and balances for reproducibility, compromising the ability to reproduce findings, particularly in preclinical research studies involving animal models. These include the hyper-competitive funding climate, inadequate education, less than optimal peer review, and perverse incentives. These issues span the life cycle of a research project and are problems in all areas of research. Over the past several years, NIH has launched a multi-faceted suite of activities to address these challenges that remain ongoing. These activities include changes to research applications and review processes, new training modules, development of requirements specific for both human and animal research models, and continued stakeholder engagement.

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### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

NIH has formed several external advisory committees to tackle issues in rigor and reproducibility, both across the research enterprise and complementing activities in clinical research, for animal research. NIH is working to implement recommendations to protect the quality of funded and published research by adoption of more systematic review processes, developing and requiring formal training, improving stability for investigators, and encouraging data sharing. Previously, NIH launched a multi-faceted suite of activities to address these ongoing challenges. These activities include changes to research applications and review processes, new training modules, development of requirements specific for both human and animal research models, consideration of relevant biological variables (including sex as a biological variable), and authentication of key resources and stakeholder engagement.

### KEY CHALLENGES TO DATE

- Raising Awareness and Changing Culture: Changing research culture is slow and challenging, partly due to perverse incentives. NIH continues to implement updates for enhancing reproducibility through rigor and transparency. NIH ICs continue to hold and participate in public conferences about reproducibility concerns in their specific communities.
- Training in Rigor: Training in rigorous scientific practices is variable across the research enterprise. A requirement for formal training in rigor was implemented in 2020. Several ICs have supported the development of training resources (NIGMS public clearinghouse site).
- Sex as a Biological Variable (SABV) Policy: Despite increased inclusion of sex in studies, the percentage of studies that included sex-based analyses of the data declined in most fields in 2019 compared to 2009.

### NEXT STEPS

(b) (5)

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Michael Lauer, M.D.** | Deputy Director for Extramural Research | michael.lauer@nih.gov | Director, Office of Extramural Research |
| **Lawrence A. Tabak, D.D.S., Ph.D.** | NIH Principal Deputy Director | lawrence.tabak@nih.gov | Chair, ACD WG on Enhancing Rigor, Transparency, and Translatability in Animal Research |
| **Carrie D. Wolinetz, Ph.D.** | Associate Director for Science Policy | carrie.wolinetz@nih.gov | Director, NIH Office of Science Policy |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Elisabeth (Lis) Handley, M.P.A.** | Director of the HHS Office of Research Integrity | Elisabeth.Handley@hhs.gov | Oversees research misconduct proceedings and RCR resources |
| **Marcia McNutt, Ph.D.** | President of the National Academy of Sciences (NAS) | MMcNutt@nas.edu | Chair of the National Research Council |
| **Lisa Nichols, Ph.D.** | Assistant Director for Academic Engagement | Lisa.M.Nichols@ostp.eop.gov | OSTP JCORE lead for Rigor and Integrity |

## SUSTAINING THE PROGRESS OF THE CANCER MOONSHOT℠

### EXECUTIVE SUMMARY

The Cancer Moonshot℠ is a national effort to accelerate the pace of cancer research by breaking down barriers to progress. The passage of the 21st Century Cures Act, in December of 2016, provided an unprecedented opportunity to advance cancer research. The Cures Act authorized a total of $1.8 billion to fund the Cancer Moonshot℠ over 7 years, from FY 2017 through FY 2023, at varying annual amounts. Funding for the Cancer Moonshot℠ peaked in FY 2019 and declined by more than half in FY 2020.

(b) (5)

(b) (5)

### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

In 2016, a Blue Ribbon Panel (BRP) of the National Cancer Advisory Board put forth 10 bold recommendations for achieving the goals of the Cancer Moonshot℠. The 21st Century Cures Act then provided an unprecedented opportunity to advance cancer research by authorizing seven years of funding to implement the Cancer Moonshot℠ recommendations. To date, the National Cancer Institute (NCI) has awarded over 200 new projects in support of the Cancer Moonshot℠ goals. These include research across the cancer continuum from projects to increase our fundamental understanding of the drivers of childhood cancers; an Adult Immuno-Oncology Network and a Pediatric Immunotherapy Discovery and Development Network; efforts to improve and implement smoking cessation programs for socioeconomically disadvantaged populations; and efforts to improve the quality of life of cancer patients and survivors, particularly pediatric cancer survivors who deal with the long-term side effects of cancer treatments well into adulthood.

The Cancer Moonshot℠ also highlights the need for collaboration and partnerships. NCI is collaborating with the DOE to use advanced computation capacity to accelerate cancer research through the Joint Design of Advanced Computing Solutions for Cancer (JDACS4C) Program. The Partnership for Accelerating Cancer Therapies (PACT) is a novel five-year public-private research collaboration between the NIH and 12 biopharmaceutical companies focused on identifying, developing, and validating biomarkers to advance immunotherapy.

### KEY CHALLENGES TO DATE

(b) (5)

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Blue Ribbon Panel (BRP)/National Cancer Advisory Board (NCAB)** | Cancer Moonshot℠ BRP | n/a | Developed the Moonshot recommendations |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **American Association for Cancer Research** | n/a | n/a | AACR provides leadership on the current state of cancer research |

## UNIVERSAL FLU VACCINE

### EXECUTIVE SUMMARY

Each year in the United States, seasonal influenza sickens millions and causes thousands of hospitalizations and flu-related deaths. Most individuals who get the flu get better within two weeks. Some people, however, may develop serious complications, such as pneumonia. Pandemic influenza occurs when a new flu virus strain arises that can spread easily from person-to-person and the virus is one for which most people have no immunity.

(b) (5)

[redacted]

### KEY PROGRESS TO DATE/HISTORY OF KEY MANAGEMENT INITIATIVES AND MANDATES

NIH scientists have advanced several promising universal influenza vaccine candidates into clinical testing. One vaccine candidate, called H1ssF_3928 that is in Phase 1 clinical trial, leverages a strategy to target the largely unchanging "stem" region of the influenza hemagglutinin (HA) protein on the surface of the virus. Another promising vaccine candidate, which uses nanoparticle technology to expose the immune system to the HA stem derived from group 1 influenza viruses, was shown to be safe and to induce an immune response in a Phase 1 clinical trial. In addition, NIH is developing a "mosaic nanoparticle"–based vaccine candidate for human testing. This vaccine incorporates HAs from multiple influenza strains into nanoparticles, which may induce a broader immune response than current vaccines. In partnership with industry, NIH scientists also are assessing a novel peptide-based candidate vaccine that is designed to prompt a different type of immune response than most vaccines. The experimental vaccine, called FLU-v, targets several other influenza proteins which tend to be conserved across influenza strains. A Phase 2 trial of Flu-v showed that volunteers who received the vaccine were less likely to develop mild to moderate influenza disease compared to those who received a placebo.

### KEY CHALLENGES TO DATE

- Due to the long timeframe for influenza vaccine production, vaccines cannot be readily available if a previously unidentified strain of pandemic influenza suddenly emerges.
- A novel vaccine is needed for each new strain of influenza with pandemic potential, which is an ineffective strategy for long-term preparedness. During the most recent influenza pandemic in 2009, a strain-specific vaccine was not available until well after the peak of the pandemic.
- Continually chasing influenza viruses that jump from animals to humans comes at a substantial economic cost and leaves human health at risk.

### NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Alan Embry, Ph.D.** | Section Chief, Respiratory Diseases Branch | embrya@niaid.nih.gov | Chairs the Influenza Working Group |
| Matt Memoli, M.D., M.S.<br>Barney Graham, M.D., Ph.D.<br>Karin Bok, Ph.D., M.S. | NIAID Influenza Challenge Studies Working Group | memolim@niaid.nih.gov<br>bgraham@mail.nih.gov<br>Karin.bok@nih.gov | Responsible for designing influenza challenge studies |

**External**

None Identified

## CORONAVIRUS DISEASE 2019 (COVID-19) RESPONSE

The sudden emergence and rapid global spread of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes, COVID-19, has created a daunting public health challenge. As part of the U.S. government's response to the COVID-19 pandemic, NIH is conducting and supporting clinical research to diagnose, prevent, and treat COVID-19 and characterize the causative agent SARS-CoV-2. In June 2020 NIH released a NIH-Wide Strategic Plan for COVID-19 Research to provide a framework for accelerating foundational studies, creating models, and identifying or screening existing therapeutic drugs against SARS-CoV-2, as well as supporting the development of vaccine and diagnostic and their delivery platforms to prevent and detect the virus.

### CORONAVIRUS SUPPLEMENTAL APPROPRIATIONS AND STATUS OF FUNDS

NIH received a total of $3.587 billion from three FY 2020 supplemental appropriations enacted in response to the COVID-19 pandemic, including $836 million in P.L. 116-123, $945 million in P.L. 116-136, and $1.806 billion in P.L. 116-139 (by transfer from the Public Health and Social Services Emergency Fund). The funds were provided to seven ICs (NIAID, NIBIB, NCI, NHLBI, NCATS, NIEHS, and NLM) and OD. The largest portion of the funds are for Diagnostics, including over $1 billion for the Rapid Acceleration of Diagnostics (RADx$^{SM}$) initiative implemented by NIBIB and OD. The other major categories are Vaccines, Therapeutics, Basic Research, and Facilities. As of September 30, 2020, NIH has obligated a total of $1.535 billion and disbursed $254 million, in addition Operation Warp Speed (OWS), NIH is implementing several major clinical trials on behalf of the Biomedical Advanced Research and Development Authority (BARDA). This includes vaccine and therapeutic trials under the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership and programmatic support. As of the end of September 2020, NIH has obligated about $1.573 billion for OWS.

**Status of Funds**

(Dollars in Millions)

| Obligations Tracking[1] | Total Supplemental | Total Obligations | Total Outlays |
|---|---|---|---|
| **National Cancer Institute** | 306.00 | 80.38 | 3.31 |
| **National Center for Advancing Translational Sciences** | 36.00 | 21.70 | 3.90 |
| **National Heart, Lung, and Blood Institute** | 103.40 | 53.15 | 0.44 |
| **National Institute of Allergy and Infectious Diseases** | 968.66 | 547.10 | 110.94 |
| **National Institute of Allergy and Infectious Diseases, Construction** | 156.00 | 0.05 | 0.00 |
| **National Institute of Allergy and Infectious Diseases, Diagnostics** | 25.08 | 14.62 | 0.42 |
| **National Institute of Allergy and Infectious Diseases, Therapeutics** | 231.78 | 92.85 | 3.19 |
| **National Institute of Allergy and Infectious Diseases, Vaccines** | 150.48 | 63.46 | 3.16 |
| **National Institute of Biomedical Imaging and Bioengineering** | 560.00 | 358.92 | 94.95 |
| **National Institute of Environmental Health Sciences** | 10.00 | 6.28 | 0.63 |
| **National Library of Medicine** | 10.00 | 5.74 | 1.54 |
| **Office of the Director** | 1,030.00 | 290.58 | 31.37 |
| **NIH TOTAL** | 3,587.40 | 1,534.83 | 253.85 |

[1]Report Reflecting Obligations Through October 5, 2020

## KEY ACTIVITIES

### Operation Warp Speed (OWS)

Operation Warp Speed is a partnership among components of HHS—including the CDC, FDA, NIH, and BARDA—and the Department of Defense (DoD). OWS engages with private firms and other Federal agencies, including the Department of Agriculture, the DOE, and the Department of Veterans Affairs (VA). It coordinates existing HHS-wide efforts, including the NIH's ACTIV partnership, NIH's RADx[SM] initiative, and work by BARDA. The goal of OWS is to produce and deliver 300 million doses of safe and effective vaccines, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Health and Human Services Secretary Alex Azar and Defense Secretary Mark Esper oversee OWS, with Dr. Moncef Slaoui designated as chief advisor and General Gustave F. Perna confirmed as the chief operating officer.

### Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

ACTIV is a public-private partnership led by NIH to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. Announced April 17, 2020, and managed by the Foundation for the National Institutes of Health (FNIH), ACTIV brings NIH together with the BARDA; CDC; FDA; OWS; DOD; the DVA the European Medicines Agency (EMA); and representatives from numerous biopharmaceutical companies, academia, and philanthropic organizations. The ACTIV governance consists of a Leadership Group, an Executive Committee, and four working groups, each pursuing one of four fast-track focus areas and led by senior scientists representing the different organizations involved. The four working groups focus on preclinical, therapeutics clinical, clinical trial capacity, and vaccines to evaluate on an ongoing basis hundreds of available therapeutic agents with potential application for COVID-19, prioritizing the most promising candidates, designing and harmonizing multiple adaptive master protocols for ACTIV clinical trials, and selecting numerous NIH-supported networks to launch these clinical trials to test prioritized therapeutic candidates. Several ACTIV clinical trials to evaluate the safety and efficacy of various therapeutics are underway.


Along with therapeutics, ACTIV advised on the protocol designs and endpoints to ensure a harmonized approach across multiple vaccine efficacy trials supported by OWS. The vaccine protocols enable analyses of correlates of protection across several vaccine trials being implemented under OWS and activated at NIH COVID-19 Prevention Network sites.

**Vaccines and Therapeutics**
Research programs directed at specific pathogens provide valuable information that can be applied to newly EIDs, allowing for the rapid generation of vaccines and therapeutics. Given the urgency of the public health response to the COVID-19 pandemic, the capacity to pivot research focus within established clinical networks across the globe has been of paramount importance. Studies that inform efforts to control COVID-19 spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are priorities.

The first Phase 1 clinical trial of mRNA-1273 launched on March 16, 2020 to evaluate different doses for safety and the ability to generate an immune response as diagnosed cases began to escalate in the United States. The rapid recruitment of healthy volunteers resulted in a quick assessment of the vaccine's ability to generate an appropriate immune response and showed that it was well-tolerated in humans. Through the coordinated efforts of NIAID researchers and its partners, the prompt activation of clinical sites across the United States allowed for the Phase 2 clinical trial for this vaccine to by fully enrolled in early July and the initiation of the Phase 3 clinical trial began at the end of July 2020. NIAID plays an active role in coordinating several experimental vaccine candidates developed by its industry partners through the clinical trial pipeline by directing them to the Coronavirus Prevention Network (CoVPN) for human testing. These efforts allow the rapid advancement of appropriate countermeasures by harnessing an established framework with clinical expertise to safely evaluate candidates as they become available.

The identification of treatments for active COVID-19 disease are essential to minimizing the public health burden given the lack of a currently licensed vaccine. NIAID researchers first reported encouraging results using the broad-spectrum antiviral drug remdesivir to treat MERS, a related coronavirus, in rhesus macaques. These results prompted the initiation of a randomized clinical trial to treat patients with advanced COVID-19 that were hospitalized with lung involvement. The resulting data from this trial suggests that treatment with remdesivir accelerates the time to recovery in these patients. NIAID is supporting additional arms of this study across the globe through its established clinical networks to evaluate the addition of baricitinib, an anti-inflammatory drug, or interferon-beta, an immunomodulator, to remdesivir treatment to reduce the recovery time even further when compared to remdesivir alone. The results from these groundbreaking studies will facilitate the development of the first therapeutic intervention for patients with advanced COVID-19 disease.

**Community Engagement Alliance Against COVID-19 Disparities (CEAL)**
Racial and ethnic minorities and individuals from low-income households are disproportionately represented among COVID-19 infections, hospitalizations, and deaths, and there is an urgent need to understand and address this trend. On behalf of the NIH, NHLBI and NIMHD have led the development of an initiative on **C**ommunity **E**ngagement **Al**liance (CEAL) Against COVID-19 Disparities, which aims to: (1) conduct urgently needed community-engaged research and outreach focused on COVID-19 awareness and education to address the widespread misinformation about COVID-19; (2) promote and facilitate inclusion of diverse racial and ethnic populations in COVID-19 clinical studies on therapeutics, vaccines, and other prevention strategies; and (3) promote the dissemination and implementation of research findings to reduce the burden of COVID-19 in the communities that have been disproportionately affected by the pandemic.

To achieve these aims, NIH is funding consortia of community engagement researchers and their community-based organization partners in 11 states with rising numbers of confirmed cases of

COVID-19, COVID-19 hospitalizations, and a high proportion of medically underserved racial/ethnic minority groups with disproportionate burden at the state and/or specific community levels. Collectively, the CEAL projects will serve as one alliance of interlinked community-engaged research and outreach.

**Rapid Acceleration of Diagnostics (RADx$^{SM}$)**

NIH is working in partnership with other government organizations, including BARDA, CDC, Defense Advanced Research Projects Agency (DARPA), and FDA, to increase the overall testing capacity of the nation to millions of tests per week and ensure availability of testing to those most vulnerable to or disproportionately impacted by COVID-19. In April 2020, the NIH launched the Rapid Acceleration of Diagnostics (RADx$^{SM}$) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. The RADx$^{SM}$ initiative consists of four major programs:

- RADx$^{SM}$ Tech: Uses a "shark tank" approach for rapid development and commercialization of innovative point-of-care (POC) and lab-based diagnostic technologies. Together with RADx$^{SM}$ ATP, companies have received RADx$^{SM}$ Phase 2 funding totaling more than $378 M in FY 2020 and are projected to add more than 2 million tests per day to U.S. testing capacity.
- RADx$^{SM}$ Advanced Technology Platforms (RADx-ATP): Focuses on rapid scale-up technologies to create ultra-high throughput machines and facilities that could rapidly increase scale-up or geographical distribution of testing. In FY 2020, nearly $220M in awards were made.
- RADx$^{SM}$ Underserved Populations (RADx-UP): Aims to enhance COVID-19 testing among underserved and vulnerable populations and understand the social, ethical, and behavioral implications of COVID-19 testing in these populations. RADx-UP released four FY20 funding opportunity announcements (FOAs) and nearly $300M in awards in Fall 2020 with a second round awards to be made in FY 2021.
- RADx$^{SM}$ Radical (RADx-rad): Develops and leverages existing non-traditional strategies, including new POC devices and home-based tests, as well as supports new or non-traditional applications of existing approaches to make them more usable, accessible, or accurate. Twelve FOAs issued in FY 2020 spanned COVID-19 testing, screening, and community surveillance, and over $140M in awards were made in December 2020.

Further, a $70M effort to coordinate and manage the data across RADx$^{SM}$ is under development and has recently deployed an early prototype of a Data Hub. An Executive Committee provides overarching governance and coordination of RADx$^{SM}$, with final funding approval provided by the NIH Director. Separate governance committees guide each RADx$^{SM}$ program, ensuring effective stewardship and management of funds throughout the programs. Representatives from each RADx$^{SM}$ program governance committee participate in Executive Committee meetings.

**Serological Sciences Network for COVID-19 (SeroNet)**

The Serological Sciences Network (SeroNet) is the nation's largest coordinated effort to study the immune response to COVID-19. The network aims to combat the pandemic by improving the ability to test for infection, especially among diverse populations, and speed the development of treatments and vaccines. The network was established using funds from an emergency appropriation of $306 million to NCI "to develop, validate, improve, and implement serological testing and associated technologies." Lessons learned from SeroNet research can be applied immediately and may prove valuable to public health beyond the current pandemic.

**Trans-NIH Research Efforts**

Trans-NIH activities to address the pandemic have brought together experts from across the NIH to pool resources and align efforts in support of promising research, to develop and maintain needed infrastructure, and to address scientific needs that extend beyond the missions of individual ICOs.

- **Developing technologies needed for safe release from sheltering in place:** The work could lead to user-friendly tools such as smartphone apps, wearable devices, and software that can identify and trace contacts of infected individuals, keep track of verified COVID-19 test results, and monitor the health status of infected and potentially infected individuals.
- **Bringing NIH clinical trial networks together:** To develop an inventory of clinical trial capacity, including networks from NIH Institutes and Centers and contract research organizations, that will serve as potential settings in which to implement effective COVID-19 clinical trials
- **Behavioral and social science research/Impact on vulnerable populations:** To address the disproportionate burden of COVID-19 on racial/ethnic minorities, the COVID-19 Social Behavioral and Economic Health (SBE) Initiative will assess effective mitigation strategies and interventions to improve the response to the pandemic across underserved communities.
- **Data Coordination and Data Warehouse:** Data Coordination and Data Warehouse: A centralized, secure and federated data resource for researchers to access and analyze medical record data from individuals with COVID-19. This includes the National COVID Cohort Collaborative (N3C), the *All of Us* Research Program, and NHLBI's Biodata Catalyst and potentially other NIH supported resources. This effort aims to help scientists analyze near-to-real time clinically and medically related data to understand COVID-19 development, identify treatments, and inform clinical practices to address critical gaps in our understanding of the disease, including identifying health factors that may impact disease outcomes.
- **Impact on pregnant women and children:** Efforts included funding opportunities for research on the development of approaches for identifying children at risk of Multisystem Inflammatory Syndrome in Children (MIS-C). This program, called Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL kIds) is part of the RADx-rad program. As a part of PreVAIL kIds, researchers will use artificial intelligence to investigate genes and other potential biomarkers in pediatric cases of COVID-19 to uncover predictive disease patterns.
- **Preclinical therapeutic discovery:** Standardize and share preclinical evaluation resources and methods and accelerate testing of candidate therapies and vaccines to support entry into clinical trials.
- **Using *All of Us* to Understand the COVID-19 Pandemic:** The *All of Us* Research Program is testing blood samples from more than 15,000 participants for the presence of SARS-CoV-2 antibodies, indicating prior infection. Additionally, ***All of Us*** is collecting relevant information from the EHRs of more than 200,000 participants to help researchers look for patterns and learn more about COVID-19 symptoms and the effects of different medicines and treatment. Finally, another effort focuses on understanding the mental and physical impacts of the COVID-19 pandemic on participants.

**Relevant Stakeholders**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Anthony Fauci, M.D.** | Director, NIAID | afauci@niaid.nih.gov | COVID Vaccines and Therapeutics |
| **Bruce Tromberg, Ph.D.** | Director, NIBIB | bruce.tromberg@nih.gov | COVID Diagnostics |

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Gary Gibbons, M.D.** | Director, NHLBI | gary.gibbons@nih.gov | CEAL Co-Chair; COVID Therapeutics |
| **Eliseo Pérez-Stable, M.D.** | Director, NIMHD | eliseo.perez-stable@nih.gov | CEAL Co-Chair; RADx-UP |
| **Ned Sharpless, M.D.** | Director, NCI | norman.sharpless@nih.gov | SeroNet |
| **Rick Woychik, Ph.D.** | Director, NIEHS | rick.woychik@nih.gov | RADx$^{SM}$ Executive Committee, RADx-rad |
| **Tara A. Schwetz, Ph.D.** | Associate Deputy Director, NIH | tara.schwetz@nih.gov | RADx$^{SM}$ Executive Committee, RADx-rad, RADx-UP |

## KNOWN AND EXPECTED CHALLENGES

- Supply chain bottlenecks of research and clinical trial supplies, including PPEs, swabs and research reagents, have presented challenges in the research response to COVID-19.
- The availability of appropriate animal models, including non-human primates.
- Steady enrollment of key populations has presented a challenge toward rapidly completing the testing of critical vaccines or therapeutics prior to release to the public.
- The ability of external research institutions to restart research operations.
- Unpredictable Congressional appropriations impact the NIH's ability to plan and release funding opportunities to address the new, emerging scientific concerns related to COVID-19 and balance research support for science not related to COVID-19.
- To rapidly address research related to COVID-19, NIH has, to date, predominantly relied on funding mechansims that can be implemented quicly, often building on already funded efforts.

# BUDGET OVERVIEW

## BASIC BUDGET GUIDANCE

The NIH budget consists of four recurring types of funding:

- **Discretionary budget authority (96.5 percent of FY 2020 total budget)** received from annual appropriations under the jurisdiction of the *Labor, Health and Human Services, Education, and Related Agencies* subcommittee (L/HHS). Most L/HHS appropriations are available for obligation only during the current fiscal year (one-year money).
- **Discretionary budget authority (0.2 percent)** received from annual appropriations under the jurisdiction of the *Interior, Environment, and Related Agencies* subcommittee (Interior). These funds are dedicated to the Superfund Research program.
- **Program Evaluation (PE) financing (3.0 percent)** designated in the L/HHS appropriations bill. These funds are collected primarily from L/HHS appropriations to NIH, but a portion comes from L/HHS appropriations to other programs of the Department of Health & Human Services (HHS) that are authorized under the Public Health Service Act.
- **Mandatory budget authority (0.3 percent)** from the *Type 1 Diabetes (T1D) Special Statutory Program* account, currently authorized through November 30, 2020. These funds are available until expended (no-year money).

NIH also receives emergency supplemental appropriations from time to time, either directly or through HHS. These can be in response to public health emergencies such as the COVID-19 pandemic in 2020 or other infectious diseases (e.g., Ebola, Zika). Additional examples include severe downturns in the economy (e.g. American Recovery and Reinvestment Act of 2009) or domestic natural disasters such as hurricanes that harm extramural research programs. Another form of one-time funding comes from the HHS Nonrecurring Expenses Fund for facilities projects approved by HHS and the Office of Management and Budget (OMB).

As shown in the NIH Operating Plan, most of the NIH Institutes and Centers (ICs) have their own appropriation account. In some cases, especially in the Office of the Director, there are multiple programs, projects and activities (PPA) within an account because Congress has included bill or report language setting aside funds for specific PPAs. Three centers are funded internally rather than directly from Congress: The Center for Information Technology, the Center for Scientific Review, and the Clinical Center. The budgets for these Centers are determined through the Central Services budget process described in the Governance section of these materials.

One aspect of the NIH budget is that it is treated as a single request, rather than separately by appropriation account, until the final stage of the President's Budget process. The submissions to HHS in the summer, and to OMB in the fall, use NIH-wide estimates and generally do not specify individual ICs. Projections for the number of grants that can be funded at specific spending levels are developed centrally through a modeling process, based on assumptions provided by NIH leadership. After the OMB passback and settlement, NIH leadership decides on an allocation of the total budget among the ICs, based on priorities for specific and general funding. The ICs then prepare their individual plans, and the details are compiled to arrive at the overall NIH request. This approach has many advantages but makes it hard to compress the schedule for budget preparation if OMB decisions are delayed.

A second aspect of the NIH budget stems from the fact that most NIH grants are awarded for multiple years but funded incrementally. This means that a large portion of the NIH budget each year supports grants that were awarded in prior years, called "noncompeting" grants. The portion of each year's budget that is available for "competing" awards (either brand new or a competing renewal of an existing award) is relatively small due to the need to fund the "commitment base" represented by noncompeting grants, so rapid changes to funding priorities are difficult. As a result, budget allocation flexibility for each year is dependent on the commitment base from prior years, which can cause a roller coaster effect on the number of competing grants when a large increase is followed by a flat or declining budget. Two common metrics for the NIH portfolio are the number of competing Research Project Grants (RPGs), the largest component of NIH research grants, and the success rate (competing RPGs divided by the number of applications). The number of competing RPGs has varied substantially over the last eight years, growing from 8,234 in FY 2013 to 10,364 in FY 2016 (26 percent), then showing a more moderate growth from 10,123 in FY 2017 to a projected 11,197 for FY 2020 (11 percent). During the same period, the number of applications increased from 49,411 in FY 2013 to 54,903 in FY 2020, or approximately 11 percent. As a result, success rates have varied from below 17 percent (FY 2013) to slightly over 20 percent (FY 2020). A snapshot for the last two years is provided in the table below. The best way for NIH to increase competing awards and maintain or improve grantee success rates is with a budget that goes up at a steady pace.

Due to the uncertainties introduced by funding only the best science as determined by peer review, many NIH budget numbers below the IC level are estimates of how funds are likely to be spent, rather than firm commitments to spend a specific amount in a defined way. NIH provides the Appropriations Committees with updates on such budget details on a quarterly basis.

**NIH Research Project Grants (RPGs): Success Rates of Competing**

| | FY 2020 Enacted | FY 2021 Continuing Resolution |
|---|---|---|
| **Competing RPGs** | 11,197 | (b) (5) |
| **Applications** | 55,230 | |
| **Success Rates** | 20% | |

Note: The application estimates are as

## BUDGET DASHBOARD

### NIH Operating Plan for FY 2020

(Dollars in Millions)

| Activities | FY 2019 Final [1] | FY 2020 Enacted[1] |
|---|---|---|
| National Cancer Institute: | | |
| All Other NCI | 5,703 | 6,140 |
| NIH Innovation, 21st Century Cures (CURES) Act | 400 | 195 |
| Childhood Cancer Data Initiative | - | 50 |
| Childhood Cancer Survivorship, Treatment, Access, Research (STAR) Act | - | 25 |
| Repairs & Improvements at NCI-Frederick, MD | 18 | 30 |
| Subtotal, NCI | 6,121 | 6,440 |
| National Heart, Lung and Blood Institute | 3,482 | 3,624 |
| National Institute of Dental and Craniofacial Research | 461 | 477 |
| National Institute of Diabetes & Digestive & Kidney Diseases: | | |
| National Institute of Diabetes & Digestive & Kidney Diseases | 2,026 | 2,114 |
| Mandatory Type 1 Diabetes | 150 | 150 |
| Subtotal, NIDDK [2] | 2,176 | 2,264 |
| National Institute of Neurological Disorders and Stroke: | | |
| National Institute of Neurological Disorders and Stroke | 1,948 | 2,110 |
| Research Related to Opioid Addiction | 241 | 266 |
| NIH Innovation, CURES Act | 58 | 70 |
| Subtotal, NINDS | 2,246 | 2,445 |
| National Institute of Allergy and Infectious Diseases: | | |
| National Institute of Allergy and Infectious Diseases [3,9] | 5,401 | 5,684 |
| Universal Influenza Vaccine | 140 | 200 |
| Research related to Opioid Addiction | 5 | - |
| NASEM Study of Antimicrobial Resistance | - | 2 |
| Subtotal, NIAID[17] | 5,545 | 5,885 |
| National Institute of General Medical Sciences: | | |
| All Other NIGMS | 1,313 | 1,320 |
| IDeA | 362 | 387 |
| PHS Program Evaluation | 1,147 | 1,231 |
| Subtotal, NIGMS | 2,822 | 2,937 |
| Eunice K. Shriver Natl. Institute of Child Health & Human Development | 1,501 | 1,557 |
| National Eye Institute | 794 | 824 |
| National Institute of Environmental Health Sciences: | | |
| Labor - HHS Appropriation | 772 | 800 |
| Hurricane Harvey Research | - | 3 |
| Interior - Superfund Activities | 79 | 81 |
| Subtotal, NIEHS | 851 | 884 |
| National Institute on Aging [4] | 3,080 | 3,544 |
| Natl Institute of Arthritis & Musculoskeletal & Skin Diseases | 603 | 625 |
| Natl Institute on Deafness and Communication Disorders | 473 | 491 |
| National Institute of Mental Health: | | |
| National Institute of Mental Health | 1,814 | 1,968 |
| NIH Innovation, CURES Act | 58 | 70 |
| Subtotal, NIMH | 1,872 | 2,038 |

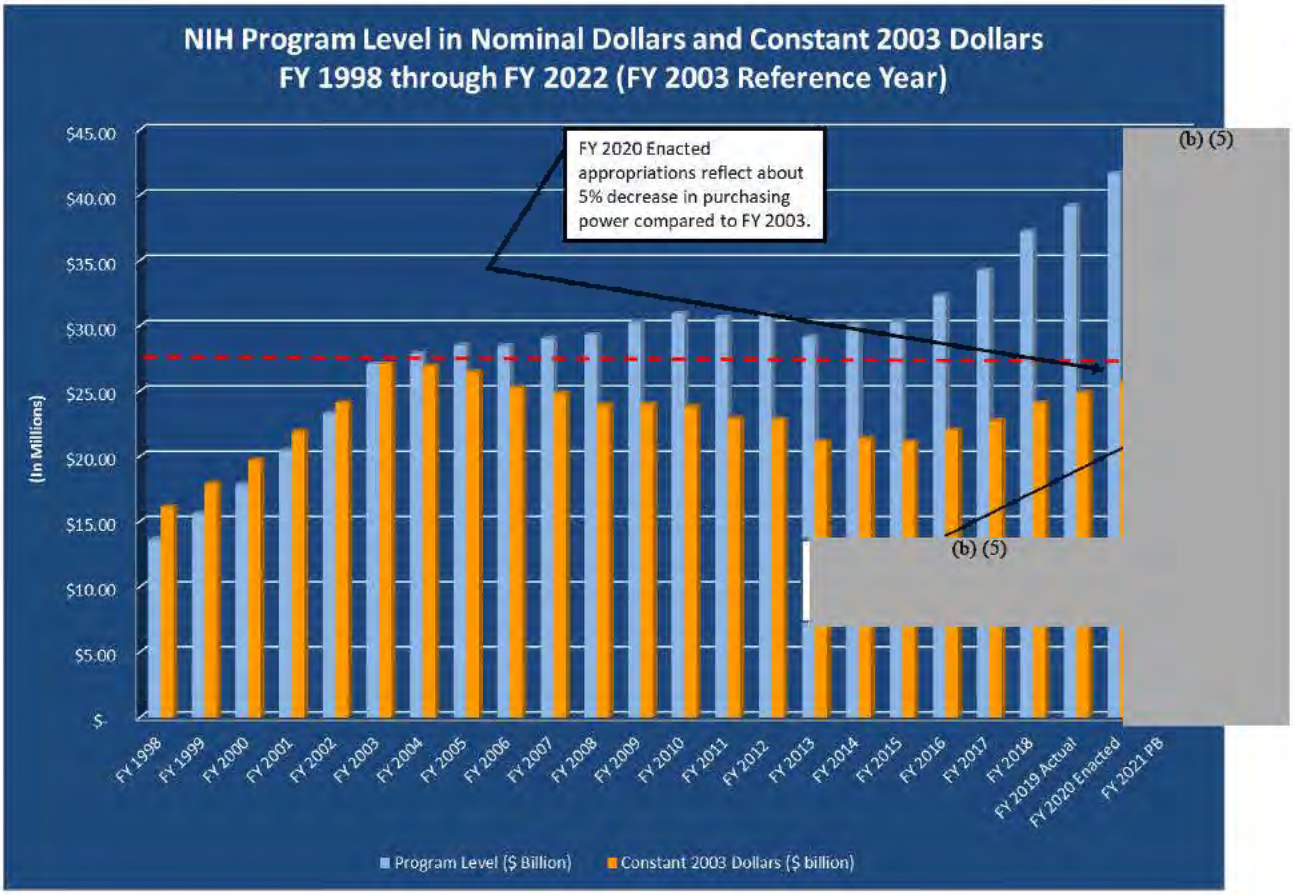
| Activities | FY 2019 Final [1] | FY 2020 Enacted[1] |
|---|---|---|
| National Institute on Drug Abuse: | | |
| National Institute on Drug Abuse | 1,150 | 1,196 |
| Research related to Opioid Addiction | 258 | 266 |
| Subtotal, NIDA | 1,408 | 1,462 |
| National Institute on Alcohol Abuse and Alcoholism | 525 | 545 |
| National Institute of Nursing Research | 163 | 169 |
| National Human Genome Research Institute [10] | 575 | 606 |
| Natl Institute of Biomedical Imaging and Bioengineering | 388 | 404 |
| Natl Institute on Minority Health and Health Disparities: | | |
| Natl Institute on Minority Health and Health Disparities | 250 | 261 |
| Research Centers in Minority Institutions (RCMIs) | 63 | 75 |
| Subtotal, NIMHD | 313 | 336 |
| Natl Center for Complementary and Integrative Health | 146 | 152 |
| National Center for Advancing Translational Sciences: | | |
| All Other NCATS | 201 | 205 |
| Cures Acceleration Network (CAN) | 45 | 49 |
| Clinical and Translational Science Awards (CTSAs) | 558 | 578 |
| Research related to Opioid Addiction | 12 | - |
| Subtotal, NCATS | 816 | 833 |
| Fogarty International Center | 78 | 81 |
| National Library of Medicine: | | |
| All Other NLM | 437 | 453 |
| Information Systems Improvements | 4 | 4 |
| Subtotal, NLM | 441 | 457 |
| Office of the Director: | | |
| All Other OD [5,6] | 1,066 | 1,253 |
| All of Us Research Program (non-add) [7] | 190 | 351 |
| All Other Common Fund | 607 | 627 |
| Common Fund (Pediatric Research Initiative Fund) | 13 | 13 |
| Subtotal, Common Fund (with Pediatric Research Initiative Fund) | 619 | 639 |
| Extramural Construction – Biomedical Research Facilities | 50 | 50 |
| National Children's Study (ECHO) | 165 | 180 |
| Firearms Research | - | 13 |
| INCLUDE | - | 60 |
| Chief Data Strategist | - | 30 |
| AIDS Conference | - | 5 |
| Office of National Security | - | 5 [16] |
| NASEM Study of Women's Health | - | 2 |
| NASEM Study of Organ Donation | - | 2 |
| NASEM Study of Inclusion | - | 1 |
| OAR Construction Grants | 8 | 8 |
| Subtotal, OD [6,11,12,13,17] | 1,908 | 2,247 |
| NIH Innovation, CURES Act [8] | 196 | 157 |
| All of Us Research Program (non-add) [7] | 186 | 149 |
| Regenerative Medicine (non-add) | 10 | 8 |
| Subtotal, CURES | 196 | 157 |

| Activities | FY 2019 Final [1] | FY 2020 Enacted[1] |
|---|---|---|
| Buildings and Facilities | 199 | 200 |
| **Total, NIH Program Level *** | **39,184** | **41,685** |
| Buildings and Facilities NEF Financing [14] | - | 225 |
| **Total, NIH Program Level and NEF Financing** | **39,184** | **41,910** |
| Less Funds Allocated from different sources: | | |
| PHS Program Evaluation | (1,147) | (1,231) |
| Buildings and Facilities NEF Financing [14] | - | (225) |
| Type 1 Diabetes | (150) | (150) |
| **Total, NIH Discretionary Budget Authority** | **37,887** | **40,304** |
| Interior - Superfund Activities | (79) | (81) |
| **Total, Labor - HHS Discretionary Budget Authority [15,17]** | **37,808** | **40,224** |

[1] Includes transfer authority under the NIH Innovation Account, 21st Century Cures (CURES) Act.
[2] Includes FY 2020 mandatory funding for Special Type 1 Diabetes research program, provided in P.L. 116-94.
[3] Amount includes the $50 million increase for antibiotic resistance research provided in FY 2020.
[4] Amount includes the $350 million increase for Alzheimer's disease research provided in FY 2020.
[5] Includes up to $10,000 for official reception and representation expenses.
[6] Reflects $5 million transferred to the Health and Human Services Office of Inspector General (OIG).
[7] Office of the Director (OD) includes a total of $500 million for the All of Us Research Program (Precision Medicine Initiative), including $351 million in All Other OD, and $149 million from the NIH Innovation CURES Act.
[8] Funds authorized in P.L. 114-255, CURES Act.
[9] Amount includes a $25 million increase to HIV/AIDS research provided in FY 2020.
[10] Amount includes a $10 million increase for Emerging Centers of Excellence in Genomic Sciences research provided in FY 2020.
[11] Amount includes $500 million for BRAIN Initiative research provided in FY 2020.
[12] Amount includes $25 million for Best Pharmaceutical for Children Act research provided in FY 2020.
[13] Amount includes $51 million for Centers for AIDS Research provided in FY 2020.
[14] The FY 2020 Appropriations Act allocates $225,000,000 in the Nonrecurring Expenses Fund for NIH.
[15] Funds provided in P.L. 116-20 for disaster response are not displayed on this plan.
[16] NIH obligated $4 million instead of the $5 million cited in the report for Office of National Security's (ONS) implementation of the NIH Counterintelligence/Insider Threat Program. This is funded from NIH-wide contributions rather than OD alone. The maximum amount ONS can execute given competing ONS priorities in FY 2020 for COVID-19 is $2.35 million. The remaining funding will be carried over to FY 2021 for use by ONS.
[17] Total does not add up due to rounding.

## MAJOR BUDGETARY CONSTRAINTS

Due to strong Congressional support, the NIH budget rose from $32.3 billion in FY 2016 to $41.7 billion in FY 2020. (b) (5) . The large increases helped address many years of declining purchasing power when the NIH budget was eroded by inflation. Based on the rate of biomedical research inflation (BRDPI), NIH's purchasing power in FY 2015 was 22 percent below its peak in FY 2003, but the recent increases have made up all but (b) (5) of that loss in real dollars.




One current specific budgetary constraint for NIH is periodic expiration of mandatory funding for the Special Type 1 Diabetes Program (T1D). The T1D program has enabled the creation of innovative, collaborative research consortia and supports clinical trials networks. This account contributes $150 million of mandatory funding annually but is particularly vulnerable to reauthorization delays. Expirations create challenges in planning long-term research efforts. Funding extensions usually occur before the expiration date, but in FY 2017, the program expired and was not extended until nearly three months into the fiscal year. Current authorization for the T1D program ends December 11, 2020, and reauthorization has been proposed. Depending on the time period of reauthorization, T1D may be subject to sequestration of mandatory appropriations in some years. This could reduce funding (by a percentage determined each year) for a fiscal year that is reauthorized early enough to be included in OMB's annual sequestration calculations.

**NIH Biomedical Research and Development Price Index (BRDPI)**

| Annual Rate of Change [1] | | | |
|---|---|---|---|
| Actual | Projected | | |
| 2019 | 2020 | 2021 | 2022 |
| 2.1% | 2.5% | (b) (5) | |

[1]NIH BRDPI statistics are updated annually and stored on the NIH Office of Budget (OB) website. Refer to Price Indexes page on OB website.

**INFRASTRUCTURE**

NIH is one of the four land-holding agencies in HHS. With a backlog of maintenance and repairs (BMAR) of $2.1 billion and growing, the state of some NIH buildings compromises the operational effectiveness of programmatic activities and the safety of patients, staff, visitors, and animals. The operational reliability of major utilities is jeopardized at some facilities, which affects NIH's ability to maintain research and hospital functions.

An independent review of the facility needs of NIH's main campus by the National Academies of Sciences, Engineering, and Medicine released in August 2019 highlights pressing campus-wide infrastructure needs and recommends improvements to NIH's capital planning and funding processes, including prioritizing projects of highest functional research value. The report further recommends a total of $1.3 billion in new funding to address the Bethesda Campus's needs to upgrade its buildings and facilities. NIH asserts that a sustained increase in building and facilities funding along with new transfer authorities are necessary to halt the backlog growth.

**DATA SCIENCE AND ARTIFICIAL INTELLIGENCE**

The complexity and volume of basic, translational, and clinical research data generated by NIH-supported investigators continues to rapidly increase. To take full advantage of these data, NIH must integrate the collection, storage, analysis, use, and sharing of these data according to findability, accessibility, interoperability, and reusability (FAIR) practices and foster a talented and diverse data science workforce. In June 2018, NIH released a new roadmap to modernize the NIH-funded biomedical data ecosystem, the NIH Strategic Plan for Data Science. The Office of Data Science Strategy coordinates activities across NIH, including the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative. STRIDES is an ongoing effort that enables NIH to provide researchers cost-effective access to industry-leading cloud service providers for the storage of rich datasets, advanced computational infrastructure, tools, and professional services.

Artificial intelligence (AI) methodologies offer the ability to make sense of complex datasets that are too large for humans to manually process, to reduce noise in the data, and to find the most relevant data relating to the question being asked. AI has the potential to accelerate biomedical and clinical research, and improve clinical care, if used with an understanding of its limitations and consideration of the ethical complications. In 2019, the NIH Director announced the formation of an AI working group of the Advisory Committee to the Director that made recommendations for how NIH can best collaborate with computer and data science communities, encourage computer scientists to engage in biomedical research, and identify the major ethical considerations related to AI in health research and care.

## BUDGET HISTORY

### History of Congressional Appropriations, Fiscal Years 2012-2020
(Dollars in Millions)

| Institute or Center | FY 2012 | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 | FY 2018 | FY 2019 | FY 2020 |
|---|---|---|---|---|---|---|---|---|---|
| NCI | 5,072 | 4,807 | 4,923 | 4,950 | 5,215 | 5,689 | 5,965 | 6,144 | 6,440 |
| NHLBI | 3,079 | 2,918 | 2,989 | 2,998 | 3,116 | 3,207 | 3,383 | 3,488 | 3,624 |
| NIDCR | 411 | 389 | 399 | 400 | 416 | 426 | 448 | 462 | 477 |
| NIDDK[1] | 1,947 | 1,846 | 1,883 | 1,900 | 1,968 | 2,010 | 2,121 | 2,180 | 2,265 |
| NINDS | 1,626 | 1,541 | 1,588 | 1,605 | 1,696 | 1,784 | 2,188 | 2,274 | 2,445 |
| NIAID | 4,491 | 4,256 | 4,359 | 4,359 | 4,630 | 4,907 | 5,260 | 5,523 | 5,885 |
| NIGMS[2] | 2,430 | 2,303 | 2,364 | 2,371 | 2,512 | 2,651 | 2,785 | 2,873 | 2,937 |
| NICHD | 1,321 | 1,252 | 1,283 | 1,287 | 1,340 | 1,380 | 1,452 | 1,506 | 1,557 |
| NEI | 703 | 666 | 682 | 684 | 716 | 733 | 772 | 797 | 824 |
| NIEHS[3] | 764 | 725 | 743 | 745 | 771 | 792 | 828 | 854 | 884 |
| NIA | 1,103 | 1,046 | 1,171 | 1,199 | 1,600 | 2,049 | 2,574 | 3,083 | 3,544 |
| NIAMS | 536 | 508 | 520 | 522 | 542 | 558 | 587 | 605 | 625 |
| NIDCD | 416 | 395 | 404 | 405 | 423 | 437 | 460 | 474 | 491 |
| NIMH | 1,480 | 1,403 | 1,446 | 1,463 | 1,548 | 1,602 | 1,755 | 1,870 | 2,038 |
| NIDA | 1,053 | 998 | 1,025 | 1,029 | 1,077 | 1,091 | 1,384 | 1,420 | 1,462 |
| NIAAA | 460 | 436 | 446 | 447 | 468 | 483 | 510 | 526 | 545 |
| NINR | 145 | 137 | 141 | 141 | 146 | 150 | 158 | 163 | 169 |
| NHGRI | 513 | 486 | 498 | 499 | 519 | 529 | 557 | 576 | 606 |
| NIBIB | 338 | 321 | 329 | 330 | 347 | 357 | 378 | 389 | 404 |
| NIMHD | 276 | 262 | 268 | 269 | 280 | 289 | 303 | 315 | 336 |
| NCCAM/NCCIH[4] | 128 | 121 | 124 | 125 | 131 | 135 | 142 | 146 | 152 |
| NCATS | 575 | 545 | 633 | 635 | 685 | 706 | 742 | 806 | 833 |
| FIC | 70 | 66 | 68 | 68 | 70 | 72 | 76 | 78 | 81 |
| NLM[5] | 338 | 320 | 328 | 337 | 395 | 408 | 429 | 442 | 457 |
| OD[6] | 1,459 | 1,448 | 1,400 | 1,414 | 1,571 | 1,730 | 1,926 | 2,118 | 2,404 |
| B&F | 125 | 119 | 129 | 129 | 129 | 129 | 129 | 200 | 200 |
| Total Budget Authority | 30,861 | 29,316 | 30,143 | 30,311 | 32,311 | 34,301 | 37,311 | 39,313 | 41,685 |
| NLM P&E | 8 | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| Institute or Center | FY 2012 | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 | FY 2018 | FY 2019 | FY 2020 |
|---|---|---|---|---|---|---|---|---|---|
| **Program Total*** | **30,869** | **29,324** | **30,143** | **30,311** | **32,311** | **34,301** | **37,311** | **39,313** | **41,685** |
| | | | | | | | | | |
| **Non-Recur Sources:** | | | | | | | | | |
| **Ebola Supplemental[7]** | .. | .. | .. | 238 | .. | .. | .. | -- | .. |
| **Zika Supplemental[8]** | .. | .. | .. | .. | .. | 152 | .. | .. | .. |
| **Hurricane Supplemental[9]** | .. | 149 | .. | .. | .. | -- | 50 | 1 | .. |
| **Coronavirus Supplemental[10]** | .. | .. | .. | .. | .. | .. | .. | -- | 3,587 |
| **NEF[11]** | | | | | | | | | 225 |
| **Program Total** Incl. Non-Recur Sources | **30,869** | **29,473** | **30,143** | **30,549** | **32,311** | **34,453** | **37,361** | **39,314** | **45,497** |

* Derived from recurring funding sources consistent with typical NIH budget requests prepared and presented annually to the Congress. Excludes resources provided from Nonrecurring Expenses Fund (NEF).

[1] Includes $150 million for mandatory Special type 1 Diabetes Research funding. This amount is not included in the Operating Plan table provided in this document.

[2] Includes Program Evaluation (PE) financing o $780 million in FY 2016, $824 million in FY 2017, $923 million in FY 2018, $1,147 million in FY 2019 and $1,231 million in FY 2020.

[3] Includes amounts received from the Interior Appropriation for Superfund Research.

[4] The National Center for Complementary and Alternative Medicine (NCCAM) was renamed as NCCIH in FY 2015.

[5] Includes Program Evaluation financing of $8.2 million in FY 2014 that was previously received as a transfer-in from HHS.

[6] Figure for FY 2020 reflects $5 million transferred to the Health and Human Services Office of Inspector General (OIG).

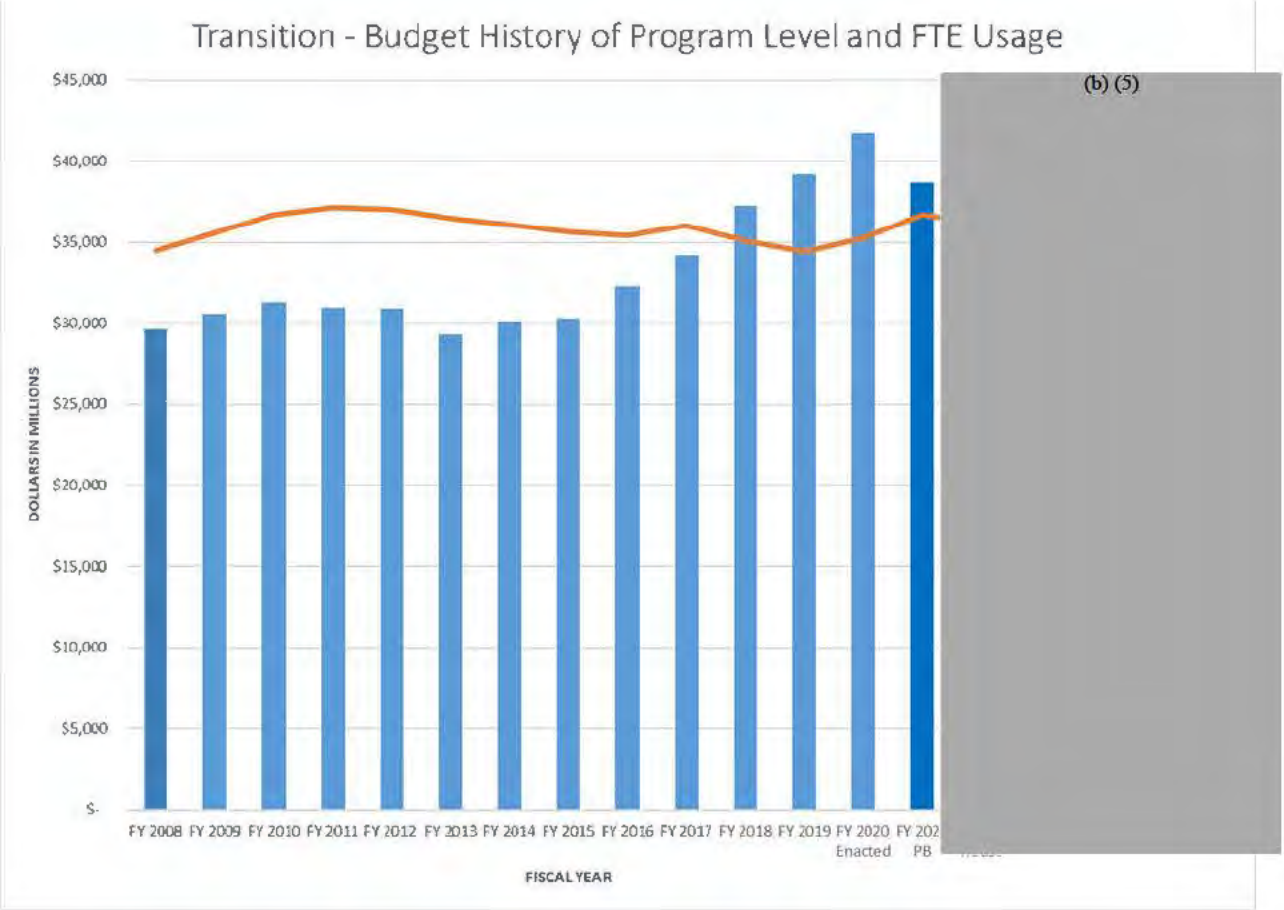
[7] Amount provided to NIAID by the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235). Available for obligation for 2 years (FY 2015 and FY 2016).

[8] In FY 2017, $152 million was received by NIAID from the "Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act", enacted in September 2016.

[9] NIH received supplemental funding from allocations from HHS in FY 2013 derived from the Disaster Relief Appropriations Act of 2013 (DRAA; P.L. 113-2), direct appropriations to OD in FY 2018 from the Bipartisan Budget Act of 2018 (P.L. 115-123), and direct appropriations to NIEHS from the Additional Supplemental Appropriations for Disaster Relief Act, 2019 (P.L. 116-20).

[10] Consists of three supplementals for COVID-19. The amounts are $836 million in P.L. 116-123, $945 million in P.L. 116-136, and $1,806 million in P.L. 116-139 that was provided to NIH through directive transfer from the PHSSEF.

[11] NIH received $225 million from the "Nonrecurring Expenses Fund" for buildings and facilities in the Further Consolidated Appropriations Act, 2020 (P.L. 116-94). This table does not include similar amounts that were allocated within HHS rather than specified by Congress.




## MISCELLANEOUS FUNDING SOURCES

Virtually all of NIH funding is provided by Congress in the annual appropriations acts. NIH also partners with other Federal agencies, such as the U.S. Food and Drug Administration (FDA), as well as with private firms and non-profit entities leveraging a small amount of funding received through gifts, Cooperative Research and Development Agreements, and royalties.

Royalty and gift accounts allow NIH the flexibility to collaborate with pharmaceutical companies and non-profits in a way that taps each collaborator's strength to ensure the best contributions to science. The Foundation for the National Institutes of Health (FNIH) is a public charity created by Congress to support the mission of NIH. FNIH has helped with initiatives such as the Accelerating Medicines Partnership, which seeks to identify new drug targets for Alzheimer's disease, type 2 diabetes, and the autoimmune disorders lupus and rheumatoid arthritis.

## CORONAVIRUS SUPPLEMENTAL APPROPRIATIONS

NIH received a total of $3.587 billion from three FY 2020 supplemental appropriations enacted in response to the COVID-19 pandemic, including $836 million in P.L. 116-123, $945 million in P.L. 116-136, and $1.806 billion in P.L. 116-139 (by transfer from the Public Health and Social Services Emergency Fund). The funds were provided to seven ICs (NIAID, NIBIB, NCI, NHLBI, NCATS, NIEHS, and NLM) and OD. The largest portion of the funds are for Diagnostics, including over $1 billion for the Rapid Acceleration of Diagnostics (RADx[SM]) initiative implemented by NIBIB and OD. The other major categories are Vaccines, Therapeutics, Basic Research, and Facilities. As of September 30, 2020, NIH has obligated a total of $1.535 billion and disbursed $254 million. In addition, Operation Warp Speed (OWS), NIH is implementing several major clinical trials on behalf of the Biomedical Advanced Research and Development Authority (BARDA). This includes vaccine and therapeutic trials under the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership and programmatic support. As of the end of September 2020, NIH has obligated about $1.573 billion for OWS.

## EXPENDITURES

There are many ways to display the NIH budget. One dimension is whether funds are spent "outside" or "inside" NIH. Extramural research reflects expenditure of dollars external to the NIH and all other spending is treated as internal to NIH.

- **Extramural research**. NIH typically makes grants for a multi-year period and awards funding one year at a time. A large portion of the research budget is committed to noncompeting renewals, with a smaller portion for new competing awards.
- **Intramural research**. Conducted by NIH employees in NIH labs and the Clinical Center. Expenses include personnel costs (30%) and contract and other non-personnel costs (70%).
- **Research management and support (RMS)**. RMS covers administrative, budgetary, logistical, and scientific support activities. Expenses include personnel costs (46%) and contract and other non-personnel costs (54%).
- **Facilities**. Facilities spending funds construction projects and repairs, improvements, and renovations at NIH-owned facilities on the main Bethesda campus and at other sites.


A second breakdown is how resources are aligned by delivery mode, i.e. "mechanism." Each year, the majority of NIH's budget goes to fund research and training grants. These grants, and other expenditures such as the NIH intramural program, are broken out in the budget mechanism table. This table is used at both the NIH-wide level and for individual ICs to provide a common format for budget details in terms of the funding mechanisms used throughout NIH. (Individual ICs also display their budgets by activity, which is unique to each IC and usually more closely aligned to organizational structure than to budget mechanism.)

## Mechanism Table
(Dollars in Millions)

TOTAL – INCLUDING AIDS

| Mechanism[1] | FY 2019 Final Allocation[5] | | FY 2020 as of June 30, 2020[5] | |
|---|---|---|---|---|
| | No. | Amount | No. | Amount |
| Research Projects | | | | |
| Noncompeting | 27,624 | $14,565 | 28,766 | $15,862 |
| Administrative Supplements | *(2,341)* | $437 | *(2,187)* | $528 |
| Competing | 11,020 | $6,314 | 11,197 | $6,271 |
| Subtotal, RPGs | 38,644 | $21,316 | 39,963 | $22,662 |
| SBIR/STTR | 2,023 | $1,052 | 2,106 | $1,130 |
| Research Project Grants | 40,667 | $22,368 | 42,069 | $23,792 |
| | | | | |
| Research Centers | | | | |
| Specialized/Comprehensive | 998 | $1,928 | 1,024 | $1,919 |
| Clinical Research | 70 | $421 | 70 | $433 |
| Biotechnology | 85 | $142 | 79 | $129 |
| Comparative Medicine | 50 | $137 | 51 | $137 |
| Res. Centers in Minority Institutions | 19 | $63 | 29 | $74 |
| Subtotal, Centers | 1,222 | $2,691 | 1,253 | $2,691 |
| | | | | |
| Other Research | | | | |
| Research Careers | 4,222 | $790 | 4,443 | $840 |
| Cancer Education | 77 | $20 | 72 | $20 |
| Cooperative Clinical Research | 257 | $468 | 266 | $499 |
| Biomedical Research Support | 131 | $81 | 134 | $84 |
| Minority Biomed. Res. Support | 286 | $100 | 280 | $98 |
| Other | 2,134 | $1,114 | 2,279 | $1,196 |
| Subtotal, Other Research | 7,107 | $2,574 | 7,474 | $2,738 |
| Total Research Grants | 48,996 | $27,633 | 50,796 | $29,221 |
| | | | | |
| Training | FTTPs | | FTTPs | |
| Individual | 3,654 | $170 | 3,880 | $189 |
| Institutional | 13,221 | $695 | 13,696 | $729 |
| Total, Training | 16,875 | $865 | 17,576 | $917 |
| | No. | | No. | |
| Research & Develop. Contracts | 2,455 | $3,165 | 2,643 | $3,285 |
| *SBIR/STTR (non-add) ** | *(129)* | *$91* | *(109)* | *$73* |
| | | | | |
| Intramural Research | | $4,144 | | $4,468 |
| Res. Management & Support | | $1,883 | | $2,012 |
| *SBIR Admin (non-add) ** | | *$8* | | *$10* |
| | | | | |
| Office of the Director | | | | |

| Mechanism[1] | FY 2019 Final Allocation[5] | | FY 2020 as of June 30, 2020[5] | |
|---|---|---|---|---|
| | No. | Amount | No. | Amount |
| OD – Other | | $1,197 | | $1,471 |
| *OD Common Fund (non-add) *[2]* | | *$619* | | *$639* |
| *ORIP/SEPA (non-add) *[2]* | | *$288* | | *$294* |
| *OD Appropriation (non-add) *[2]* | | *$2,104* | | *$2,404* |
| | | | | |
| Buildings and Facilities [3] | | $217 | | $230 |
| Type 1 Diabetes [4] | | -$150 | | -$150 |
| Program Evaluation Financing | | -$1,147 | | -$1,231 |
| | | | | |
| **Total, Labor/HHS Budget Authority (BA)** | | **$37,808** | | **$40,223** |
| Superfund Activities | | $79 | | $81 |
| **Total Discretionary BA** | | **$37,887** | | **$40,304** |
| Type 1 Diabetes | | $150 | | $150 |
| **Total, NIH BA** | | **$38,037** | | **$40,454** |
| Program Evaluation Financing | | $1,147 | | $1,231 |
| **Total, Program Level** | | **$39,184** | | **$41,685** |

*All numbers in italics and brackets are non-add

[1]All Subtotal and Total numbers may not add due to rounding.

[2]Number of grants and dollars for the Common Fund, ORIP, and SEPA components of OD are distributed by mechanism and are noted here as non-add. Office of the Director – Appropriations is the non-add total of these amounts and the funds are accounted for under OD – Other.

[3]Includes B&F appropriation and monies allocated pursuant to appropriations act provisions that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

[4]Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.

[5]Excludes supplemental funding.

Another way to look at NIH expenditures is by "object class" which involves a line-item breakdown of what goods and services are purchased. The table below shows the distribution of resources associated with object class that fund salaries and benefits ("pay costs") and those unrelated to employee payroll ("non-pay costs"). Employee payroll is a relatively small portion of NIH spending. The largest object class by far is the one that covers grants.

## Transition – FY 2020 and FY 2021 Expenditure Breakdown (Object Class)[1]

(Dollars in Millions)

| Object Classes | FY 2019 Actual Obligations | FY 2020 Enacted Budget Authority |
|---|---|---|
| <u>Personnel Compensation</u> | | |
| Full-Time Permanent (11.1) | $1,009 | $1,084 |
| Other Than Full-Time Permanent (11.3) | $527 | $564 |
| Other Personnel Compensation (11.5) | $49 | $52 |
| Military Personnel (11.7) | $18 | $19 |
| Special Personnel Services Payments (11.8) | $197 | $207 |
| **Subtotal Personnel Compensation (11.9)** | **$1,800** | **$1,925** |

| Object Classes | FY 2019 Actual Obligations | FY 2020 Enacted Budget Authority |
|---|---|---|
| **Civilian Personnel Benefits (12.1)** | $527 | $599 |
| **Military Personnel Benefits (12.2)** | $14 | $15 |
| **Benefits to Former Personnel (13.0)** | $0 | $0 |
| **Total Pay Costs** | **$2,340** | **$2,538** |
| | | |
| **Travel & Transportation of Persons (21.0)** | $61 | $63 |
| **Transportation of Things (22.0)** | $5 | $5 |
| **Rental Payments to GSA (23.1)** | $24 | $26 |
| **Rental Payments to Others (23.2)** | $1 | $1 |
| **Communications, Utilities & Misc. Charges (23.3)** | $19 | $19 |
| **Printing & Reproduction (24.0)** | $0 | $0 |
| **Consultant Services (25.1)** | $226 | $277 |
| **Other Services (25.2)** | $1,436 | $1,539 |
| **Purchase of Goods and Services from Government accounts (25.3)** | $3,507 | $3,764 |
| **Operation & Maintenance of Facilities (25.4)** | $232 | $241 |
| **R&D Contracts (25.5)** | $1,555 | $1,631 |
| **Medical Care (25.6)** | $35 | $36 |
| **Operation & Maintenance of Equipment (25.7)** | $172 | $174 |
| **Subsistence & Support of Persons (25.8)** | $0 | $0 |
| **Subtotal Other Contractual Services (25.0)** | **$7,182** | **$7,663** |
| | | |
| **Supplies & Materials (26.0)** | $241 | $261 |
| **Equipment (31.0)** | $178 | $199 |
| **Land and Structures (32.0)** | $2 | $41 |
| **Investments & Loans (33.0)** | $0 | $0 |
| **Grants, Subsidies & Contributions (41.0)** | $27,707 | $29,637 |
| **Insurance Claims & Indemnities (42.0)** | $0 | $0 |
| **Interest & Dividends (43.0)** | $0 | $0 |
| **Refunds (44.0)** | $0 | $0 |
| **Subtotal Non-Pay Costs** | **$35,420** | **$37,916** |
| **Total** | **$37,760** | **$40,454** |

[1]Includes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Subcommittee. Excludes P&E financing and supplemental resources.

# COMPONENT INFORMATION

# OFFICE OF THE DIRECTOR (OD)

**Budget Summary**
(Dollars in Millions)

| OD | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 1,571.2 | 3,277.3 | |
| Less (specify sources) | | 1,030.0 | |
| Total Budget Authority | 1,571.2 | 2,247.3 | |
| FTE | 685 | 778 | |

## OD MISSION

The Office of the Director (OD) provides leadership and guidance to foster trans-NIH activities by strategically planning, managing, and implementing policies and procedures to facilitate cutting-edge biomedical research. OD, through the NIH Director, is responsible for providing leadership to the Institutes and Centers (ICs) and for identifying needs and collaborative opportunities.

**OD OPERATIONS OFFICES**

- **Immediate Office of the Director (IMOD)** directly serves the NIH Director and the NIH Principal Deputy Director in a wide range of support functions to aid them in their leadership of the Agency.
- **Office of Equity, Diversity, and Inclusion (EDI)** is a Federally mandated policy portfolio whose purpose is to foster an inclusive culture at NIH, increase diversity representation, provide demographic diversity data analyses, and manage the agency's civil rights program.
- **Executive Secretariat (ES)** is a confidential agent of the NIH Director and Principal Deputy Director and part of IMOD. ES manages all policy/administrative documents, including their official email, all other mail, HHS and EOP assignments, congressional reports, meeting materials, invitations, FOIA, and records.
- **NIH Ethics Office (NEO)** provides leadership and oversight to the NIH Ethics Program to ensure that employees are educated on and in compliance with ethics statutes, regulations, and policies.
- **Office of the Chief Information Officer (OCIO)** provides advice to the NIH Director and IC leadership on the strategic direction and management of NIH IT and Cybersecurity activities and supports NIH and HHS compliance with OMB mandates and Federal law.
- **Office of Communications and Public Liaison (OCPL)** communicates the NIH mission, scientific research results, and health information to the public; provides leadership and guidance to the communications offices at NIH's other Institutes and Centers; and speaks for NIH as a whole.
- **Executive Office (ODEO)** is the primary administrative support for the NIH OD. The ODEO advises the NIH Principal Deputy Director/OD Director, NIH Associate Deputy Director/OD Deputy Director, and other key OD officials in the areas of OD administration, financial management, program analysis, information technology (IT), IT security and network operations.
- **Office of Extramural Research (OER)** provides the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship. Its activities serve NIH staff and extramural constituents and include high profile digital platforms, grant compliance, peer review policy, outreach, and laboratory animal welfare.

- **Office of Federal Advisory Committee Policy (OFACP)** is responsible for NIH-wide development and implementation of policies and procedures for the establishment, appointment of members, and management of approximately 150 Federal advisory committees.
- **NIH Branch of the HHS Office of the General Counsel's (OGC) Public Health Division** provides advice, representation, and other legal services to NIH. OGC coordinates with the DOJ when NIH is involved in litigation and advises and represents NIH on HHS-wide matters.
- **Office of Intramural Research (OIR)** oversees NIH-wide policies covering laboratory, clinical, and population-based research that is conducted in NIH Federal labs across the United States, including Maryland, North Carolina, Montana, Arizona, Massachusetts, and Michigan. OIR oversees research review, training of future scientists, career development, human subjects research, research animal care and use, and technology transfer.
- **Office of Legislative Policy and Analysis (OLPA)** provides essential information, advice, and guidance on congressional actions affecting NIH to the NIH community, and is the principal point-of-contact and liaison with members of Congress and their staff.
- **Office of Management (OM)** is responsible for NIH-wide administration and management. OM provides leadership, direction, and oversight to diverse organizations at NIH in budget and finance, human resources, management assessment and policy, program integrity, contract, procurement, and logistics, engineering services, safety, space, facility management, support services, and security operation.
- **Office of the Ombudsman/Center for Cooperative Resolution (OOCCR)** facilitates collaborative processes and the creative resolution of conflict for the entire NIH community.
- **Office of Science Policy (OSP)** is the primary advisor to the NIH Director on matters of biomedical research policy issues that are of broad significance to the agency in key areas of emerging technologies, biosafety, biosecurity, technology transfer, data sharing, human subjects protections, and clinical and healthcare research.
- **Office of the Chief Officer for Scientific Workforce Diversity (COSWD)** uses data-driven, evidence-based approaches in leading NIH's effort to diversify the national scientific workforce through expanded recruitment and retention.

**OD PROGRAMMATIC OFFICES**

- **Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)** provides leadership for identifying, reporting, and funding trans-NIH research that represents areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps meriting further research and benefiting from collaboration, strategic coordination, and planning across the ICOs. DPCPSI offices include:
    - **Office of AIDS Research (OAR)** coordinates the scientific, budgetary, and policy elements of a diverse HIV research program across the NIH. Over the past 30 years, OAR has coordinated the expansion of NIH-supported HIV research using a science- and evidence-based approach into a robust, multi-institute, multidisciplinary global research program with a substantial research pipeline, from basic science to public health and policy.
    - **Office of Behavioral and Social Sciences Research (OBSSR)** coordinates behavioral and social sciences research conducted or supported by NIH, integration of these sciences within the larger NIH research enterprise, and communication of health-related behavioral and social sciences research findings to various stakeholders within and outside the Federal government.
    - **Office of Data Science Strategy (ODSS**) is building a modernized and integrated biomedical data ecosystem, leading implementation of the NIH Strategic Plan for Data Science and collaborating closely with across NIH. Under these efforts, NIH is developing technical infrastructure;

integrating data collection, storage, analysis, use, and sharing according to findable, accessible, interoperable, and reusable practices; and fostering a talented and diverse data science workforce.
    - **Office of Dietary Supplements (ODS)** strengthens knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.
    - **Office of Disease Prevention (ODP)** is responsible for assessing, facilitating, and stimulating research in disease prevention, and disseminating the results of this research to improve public health.
    - **Office of Evaluation, Performance, and Reporting (OEPR)** provides leadership, capacity building, and coordination of NIH stewardship efforts pertaining to strategic planning, progress monitoring, evaluation, and reporting.
    - **Office of Nutrition Research (ONR)** elevate attention to and ensure a coordinated approach to nutrition research across NIH.
    - **Office of Portfolio Analysis (OPA)** accelerates the impact of biomedical research funding through development and dissemination of new methods, tools, and best practices that enable scientific analysis of NIH investments and their role in advancing knowledge that improves human health.
    - **Office of Research Infrastructure Programs (ORIP)** advances the NIH mission by strengthening scientific infrastructure through support of research resources, such as animal models of human disease and cutting-edge biomedical instrumentation and research-training opportunities for veterinary scientists.
    - **Office of Research on Women's Health (ORWH)** ensures that NIH-funded research rigorously addresses issues concerning the health of women, accounts for the potential influence of sex and gender in health and disease, and incorporates appropriate representation of women in studies—as research participants and as biomedical scientists—in collaboration with the ICOs.
    - **Office of Strategic Coordination (OSC)** manages the NIH Common Fund, which supports bold, goal-driven programs that accelerate emerging science, remove research roadblocks, enhance the biomedical research workforce, or support high-risk, high-reward science.
    - **Sexual & Gender Minority Research Office (SGMRO)** coordinates Sexual and Gender Minority (SGM) health-related research and activities by working directly with the ICOs. The Office also serves as a resource for extramural investigators interested in SGM health research.
    - **Tribal Health Research Office (THRO)** coordinate tribal health research across NIH and serves to ensure meaningful and timely input from Tribal Nations on the development of NIH programs and policies.
    - **Office of Administrative Management and Communications (OAMC)** provides administrative management, strategic business solutions, and communications support and services to the 13 offices that comprise DPCPSI.
- ***All of Us* Research Program** leads and coordinates the *All of Us* Research Program, an effort to collect and study data from one million or more people living in the United States. It implements the study's protocol with its Consortium partners and assists the research community, including ICs, to use its platform.
- **Environmental influences on Child Health Outcomes (ECHO)** is an extramural research program office to enhance the health of children for generations to come. ECHO investigators study the effects of a broad range of early environmental influences on child health and development.
- **Helping to End Addiction Long-term (HEAL)** coordinates of NIH HEAL Initiative programmatic activities between the Office of the Director and relevant Institutes and Centers.

## OD BUDGET

The FY 2020 budget supported activities managed by the OD's operational and research offices. The OD's FY 2020 budget included resources to support new and expanding initiatives and research efforts on firearm injury and mortality prevention, maternal mortality and morbidity, preterm, low birthweight & health of newborns, the INCLUDE, and the Common Fund programs that address emerging scientific opportunities and pressing challenges in biomedical research. The FY 2020 budget also supported three National Academy of Sciences, Engineering, and Medicine (NASEM) Studies and the ECHO Program designed to capitalize on existing participant populations and support approaches that can evolve with the science and take advantage of the growing number of clinical research networks and technological advances. In addition, to the FY 2020 enacted budget level, the OD received funding as follows:

**21st Century Cures Act**

- $149.0 million for the *All of Us* Research Program, a signature program at NIH, that brings together expert collaborators to create a national cohort of one million or more participants to enable research across all aspects of health and disease.
- $8.0 million for the Regenerative Medicine Innovation Project established to accelerate progress in the field by supporting clinical research on adult stem cells, while promoting scientific rigor and protecting patient safety.

**COVID-19**

- $30.0 million of supplemental funding through the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) to enable the NIH Common Fund to support high impact research throughout NIH on COVID-19, through its High Risk/High Reward program.
- $1,000.0 million from the Paycheck Protection Program and Health Care Enhancement Act Spend Plan (P.L. 116-139) to speed innovation, development, and commercialization of COVID-19 testing through the RADx℠ initiative.

**Budget Authority by Activity**

(Dollars in Millions)

| OD Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Enacted |
|---|---|---|---|---|---|
| **OD Operations** | 143.217 | 243.679 | 226.734 | 217.733 | 290.708 |
| **NIH Director's** | (1.413) | (1.413) | (1.413) | (1.413) | (1.413) |
| **Division of Program Coordination, Planning and Strategic Initiatives** | 13.074 | 15.281 | 16.566 | 17.091 | 20.030 |
| **Office of Behavioral & Social Sciences** | 26.720 | 26.708 | 27.817 | 27.871 | 28.932 |
| **Office of AIDS** | 62.222 | 62.235 | 62.245 | 62.254 | 62.256 |
| **Office of Research on Women's Health** | 42.000 | 41.983 | 43.730 | 43.812 | 45.458 |
| **Office of Disease** | 9.942 | 10.011 | 10.489 | 12.585 | 13.330 |
| **Office of Dietary** | 25.278 | 25.263 | 25.300 | 25.351 | 26.302 |
| **Office of Research Infrastructure** | 277.242 | 279.130 | 289.205 | 288.096 | 293.976 |

| OD Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Enacted |
|---|---|---|---|---|---|
| Science Education Partnership Awards/Office of | 18.541 | 0 | 0 | 0 | 0 |
| Director's Discretionary | 9.989 | 10.000 | 9.976 | 10.000 | 10.000 |
| Foundation for the National Institutes of Health | 1.000 | 1.059 | 1.250 | 1.250 | 1.250 |
| Intramural Loan Repayment and Scholarship | 7.443 | 7.442 | 7.788 | 7.823 | 8.255 |
| Nuclear Radiological Chemical | 93.392 | 93.382 | 97.123 | 97.128 | 100.042 |
| Environmental Influences on Child Health Outcomes | 164.984 | 164.969 | 164.991 | 165.000 | 180.000 |
| Reception and Representation Fund | 2 | 4 | 0 | 4 | 10 |
| Common Fund[2] | 675.628 | 695.430 | 600.707 | 619.166 | 639.111 |
| All of Us Research Program[2] | 0 | 0 | 189.996 | 189.995 | 351.000 |
| INCLUDE | 0 | 0 | 20.218 | 32.695 | 60.000 |
| BRAIN – Non-Cures | 0 | 0 | 10.000 | 10.000 | 10.000 |
| Biomedical & Behavioral Research Facilities | 0 | 0 | 0 | 50.000 | 50.000 |
| Office of Data Science Strategy[3] | 0 | 0 | 0 | 30.000 | 30.000 |
| Firearms Research | 0 | 0 | 0 | 0 | 12.500 |
| Office of National | 0 | 0 | 0 | 0 | 5.000 |
| NASEM Studies | 0 | 0 | 0 | 0 | 4.200 |
| Maternal Mortality and Morbidity | 0 | 0 | 0 | 0 | 5.000 |
| Total | 1,570.674 | 1,676.576 | 1,804.135 | 1,907.854 | 2,247.387 |

[1]FY 2017 - Science Education Partnership Awards and Office of Science Education budgets were reallocated from the OD to NIGMS.
[2]FY 2018 – All of Us Research Program-Non Cures (formerly Precision Medicine Initiative) budget level established with $130 million of resources reallocated from the Common Fund.
[3]FY 2019 – Establishment of the Office of Data Science Strategy.

## OD PRIORITY ISSUES

**Use and Availability of Non-Human Primates in NIH Funded Research:** Ensuring an adequate supply of Non-Human Primates (NHPs) to sustain NIH supported research has been an ongoing challenge and research on COVID-19 pathogenesis, treatments, and preventions has exacerbated this issue. (b) (5)

(b) (5)

[redacted]

**OD SIGNIFICANT CHANGES**

In FY 2017, a total of $18.5 million was transferred from the OD to NIGMS to reallocate resources to support the Science Education Partnership Awards and the Office of Science Education. These components were previously housed within OD's DPCPSI.

In FY 2018, a $190.0 million budget was established for the non-Cures component of the *All of Us* Research Program (formerly Precision Medicine Initiative) of which $130 million was reallocated from the Common Fund. In FY 2016, the Common Fund budget was increased by $130.0 million to support the PMI Cohort Program. In FY 2020, the *All of Us* Research Program's non-Cures budget was increased to a level of $351.0 million.

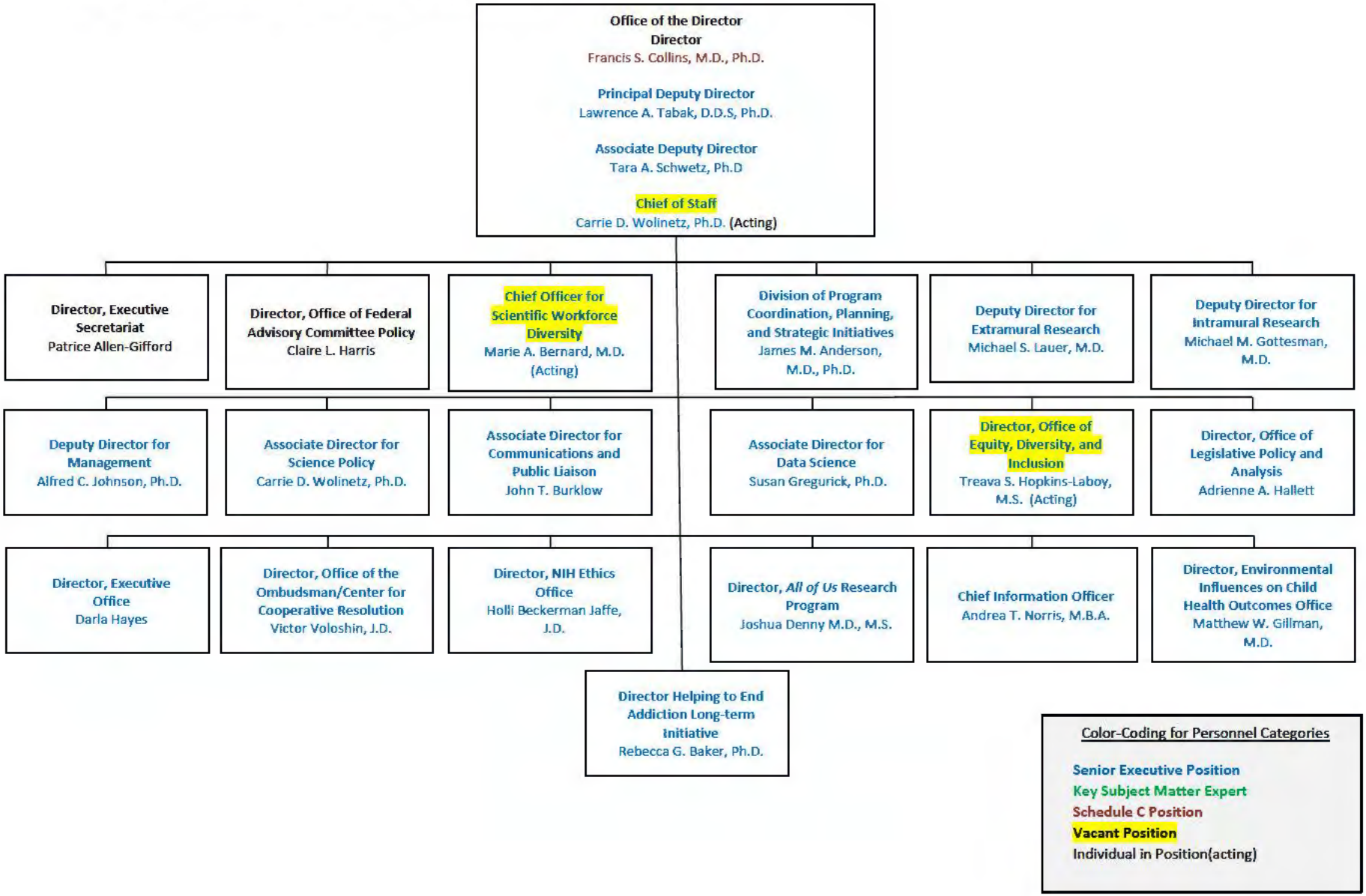
Also, in FY 2018, a $20.2 million budget was established to launch the INCLUDE project in support of a Congressional directive in the FY 2018 Omnibus Appropriations. For FY 2020, the INCLUDE budget was increased to $60.0 million.

In FY 2019, the Office of Data Science Strategy was established with a $30.0 million budget to lead the implementation of the NIH Strategic Plan for Data Science through scientific, technical, and operational collaboration with the NIH Institutes and Centers; and a budget of $50.0 million was established to support the renovation and construction of extramural biomedical and behavioral research facilities.

In FY 2020, the ECHO Program received a $15.0 million increase to support the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network.

The FY 2020 budget also included $12.5 million to support research with a broad public health approach to firearm injury and mortality prevention including identifying those at risk for firearm injury and mortality (both victims and perpetrators), development and evaluation of theoretically-grounded programs to prevent firearm injury and mortality, and implementation research to explore the barriers and facilitators to support broader adoption of effective programs.

## OD ORGANIZATIONAL CHART AND WORKFORCE



**National Institutes of Health**

Office of the Director

- Director, Francis S. Collins, M.D., Ph.D. (Schedule C Position)
- Principal Deputy Director, Lawrence A. Tabak, D.D.S., Ph.D. (Senior Executive Position)

The following report directly to the Director or Principal Deputy Director:

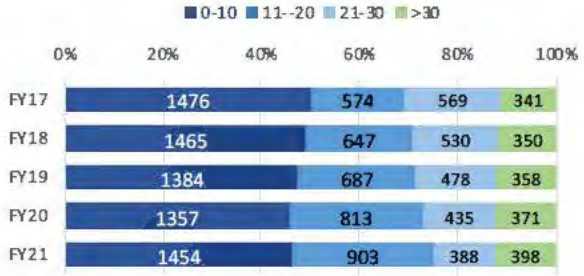
- Director, Executive Secretariat
  - Patrice Allen-Gifford
- Director, Office of Federal Advisory Committee Policy
  - Claire L. Harris
- Chief Officer for Scientific Workforce Diversity
  - Marie A. Bernard, M.D. (Acting; Senior Executive Position)
- Director, Division of Program Coordination, Planning, and Strategic Initiatives
  - James M. Anderson, M.D., Ph.D. (Senior Executive Position)
- Deputy Director for Extramural Research
  - Michael S. Lauer, M.D. (Senior Executive Position)
- Deputy Director for Intramural Research
  - Michael M. Gottesman, M.D. (Senior Executive Position)
- Deputy Director for Management
  - Alfred C. Johnson, Ph.D. (Senior Executive Position)
- Associate Deputy Director
  - Tara A. Schwetz, Ph.D. (Senior Executive Position)
- Associate Director for Science Policy
  - Carrie D. Wolinetz, Ph.D. (Senior Executive Position)
- Associate Director for Communications and Public Liaison
  - John T. Burklow (Senior Executive Position)
- Associate Director for Data Science and Director, NIH Office of Data Science Strategy
  - Susan Gregurick, Ph.D.
- Director, Office of Equity, Diversity, and Inclusion
  - Treava S. Hopkins-Laboy, M.S. (Acting; Senior Executive Position)
- Director, Office of Legislative Policy and Analysis
  - Adrienne A. Hallett (Senior Executive Position)
- Director, Executive Office
  - Darla Hayes (Senior Executive Position)
- Director, Office of the Ombudsman/Center for Cooperative Resolution
  - Victor Voloshin, J.D. (Senior Executive Position)
- Director, NIH Ethics Office
  - Holli Beckerman Jaffe, J.D. (Senior Executive Position)
- Director, *All of Us* Research Program
  - Joshua Denny M.D., M.S. (Senior Executive Position)
- Chief Information Officer
  - Andrea T. Norris, M.B.A. (Senior Executive Position)
- Director, Environmental Influences on Child Health Outcomes Office
  - Matthew W. Gillman, M.D. (Senior Executive Position)
- Director Helping to End Addiction Long-term Initiative
  - Rebecca G. Baker, Ph.D.

National Institutes of Health
*Turning Discovery Into Health*

# OD WORKFORCE SNAPSHOT[1]

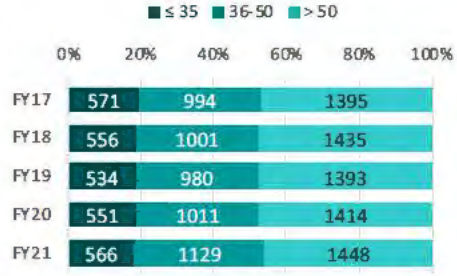
## Federal Employee Onboard (Headcount) Trending


## Federal Length of Service (Yr.) Trending

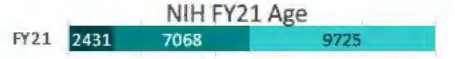



## NIH FY21 Federal Length of Service (Yr.)

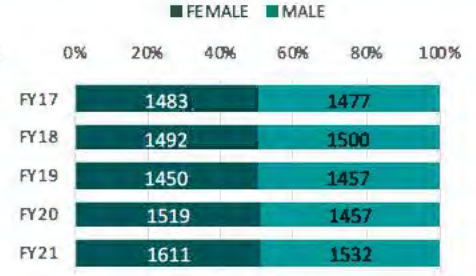

## Age Trending




## NIH FY21 Age




## Gender Trending

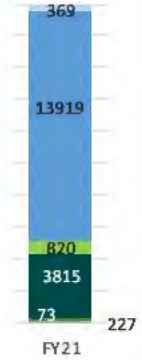



## NIH FY21 Gender


## Pay Plan Trending[2]

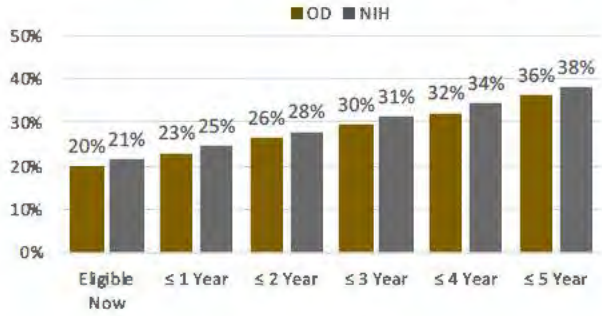

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 307 | 313 | 314 | 296 | 302 |
| GS | 2434 | 2459 | 2381 | 2452 | 2584 |
| EI | 96 | 97 | 85 | 100 | 126 |
| T42 | 75 | 74 | 69 | 67 | 74 |
| SES | 18 | 19 | 20 | 20 | 19 |
| CC | 30 | 30 | 38 | 41 | 38 |

## NIH FY21 Pay Plan




## Accession & Separation Trending


## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
OD = 4.84 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL CANCER INSTITUTE (NCI)

**Budget Summary**
(Dollars in Millions)

| NCI | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 5,214.701 | 6,440.000 | |
| Less (specify sources) | | | |
| Total Budget Authority | 5,214.701 | 6,440.000 | |
| FTE | 2,991 | 3,035 | |

## NCI MISSION

The National Cancer Institute (NCI) leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.

Established under the National Cancer Act of 1937, NCI is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 expanded NCI's scope and responsibilities, including the requirement to submit an annual plan and professional judgment budget proposal directly to the President of the United States.

NCI-supported research contributes directly to reducing deaths from cancer in the United States, major advances in cancer prevention, and improved treatments for common and rare cancers. NCI uses a broad range of programs and mechanisms to support cancer science. Foremost among these are grants NCI issues to support investigator-initiated research at universities and other institutions. NCI conducts clinical trials and supports clinical trials conducted by others and larger research networks formed to conduct clinical trials in targeted areas of cancer science. NCI supports 71 NCI-designated Cancer Centers in 36 states and the District of Columbia (DC) that collectively serve as the backbone of NCI's extramural program for studying and controlling cancer.

Through its intramural research program, NCI conducts and supports basic, clinical, and population research. NCI manages research contracts, including the only Federally Funded Research and Development Center (FFRDC) devoted to biomedical research. This FFRDC at the Frederick National Laboratory for Cancer Research (FNLCR) has a leadership role in SeroNet, NCI's Serological Sciences Network, an initiative funded with emergency appropriations to understand the human immune response to SARS-CoV-2, the virus that causes COVID-19.

## NCI BUDGET

The NCI budget supports basic and applied cancer research to advance five broad scientific goals:

- Understanding How Cancer Develops
- Understanding the Causes of Cancer
- Detecting and Diagnosing Cancer
- Treating Cancer and Improving Survivorship
- Improving Cancer Prevention and Control

The NCI budget also supports the NCI Intramural Research Program, which supports all five scientific goals. NCI intramural research is a crosscutting activity that complements all aspects of the National Cancer Program. Two other crosscutting areas are Cancer Centers and Research Workforce Development. NCI supports general and specialized cancer research centers. Foremost among these centers are 71 NCI-Designated Cancer Centers, recognized as the nation's single most important source of new insights into the causes of cancer and strategies to prevent, diagnose, and treat cancer. Through our Research Workforce Development programs, NCI helps build a robust, 21st century workforce capable of conducting and advancing all facets of cancer research. NCI achieves these goals by developing and supporting research education, training, and career development in NCI laboratories and clinics, and at other institutions nationwide.

The Building and Facilities account supports modern research laboratories at NCI's FNLCR at Fort Detrick, Maryland. NCI Research Management and Support provides essential management and administration to ensure the success of all NCI-funded programs.

**NCI Budget Authority by Activity**

(Dollars in Millions)

| NCI Activity | FY 2016 Enacted | FY 2020 Enacted | FY 2021 President's Budget | FY 2021 House Level |
|---|---|---|---|---|
| | | | (b) (5) | |
| **Understanding How Cancer Develops** | 648.176 | 818.559 | | |
| **Understanding the Causes of Cancer** | 900.007 | 992.011 | | |
| **Detecting & Diagnosing Cancer** | 465.636 | 600.048 | | |
| **Treating Cancer & Improving Survivorship** | 986.970 | 1,338.748 | | |
| **Improving Cancer Prevention & Control** | 189.623 | 267.095 | | |
| **Cancer Centers** | 545.332 | 596.947 | | |
| **Research Workforce Development** | 168.664 | 208.169 | | |
| **Buildings & Facilities** | 16.000 | 30.000 | | |
| **Childhood Cancer Data Initiative** | $0.000 | $50.000 | | |
| **Subtotal, Extramural** | 3,920.408 | 4,901.578 | | |
| **Intramural Research** | 894.528 | 1,087.982 | | |
| **Research Management and Support** | 399.765 | 450.441 | | |
| **NCI TOTAL** | 5,214.701 | 6,440.000 | | |

## NCI PRIORITY ISSUES

**Frederick National Laboratory for Cancer Research (FNLCR)**: The FNLCR provides essential, flexible, rapidly deployable, national biomedical research capacity to hasten the development and delivery of effective preventive, diagnostic, and therapeutic advances for people living with cancer and Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome (HIV/AIDS), along with those threatened by infectious diseases. FNLCR has devoted considerable research for the coronavirus

pandemic, including a serology laboratory to work on antibody testing for the novel coronavirus. To maximize the impact of FNLCR's research going forward, NCI is exploring no-year appropriations and flexible contracting authority for this FFRDC.

**Childhood Cancer Data Initiative**: In 2019, NCI launched the Childhood Cancer Data Initiative (CCDI) in alignment with the Presidentially proposed Federal investment of $500 million over 10 years to make progress against childhood cancers. The CCDI provides a bold vision of learning from every child with cancer while providing each of them state-of the-art clinical care and ultimately changing the course of cancer in all children. Through the CCDI, NCI will connect data repositories and registries, collect standardized, high-quality data on childhood and adolescent cancers, and promote efficient data sharing to accelerate research and discovery. Sustained funding is needed to ensure progress keeps pace with the efforts made so far through the CCDI.

(b) (5)

[redacted]

## NCI SIGNIFICANT CHANGES

Recent significant changes that deeply influence the NCI mission and operations are efforts to increase the payline that NCI relies on to fund R01 applications and to implement legislative developments, most notably the Cancer Moonshot℠ enacted under the 21st Century Cures Act, P.L. 114-255.

Steep Decline in the NCI Payline – Research project grants, such as R01s, are the source of some of the most innovative ideas in cancer research. Researchers are eager to submit their research ideas to NCI, and the best evidence of the boundless opportunities in cancer research is the dramatic increase in the volume of R01 applications in recent years. Nevertheless, NCI has struggled to respond to this burst of innovation, as the growing volume of applications far outpaces funding available to support them. Over the past 20 years, the NCI success rate has been lower than the NIH-wide rate every year. While the NIH application success rate has improved across the past 7 years, the NCI success rate has declined during the same period. A success rate that hovers in the low teens is disheartening to aspiring cancer researchers, and it discourages the most talented minds from a career in cancer research. Most cancers are highly complex and challenging diseases to study, diagnose, treat, and prevent, and we will struggle to navigate the challenging pathways of discovery unless NCI has adequate funding to attract and retain top researchers through NCI grants.

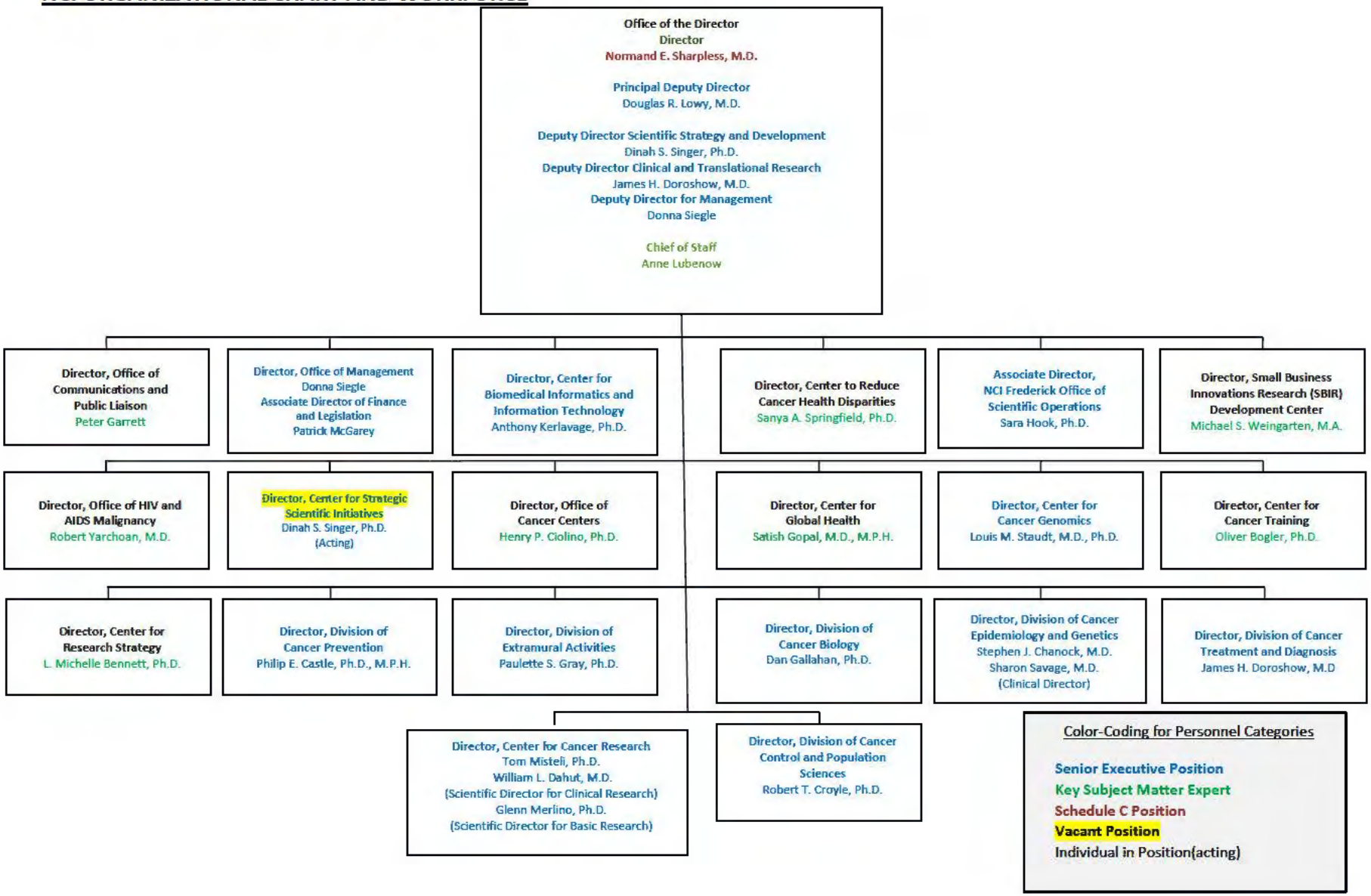
The Cancer Moonshot℠ – The Cancer Moonshot℠ began in 2016 with the goal of accelerating the pace of cancer research. The 21st Century Cures Act authorized $1.8 billion to fund the Moonshot over 7 years, from FY 2017 through FY 2023, at varying annual amounts. Funding for the Moonshot peaked in FY 2019, declined by more than half in FY 2020, (b) (5)

[redacted]

(b) (5)

R35 and R37 Grants, Seven Year Awards – Over the past 6 years, NCI has created 2 new award programs that provide up to 7 years of funding. The Outstanding Investigator Award (OIA), R35, launched in FY 2015, supports accomplished leaders in cancer research with outstanding records of productivity by providing extended funding stability and encouraging investigators to continue or embark on projects of unusual potential in cancer research. The R37 Method to Extend Research in Time (MERIT) Award, introduced in FY 2018, provides longer term grant support to Early Stage Investigators (ESIs). Eligible ESIs may obtain up to 7 years of support in two segments: an initial award of up to 5 years and an opportunity for an extension of up to 2 additional years. Both of these awards are opportunities for increased funding stability for these select groups of investigators, however, they impact the NCI budget out year (non-competing) commitments beyond a traditional 5-year R01 timeframe.

## NCI ORGANIZATIONAL CHART AND WORKFORCE



**National Cancer Institute**

Office of the Director

- Director (Schedule C Position), Norman Sharpless, M.D. (Senior Executive Position)
- Principal Deputy Director, Douglas R. Lowy, M.D. (Senior Executive Position)
- Deputy Director for Scientific Strategy and Development, Dinah Singer, Ph.D. (Senior Executive Position)
- Deputy Director for Clinical and Translational Research, James H. Doroshow, M.D. (Senior Executive Position)
- Deputy Director for Management, Donna Siegle (Senior Executive Position)
- Chief of Staff, Anne Lubenow (Key Subject Matter Expert)

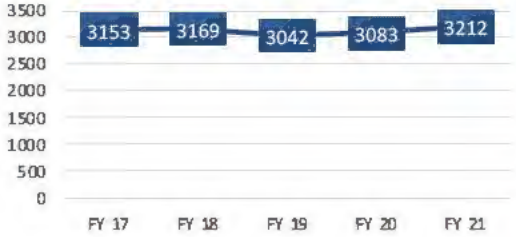
The following offices report directly to the Director:

- Director of the Office of Communication and Public Liaison
    - Peter Garrett (Key Subject Matter Expert)
- Director of the Office of Management
    - Donna Siegle (Senior Executive Position)
- Director of the Center for Biomedical Informatics and Information Technology
    - Anthony Kerlavage, Ph.D. (Senior Executive Position)
- Director of the Center to Reduce Cancer Health Disparities
    - Sanya A. Springfield, Ph.D. (Key Subject Matter Expert)
- Associate Director of the NCI Frederick Office of Scientific Operations (Senior Executive Position)
    - Sara Hook, Ph.D.
- Director of the Small Business Innovation Research (SBIR) Development Center
    - Michael S. Weingarten, M.A. (Key Subject Matter Expert)
- Director of the Office of HIV and AIDS Malignancy
    - Robert Yarchoan, M.D. (Key Subject Matter Expert)
- Director of the Center for Strategic Scientific Initiatives
    - Dinah Singer, Ph.D. (Acting; Senior Executive Position)
- Director of the Office of Cancer Centers
    - Henry P. Ciolino, Ph.D. (Key Subject Matter Expert)
- Director of the Center for Global Health
    - Satish Gopal, M.D., M.P.H. (Key Subject Matter Expert)
- Director of the Center for Cancer Genomics
    - Louis M. Staudt, M.D., Ph.D. (Senior Executive Position)
- Director of the Center for Cancer Training
    - Oliver Bogler, Ph.D. (Key Subject Matter Expert)
- Director of the Center for Research Strategy
    - L. Michelle Bennett, Ph.D. (Key Subject Matter Expert)
- Director of the Division of Cancer Prevention
    - Philip E. Castle, Ph.D., M.P.H. (Senior Executive Position)
- Director of the Division of Extramural Activities)
    - Paulette S. Gray, Ph.D. (Senior Executive Position
- Director of the Division of Cancer Biology
    - Dan Gallahan, Ph.D. (Senior Executive Position)

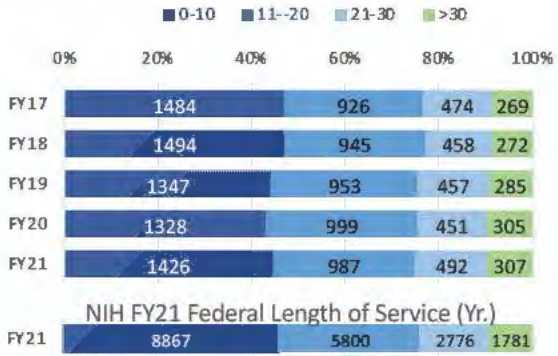
- Director of the Division of Cancer Epidemiology and Genetics
    - Stephen J. Chanock, M.D. (Senior Executive Position)
- Clinical Director for the Division Cancer Epidemiology and Genetics
    - Sharon Savage, M.D. (Senior Executive Position)
- Director of the Division of Cancer Treatment and Diagnosis
    James H. Doroshow, M.D. (Senior Executive Position)
- Director of the Center for Cancer Research
    - Tom Misteli, Ph.D. (Senior Executive Position)
- Scientific Director for Clinical Research of the Center for Cancer Research
    - William L. Dahut, M.D. (Senior Executive Position)
- Scientific Director for Basic Research of the Center for Cancer Research
    - Glenn Merlino, Ph.D. (Senior Executive Position)
- Director of the Division of Cancer Control and Population Sciences
    - Robert T. Croyle Ph.D. (Senior Executive Position)

# NCI WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending



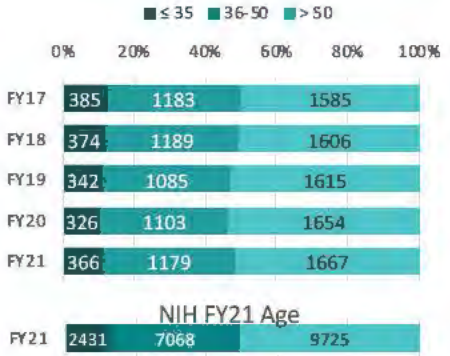

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



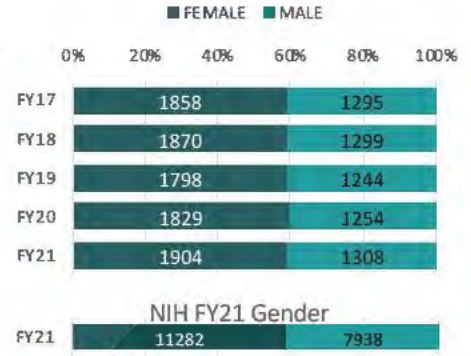

## Age Trending




## NIH FY21 Age



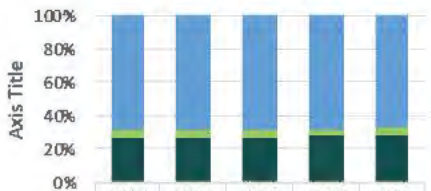

## Gender Trending




## NIH FY21 Gender

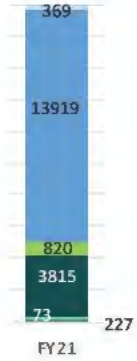



## Pay Plan Trending[2]

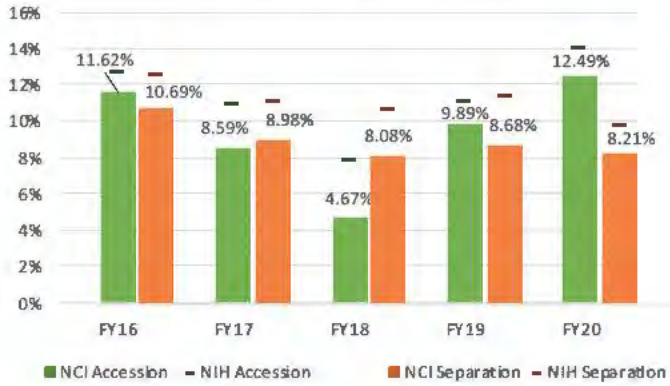



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 1 | 1 | 1 | 1 | 1 |
| GS | 2177 | 2188 | 2096 | 2103 | 2144 |
| EI | 122 | 140 | 122 | 124 | 130 |
| T42 | 802 | 796 | 781 | 814 | 899 |
| SES | 23 | 17 | 11 | 9 | 8 |
| CC | 28 | 27 | 31 | 32 | 30 |

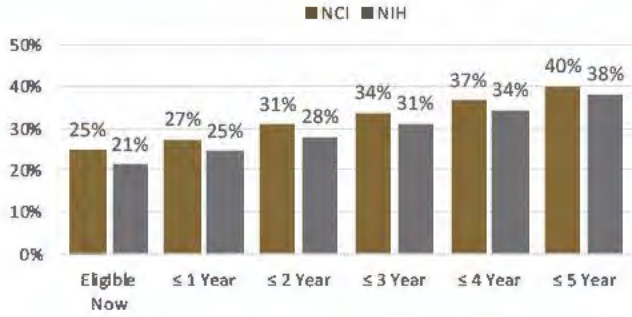
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NCI = 5.86 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC=CC; SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL EYE INSTITUTE (NEI)

**Budget Summary**
(Dollars in Mil

| NEI | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 715.903 | 823.325 |
| Less (specify sources) | | |
| Total Budget Authority | 715.903 | 823.325 |
| FTE | 256 | 273 |

(b) (5)

[redacted]

## NEI MISSION

The National Eye Institute (NEI) conducts and supports research and training into blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the visually impaired.

Established by Congress in 1968, NEI is the largest vision research organization in the world. NEI supports vision research through research grants and training awards made to over 1,700 scientists at over 250 medical centers, universities and other institutions across 44 U.S. states and around the world. NEI also conducts laboratory and patient-oriented research at its own facilities on the NIH campus in Bethesda, Maryland. The ultimate goal of NEI research is to develop tests and implement sight-saving treatments to reduce visual impairment and blindness and improve the health and quality of life for people of all ages. The NEI National Eye Health Education Program draws on such research to support public and professional education programs on vision and eye health with a focus on early detection and prevention, in particular for vulnerable and at-risk populations.

Research funded by the NEI has resulted in numerous programs and accomplishments. For example, Regenerative Medicine in Vision is a newly developed strategic endeavor by NEI to expand support for the development of new treatment modalities for vision diseases by facilitating cross-disciplinary research. Vision research is bringing us closer to a cure for certain forms of age-related macular degeneration (AMD) with the launch of first-ever U.S. Food and Drug Administration (FDA)-approved clinical trial using replacement tissue derived from reprogramming patient-derived stem cells in humans.

Artificial intelligence (AI) has revolutionized vision research and clinical care. AI-based devices are being integrated into medical practice with two FDA approvals: EyeArt®, a tool that accurately screens for early to mild stages of diabetic retinopathy (DR), which can be deployed in telehealth settings, and a novel device that can correctly detect a severe and hard-to-clinically-diagnose form of blinding disease in premature newborns.

## NEI BUDGET

NEI currently oversees more than 1,700 grants and contracts, including over 160 research career development awards, 31 cooperative clinical research agreements, and around 50 research and development contracts. The FY 2020 operating budget is $823.3 million, of which the budget estimate for Extramural Research is $699.5 million. Core extramural programs are organized around: Corneal

Diseases, Glaucoma and Optic Neuropathies, Lens and Cataract, Low Vision and Blindness Rehabilitation, Retinal Diseases, and Strabismus, Amblyopia, and Visual Processing. In addition to these programs, there are cross-cutting programs in Myopia and Refractive Error, Ocular Genetics, Ocular Infection, Inflammation and Immunology, Ocular Pain, Training, and Research Resources.

The FY 2020 budget estimate for Intramural Research conducted on the NIH campus is $93.5 million. Basic, clinical, and translational intramural research studies are focused on the cause, prevention, and treatment of major eye diseases and vision disorders; cellular and molecular mechanisms of eye development, including the expression and function of genes within the eye; immunology and infectious diseases of the eye; mechanisms of visual perception by the brain; and developing a better understanding of the ability to guide movements under sensory control. The FY 2020 budget estimate for Research Management and Support, which sustains, guides, and monitors NEI research programs, is $30.4 million.

**Budget Authority by Activity**

(Dollars in Millions)

| NEI Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Plan |
|---|---|---|---|---|---|
| Retinal Diseases | 269.198 | 281.448 | 303.355 | 326.836 | 338.905 |
| Corneal Diseases, Cataract, and Glaucoma | 184.147 | 191.694 | 208.048 | 218.136 | 226.191 |
| Sensorimotor Disorders, Visual Processing, and Rehabilitation | 151.309 | 148.836 | 142.479 | 129.614 | 134.400 |
| Subtotal, Extramural | 604.654 | 621.978 | 653.882 | 674.586 | 699.496 |
| Intramural Research | 76.078 | 80.032 | 86.866 | 89.916 | 93.456 |
| Research Management and Support | 26.276 | 29.202 | 29.746 | 29.281 | 30.373 |
| TOTAL | 707.007 | 731.212 | 770.493 | 793.783 | 823.325 |

## NEI PRIORITY ISSUES

**Audacious Goal Initiative**: The Audacious Goals Initiative (AGI) for Regenerative Medicine is an effort by the NEI to push the boundaries of vision science and restore vision through regeneration of the retina, the light-sensitive tissue in the back of the eye. Many leading causes of blindness in the United States, like AMD, DR, and glaucoma, result from degeneration of retinal neurons in the eye. Despite recent advances in understanding vision disorders, effective therapies for many conditions are still lacking. In response, AGI launched three research consortia representing 16 projects and $62 million to support the technology, biology, and translation needed to bring the promise of regenerative medicine to patients. By facilitating and catalyzing cross-disciplinary research, AGI is tackling the most devastating and difficult-to-treat eye diseases.

**Clinical Application of Stem Cell Therapies**: Stem cell therapy holds the promise to repair, regenerate, and treat eye diseases and conditions that have limited therapeutic options. Recently, human cell-based model systems have complemented animal models and are more adequate in reflecting human tissue, but the proliferation of these models have exposed certain gaps in how they are generated and used. NEI is capitalizing on the development of stem cell technologies for eye conditions and assessing ongoing stem cell issues necessary to conduct successful ocular human clinical trials using patient-derived stem cells.

**Data Science and Artificial Intelligence in Vision Research**: Vision research has been in the forefront of disease imaging and harnessing these images to apply principals of data science and AI for disease detection. Conversely, vision researchers are collaborating with experts in the physical and computational sciences to engineer new modalities to diagnose disease, detect the progression of diseases, identify early signs of complications, and possibly identify biomarkers and patterns to predict the effectiveness of novel therapies resulting from vision researchers. Data science is a multi-disciplinary, ever-evolving field and is heavily quantitative. NEI is investing in expanding the vision research workforce to develop computational skills in unison with those who understand the diseases and disorders central to visual impairment and blindness.

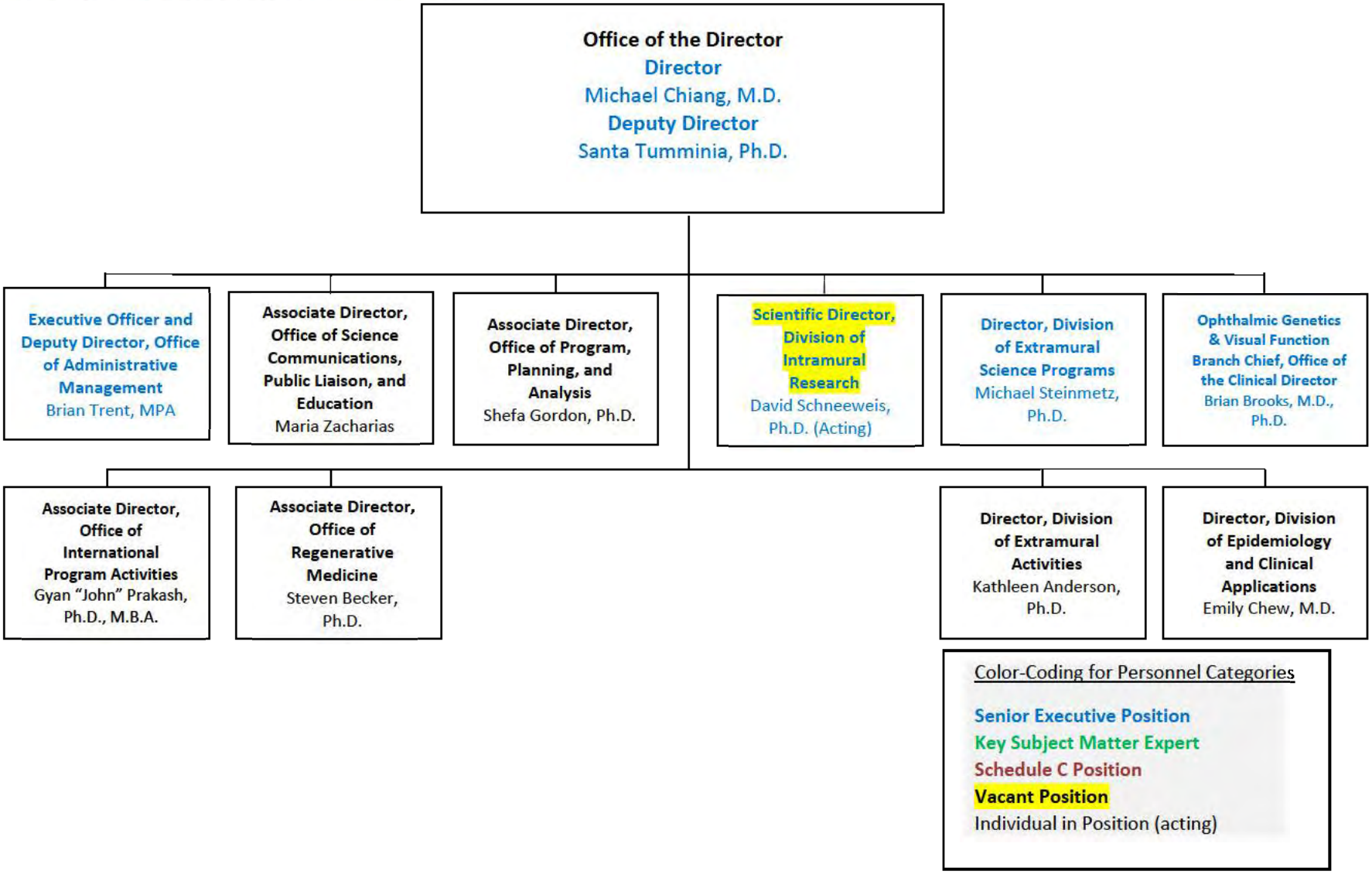
## NEI SIGNIFICANT CHANGES

NEI Director Dr. Michael Chiang was installed late 2020, as the third director in Institute history.

NEI is the only institute at the NIH with a Property Service Center, run by the Management Policy and Analysis Branch. The Service Center manages and tracks property for five ICs: NEI, the National Center for Advancing Translational Sciences (NCATS), the National Center for Complementary and Integrative Health (NCCIH), the National Institute of General Medical Sciences (NIGMS), the National Institute of Biomedical Imaging and Bioengineering (NIBIB), and the National Institute on Minority Health and Health Disparities (NIMHD). The total portfolio includes 14,000 pieces of property totaling almost $120 million. The Service Center has delivered outstanding results including implementing the NIH Property Management Portal at an 85 percent adoption rate or higher and decreasing the discrepancy rate at each IC. It was so successful in 2019 that two additional ICs have asked for NEI management services and will be added to our portfolio in FY2020.

The NEI Diversity in Vision Research and Ophthalmology (DIVRO) program continues its 9th successful year and recently expanded beyond college summer interns to include more experienced trainees and applied science researchers. The NEI DIVRO program hosts around 8-12 interns each year and offers hands-on training and mentoring for students from underrepresented groups (URGs) in vision research. Participants work closely with leading NEI scientists and get experience working in an environment that will prepare them to continue their studies and advance their careers in basic and clinical research. Since 2011, the DIVRO program has hosted 71 interns, 63 percent of them female, 45 percent African American, 42 percent Latino, with the remainder from American Indian/Alaska Native and multiracial populations. In 2015, the program expanded to include students with disabilities when the NEI hosted its first deaf student. Most of the students in the DIVRO program have been college students (48 percent), with 26 percent coming from medical school and the rest from high school or graduate school. DIVRO interns return to the program for multiple summers (28 percent); come back as postbaccalaureate fellows to the NEI and other ICs (seven to the NEI, two at NIAID, one at NHLBI); and three have become postdoctoral fellows. Former interns have moved on to graduate, medical, and optometry programs.

## NEI ORGANIZATIONAL CHART AND WORKFORCE



**National Eye Institute**
Office of the Director

- Director, Michael Chiang, M.D. (Senior Executive Position)
- Deputy Director, Santa Tumminia, Ph.D. (Senior Executive Position)

The following offices report directly to the Director:

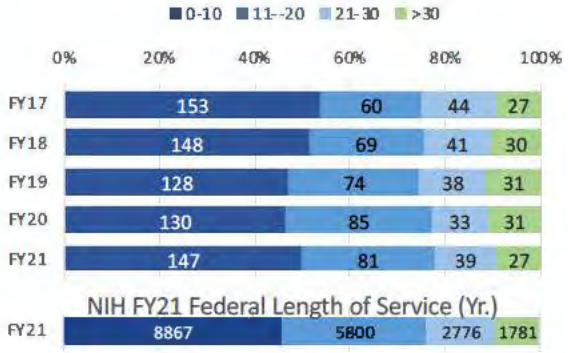
- Executive Officer and Deputy Director, Office of Administrative Management
    - Brian Trent, MPA (Senior Executive Position)
- Associate Director, Office of Science Communications, Public Liaison, and Education
    - Maria Zacharias
- Associate Director, Office of Program, Planning, and Analysis
    - Shefa Gordon, Ph.D.
- Scientific Director, Division of Intramural Research
    - David Schneeweis, Ph.D. (Senior Executive Position, Acting)
- Director, Division of Extramural Science Programs
    - Michael Steinmetz, Ph.D. (Senior Executive Position)
- Director, Division of Extramural Activities
    - Kathleen Anderson, Ph.D.
- Chief, Ophthalmic Genetics & Visual Function Branch, Office of the Clinical Director
    - Brian Brooks, MD, Ph.D. (Senior Executive Position)
- Director, Division of Epidemiology and Clinical Applications
    - Emily Chew, M.D.
- Associate Director, Office of International Program Activities
    - Gyan “John” Prakash, Ph.D., MBA
- Associate Director, Office of Regenerative Medicine
    - Steven Becker, Ph.D.

National Eye Institute
Research Today., Vision Tomorrow

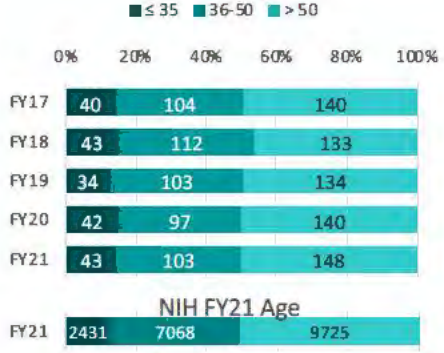
# NEI WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

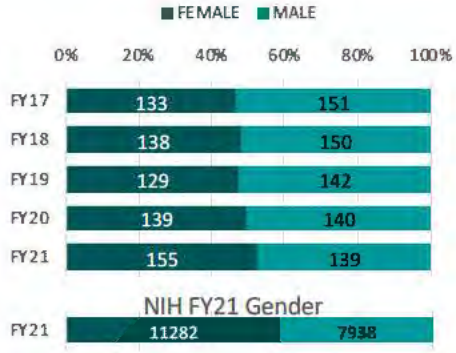

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



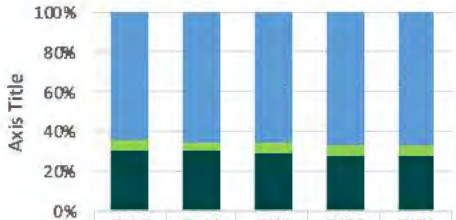

## NIH FY21 Age




## NIH FY21 Gender

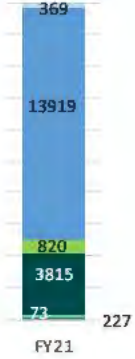



## Pay Plan Trending[2]

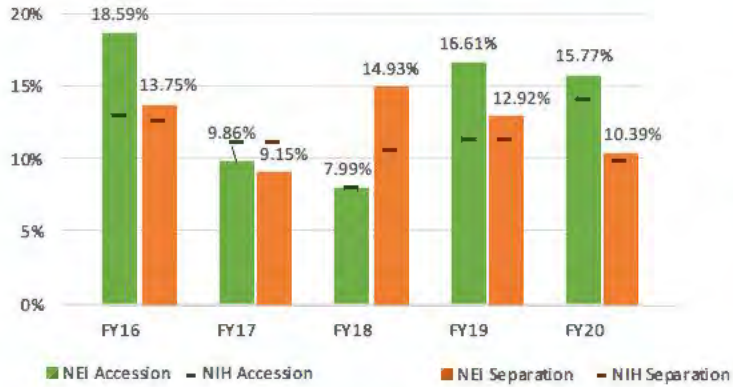



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 181 | 188 | 176 | 186 | 196 |
| EI | 17 | 14 | 15 | 14 | 18 |
| T42 | 83 | 83 | 77 | 77 | 78 |
| SES | 1 | 1 | 1 | 1 | 1 |
| CC | 2 | 2 | 2 | 1 | 1 |

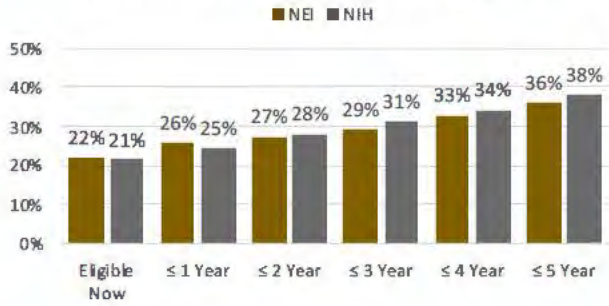
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NEI = 6.74 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

**Budget Summary**
(Dollars in Mil

| NHGRI | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 518.956 | 604.118 |
| Less (specify sources) | | |
| Total Budget Authority | 518.956 | 604.118 |
| FTE | 346 | 349 |

(b) (5)

[redacted]

## NHGRI MISSION

The origin of the National Human Genome Research Institute (NHGRI) dates back to 1989, when its preceding organizational entity (the National Center for Human Genome Research) was established to carry out the role of the NIH in the International Human Genome Project (HGP). In 1997, the United States HHS renamed the center the National Human Genome Research Institute, officially elevating it to the status of research institute. The NHGRI organizational structure supports the institute's expanding mission, which has evolved from the singular focus of sequencing the human genome to a broad set of opportunities for using genomics to advance medicine and improve human health. NHGRI is divided into the Office of the Director and six divisions to reflect the emerging landscape of genomics research.

NHGRI collaborates with the scientific and medical communities to enhance genomic technologies by driving cutting-edge research, developing new technologies, and studying the impact of genomics on society. NHGRI provides leadership and remains the chief funding agency in the world that fosters the use of genomics to improve human health. Some highlights of NHGRI programs include:

- **Impact of Genomic Variation on Function (IGVF) Consortium** – One of the central problems in biology is understanding the functional implications of differences in genome sequences. Some differences can directly lead to disease or increase risk for diseases such as cancer. The IGVF program seeks to utilize emerging experimental and computational tools to develop a framework for understanding the effects of variation in genome sequence on function and build a catalog of the results of these effects.
- **Mendelian Genomics Research Consortium** – Patients with rare and undiagnosed genetic diseases and their families often face a years-long and unpredictable journey to find a diagnosis and course of treatment, referred to as a diagnostic odyssey. The Institute will fund the Mendelian Genomics Research Consortium program in 2020 to sequence samples from patients with genetic disorders and apply novel approaches to discover the genetic variants causing disease. The centers will also aim to solve “unsolved” cases for which a candidate gene was not identified by solely using whole exome sequencing.
- **Electronic Medical Records and Genomics (eMERGE) Network** – The Network combines patients’ genetic information with longitudinal electronic medical records (EMR). These efforts contribute to our understanding of how genes contribute to a person’s risk of developing a disease and have helped to standardize the integration of genomic sequencing results into the EMR. The Network has a focus on compiling diverse datasets to understand genetic risk in all populations.

## NHGRI BUDGET

NHGRI, as the international leader in genomics research, uses its budget to develop resources, technologies, and policies for advancing genomics and its application to improving human health. It does this by planning and coordinating research, reviewing and funding research proposals, developing training programs, coordinating national and international genomics research, communicating advances in genomics to the public, and reviewing and funding proposals to address the Ethical, Legal, and Social Implications (ELSI) associated with genomic advances. No less than five percent of NHGRI's budget is committed to funding ELSI.

The overarching design for the research portfolio supported and led by NHGRI was first laid out in a February 2011 strategic vision published in Nature. That document defined an arc from basic research aiming to understand the structure and function of genomes to applied research aiming to advance medical science and to improve the effectiveness of healthcare using genomics. Over the past few years, NHGRI has fostered research along this path, enabling important genomic medicine advances to reach the clinic in areas such as oncology and rare disease diagnostics, and laying the foundation for transformational efforts in precision medicine. In October 2020, NHGRI published an updated strategic vision that identifies paradigm-shifting areas of genomics that will expand the field into new frontiers and enable novel applications to human health and disease. NHGRI supports the work of many individual investigators, but is best known for funding and leading large, consortium-based programs that coordinate activities addressing complex challenges to achieve major advances.

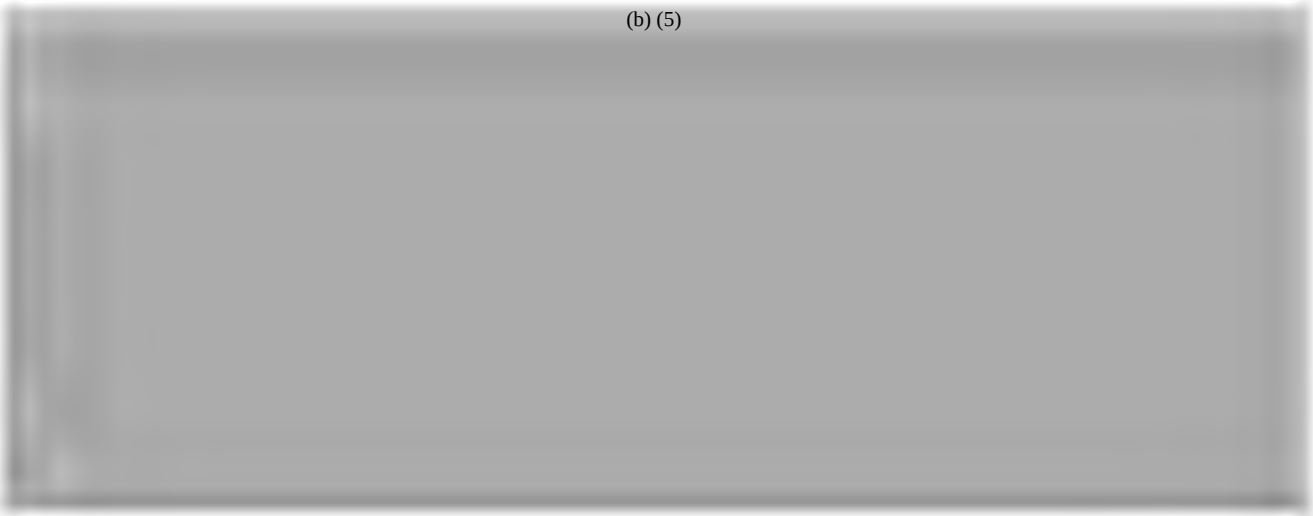
**Funding by Budget Activity**

(Dollars in Millions)

| NHGRI Activity | FY 2016 Enacted | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating |
|---|---|---|---|---|---|
| **Understanding the Structure of Genomes** | 31.825 | 26.354 | 31.366 | 35.251 | 37.169 |
| **Understanding the Biology of Genomes** | 68.703 | 91.228 | 84.635 | 89.011 | 93.719 |
| **Using Genomics to Understand the Biology of Disease** | 146.511 | 124.784 | 137.637 | 139.697 | 146.818 |
| **Using Genomics to Advance Medical Science** | 27.167 | 23.421 | 24.675 | 29.704 | 31.069 |
| **Using Genomics to Improve the Effectiveness of Healthcare** | 17.947 | 14.746 | 14.846 | 18.131 | 19.029 |
| **Bioinformatics and Computational Biology** | 125.725 | 144.653 | 151.547 | 147.399 | 155.390 |
| **Education and Training** | 22.978 | 24.279 | 25.528 | 25.971 | 27.250 |
| **Genomics and Society** | 48.863 | 48.585 | 53.781 | 56.297 | 59.323 |
| **Subtotal Program Activity*** | 489.719 | 498.051 | 524.017 | 541.461 | 569.767 |
| **Research Management and Support** | 29.237 | 30.295 | 32.747 | 33.926 | 34.351 |
| **Total** | 518.956 | 528.346 | 556.764 | 575.387 | 604.118 |

*The detail programs listed above include both Extramural and Intramural funding.

(b) (5)



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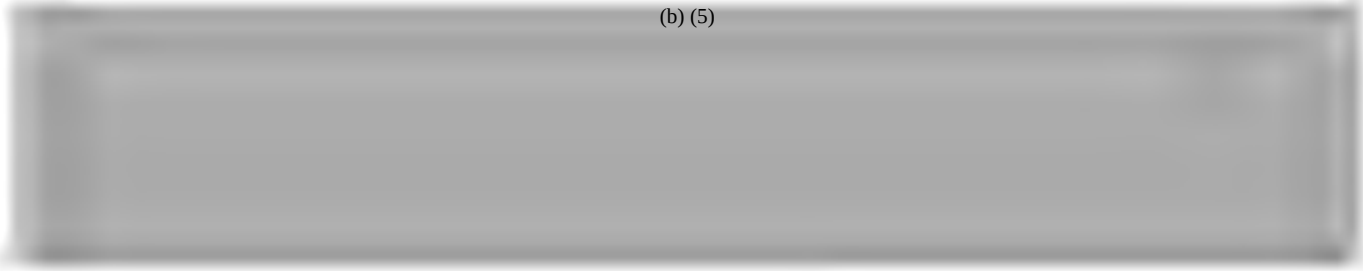


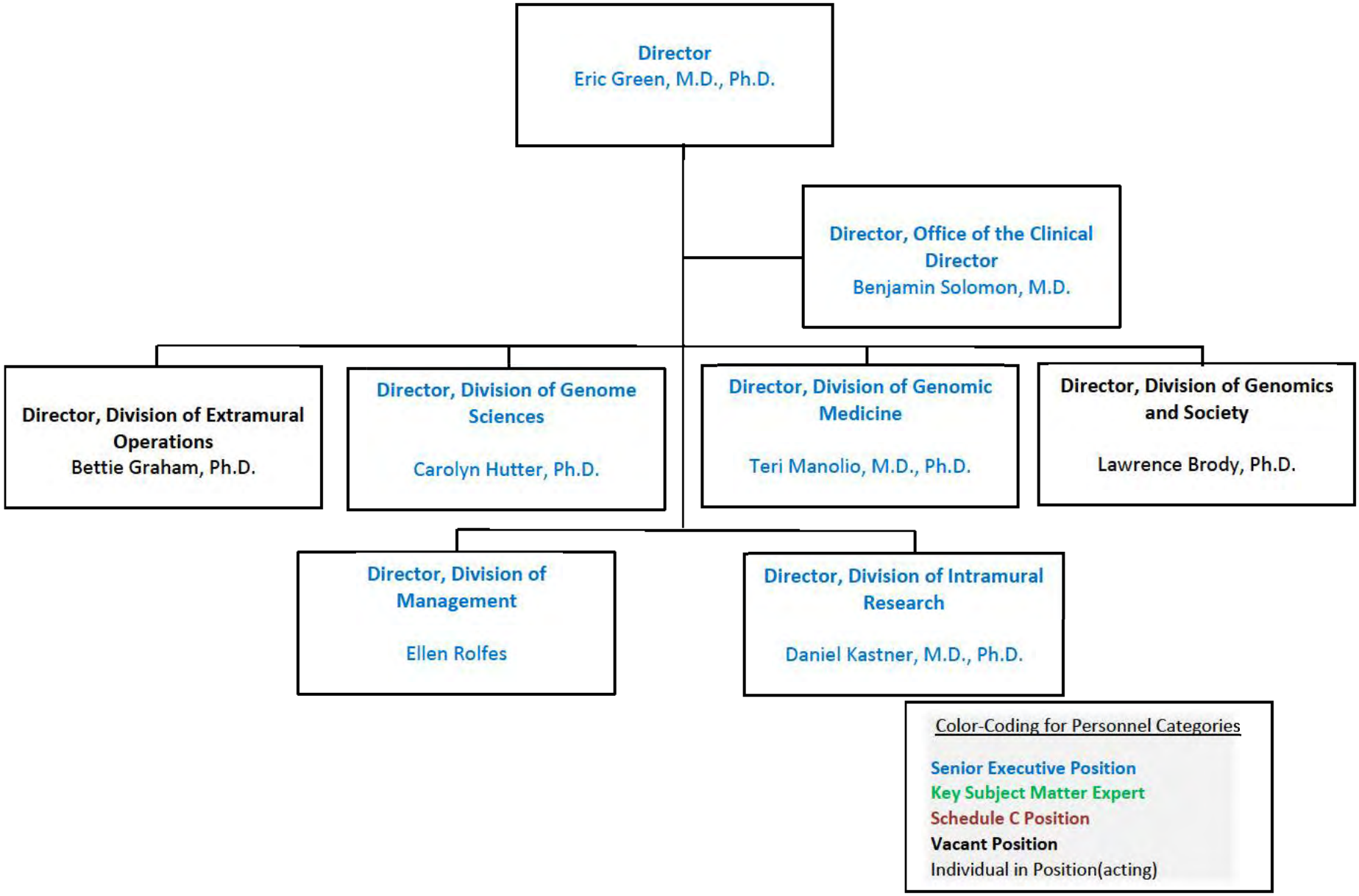
## NHGRI SIGNIFICANT CHANGES

In 2020, NHGRI proposed a reorganization of the Division of Policy, Communications and Education (DPCE). DPCE consisted of three branches: the Genomic Healthcare Branch, the Communications and Public Liaison Branch, the Policy and Program Analysis Branch, and the Education and Community Involvement Branch. The division was officially reorganized in May 2020, and the branches under DPCE were absorbed into other NHGRI divisions to enhance synergies in the areas of bioethics, policy, education, engagement and communication.

Additionally, NHGRI announced plans in 2020 to establish a new intramural precision health research program to be led by Dr. Les Biesecker, Chief of the NHGRI Medical Genomics and Metabolic Genetics Branch. Dr. Biesecker will collaborate with Dr. Josh Denny, the CEO of the *All of Us* Research Program, to develop a multi-faceted program that will utilize growing datasets from major cohort studies and facilitate the use of the NIH Clinical Center for conducting patient-specific precision health research.

Finally, as detailed in the priority issues section, NHGRI published a new Strategic Vision in October 2020. The Strategic Vision outlines the most significant opportunities for genomics research and its application to human health and disease. The publication is the culmination of a two-year round of strategic planning involving engagement of experts and diverse public communities. The areas in the Strategic Vision will be the concentration of NHGRI programming in the coming years.

## NHGRI ORGANIZATIONAL CHART AND WORKFORCE



**National Human Genome Research Institute**

Office of the Director (Senior Executive Position)

- Director, Eric Green, M.D., Ph.D.

The following components/individuals report directly to the NHGRI Director:

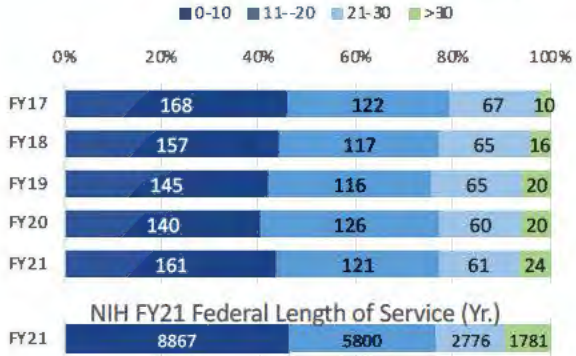
- Director, Division of Intramural Research
  - Daniel Kastner, M.D., Ph.D. (Senior Executive Position)
- Director, Office of the Clinical Director
  - Benjamin Solomon, M.D. (Senior Executive Position)
- Director, Division of Extramural Operations
  - Bettie Graham, Ph.D.
- Director, Division of Genome Sciences
  - Carolyn Hutter, Ph.D. (Senior Executive Position)
- Director, Division of Genomic Medicine)
  - Teri Manolio, M.D., Ph.D. (Senior Executive Position
- Director, Division of Genomics and Society
  - Lawrence Brody, Ph.D.
- Director, Division of Management
  - Ellen Rolfes, M.S. (Senior Executive Position)

National Human Genome Research Institute

# NHGRI WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

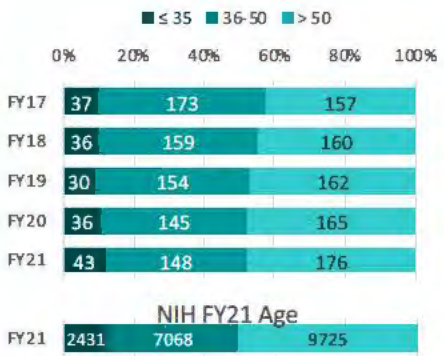

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



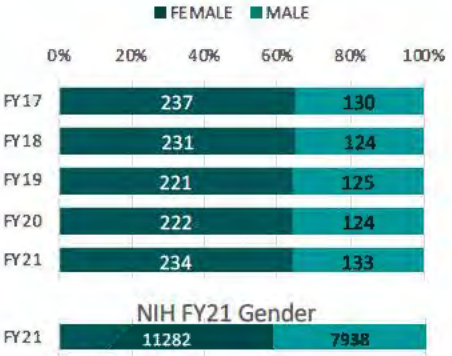

## Age Trending




## NIH FY21 Age



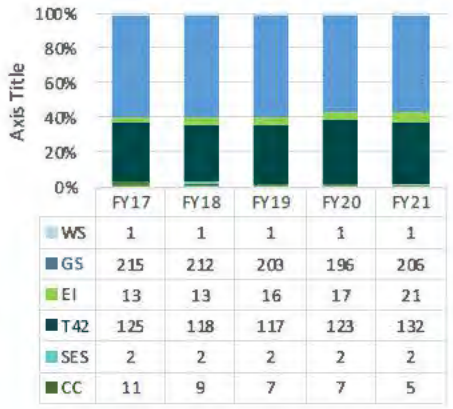

## Gender Trending




## NIH FY21 Gender



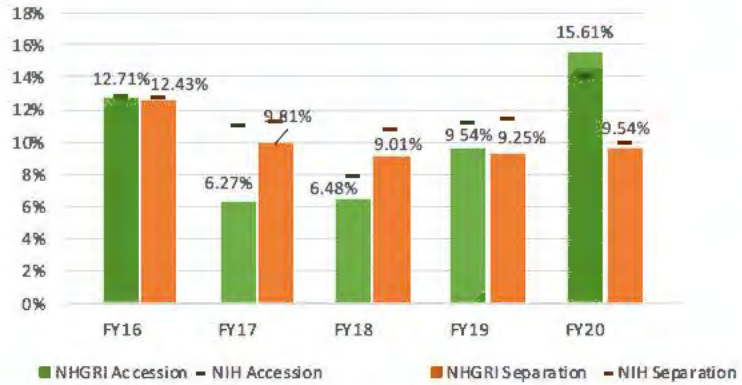

## Pay Plan Trending[2]



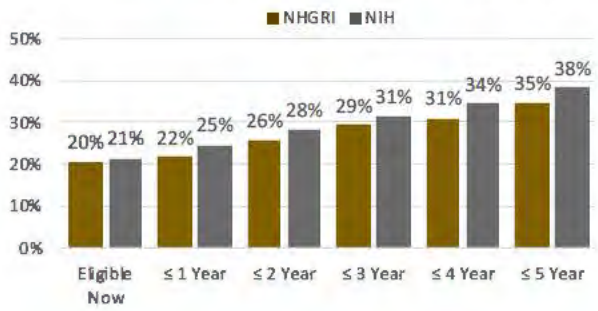

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 1 | 1 | 1 | 1 | 1 |
| GS | 215 | 212 | 203 | 196 | 206 |
| EI | 13 | 13 | 16 | 17 | 21 |
| T42 | 125 | 118 | 117 | 123 | 132 |
| SES | 2 | 2 | 2 | 2 | 2 |
| CC | 11 | 9 | 7 | 7 | 5 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NHGRI = 4.01 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

**Budget Summary**
(Dollars in Mil

| NHLBI | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 3,115.538 | 3,728.658 |
| Less (specify sources) | | 103.400 |
| Total Budget Authority | 3,115.538 | 3,625.258 |
| FTE | 931 | 962 |

(b) (5)

*$103.4 million in FY 2020 was appropriated through the activities.

## NHLBI MISSION

The National Heart, Lung, and Blood Institute (NHLBI), established in 1948, supports research to prevent and treat heart lung, blood, and sleep disorders. NHLBI's portfolio includes groundbreaking fundamental discovery science, epidemiological studies, high-impact clinical trials, health education and dissemination efforts, and initiatives in emergent fields such regenerative medicine, precision medicine, and data science. NHLBI's research programs have helped improve longevity and quality of life for people around the world and have an increasing focus on reaching communities with a disparate burden of heart, lung, blood, and sleep disorders. Thanks in part to NHLBI-funded research, the rate of heart disease deaths has declined by 70 percent over the past 50 years. NHLBI's research also has informed guidelines to treat high blood pressure, improved heart surgery procedures, and generated new treatments for asthma and other debilitating lung diseases. While congenital heart disease and sickle cell disease (SCD) once meant a death sentence in childhood, children with these diseases are now living and thriving into adulthood. Despite these advances, heart, lung, blood and sleep disorders continue to be among the leading causes of death and disability in the United States, and among the top drivers of rising health care costs.

A major concern for the Institute at present is to respond quickly to the COVID-19 pandemic, given the profound impact of SARS-CoV-2 infection on the heart, lung, blood, and vasculature. As a centerpiece of the Institute's efforts, NHLBI established the Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (CONNECTS) to better understand the clinical impact of the disease and to identify therapies that will slow or halt its progression and speed recovery (see Priority Issues below).

A few examples of other major NHLBI scientific programs are provided below:

- **The Trans-Omics for Precision Medicine (TOPMed) Program** – exploring how biology and environment interact to affect susceptibility to heart, lung, blood, and sleep disorders; their progression; and responses to treatment. The program supports analysis of whole-genome sequence data—as well as clinical, imaging, environmental, and behavioral data—from NHLBI's diverse population-based studies, including the Framingham Heart Study, the Jackson Heart Study, and the Hispanic Community Health Study/Study of Latinos. The TOPMed database now contains data from more than 155,000 participants from about 80 such cohort studies, making it

one of the most diverse databases of its kind. TOPMed is examining diseases that span the NHLBI portfolio, such as atrial fibrillation, cardiometabolic disorders, and venous thrombosis, asthma, and sickle cell disease. The volume and diversity of data within TOPMed—combined with powerful computing tools embedded in the recently launched a new cloud-based platform, BioData Catalyst—are expected to lead to the development of new diagnostic tools, therapeutics, and prevention strategies.

- **The Sickle Cell Disease (SCD) program** – supports research on this genetic blood disorder that affects millions of people worldwide and about 100,000 people in the United States, predominantly African Americans. It manifests in early childhood and damages the body's blood vessel, causing recurrent, often severe pain; and progressive, life-threatening organ damage. NHLBI-supported clinical trials have contributed significantly to increasing the lifespan of people with SCD through the use of chronic blood transfusion to reduce stroke risk; antibiotics to prevent fatal infections; and hydroxyurea to reduce painful crises; however, much work remains. Toward curing every patient with SCD, the NHLBI launched the Cure Sickle Cell Initiative in 2018 (see Priority Issues below), which is building on the latest genetic discoveries and technological advances to move the most promising gene-based curative therapies safely into clinical trials within five to 10 years. NHLBI also supports global research efforts in SCD that are expected to benefit patients in the United States and in other parts of the world. For example, sub-Saharan Africa is home to more than 75 percent of SCD births worldwide, and more than half of infants born with SCD die before age 5. NHLBI supports major programs in the region, including the Sickle Pan-African Research Consortium, that are working to build research capacity and develop an infrastructure to enhance disease surveillance and delivery of care. NHLBI is also a key partner in a collaboration between NIH and the Bill & Melinda Gates Foundation to develop affordable, gene-based cures for SCD that will be accessible to low- and middle-income countries.
- **NHLBI also has a large program dedicated to reducing the burden of chronic respiratory diseases** – including asthma and chronic obstructive pulmonary disease (COPD). Asthma currently affects more than 25 million people in the United States, with the highest prevalence among children in low-income and minority populations. The disease can profoundly affect quality of life and financial and emotional health and is a major cause of missed time from school and work. Severe asthma attacks may require emergency room visits and hospitalizations and can be fatal. NHLBI's Severe Asthma Research Program, established nearly 20 years ago, has helped reveal distinct subtypes of this disease, proving the foundational knowledge for a new effort that aims to develop more personalized approaches to asthma treatment—the Precision Interventions for Severe and Exacerbation Prone Asthma (PrecISE) clinical trial network. This network will evaluate novel and approved treatments for severe asthma by targeting them to defined groups of patients who share certain characteristics, such as certain genetic factors or biomarkers. COPD is the fourth leading cause of death and the third most common cause of disability in the United States, affecting 16 million people nationwide. At the request of Congress, NHLBI took the lead in engaging the COPD community and developing a comprehensive COPD National Action Plan, which was released in May 2017. The plan sets key objectives in research, public health, patient care, and awareness, specifying where possible the roles of Federal agencies and other strategic partners. The plan is being implemented and progress is being made to address the national burden of COPD, especially in rural and underserved communities, where rates are nearly twice the national average. For example, a new initiative is supporting research to increase patients' access to and use of pulmonary rehabilitation, which can help manage COPD and could even slow progression but is used by just four percent of eligible patients.

## NHLBI BUDGET

The following graph represents funding by scientific areas, for carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases.

**Funding by Activity**
(Dollars in Millions)

| NHLBI Activity | FY 2016 Enacted | FY 2017 Enacted | FY 2018 Enacted | FY 2019 Enacted | FY 2020 Enacted |
|---|---|---|---|---|---|
| Heart and Vascular Diseases | 1,710 | 1,765 | 1,855 | 1,865 | 1,945 |
| Lung Diseases | 676 | 690 | 734 | 740 | 772 |
| Blood Diseases and Resources | 396 | 413 | 431 | 491 | 512 |
| Center for Translation Research and Implementation Sciences | | | | 27 | 29 |
| Subtotal, Extramural | 2,798 | 2,868 | 3,020 | 3,123 | 3,257 |
| Intramural Research | 204 | 210 | 215 | 221 | 226 |
| Research Management & Support | 129 | 133 | 139 | 142 | 142 |
| TOTAL | 3,116 | 3,210 | 3,374 | 3,485 | 3,625 |

## NHLBI PRIORITY ISSUES

**Rising to the Public Health Challenge of COVID-19: NHLBI's Strategic Research Framework**: Given the major impact of underlying cardiovascular, pulmonary, and hematologic conditions on morbidity and mortality among patients with COVID-19, NHLBI is implementing a multidimensional research strategy aimed at slowing or halting COVID-19 progression and speeding complete recovery. NHLBI's focus is on understanding the short and long term trajectory of heart, lung, blood, and vascular injury and the underlying pathogenic mechanisms; identifying therapies for COVID-19 via scientifically robust clinical trials; ensuring that COVID-19 clinical research findings are relevant and implementable, particularly for those populations most severely affected; and promoting broad sharing of data and biospecimens. Toward these ends, the NHLBI has launched longitudinal/observational studies that will help to shed light on COVID-19 pathobiology and sequelae, risk stratification and resilience, and long-term outcomes, as well as help in assessing blood safety and conducting serosurveillance. NHLBI is also engaged in clinical trials across four host-directed therapeutic domains (passive immunization/neutralizing antibodies, anti-thrombotics, anti-inflammatory/immunomodulatory, host tissue response), and has established a network of networks (CONNECTS) to ensure efficiencies and expand bandwidth for these trials, and is developing a patient registry to facilitate enrollment in clinical trials and longitudinal studies. NHLBI is also co-leading a NIH effort to conduct urgently needed community-engaged research and outreach focused on COVID-19 awareness and education to address misinformation and mistrust, and to promote and facilitate inclusion of diverse racial and ethnic populations in clinical trials, reflective of the populations disproportionately affected by the pandemic.

**Finding a Cure for Sickle Cell Disease**: NHLBI is the principal funder of biomedical research for SCD, a life-long, rare genetic blood disorder that affects approximately 100,000 Americans. This disease disproportionately affects African Americans and Hispanics and has a range of severity and symptoms including severe pain, stroke, organ damage, and even death. To supplement its current support for

SCD research, the NHLBI established the Cure Sickle Cell Initiative (CureSCi). Launched in late FY 2018, this Initiative is a collaborative, patient-focused research effort designed to identify safe and effective ways to treat sickle cell disease at the genetic level. It aims to develop genetic therapy-based cures for SCD in under 10 years. The CureSCi has focused on seven strategic areas to advance the development of a cure for SCD: (1) Patients and community organizations engagement; (2) Translational and pre-clinical research; (3) Development of clinical research resources that are critical to regulatory approval for all curative therapies for SCD; (4) Tools to accelerate clinical trials of curative genetic therapies; (5) Robust regulatory support for funded investigators; (6) Collaborative platforms for partnerships; and (7) Data resources for clinical practice. Together, these collaborative research efforts work to accelerate the development of genetic therapies to cure SCD.

**Cardiovascular Disease (CVD) and Maternal Health:** CVD is the leading cause of death for all American women and the leading cause of pregnancy-related deaths. African American, American Indian/Alaska Native, and rural women have a disproportionate burden of CVD, and are also at higher risk for maternal morbidity and mortality (MMM). Rising rates of MMM in the United States may be a wake-up call signaling poor cardiovascular health (CVH) among reproductive-age American women generally. NHLBI supports research toward preventing or managing cardiovascular risk factors and CVD across a woman's entire lifespan.

**Research to address chronic disease, with emphasis on underserved populations**: Heart disease, hypertension, and chronic respiratory diseases are among the most common, costly and preventable of all health conditions in the United States. A high burden of chronic disease persists among racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities. NHLBI supports diverse cohort studies, including a new study focused on rural populations, to identify risk factors, understand mechanisms, and develop intervention strategies for chronic diseases. The Institute also supports clinical trials testing promising new interventions and continues to amplify its support for community-engaged research to address the roots of disparities in chronic disease, including COVID-19.

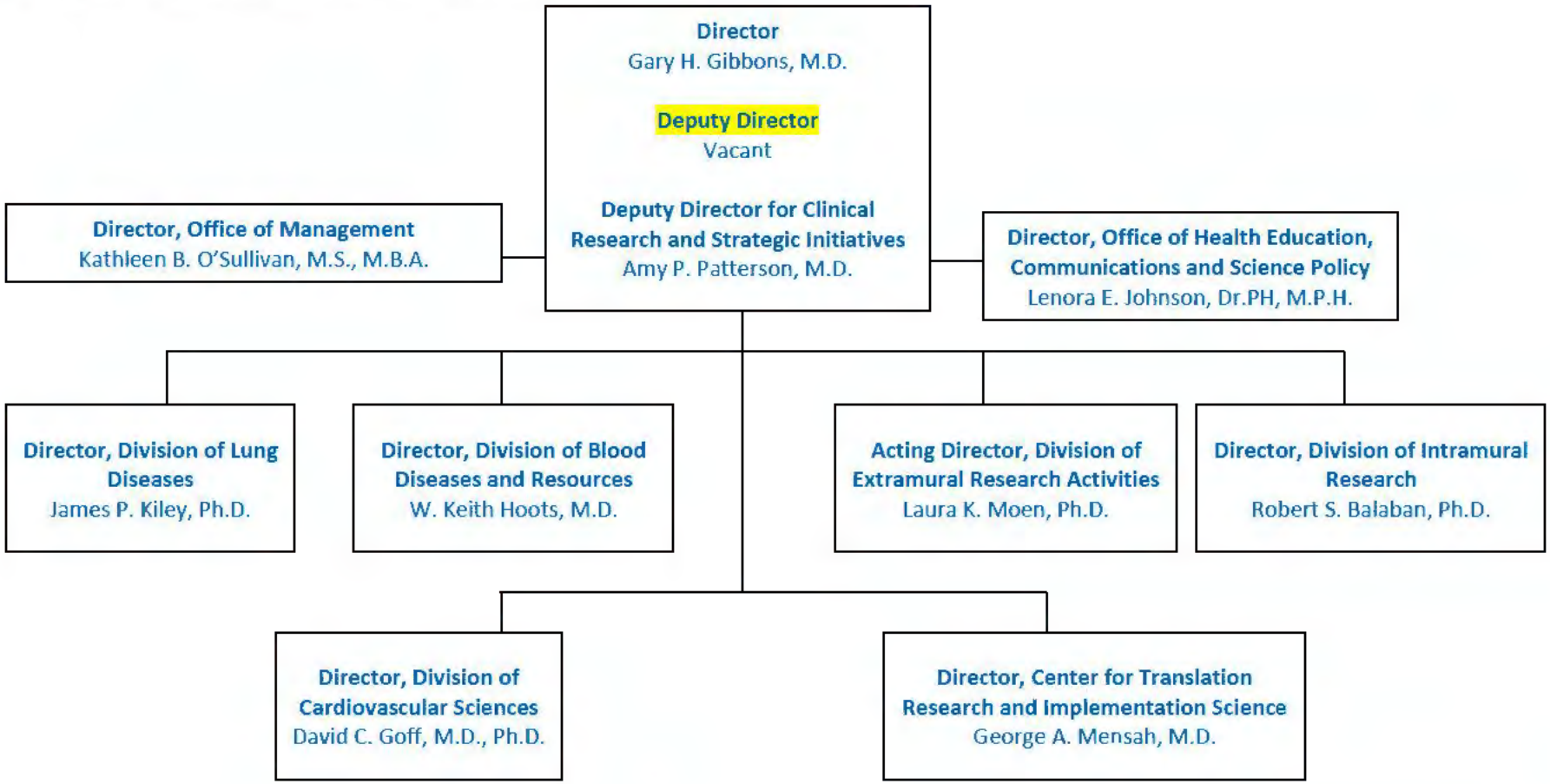
**Risks of vaping - E-cigarette/Vaping Associated Lung Injury (EVALI) and other health outcomes:** Electronic cigarettes (e-cigs) and other vaping products are the most commonly used form of nicotine among youth and young adults. Early evidence suggests that vaping may be a gateway to conventional cigarettes, which are known to increase the risk of cancer, heart disease, and lung disease. The acute risks from vaping became dramatically evident with an outbreak of EVALI in March 2019, resulting in thousands of hospitalizations and nearly 70 deaths. NHLBI has worked with its Federal partners to address this ongoing public health threat from many angles, including additional support to cardiopulmonary researchers working on tobacco-related products and new cohort studies that will help reveal long-term effects of vaping.

## NHLBI SIGNIFICANT CHANGES

NHLBI has developed a framework for making science-driven, strategic resource allocations that utilizes data-driven decision-making, aligns authority with responsibility, and fosters transparency, inclusiveness, and collaboration. This has contributed to transforming NHLBI into a nimble, learning organization that is data-guided, team-oriented, and less hierarchical. A centerpiece of these efforts has been the Strategic Visioning process that anticipates and capitalizes on emerging scientific opportunities, as well as identifies approaches to overcome new barriers to progress. Strategic Visioning entailed unprecedented efforts to solicit input from NHLBI's diverse stakeholder communities. The Strategic Investment and Management Steering Committee, which is comprised of

the executive leadership of NHLBI, was established to inform and advise the Institute Director. Recognizing the complexity and magnitude of change, the Institute has utilized change management and leadership techniques to provide the staff and unit leaders with the business and administrative tools necessary to be successful. This kind of change management strategy has been instrumental in helping the Institute cope with the exigencies and stresses created by the COVID-19 pandemic, in terms of research prioritization and general management and operations. Moving forward, NHLBI will build on its proud legacy in pioneering discovery science that improves public health.

## NHLBI ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
**Vacant Position**
Individual in Position(acting)

**National Heart, Lung, and Blood Institute**

Office of the Director

- Director, Gary H. Gibbons, M.D. (Senior Executive Position)
- Deputy Director, Vacant (Senior Executive Position)
- Deputy Director for Clinical Research and Strategic Initiatives, Amy Patterson, M.D. (Senior Executive Position)

The following offices report directly to the Director:

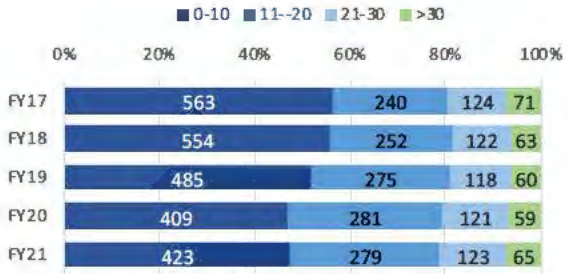
- Director of the Office of Management
    - Kathleen B. O'Sullivan, M.S., M.B.A. (Senior Executive Position)
- Director of the Office of Science Policy, Engagement, Education and Communications
    - Lenora Johnson, Ph.D. (Senior Executive Position)
- Director of the Division of Lung Diseases
    - James P. Kiley, Ph.D. (Senior Executive Position)
- Director of the Division of Blood Diseases and Resources
    - W. Keith Hoots, M.D. (Senior Executive Position)
- Acting Director of the Division of Extramural Research Activities
    - Valerie Prenger, Ph.D., M.H.S. (Senior Executive Position)
- Director of the Division of Intramural Research
    - Robert S. Balaban, Ph.D. (Senior Executive Position)
- Acting Director of the Division of Cardiovascular Sciences
    - David C. Goff, M.D., Ph.D. (Senior Executive Position)
- Director of the Center for Translation Research and Implementation Science
    - George A. Mensah, M.D. (Senior Executive Position)

National Heart, Lung, and Blood Institute

# NHLBI WORKFORCE SNAPSHOT[1]

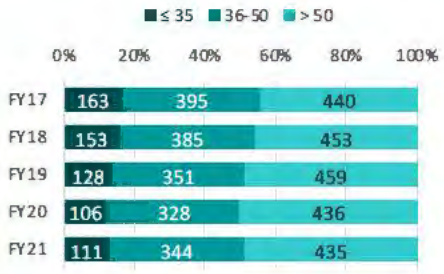
## Federal Employee Onboard (Headcount) Trending


## Federal Length of Service (Yr.) Trending

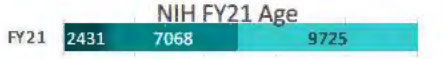



## NIH FY21 Federal Length of Service (Yr.)

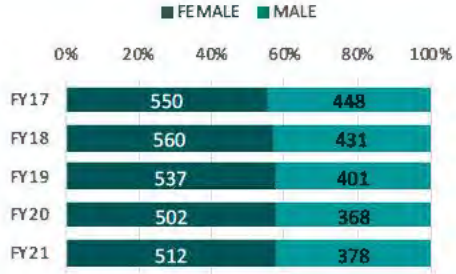

## Age Trending




## NIH FY21 Age

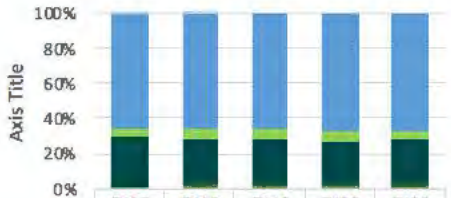



## Gender Trending



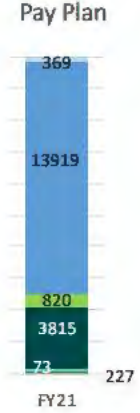

## NIH FY21 Gender


## Pay Plan Trending[2]

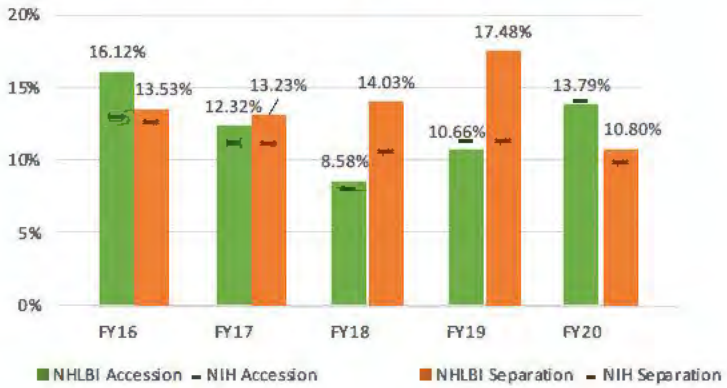



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 1 | 1 | 0 | 0 | 0 |
| GS | 658 | 647 | 615 | 585 | 596 |
| EI | 46 | 54 | 56 | 46 | 39 |
| T42 | 277 | 266 | 244 | 216 | 236 |
| SES | 3 | 3 | 2 | 2 | 2 |
| CC | 12 | 20 | 21 | 21 | 17 |

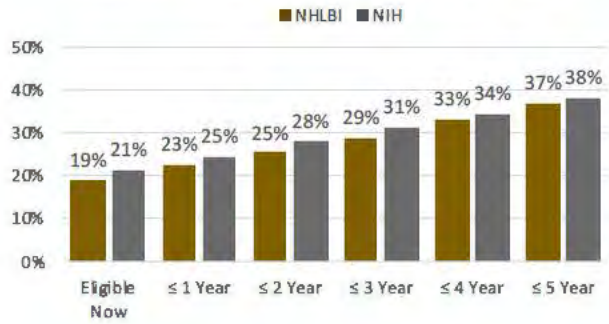
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NHLBI = 6.39 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE ON AGING (NIA)

**Budget Summary**
(Dollars in Millions)

| NIA | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 1,600.191 | 3,545.869 |
| Less (specify sources) | | |
| Total Budget Authority | 1,600.191 | 3,545.869 |
| FTE | 403 | 435 |

(b) (5)

[redacted]

## NIA MISSION

The mission of the National Institute on Aging (NIA), established in 1974, is to:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans.
- Foster the development of research and clinician scientists in aging.
- Provide research resources.
- Communicate information about aging and advances in research.

NIA's focus is on aging as a contributor or cause of diseases or conditions. NIA is the lead NIH Institute for Alzheimer's disease (AD) and related dementias (ADRD) research. NIA funds research at universities and medical centers across the United States and around the world and conducts its own research program in Baltimore and Bethesda, Maryland. Recent accomplishments include advancing AD diagnostic approaches; data sharing advances in AD genetics and the NIH Accelerating Medicines Project (AMP); expanding NIA-funded caregiver interventions; developing geroscience as an interdisciplinary approach to aging research; and enhancing diverse clinical trial recruitment.

**Three key IC programs:**

- **Accelerating Medicines Partnership - Alzheimer's Disease (AMP-AD) Program:** AMP-AD is a precompetitive partnership among government, industry, and nonprofit organizations managed by the Foundation for the NIH, focused on discovering novel, clinically relevant therapeutic targets and on developing biomarkers to help validate existing targets for AD. Established by the AMP-AD Target Discovery and Preclinical Validation Project, an AD Knowledge Portal serves as the data sharing hub for AMP-AD and several NIA-supported systems biology consortia and translational infrastructure programs. The portal operates an open access database that disseminates data, tools, and analytical results contributed by more than 250 researchers. All data, methods, and results generated within the network are distributed under FAIR (Findability, Accessibility, Interoperability, and Reuse of digital assets) data principles.
- **Health and Retirement Study (HRS):** This study follows a population-representative cohort of over 20,000 older Americans from age 50 until death, and includes measures of a wide variety of health, physical, psychological, and economic outcomes. The study's main purpose is to learn if individuals and families are preparing for the economic and health requirements of advancing age, and the types of actions and interventions that can promote or threaten health and wealth in retirement. The HRS has also been utilized as the base for the Healthy Cognitive Aging Project (HCAP), a nationally representative study that will help shed light on how and when cognitive decline progresses in older adults.

- **Interventions Testing Program (ITP):** This multi-institutional study is focused on investigating potential treatments to extend lifespan and delay disease and dysfunction in mice. Such treatments include drug therapies, foods and diets, dietary supplements, and many other substances.

## NIA BUDGET

**Budget Authority By Activity**
(Dollars in Millions)

| NIA Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual |
|---|---|---|---|---|
| **Extramural Research** | | | | |
| **Aging Biology** | 179.154 | 205.131 | 262.439 | 313.286 |
| **Behavioral & Social Research** | 214.431 | 213.780 | 305.613 | 436.577 |
| **Neuroscience** | 873.878 | 1,271.883 | 1,575.481 | 1,794.136 |
| **Geriatrics & Clinical Gerontology** | 152.539 | 156.062 | 215.156 | 290.599 |
| **Subtotal, Extramural** | 1,420.001 | 1,846.856 | 2,358.689 | 2,834.598 |
| **Intramural Research** | 129.476 | 148.224 | 148.566 | 170.959 |
| **Research Management & Support** | 46.554 | 53.734 | 64.248 | 74.520 |
| **TOTAL** | 1,596.031 | 2,048.814 | 2,571.502 | 3,080.077 |

## NIA PRIORITY ISSUES

**Alzheimer's Disease:** As a result of substantial increases in appropriated funds for AD/ADRD research, NIH spending on AD/ADRD research increased nearly 4.5-fold from FY 2015 ($631 million) to FY 2020 (an estimated $2.818 billion). This has enabled the institute to stimulate hundreds of additional research proposals and to accelerate research progress in basic, translational, and clinical research, as well as health disparities- and care and caregiving research. Long-range research planning in AD/ADRD research is informed by extensive input from the research community and affected populations.

**Geroscience**: NIA is also the lead NIH Institute for promoting geroscience research. Geroscience aims to understand what about the biology of aging makes it the major risk factor for chronic disease and frailty in older adults. Researchers in the field hypothesize that slowing the rate of aging will have a beneficial impact on the health of older adults by delaying the onset or reducing the severity of most chronic diseases and frailty, i.e., improving health at older ages.

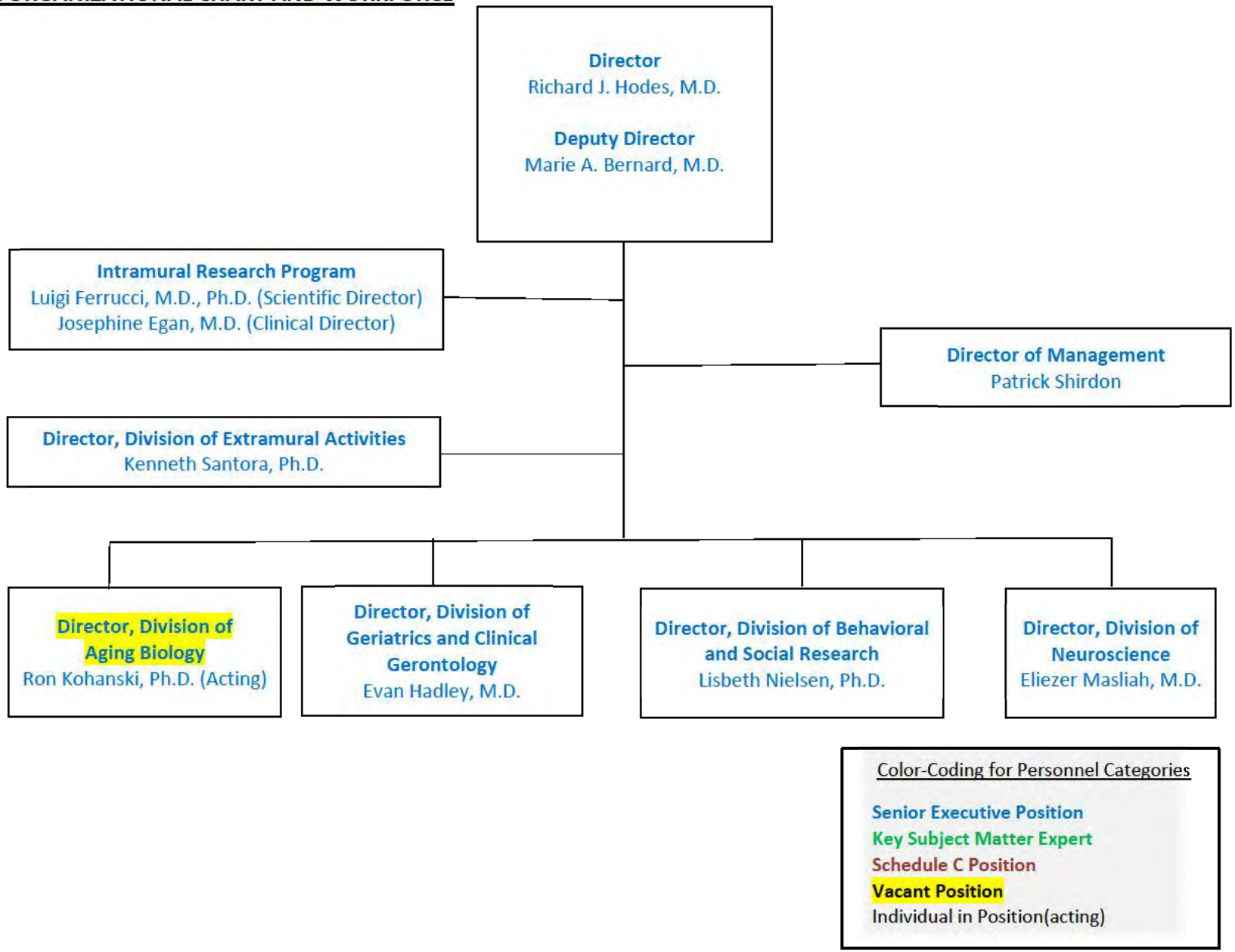
## NIA SIGNIFICANT CHANGES

- Alzheimer's Disease Bypass Budget**:** The FY 2015 Appropriations Act requires NIH to produce a professional judgment budget estimate for AD/ADRD, to be submitted to the President on an annual basis through 2025. As a result, NIH has produced Bypass Budgets for AD/ADRD for all subsequent years; the most recent Bypass Budget was released in July 2020. Many strategic planning efforts in AD and ADRD informed the development of these AD Bypass Budgets, including multiple scientific research meetings held between 2012 and 2020. While the Bypass Budget process is separate from the standard Federal budget development process, the additional appropriations for AD/ADRD received for the past several years have

enabled many of the activities outlined and estimated for each Bypass Budget to be accelerated a year earlier than planned.

- **Clinical Research Operations & Management:** Over the last several years, NIA's budget has tripled, resulting in substantial growth in its operations as well as its clinical research portfolio, number of grantees, participating sites, and clinical research data to manage. To address this need, NIA has recently awarded a contract to design/adapt, develop, maintain, and operate a unified Clinical Research Operations & Management System (CROMS) that supports the unique data and clinical research process needs of NIA's programs and provides an institute-wide informatics capability to track, report and manage NIA's clinical research data, activities, and portfolio in real time. CROMS will enable NIA to better manage clinical research, identify, and support sites not able to meet recruitment goals, learn from top-performing sites, and provide transparency regarding its recruitment efforts and successes. It will also provide critical, timely information for ensuring that NIA's clinical trial sites are making appropriate progress toward reaching recruitment goals related to multiple under-represented groups.
- **IT Modernization:** NIA has also completed the initial assessment of the IT Modernization initiative and several key areas were identified as potential technology growth and development possibilities. Amongst these were Business Process Automation, Robotic Process Automation and Integrated Data Reporting /Analytics. A plan has been formulated to execute the procurement of technology stacks, which can address these findings. Along with the injection of the new technological tools, a plan to reorganize the IT organizational structure has also been put into action. The organizational structure will allow for easier and effective execution of projects associated with the Modernization initiative. The modernization efforts benefits will be streamlined processes, better access to data, and significantly improved project and program management capabilities.

## NIA ORGANIZATIONAL CHART AND WORKFORCE



**National Institute on Aging**

Office of the Director

- Director, Richard J. Hodes, M.D. (Senior Executive Position)
- Deputy Director, Marie A. Bernard, M.D. (Senior Executive Position)

The following offices report directly to the Director, National Institute on Aging:

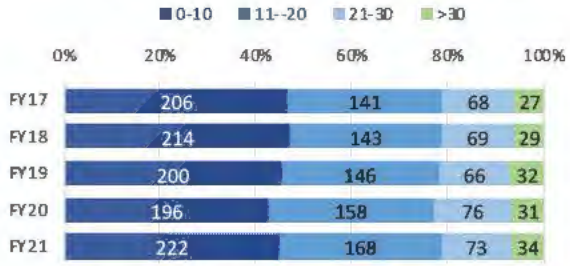
- Scientific Director, Intramural Research Program
    - Luigi Ferrucci, M.D., Ph.D. (Senior Executive Position)
- Clinical Director, Intramural Research Program
    - Josephine Egan, M.D. (Senior Executive Position)
- Director, Office of Extramural Activities
    - Kenneth Santora, Ph.D. (Senior Executive Position)
- Director of Management
    - Patrick Shirdon, M.S. (Senior Executive Position)
- Director, Division of Aging Biology
    - Ron Kohanski, Ph.D. (Acting; Senior Executive Position)
- Director, Division of Geriatrics and Clinical Gerontology
    - Evan Hadley, M.D. (Senior Executive Position)
- Director, Division of Behavioral and Social Research
    - Lisbeth Nielsen, Ph.D. (Senior Executive Position)
- Director, Division of Neuroscience
    - Eliezer Masliah, M.D. (Senior Executive Position)

# NIA WORKFORCE SNAPSHOT[1]

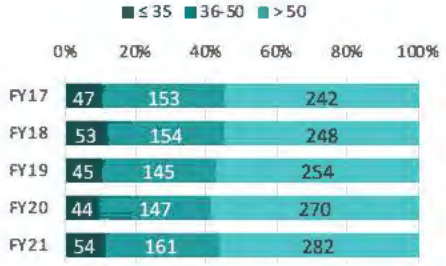
National Institute on Aging

## Federal Employee Onboard (Headcount) Trending

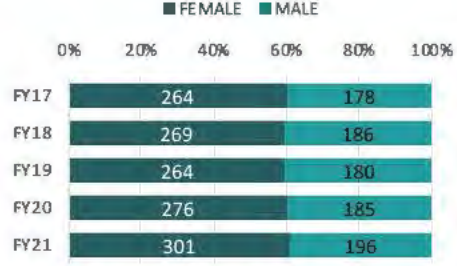

## Federal Length of Service (Yr.) Trending




## Age Trending

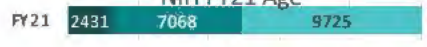



## Gender Trending

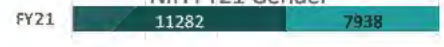



## NIH FY21 Federal Length of Service (Yr.)

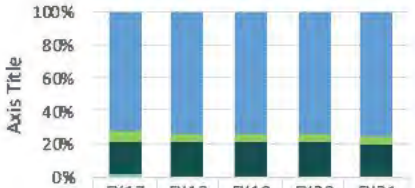

## NIH FY21 Age




## NIH FY21 Gender



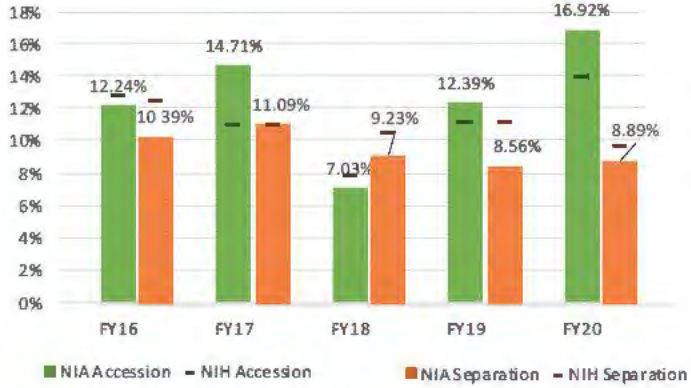

## Pay Plan Trending[2]



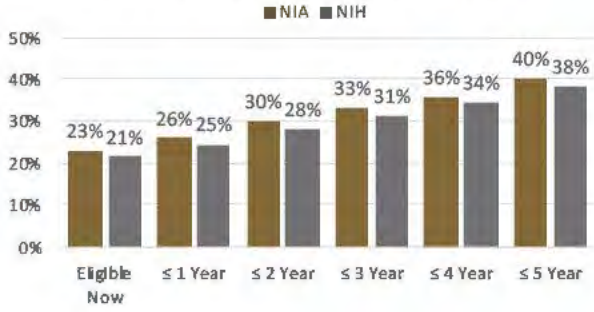

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 320 | 334 | 327 | 341 | 371 |
| EI | 25 | 25 | 24 | 24 | 31 |
| T42 | 91 | 91 | 88 | 91 | 92 |
| SES | 2 | 2 | 2 | 2 | 2 |
| CC | 4 | 3 | 3 | 3 | 1 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIA = 4.98 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

**Budget Summary**
(Dollars in Mi

(b) (5)

| NIAAA | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 466.800 | 546.700 |
| Less (specify sources) | | |
| Total Budget Authority | 466.800 | 546.700 |
| FTE | 238 | 238 |

## NIAAA MISSION

Since its inception in 1970, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has served as the primary U.S. agency for conducting and supporting alcohol research across a wide range of scientific disciplines. A leader in the national effort to reduce alcohol misuse and related problems, NIAAA also translates and disseminates evidence-based research findings to a variety of audiences, including healthcare professionals, researchers, policymakers, and the general public. Over the past 50 years, the Institute has supported basic, translational, and clinical research on the causes, consequences, diagnosis, epidemiology, prevention, and treatment of alcohol-related health problems across the lifespan.

The Institute is proud to highlight the development and launch of the NIAAA Alcohol Treatment Navigator®. The Navigator is a web-based resource designed to help individuals and their loved ones understand treatment options for alcohol use disorder (AUD) and search for nearby treatment that is professionally led and evidence-based. More recent updates include addition of information about telehealth services and a portal to assist healthcare providers in making referrals for their patients. Efforts are also underway to create a web-based "core resource" of essential information to help clinicians better recognize the effects of alcohol in their patients and deliver improved care.

While NIAAA supports research on a diverse range of topics, three major program priorities include:

- **Underage drinking research** – Underage drinking can lead to impaired brain development, compromised cognitive functioning, and an increased likelihood of developing AUD later in life. NIAAA supports longitudinal and other basic research studies on the effects of adolescent drinking on the developing brain and factors that contribute to underage drinking with the goal of informing preventive and treatment interventions. The Institute also funds research to develop and evaluate preventive interventions at the individual, family, school, community, and policy levels, and provides resources for conducting alcohol screening and brief intervention among youth and addressing harmful and underage drinking among college students.
- **Fetal alcohol spectrum disorders (FASD)** – Prenatal alcohol exposure is a leading preventable cause of birth defects and neurodevelopmental deficits in the United States. It can cause a range of intellectual and behavioral problems, which appear at any time during childhood and last a lifetime. NIAAA funds basic, translational, and clinical research focused on preventing prenatal alcohol exposure, improving the diagnosis of FASD, and developing effective treatment interventions to mitigate the health effects in individuals prenatally exposed to alcohol. The Institute supports multiple research centers and consortia that conduct FASD research.

- **Treatment** – Although there are three FDA-approved medications for AUD, the heterogeneous nature of AUD suggests that additional treatment options may enable more effective, individualized treatment. NIAAA supports research to develop behavioral and pharmacological therapies for AUD as well as effective treatments for alcohol-associated liver disease. NIAAA has a robust medications development portfolio that includes preclinical studies, a Human Laboratory Program that screens candidate compounds for potential effectiveness prior to clinical trials, and the NIAAA Clinical Investigations Group, a network of research sites for conducting rapid phase II clinical trials of promising compounds. In addition to the development of AUD therapies, NIAAA is also working to improve consistency in the assessment of recovery from AUD through the development of a consensus recovery definition for research. NIAAA also supports an Alcoholic Hepatitis Clinical and Translational Network to maximize the use of research resources and promote the sharing of research expertise with the goal of accelerating the development of effective treatment for patients with this severe liver condition.

## NIAAA BUDGET

The FY 2020 appropriation for NIAAA provides $546.7 million, including a $1.3 million HIV/AIDS transfer supplement. This represents a $79.9 million or a 17 percent increase over the FY 2016 enacted budget level. NIAAA estimates it will support a total of 790 Research Project Grants (RPGs) in FY 2020 which is a 19% increase over the FY 16 funded RPGs.

NIAAA's extramural programs are organized by stage of life (Budget Authority by Activity Table) to encourage consideration of how changes in biology, behavior, and environmental inputs over time influence the emergence and progression of drinking behavior, and prevention/treatment of alcohol misuse and associated health consequences.

**Budget Authority By Activity**
(Dollars in Millions)

| NIAAA Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Actual |
|---|---|---|---|---|---|
| **Extramural Research** | | | | | |
| **Embryo and Fetus** | 16.9 | 16.6 | 16.8 | 17.4 | 18.1 |
| **Youth/Adolescence** | 57.6 | 46.4 | 42.1 | 43.5 | 45.3 |
| **Young Adult** | 168.4 | 176.3 | 189.5 | 200.2 | 203.9 |
| **Mid-Life/Senior Adult** | 140.8 | 157.6 | 172.6 | 174.1 | 185.7 |
| **Subtotal, Extramural** | 393.7 | 396.9 | 421.0 | 435.3 | 453 |
| **Intramural Research** | 49.6 | 51.0 | 52.8 | 54.4 | 56.5 |
| **Research Management & Support** | 33.5 | 34.5 | 34.6 | 35.6 | 37.2 |
| **TOTAL** | 466.8 | 482.5 | 508.4 | 525.3 | 546.7 |

The Research Management and Support provides for administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of grants, training awards, and contracts; strategic planning, coordination, and evaluation of the NIAAA's programs; regulatory compliance; and liaison with other Federal agencies, Congress, and the public.

NIAAA's Intramural Research Program (IRP) supports highly innovative research to understand the biological and behavioral basis of AUD, to investigate the impact of and processes underlying the effects of alcohol on brain structure, and to develop treatments for AUD and other alcohol-related conditions.

The mandatory expenditures within the RMS and IRP consist of personnel cost and assessment budget. Within mandatory expenditures, the assessment increased from $44.9 million to $49.5 million, or 10.1 percent from FY 2016 to FY 2020. The personnel cost of the Institute increased from $39.7 million to $45.1 million, or 14 percent from FY 2016 to FY 2020. The level of FTE numbers remained the same, 238 from FY 2016 to FY 2020.

(b) (5)

[redacted]

## NIAAA PRIORITY ISSUES

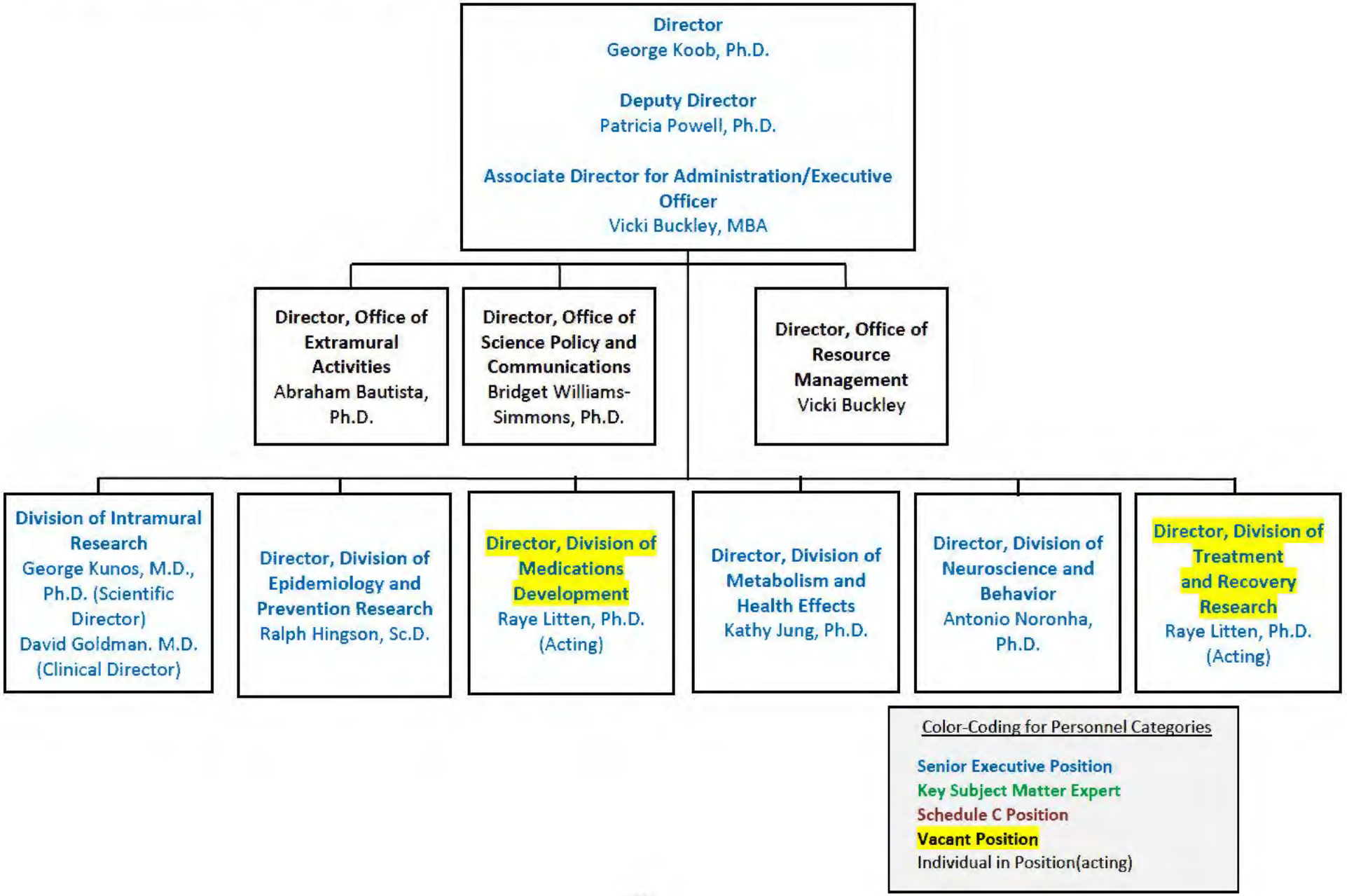
**U.S. Dietary guidelines for alcohol consumption:** The 2015-2020 Dietary Guidelines for Americans recommend no more than one drink per day for women and no more than two drinks per day for men. The 2020 Dietary Guidelines Advisory Committee, which is developing the 2020-2025 guidelines, has endorsed revising the recommendation for men to no more than one drink per day. This proposal has attracted attention from the media and the alcoholic beverage industry. NIAAA anticipates ongoing requests for comments on this proposed change.

## NIAAA SIGNIFICANT CHANGES

In 2017, Dr. Patricia Powell was named deputy director of NIAAA. Dr. Powell was preceded by former NIAAA deputy director, Dr. Kenneth Warren, who retired from Federal service in 2015.

In 2018, Dr. Bridget Williams-Simmons was named chief for the Office of Science Policy and Communications. Dr. Williams-Simmons was preceded by the former chief, Dr. Vivian Faden, who retired from Federal service in 2017.

## NIAAA ORGANIZATIONAL CHART AND WORKFORCE



**National Institute on Alcohol Abuse and Alcoholism**

Office of the Director

- Director, George F. Koob, Ph.D. (Senior Executive Position)
- Deputy Director, Patricia Powell, Ph.D. (Senior Executive Position)
- Associate Director for Administration/Executive Officer, Vicki Buckley, M.B.A. (Senior Executive Position)

The following Offices and Divisions report directly to the Director, NIAAA:

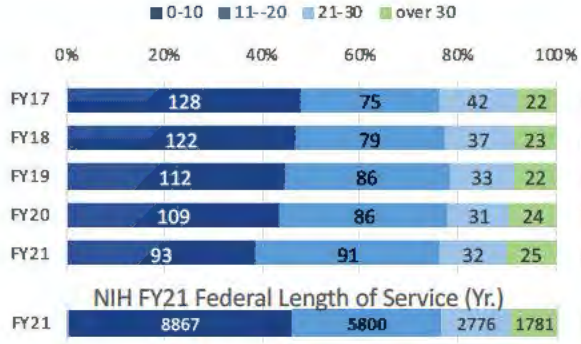
- Director of Office of Extramural Activities
    - Abraham Bautista, Ph.D.
- Director of Office of Science Policy and Communications
    - Bridget Williams-Simmons, Ph.D.
- Director of Office of Resource Management
    - Vicki Buckley, M.B.A.
- Director of Division of Intramural Research
    - George Kunos, M.D., Ph.D. (Senior Executive Position)
- Clinical Director of Division of Intramural Research
    - David Goldman, M.D. (Senior Executive Position)
- Director of Division of Epidemiology and Prevention Research
    - Ralph Hingson, Sc.D. (Senior Executive Position)
- Director of Division of Medications Development
    - Raye Litten, Ph.D. (Acting; Senior Executive Position)
- Director of Division of Metabolism and Health Effects
    - Kathy Jung, Ph.D. (Senior Executive Position)
- Director of Division of Neuroscience and Behavior
    - Antonio Noronha, Ph.D. (Senior Executive Position)
- Director of Division of Treatment and Recovery Research
    - Raye Litten, Ph.D. (Acting; Senior Executive Position)

National Institute on Alcohol Abuse and Alcoholism

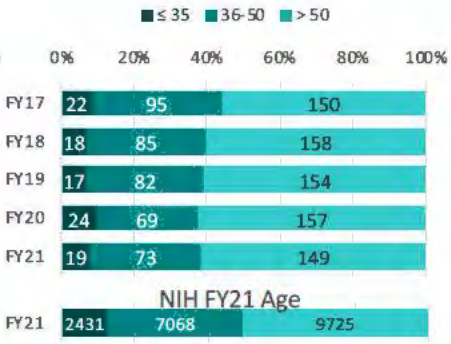
# NIAAA WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

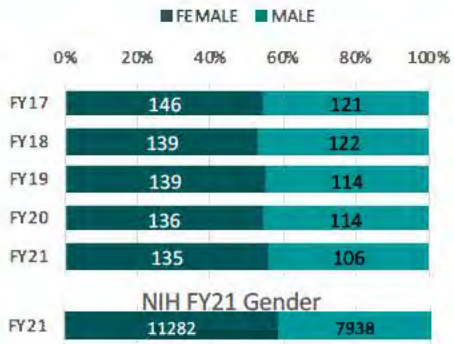

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)




## NIH FY21 Age



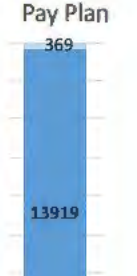

## NIH FY21 Gender




## Pay Plan Trending[2]

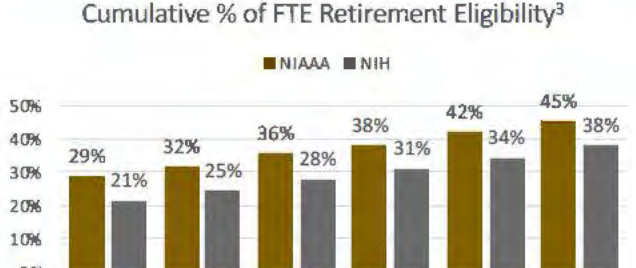

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 178 | 176 | 174 | 167 | 162 |
| EI | 27 | 27 | 26 | 27 | 24 |
| T42 | 57 | 53 | 49 | 52 | 52 |
| SES | 4 | 4 | 3 | 3 | 2 |
| CC | 1 | 1 | 1 | 1 | 1 |

## NIH FY21 Pay Plan




## Accession & Separation Trending


## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIAAA = 4.97 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

**Budget Summary**
(Dollars in Millions)

| NIAID | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 4749.897 | 7408.195 | |
| Less (specify sources) | 119.969 | 1522.725 | |
| Total Budget Authority | 4629.928 | 5885.470 | |
| FTE | 1,943 | 1,963 | |

** 2016 Sources – intra NIH transfers - $34M to Zika and $85M*
** 2020 Sources – intra NIH transfers - -$9M to Other NIH Institutes for AIDS from NIAID*
** 2020 Sources – COVID-19 emergency supplemental - $1,532M*

## NIAID MISSION

The National Institute of Allergy and Infectious Diseases (NIAID) was created as an NIH institute more than 60 years ago to understand, diagnose, prevent, treat, and, ultimately, cure infectious and immune-mediated diseases. In support of this mission, NIAID conducts and supports basic, translational, and clinical research in microbiology, infectious diseases, immunology, allergy, and other immune-mediated diseases. In addition, NIAID has designed its flexible research infrastructure to fulfill a unique facet of its mandate: to respond rapidly to emerging and re-emerging infectious diseases, such as pandemic influenza and Zika virus disease. With the increasing movement of people and goods, many infectious diseases are global concerns. Infectious diseases are among the primary causes of mortality and suffering worldwide, and their impact can affect political and economic stability. NIAID embraces its leadership role in the global effort to defeat infectious diseases, working with other NIH Institutes, U.S. agencies, universities, and industry and global partners.

NIAID's research programs encompass three main areas:

- **HIV/AIDS** – NIAID conducts and supports research to achieve an AIDS-free generation, in which new HIV infections, as well as illness and death due to AIDS, are rare. This goal is now feasible, thanks to a sustained research effort since HIV was identified. NIAID continues efforts to develop, refine, and optimize HIV treatment and prevention approaches; to develop a safe and effective HIV vaccine; and ultimately to cure individuals with HIV—that is, to suppress the virus to the point where a person with HIV can stop antiretroviral therapy (ART) without having the virus rebound.
- **Infectious and Immunologic Diseases** – NIAID conducts and supports research to develop diagnostics, vaccines, and treatments for a myriad of infectious diseases, including malaria, diarrheal diseases, and respiratory diseases such as tuberculosis and influenza. NIAID also supports research to expand the understanding of the human immune system, including how to suppress aberrant immune responses and enhance deficient ones, and to improve treatment strategies for immune-mediated disorders such as asthma, allergy, autoimmune diseases, and transplant rejection.
- **Biodefense and Emerging Infectious Diseases** – In addition to supporting research to respond to emerging and re-emerging infectious disease threats, such as Ebola, SARS-CoV-2, and dengue

viruses, NIAID scientists and grantees are designing innovative technologies that address more than one disease and obviate the need for new vaccines and treatments for every disease that emerges. Urgent research priorities include combating antimicrobial resistance (AMR), developing medical countermeasures to prevent and treat COVID-19, and developing a "universal" influenza vaccine that generates long-lasting protection against multiple strains of seasonal and pandemic influenza.

## NIAID BUDGET

NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID is committed to fulfilling this mission, and through its dual mandate, to maintain its capability to quickly launch research responses to new and re-EIDs. The NIAID FY 2020 operating budget of $5.9 billion, which is funded through discretionary appropriations, is distributed across three major programs or mission areas: HIV/AIDS, Biodefense and Emerging Infectious Diseases, and Infectious and Immunologic Diseases, with extramural operating budgets of $1.4 billion, $1.4 billion and $1.9 billion respectively. NIAID allocates $0.8 billion to its intramural research (IR) program, and $0.4 billion for research management and support (RMS) of these programs. The above IR and RMS figures each include approximately $0.2 billion in Federal personnel costs, allocated equally between the two budget mechanisms.

Budget Authority – The table below summarizes the actual budget authority by activity provided to NIAID for FY 2016 to FY 2020 budget. Excluded from these figures are emergency supplemental appropriations for Ebola and Zika in FY 2015 to FY 2017 and COVID-19 in FY 2020, as well as funds provided by HHS, via intra-departmental delegations of authority, to support programs such as Operation Warp Speed (OWS) and pandemic influenza research.

**Budget Authority By Activity**
(Dollars in Millions)

| NIAID Activity | FY 2016 | FY 2017 | FY 2018 | FY 2019[1] | FY 2020 |
|---|---|---|---|---|---|
| **Extramural HIV/AIDS** | 1,384.4 | 1,361.9 | 1,355.1 | 1,403.8 | 1,423.8 |
| **Extramural BIOD/EID** | 1,379.4 | 1,490.6 | 1,662.4 | 1,799.0 | 1,928.9 |
| **Extramural IID** | 1,066.5 | 1,111.8 | 1,239.6 | 1,272.9 | 1,392.5 |
| **Intramural** | 619.9 | 630.6 | 681.4 | 715.5 | 758.3 |
| **RMS** | 299.6 | 310.8 | 329.8 | 348.9 | 372.6 |
| **Total** | 4,749.9 | 4,905.7 | 5,268.3 | 5,540.1 | 5,876.2 |

[1]Excludes $5 million in HEAL funds transferred from NINDS

## NIAID PRIORITY ISSUES

**Dual Mandate and Responding to Emerging and Reemerging Infectious Diseases**: A recurring responsibility that NIAID undertakes and that merits attention in the first year of the administration is the continued financial and resource support for NIAID's dual mandate. NIAID is unique among NIH ICs in having this dual mandate that requires it to maintain and grow a robust basic and preclinical research portfolio in microbiology, infectious diseases, and immunology while at the same time responding rapidly to new or re-emerging infectious disease threats, with the ultimate goal of developing new or improved countermeasures. NIAID supports and conducts basic research to understand a variety of emerging infections, such as those caused by the chikungunya, dengue, and enteroviruses. NIAID also employs a flexible infrastructure that enables a rapid research response to disease outbreaks such as the

unprecedented 2014–2015 EVD outbreak in West Africa and the 2015-2016 Zika virus epidemic. NIAID scientists continue working with the United States and international partners to advance critical research toward possible treatments, develop and test vaccines, and strengthen diagnostic capability in the field—today for COVID-19 and tomorrow for yet-unknown emerging disease threats.

**COVID-19 and Coronaviruses**: Continued financial and operational support for COVID-19 and Coronaviruses, including the ability of NIAID to access funding such as that appropriated to the Public Health and Emergency Social Services Fund (PHSSEF) should be an area requiring attention in the first year of the administration. In response to COVID-19, NIAID is leveraging current resources and global collaborations, including existing research programs and clinical trials networks. NIAID's research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) and includes improving fundamental knowledge of SARS-CoV-2 and COVID-19, characterizing and testing therapeutics, developing safe and effective vaccines against SARS-CoV-2, and supporting the development of diagnostics and assays. Future research, and supplemental funding, would expand these research areas to include targeted drug discovery, 2nd Generation COVID-19 vaccines, a universal coronavirus vaccine and for research into the long-term consequences of COVID-19 including those who experience symptoms of the illness many weeks or even months after having it.

**Development of Universal Influenza Vaccines**: NIAID continues to focus on developing a universal flu vaccine, or a vaccine that provides robust, long-lasting protection against multiple subtypes of flu, rather than a select few. Such a vaccine would eliminate the need to update and administer the seasonal flu vaccine each year and could provide protection against newly emerging flu strains, potentially including those that could cause a flu pandemic. Continued financial and operational support for this research area should require attention in the first year of the administration.

**HIV Prevention**: NIAID is supporting research initiatives aimed at the goal of Ending the HIV Epidemic: (EHE) and an "AIDS-free generation" in which new HIV infections, as well as illness and death due to AIDS, are rare. Effective prevention strategies are vital to reaching this goal. NIAID continues to make progress towards achieving these goals, including collaborations with community partners to develop locally relevant plans for diagnosing, treating and preventing HIV in areas with high rates of new HIV cases; research on universal "test and treat" approaches could help control the HIV epidemic in certain settings; and development of vaccines and anti-HIV broadly neutralizing antibodies (bNAbs) that suppress HIV. NIAID continues to advance research to reduce or prevent HIV infection, with intensified focus on long-acting prevention strategies including an effective HIV vaccine, the ultimate goal of HIV prevention. Continued financial and operational support for this research area should require attention in the first year of the administration.

**Combating Antimicrobial and Antibacterial Resistance**: In recent years, many of the world's most deadly and widespread pathogens have developed resistance to existing antimicrobial treatments. NIAID's research efforts are intensely focused on stemming the growth of this dangerous global health concern. As part of its efforts to achieve key goals of the multiagency 2015 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), NIAID is advancing basic and clinical research studies, as the Institute pursues an aggressive program to better understand resistance mechanisms and develop new and effective diagnostics, therapies and treatment strategies, and vaccines. Continued financial and operational support for this research area should require attention in the first year of the administration.

## NIAID SIGNIFICANT CHANGES

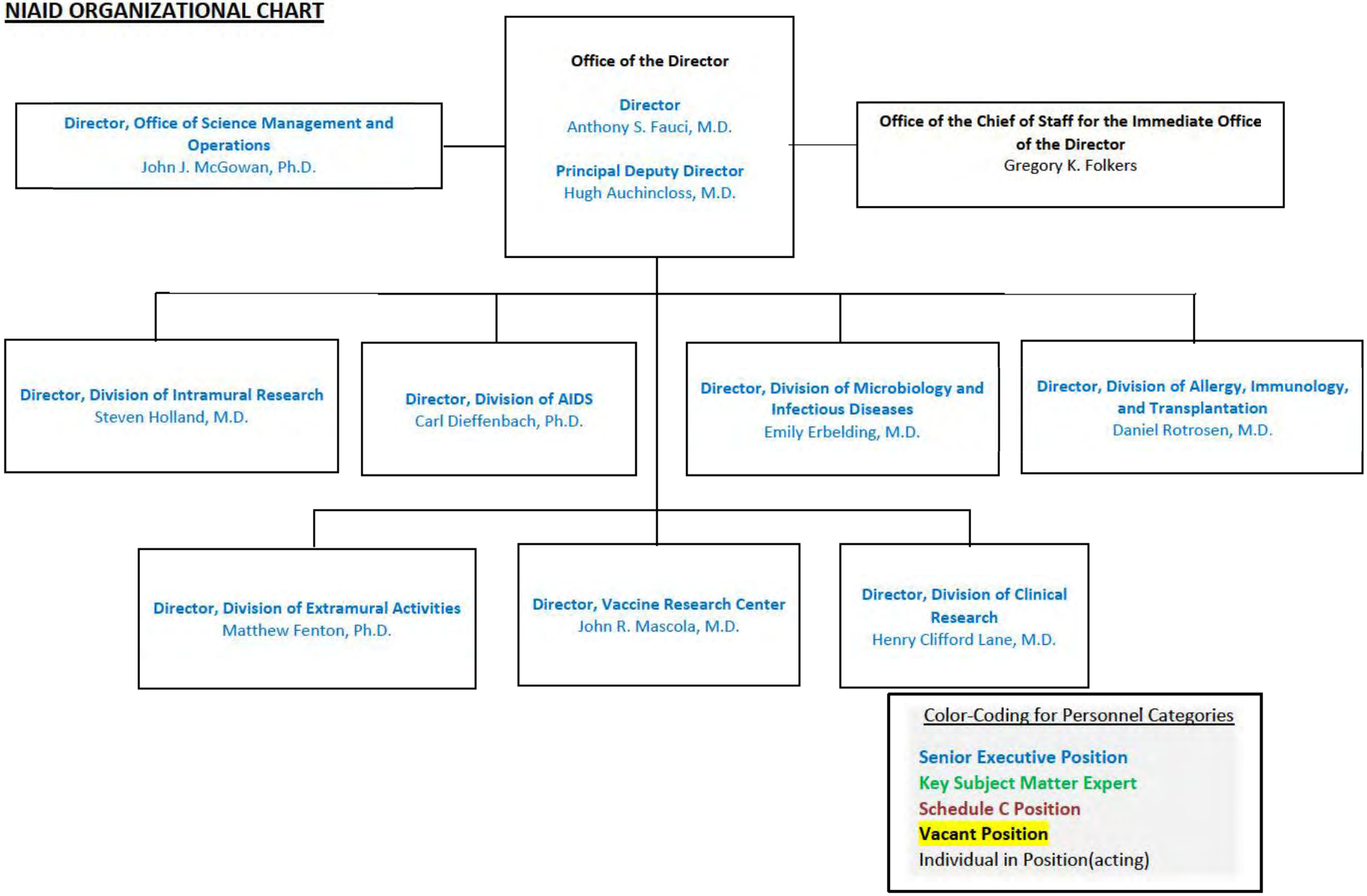
The most significant change that has affected NIAID since FY 2016 has been its response to COVID-19 in FY 2020 and Ebola and Zika in FY 2015 - 2017, as well as other emerging infectious disease outbreaks including acute flaccid myelitis (AFM) and pandemic influenza strains. Fortunately, to support NIAID's responses, it was provided with several emergency supplemental appropriations. The emergency supplemental appropriation in FY 2020 for COVID-19 was $1.5 billion, while the emergency supplemental packages for Ebola and Zika were both in excess of $240 million each.

Other changes that have occurred that have impacted NIAID's annual appropriation have included earmarks to fund an increasingly larger share of NIAID's budget to combat AMR as outlined in the National Action Plan for CARB, to advance the development of a universal influenza vaccine, and to continue HIV/AIDS research including funds to support the President's Ending the HIV Epidemic: A Plan for America.

NIAID has been fortunate to have management able to quickly redirect personnel, research facilities and relationships with extramural investigators, industry partners and other government agencies to respond rapidly and effectively to emerging and reemerging infectious disease outbreaks. While NIAID has been successful in these efforts and developing countermeasures, this has come at the expense of redirecting staff away from ongoing research as well as putting additional strain on NIAID program and administrative personnel and research facilities. Having sufficient resources to sustain these efforts and maintaining an aging research infrastructure should be a priority.

NIAID has, and continues to be, a leading IC in implementing administrative and IT processes and solutions to improve our management of NIAID's research portfolio. For example, NIAID developed processes such as an annual review and approval of future extramural research initiatives governed by the Research Initiative Committee. The process has greatly enhanced coordination and planning among operating divisions (OPDIV) within NIAID. Also, NIAID developed many software packages to improve operations, such as a property management system which has been adopted by most NIH ICOs.

## NIAID ORGANIZATIONAL CHART



**National Institute of Allergy and Infectious Diseases**

Office of the Director

- Director, Anthony S. Fauci, M.D. (Senior Executive Position)
- Principal Deputy Director, Hugh Auchincloss, M.D. (Senior Executive Position)

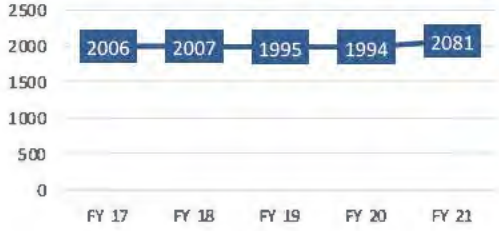
The following offices and divisions report directly to the Director:

- Office of the Chief of Staff for the Immediate Office of the Director
    - Gregory K. Folkers
- Director, Office of Science Management and Operations
    - John J. McGowan, Ph.D. (Senior Executive Position)
- Director, Division of Intramural Research
    - Steven Holland, M.D. (Senior Executive Position)
- Director, Division of AIDS
    - Carl Dieffenbach, Ph.D. (Senior Executive Position)
- Director, Division of Microbiology and Infectious Diseases
    - Emily Erbelding, M.D. (Senior Executive Position)
- Director, Division of Allergy, Immunology, and Transplantation
    - Daniel Rotrosen, M.D. (Senior Executive Position)
- Director, Division of Extramural Activities
    - Matthew Fenton, Ph.D. (Senior Executive Position)
- Director, Vaccine Research Center
    - John R. Mascola, M.D. (Senior Executive Position)
- Director, Division of Clinical Research
    - Henry Clifford Lane, M.D. (Senior Executive Position)

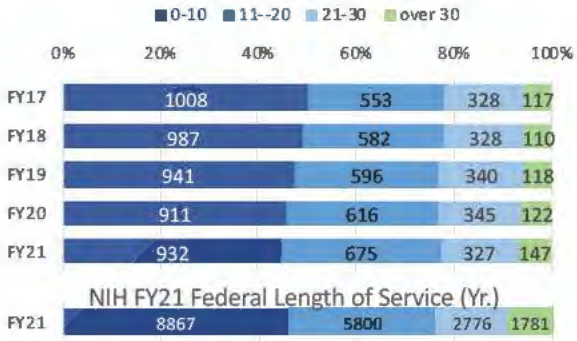
National Institute of Allergy and Infectious Diseases

# NIAID WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending



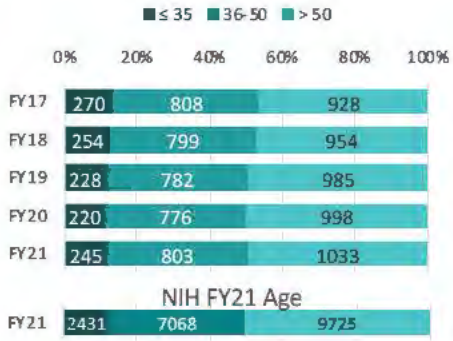

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



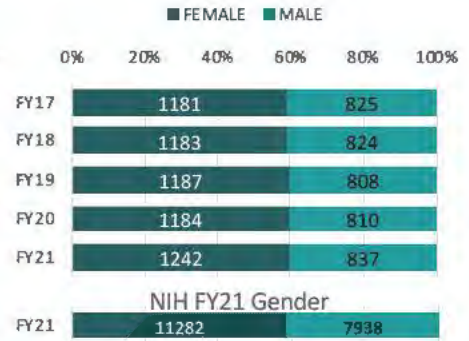

## Age Trending




## NIH FY21 Age



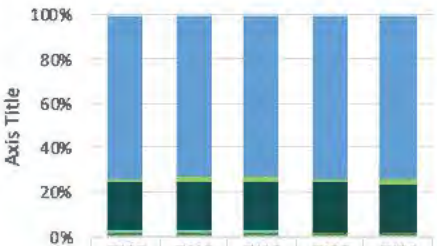

## Gender Trending




## NIH FY21 Gender

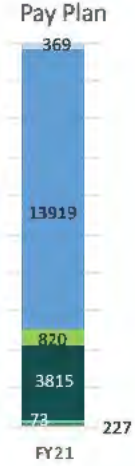



## Pay Plan Trending[2]

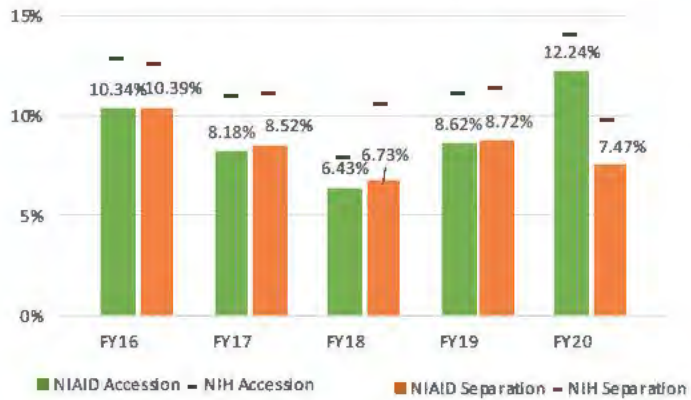



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 2 | 3 | 3 | 3 | 3 |
| GS | 1475 | 1471 | 1459 | 1464 | 1534 |
| EI | 44 | 42 | 45 | 41 | 44 |
| T42 | 434 | 439 | 433 | 438 | 459 |
| SES | 9 | 8 | 7 | 4 | 4 |
| CC | 42 | 44 | 48 | 44 | 37 |

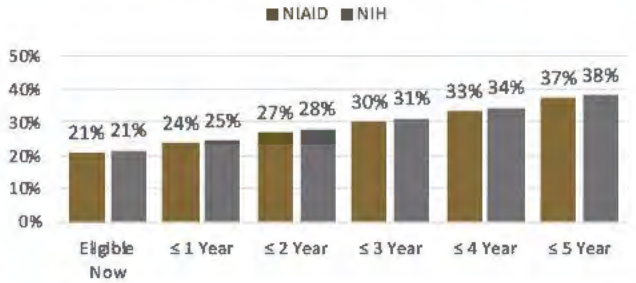
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIAID = 5.25 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC=CC; SES=ES, EX, SL, RS; T42=RF, RG, AD; EI=EI; General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

**Budget Summary**
(Dollars in Millions)

| NIAMS | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 542.141 | 624.889 |
| Less (specify sources) | | |
| Total Budget Authority | 542.141 | 624.889 |
| FTE | 227 | 238 |

(b) (5)

## NIAMS MISSION

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), established in 1986, is the primary Federal agency responsible for supporting biomedical research on diseases of the bones, joints, muscles, and skin. Arthritis and musculoskeletal and skin conditions affect people of all ages and of all racial and ethnic backgrounds. Combined, they afflict tens of millions of Americans, cause tremendous human suffering and cost the U.S. economy billions of dollars in health care costs and lost productivity. For instance, the 2017 Global Burden of Disease survey found that low back pain was the leading cause of disability in the United States, as measured in years lived with disability. The CDC estimate that 59 million adults in the United States have arthritis. As the U.S. population ages, the prevalence of arthritis and its associated costs are expected to grow.

To help address the health needs of the American public, NIAMS conducts and supports a broad portfolio of biomedical and behavioral research activities into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases. The data, resources, and scientific insights generated from many of these investments benefit the research community for years. For instance, over a decade ago, NIAMS, in partnership with the NIA, led the development of the Osteoarthritis Initiative (OAI), a nationwide, multicenter observational study to follow people who either have or are at risk for developing knee osteoarthritis (OA). Over the ensuing years, several NIH ICs (NIAMS, NIA, NCCIH, NIMHD, NIDCR, ORWH, NCCIH, NIBIB) and private sector participants have contributed funding for the OAI. To date, more than 680 peer-reviewed papers have been published by both OAI and non-OAI researchers using OAI data and, in 2020, the FDA accepted three Letters of Intent related to the qualification of biomarkers to advance drug development tools for OA.

Another investment, spearheaded by the NIAMS and NHLBI Intramural Research Programs (IRPs) in collaboration with pharmaceutical partners, led to the development of the drug tofacitinib, an inhibitor of the janus kinase (JAK) signaling molecule, for treatment of rheumatoid arthritis (RA). Since the advent of tofacitinib, additional research has grown out of the NIAMS supported discoveries related to JAK signaling. Scientists have developed several other JAK inhibitors that now are being evaluated for treatment of additional autoimmune conditions such as alopecia areata and lupus.

Another NIAMS-supported program that is providing significant resources for the research community is the Accelerating Medicines Partnership in rheumatoid arthritis and systemic lupus erythematosus (AMP RA/SLE). NIH (NIAMS and NIAID), industry, and non-profit sponsors are contributing funding and scientific expertise to this program. The AMP RA/SLE program is identifying new cell populations and

pathways involved in the pathogenesis of the diseases and making its data available to the broader research community.

NIAMS works with other NIH Institutes and Centers and Federal agencies in shared areas of interest, for example through leadership of the Muscular Dystrophy Coordinating Committee (MDCC), the Lupus Federal Working Group (LFWG), and the Federal Working Group on Bone Diseases.

NIAMS also plays a leading role in several large multi-Institute and Center initiatives, including the:

- **AMP in Autoimmune and Immune-mediated Diseases (AMP AIM)** – Over the last six years, the AMP RA/SLE program brought together public and private communities to make unprecedented progress in understanding the molecular and cellular mechanisms that cause RA and lupus. NIH is now planning for a potential next phase of this work, called AMP AIM, that would extend mapping of pathogenic cells and pathways to other diseases such as Sjogren's syndrome, psoriasis, and psoriatic arthritis. AMP AIM also would employ novel high dimensional analytics to discover how immune cells and tissue resident cells work together to cause inflammation, injury, abnormal function, and clinical disease. Integration of various types of data from clinical information to cutting-edge laboratory analyses would accelerate the discovery of new mechanisms of disease and new targets for therapeutic development.
- **Back Pain Consortium Research Program (BACPAC)** – Chronic low back pain is one of the most common forms of chronic pain among adults worldwide. However, treatment options are ineffective, leading to an increased use of opioids to manage back pain. The NIAMS-led BACPAC is a translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain. It is examining biomedical mechanisms within a biopsychosocial context using interdisciplinary methods and innovative technologies. BACPAC will develop an integrated model of chronic low back pain by using deep phenotyping to better characterize patients; identifying novel pathways and targets for intervention; combining data from translational research and Phase 2 clinical trials to deliver an integrated model of back pain; and collaborating with the Early Phase Pain Investigation Clinical Network on clinical trials of novel interventions. Ultimately, the program is expected to improve clinical management of chronic low back pain.
- **Osteoporosis/Pathways to Prevention** – Rigorous clinical studies have demonstrated that three to five years of osteoporosis medication therapy prevents fractures. Clinical guidelines recommend bisphosphonates as a first line of treatment for most people who have osteoporosis, but treatment rates are low and medication adherence is poor. Reports of rare but serious adverse events and greater public concern about them have coincided with a marked decrease in the use of osteoporosis drugs and a leveling off in what had been a promising decline in the incidence of osteoporotic fractures. In 2018, NIAMS, NIA, and the NIH Office of Disease Prevention hosted a Pathways to Prevention Workshop on the Appropriate Use of Drug Therapies for Osteoporotic Fracture Prevention to identify research gaps and focus areas that could move the field forward. As part of the next steps, NIAMS and the NIA will work with other interested Federal partners to explore near- and long-term opportunities to foster research related to the appropriate use of drug therapies to prevent osteoporosis fractures.

## NIAMS BUDGET

As shown in the Budget Authority by Activity table, the FY 2020 enacted budget for NIAMS was $624.9 million for discretionary spending. This represents a 3.6 percent increase over FY 2019. The budget can be divided into three major categories, extramural research, intramural research, and research management and support. In FY 2020, 84.0 percent of the NIAMS budget supported extramural

research in the areas of Systemic Rheumatic and Autoimmune Diseases, Skin Biology and Diseases, Muscle Biology and Diseases, Joint Biology and Diseases and Orthopedics, and Bone and Biology Diseases. Intramural Research was 10.4 percent of the NIAMS budget in FY 2020. The remaining category, Research Management and Support represented 5.6 percent of the FY 2020 budget. In addition to the FY 2020 operating plan, the table also presents the NIAMS budget authority for FY 2016 – FY 2019. The distribution of funds across the categories has been very stable over the years.

In keeping with NIH policy, NIAMS began offering a more generous payline—the cutoff point for funding a grant application--for R01 awards for new investigators in FY 2007 and changed that policy in 2018 to include only those researchers who met the more stringent Early-stage Investigator criteria. The NIAMS payline for all other R01 applicants remained constant at the 13th percentile in FYs 2016, 2017, and 2018. The payline for the past two years has dipped despite an increase in the NIAMS appropriation because the Institute had a greater increase in funds obligated for non-competing grants, leaving less funds to support competing applications. While NIAMS has a long-standing commitment to funding as many investigator-initiated R01 applications as possible, this budgetary trend threatens the Institute's ability to support a critical base of investigators and results in highly meritorious research remaining unfunded. The need to maintain even the reduced payline for investigator-initiated research abrogates, or sharply curtails, the ability to support planned initiatives such as AMP AIM and research to respond to the Pathways to Prevention recommendations regarding prevention of osteoporotic fractures.

**Budget Authority by Activity**
(Dollars in Millions)

| NIAMS | FY2016 Actual | FY2017 Actual | FY2018 Actual | FY2019 Actual | FY2020 Operating Plan |
|---|---|---|---|---|---|
| Extramural Research | | | | | |
| Systemic Rheumatic and Autoimmune Diseases | 100.593 | 110.028 | 102.200 | 103.183 | 106.878 |
| Skin Biology and Diseases | 76.273 | 79.228 | 98.019 | 98.955 | 102.498 |
| Muscle Biology and Diseases | 67.814 | 71.737 | 71.885 | 75.128 | 77.818 |
| Joint Biology and Diseases and Orthopedics | 149.523 | 144.955 | 133.523 | 147.050 | 152.316 |
| Bone and Biology Diseases | 60.368 | 61.669 | 86.571 | 82.707 | 85.668 |
| Subtotal, Extramural | 454.571 | 467.617 | 492.198 | 507.023 | 525.178 |
| Intramural Research | 56.269 | 57.999 | 60.755 | 62.580 | 64.997 |
| Research Management & Support | 30.072 | 30.990 | 32.330 | 33.315 | 34.714 |
| Total | 540.912 | 556.606 | 585.283 | 602.918 | 624.889 |

## NIAMS PRIORITY ISSUES

None identified

## NIAMS SIGNIFICANT CHANGES

In 2020, Dr. Lindsay A. Criswell, Vice Chancellor of Research at the University of California, San Francisco, was named as the next Director of NIAMS. She is expected to begin serving in this role in February 2021. Dr. Criswell is preceded by the long-time former NIAMS Director, Dr. Stephen I. Katz,

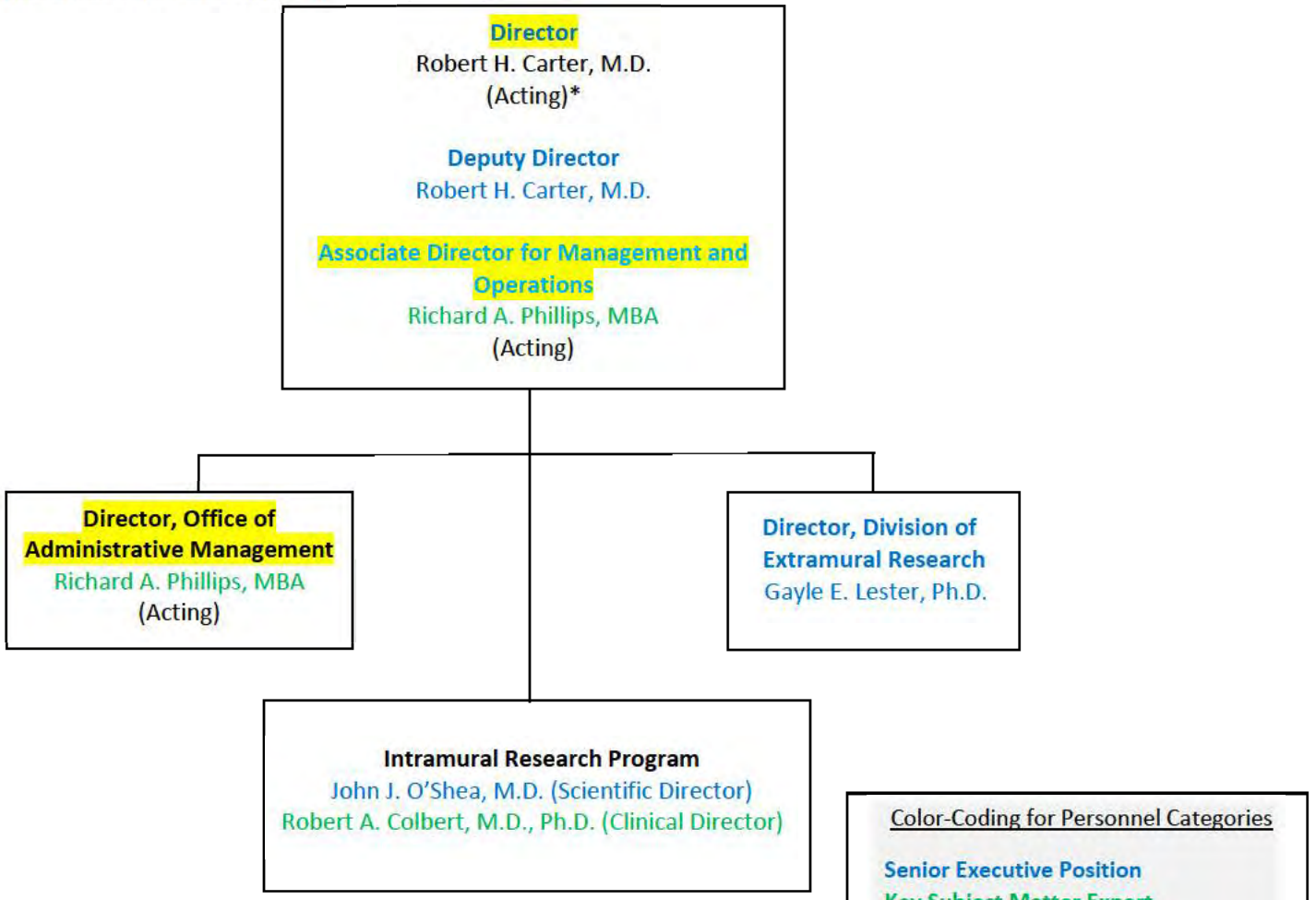
who passed away in 2018, and Dr. Robert H. Carter, the NIAMS Deputy Director who has served as the NIAMS Acting Director since that time.

The Institute is currently searching for an Associate Director for Management and Operations. Richard A. Philips, the Institute's Deputy Executive Officer, is serving as the Acting Associate Director following the death of its long-serving Executive Officer in 2019.

In 2018, NIAMS restructured its Extramural Research Program. Whereas the NIAMS extramural program previously consisted of two scientific divisions comprised of 17 research programs, the Institute reorganized these programs into five topical scientific teams under a single Division of Extramural Research (DER). The DER also manages a special programs team to oversee small business awards and training programs and includes an Office of Extramural Operations that coordinates essential Institute activities such as clinical trials oversight, grants management, and the scientific review of grant applications.

In 2017, working with colleagues at NCI, NIAMS transferred the Dermatology Branch from the NCI to the NIAMS Intramural Research Program. This move provides a great opportunity for synergy across the scientific programs within NIAMS, as well as between NIAMS labs and many others at the NIH. NIAMS continues to work through budgetary issues related to this transfer.

## NIAMS ORGANIZATIONAL CHART AND WORKFORCE




*Lindsey A. Criswell, M.D., M.P.H, D.Sc. has been selected as the next NIAMS Director and will start in January 2021

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**

Office of the Director

- Director*, Robert H. Carter, M.D. (Senior Executive Position; Acting)
- Deputy Director, Robert H. Carter, M.D. (Senior Executive Position)
- Associate Director for Management and Operations, Richard A. Phillips (Senior Executive Position; Acting)

The following offices report directly to the Director:

- Director, Office of Administrative Management
  - Richard A. Phillips, M.B.A. (Key Subject Matter Expert; Acting)
- Scientific Director, Intramural Research Program (Senior Executive Position)
  - John J. O'Shea, M.D.
- Clinical Director, Intramural Research Program
  - Robert A. Colbert, M.D., Ph.D. (Key Subject Matter Expert)
- Director, Division of Extramural Research (Senior Executive Position)
  - Gayle E. Lester, Ph.D.

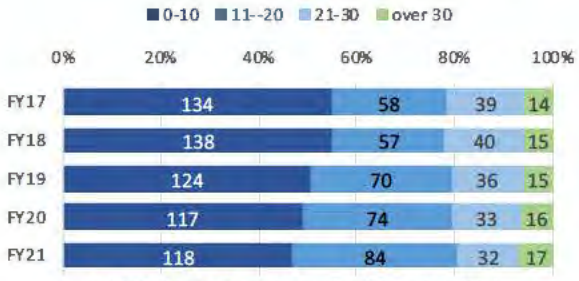
*Lindsey A. Criswell, M.D., M.P.H, D.Sc. has been selected as the next NIAMS Director and will start in January 2021

National Institute of Arthritis and Musculoskeletal and Skin Diseases

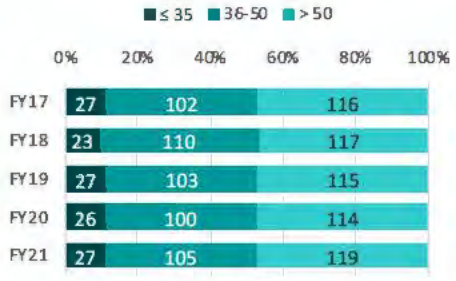
# NIAMS WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

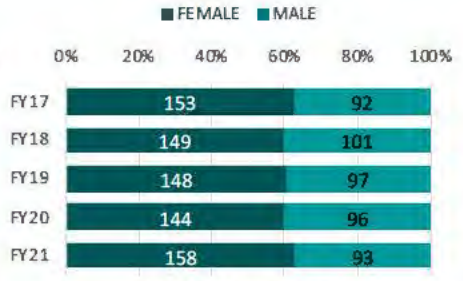

## Federal Length of Service (Yr.) Trending




## Age Trending

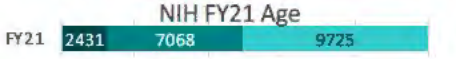



## Gender Trending



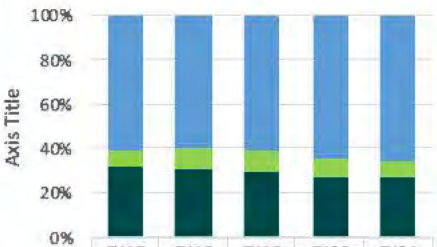

## NIH FY21 Federal Length of Service (Yr.)


## NIH FY21 Age



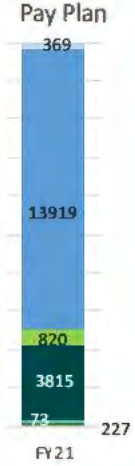

## NIH FY21 Gender


## Pay Plan Trending[2]

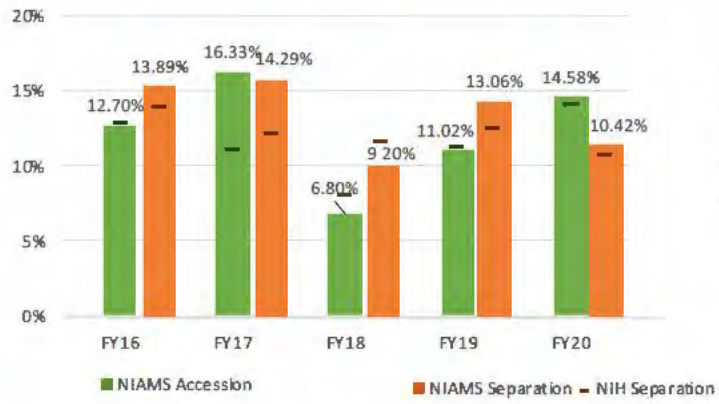



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 148 | 148 | 150 | 155 | 165 |
| EI | 18 | 24 | 22 | 20 | 17 |
| T42 | 78 | 76 | 70 | 63 | 66 |
| SES | 1 | 1 | 1 | 0 | 0 |
| CC | 0 | 1 | 2 | 2 | 3 |

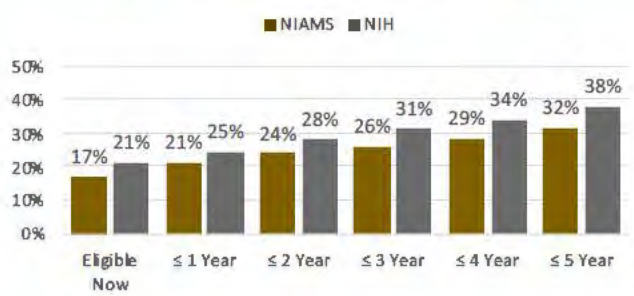
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIAMS = 5.67 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

**Budget Summary**
(Dollars in Mil

(b) (5)

| NIBIB | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 343.506 | 404.638 |
| Less (specify sources) | | |
| Total Budget Authority | 343.506 | 404.638 |
| FTE | 97 | 102 |

## NIBIB MISSION

The National Institute of Biomedical Imaging and Bioengineering's mission is to transform through engineering the understanding of disease and its prevention, detection, diagnosis, and treatment. Established in 2000, NIBIB is the only engineering institute at NIH and serves as the NIH hub to support research on technologies, across diseases and disorders, that are essential to extending the health span, personalizing diagnosis and treatment, and significantly improving quality of life. NIBIB brings the engineering and physical sciences fields together with biology and medicine to encourage multidisciplinary approaches to benefit patients and healthcare professionals and promote new biomedical discovery.

The scientific research areas supported by NIBIB cover a range of programs that lead to new, faster, and less costly ways to advance technologies from the blackboard to benchtop to bedside. One program exemplifies NIBIB's focus on developing technologies and information sharing tools that are inexpensive, easy-to-use, portable, and provide timely health status information about patients at the point of care. The Point of Care Technology Research Network, established more than a decade ago, was expanded in 2019 to five centers around the country that accelerate the development of new technologies for areas of high clinical need, including infectious diseases and cardiovascular diseases. These centers support the development of and facilitate the commercialization of new technologies that can transform healthcare, particularly in low-resource settings.

NIBIB's Concept to Clinic: Commercialization Innovation (C3i) program supports promising technologies and helps bridge the gap between the scientific innovation that occurs in a lab and achieving viability on the commercial market. NIBIB's program de-risks products to decrease the time to market and creates a robust pipeline of high-quality projects for NIBIB's Small Business Innovation Research and Small Business Technology Transfer programs.

Building on these two programs, NIBIB launched the highly successful Rapid Acceleration of Diagnostics RADx℠ Fast-Track Program for COVID-19 Test Development and Distribution (RADx℠ Tech). As part of NIH's response to addressing the COVID-19 pandemic, this targeted program accelerates the development, translation, and commercialization of diagnostic technologies to detect SARS-CoV-2 and is significantly increasing the testing capacity throughout the United States (See NIBIB Innovation Funnel Issue Paper).

Another key program area supported by NIBIB is sensing and imaging health and disease. This area supports innovative biomedical imaging technologies to apply new understanding of biological and disease processes for improving diagnostics. Sensor technologies provide the technical window to continuously monitor human biology and pathology. For example, NIBIB is developing sensors that can be three-dimensional (3D)-printed onto moving organs such as the lung to monitor function and performance during and after surgery.

NIBIB supports continual advances in large scale imaging technologies such as magnetic resonance imaging (MRI), positron emission tomography (PET), and computation tomography (CT), leading to smaller machines that are more widely accessible, and improved quality of imaging for faster scan times and greater comfort for patients. AI and computational approaches along with innovations in imaging agents are increasingly improving image quality and reducing radiation doses.

## NIBIB BUDGET

NIBIB's operating budget was $404.64 million in FY 2020, a 4 percent increase over the FY 2019 budget. With this increased budget NIBIB was able to fund over $90 million in competing Research Project Grants, spanning all core NIBIB mission research areas.

**Budget Authority by Activity**
(Dollars in Millions)

| NIAMS Activity | FY2016 Actual | FY2017 Actual | FY2018 Actual | FY2019 Actual | FY2020 Operating Plan |
|---|---|---|---|---|---|
| Extramural Research | | | | | |
| Applied Science and Technology | 148.915 | 162.271 | 109.465 | 112.9.5 | 116.716 |
| Discovery Science and Technology | 105.354 | 104.409 | 168.224 | 173.525 | 179.367 |
| Interdisciplinary Training | | | 22.458 | 23.166 | 23.946 |
| Health Informatics Technology | 30.506 | 31.160 | 36.535 | 37.686 | 38.954 |
| Technological Competitiveness – Bridging Sciences | 20.817 | 21.171 | | | |
| Subtotal, Extramural | 305.592 | 319.011 | 336.682 | 347.292 | 358.983 |
| Intramural Research | 15.280 | 15.089 | 15.985 | 16.769 | 19.590 |
| Research Management and Support | 22.154 | 22.881 | 24.064 | 24.053 | 26.065 |
| Total | 343.026 | 356.981 | 376.731 | 388.114 | 404.638 |

Source: NIH Budget Database – Budget Authority by Activity

## NIBIB PRIORITY ISSUES

Innovation Funnel for Technology Development: NIBIB received $500 million from the H.R. 266 Paycheck Protection Program and Health Care Enhancement Act. With these funds, NIBIB quickly stood up the RADx℠ Tech program, a phased Innovation Funnel approach that has rapidly developed and deployed diagnostic tests to help contain the COVID-19 global pandemic. This innovative funding structure has succeeded in accelerating the typical five to six-year technology development and commercialization path to under six months. RADx℠ Tech has been able to translate innovative ideas into novel diagnostics for COVID-19 with unprecedented efficiency. This framework is ideally suited for the entrepreneurial

innovation community that NIBIB supports. NIBIB is proposing to expand this model to harness NIH-supported innovation across the biomedical spectrum so that discoveries can more quickly reach the market to benefit the public. The Innovation Funnel is poised to quickly translate a broad range of NIH discoveries into solutions that can be deployed to meet urgent clinical needs.

## NIBIB SIGNIFICANT CHANGES

In January 2019, Dr. Bruce J. Tromberg was sworn in as the second Director of NIBIB. As a result of emergency COVID-19 supplemental funding to NIBIB, Dr. Tromberg managed a budget more than double its base (from $404 million to $964 million) a little over a year after he arrived. Dr. Tromberg made excellent use of this funding, quickly setting up successful programs that demonstrated the engineering community's potential to deliver solutions to critical health care needs.

In addition, three new intramural research labs were established:

- **Immunoengineering** – develops immune-active biomaterials for regenerative medicine and seeks to understand how the immune system interacts with biomaterials. In rapid response to COVID-19, this lab pivoted to a lead a large-scale national serology study.
- **Mechanobiology** – develops and utilizes advanced Atomic Force Microscopy technologies for cellular and tissue mechanics studies.
- **Quantitative Medical Imaging** – develops methods to derive biomarkers from data acquired by non-invasive imaging techniques.

## NIBIB ORGANIZATIONAL CHART AND WORKFORCE


Color-Coding for Personnel Categories

- Senior Executive Position
- Key Subject Matter Expert
- Schedule C Position
- Vacant Position
- Individual in Position(acting)

**National Institute of Biomedical Imaging and Bioengineering**

Office of the Director

- Director, Bruce J. Tromberg, Ph.D. (Senior Executive Position)
- Deputy Director, Jill Heemskerk, Ph.D. (Senior Executive Position)
- Director, Research Sciences and Strategic Directions, Krishna Kandarpa, M.D., Ph.D. (Senior Executive Position)

The Following Offices Report Directly to the Director:

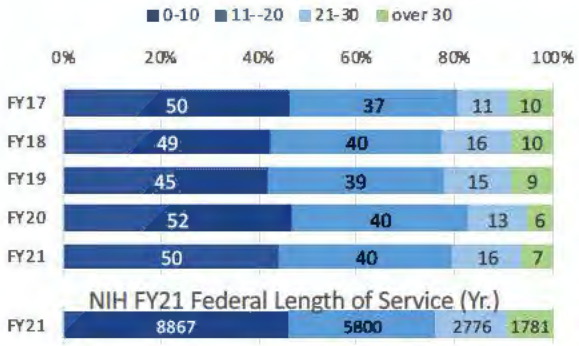
- Executive Officer, Office of Administrative Management
    - Jason Ford, M.S.
- Associate Director, Office of Research Administration
    - Director David George, Ph.D.
- Associate Director, Extramural Sciences Program
    - Vacant
- Intramural Research Program
    - Scientific Director, Richard Leapman, Ph.D. (Senior Executive Position)

National Institute of Biomedical Imaging and Bioengineering

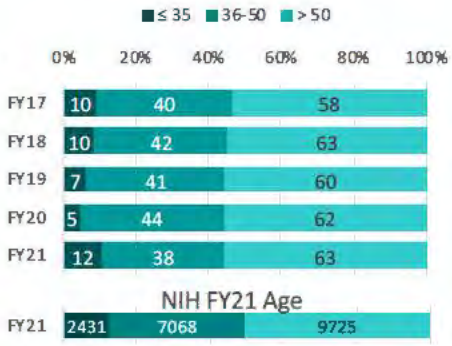
# NIBIB WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

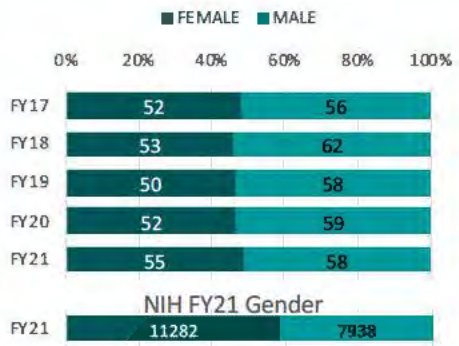

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



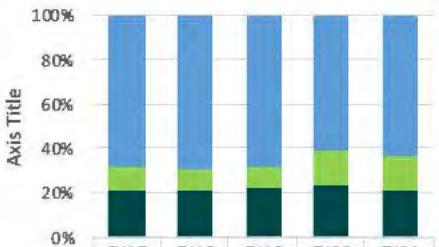

## NIH FY21 Age




## NIH FY21 Gender




## Pay Plan Trending[2]

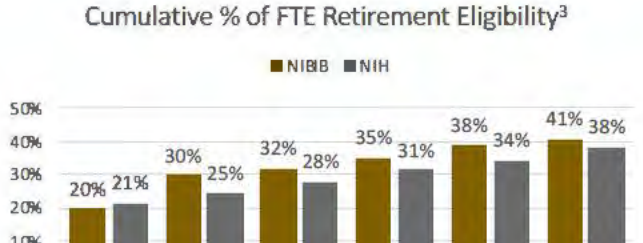



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 74 | 79 | 73 | 68 | 72 |
| EI | 11 | 11 | 11 | 17 | 17 |
| T42 | 23 | 25 | 24 | 26 | 24 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 0 | 0 | 0 | 0 | 0 |

## NIH FY21 Pay Plan


## Accession & Separation Trending


## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIBIB = 5.44 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# *EUNICE KENNEDY SHRIVER* NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

**Budget Summary**
(Dollars in M

| NICHD | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 1,339.802 | 1,556.909 |
| Less (specify sources) | | |
| Total Budget Authority | 1,339.802 | 1,556.909 |
| FTE | 546 | 561 |

(b) (5)

[redacted]

## NICHD MISSION

The National *Eunice Kennedy* Shriver National Institute of Child Health and Human Development's (NICHD) mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. NICHD was founded in 1962 to investigate human development throughout the entire life process, with a focus on understanding disabilities and important events that occur during pregnancy.

- **Healthy Pregnancies** – Over six million women are pregnant in the United States each year. NICHD leads maternal health research at NIH, including pregnancy complications that contribute to the relatively high U.S. rates of MMM. For example, NICHD supports intramural and extramural studies on how to prevent preeclampsia, a blood pressure disorder in pregnant women that can have serious effects on both mother and fetus. (See NICHD Issue Paper "Preterm Birth and the Health of the Newborn for more information.")
- **Healthy Children** – Children comprise over 22 percent of the population in the United States, with over 73 million children between the ages of 0 and 17. NICHD supports and conducts research on healthy development as well as a wide range of diseases and conditions affecting neonates, infants, children, and adolescents.
- **Healthy and Optimal Lives** – Disability affects 26 percent of adults and nearly 18 percent of children in the United States. NICHD supports research on risk factors, physiological mechanisms, and interventions for individuals with intellectual and developmental disabilities. NICHD is also the home of the National Center for Medical Rehabilitation Research (NCMRR), which coordinates rehabilitation research across NIH.

NICHD's expertise and research infrastructure helped to ensure that vulnerable populations like children, pregnant women, and people with disabilities are not left behind in the rapid response to public health emergencies. For example, as the SARS-CoV-2 virus that causes COVID-19 swept across the globe, NICHD quickly used established research networks to launch studies related to COVID-19 in children, pregnant women, and people with disabilities. In the Gestational Research Assessments for coVID (GRAVID) study, NICHD's Maternal-Fetal Medicine Units are analyzing the medical records of up to 24,500 women to assess pregnancy outcomes resulting from COVID-19. For some children, the SARS-CoV-2 virus leads to Multisystem Inflammatory Syndrome in Children (MIS-C), a severe and sometimes fatal inflammation of organs and tissues. Another NICHD-led project, called Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL kIds), aims to help scientists understand the range of symptoms that may occur in children infected with the SARS-CoV-2 virus and identify factors that may lead to MIS-C. NICHD is also supporting a new study

to maximize SARS-CoV-2 testing for children with intellectual and developmental disabilities (IDD) and school staff.

## NICHD BUDGET

**NICHD Budget by Activity**
(Dollars in Millions)

| NICHD Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Budget |
|---|---|---|---|---|---|
| Reproductive Health, Pregnancy, and Perinatology | 294.576 | 307.668 | 347.165 | 370.513 | 385.239 |
| Pediatric Health | 316.778 | 322.451 | 353.014 | 369.201 | 383.836 |
| Intellectual and Developmental Disabilities | 118.669 | 127.797 | 130.486 | 134.722 | 140.063 |
| Demography and Behavior | 272.719 | 274.779 | 276.135 | 258.236 | 268.472 |
| National Center for Medical Rehabilitation Research | 73.975 | 76.463 | 79.226 | 86.531 | 89.928 |
| Intramural Research | 190.922 | 195.275 | 198.831 | 207.756 | 212.914 |
| Research Management & Support | 70.709 | 72.175 | 72.369 | 74.292 | 76.427 |
| Total | 1,338.348 | 1,376.608 | 1,457.226 | 1,501.251 | 1,556.879 |

## NICHD PRIORITY ISSUES

**Obstetric and Pediatric Pharmacology**: Nearly two-thirds of medicines on the market are not approved for use in children, although physicians frequently prescribe these drugs "off label". Because of physiological differences between children and adults, using an adult medicine in a child can be ineffective or dangerous. The Best Pharmaceuticals for Children Act (BPCA) was passed in 2002, and reauthorized in 2007, 2012, and 2017, to encourage both government and industry to conduct research on safe and effective pharmaceutical treatments for children. Studies supported by the BPCA and NICHD infrastructure have enrolled over 7,000 children in clinical trials, studying over 70 drugs. This research has resulted in changes to FDA-approved labels to include more complete dosing, safety, and efficacy information for children in commonly used medications, including antidepressants, antivirals, and antibiotics. A new addition to NICHD's infrastructure--NICHD's *Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub* program—will provide pharmacology expertise and technology platforms to scientists conducting pharmacology research in pregnant women, lactating women, and children (NICHD MPRINT).

Historically there have been highly publicized cases of prescription drug use by pregnant women that ended with tragic results. As a result, although about 9 in 10 women take at least one medicine during pregnancy, pregnant women are often excluded from clinical research and there is very little scientific evidence available to guide treatment decisions during pregnancy and lactation. The Congressionally-mandated Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) brought together clinical, research, advocacy, regulatory, and pharmaceutical industry leaders to address the

large gap in research on safety, efficacy, and dosing of medications used by pregnant and lactating women. The Task Force generated 15 recommendations and multiple, concrete steps to guide public- and private-sector efforts to implement them. Major areas for action include developing a systematic plan to collect data on therapeutics' safety, pharmacokinetics, pharmacodynamics, and pharmacogenomics during pregnancy and lactation and establishing a prioritization process (similar to that of BPCA) for studies. Task Force recommendations also address ethical considerations and industry concerns about liability and encourage participation in obstetric therapeutics research.

**Reproductive Health**: Gynecologic conditions and diseases affect millions of women of all ages in the United States and around the world. Uterine fibroids, pelvic floor disorders, endometriosis, vulvodynia, and polycystic ovarian syndrome lead to pain and infertility for millions of American women. NICHD supports extramural and intramural research in gynecologic conditions, male and female infertility, contraception, and male reproductive disorders (andrology). NICHD's research encompasses basic and translational research studies of reproductive health at both the individual and the population levels. For example, NICHD collaborates with the CDC to support the National Survey of Family Growth, the major source of nationally representative data on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men's and women's reproductive health.

**Rehabilitation Research**: Established in 1990, NICHD's National Center for Medical Rehabilitation Research has supported research in rehabilitation across the lifespan. For example, NCMRR-supported researchers developed and tested the efficacy of constraint-induced movement therapy for individuals with cerebral palsy or stroke; in the past, individuals could not move an affected limb, but, by partially constraining their stronger limb now encourages these individuals to use and strengthen their affected limb, recovering more function. NCMRR coordinates across government to initiate and expand rehabilitation research. With the DoD, NCMRR established the NIH-DoD Limb Loss and Preservation Registry, to gather data on preservation efforts, surgery, rehabilitation, devices, and functional outcomes for individuals with limb loss and limb difference.

## NICHD SIGNIFICANT CHANGES

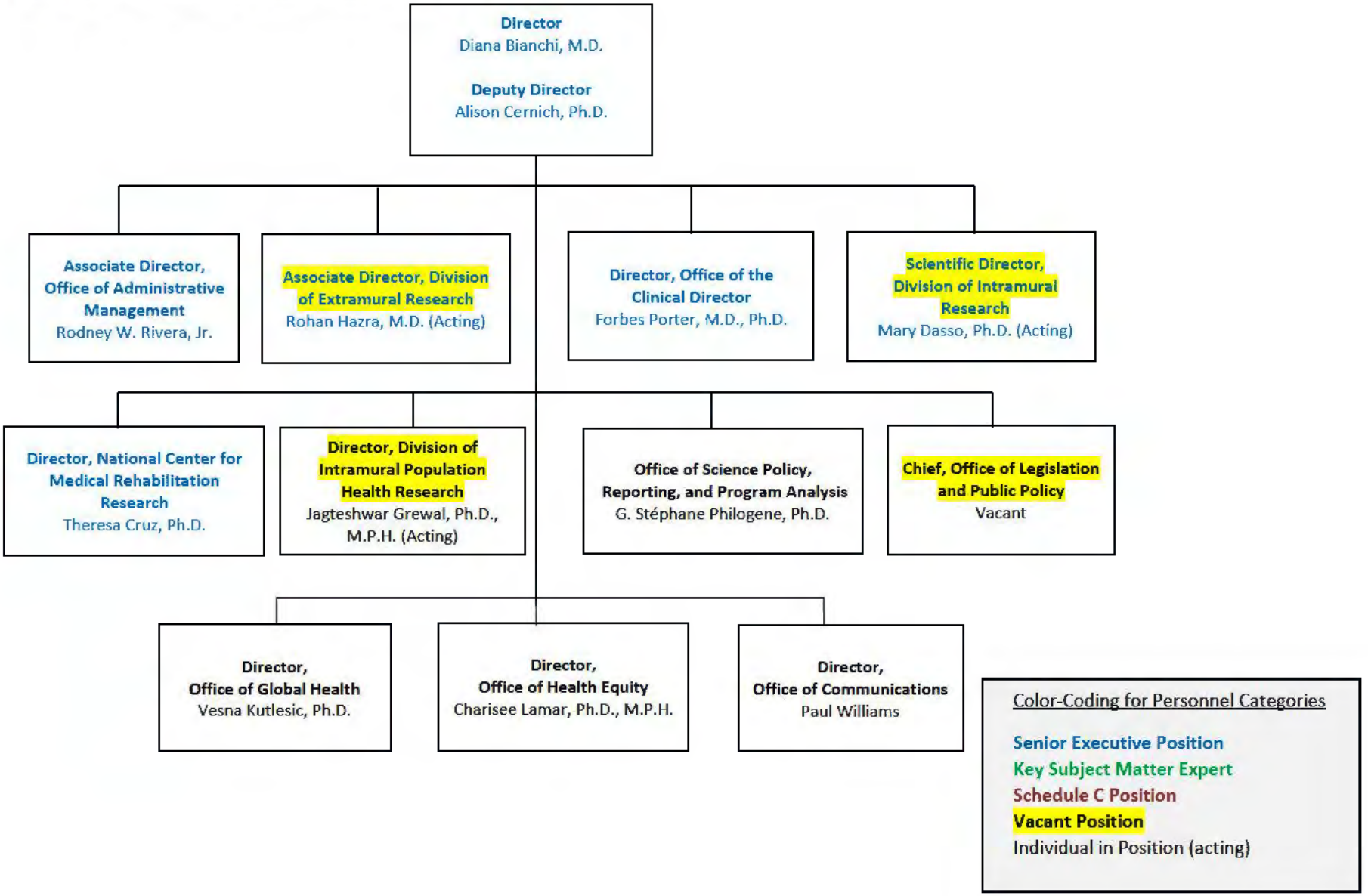
Up to 59 percent of the U.S. population consists of people who typically are not included in research studies, including pregnant women, lactating women, children, older individuals, and individuals with intellectual and physical disabilities. NIH has longstanding policies to ensure inclusion of women, minority groups, and children in research studies. Recent revisions to these inclusion policies have been aimed at increasing the enrollment of those historically underrepresented in research and improving the reporting of those participating in clinical research, including older populations, children, pregnant and lactating women, and individuals with intellectual and physical disabilities.

With the highly transmissible and potentially fatal spread of COVID-19, NICHD, alongside many government agencies, has undergone a dramatic shift in workplace operations. Generally, staff who are telework ready must telework full time. NICHD has planned and hosted many scientific workshops to bring together innovators in various scientific fields. Now, scientific meetings must all be virtual; however, this format has had a silver lining. Going virtual has made it possible for more people to participate in scientific meetings, extending our reach to different audiences. For example, NICHD sponsored a "COVID-19 in Pregnancy: Clinical, Research, and Therapeutics Updates Virtual Workshop" in September of 2020 that attracted over 1300 registrants.

The explosion of large and multidisciplinary data, from individual genetics to multisite survey information, has made it necessary to develop and apply new analytic techniques, especially in the field

of data science, artificial intelligence, and machine learning. For example, NICHD researchers have developed better methods that reduced the time in diagnosing rare genetic diseases in infants admitted to intensive care units, diagnosing jaundice using a smartphone app, and diagnosing sepsis, the body's extreme response to an infection. To promote secondary analyses and sustained utility of research-generated data, NICHD has implemented a repository called the Data and Specimen Hub. This resource currently offers anonymized clinical research data on 173 studies across 44 different topics; nine studies have linked biospecimens. NICHD also leads the Gabriella Miller Kids First Pediatric Research Program (Kids First), a NIH-wide program supported through the NIH Common Fund that aims to foster collaborative research to uncover the causes of childhood cancers and structural birth defects, while supporting data sharing within the pediatric research community. The Kids First Data Resource Portal was launched in 2018.

## NICHD ORGANIZATIONAL CHART AND WORKFORCE



***Eunice Kennedy Shriver*** **National Institute of Child Health and Human Development**

Office of the Director

- Director, Diana Bianchi, M.D. (Senior Executive Position)
- Deputy Director, Alison Cernich, Ph.D. (Senior Executive Position)

The following division/office/center directors report to the NICHD Director:

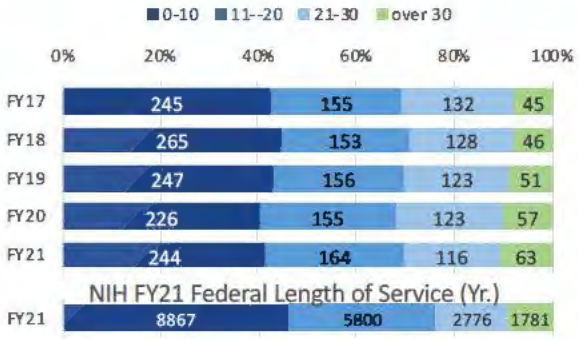
- Associate Director, Office of Administrative Management
    - Rodney W. Rivera, Jr., M.S. (Senior Executive Position)
- Associate Director, Division of Extramural Research
    - Rohan Hazra, M.D. (Acting; Senior Executive Position)
- Director, Office of the Clinical Director
    - Forbes Porter, M.D., Ph.D. (Senior Executive Position)
- Scientific Director, Division of Intramural Research
    - Mary Dasso, Ph.D. (Acting; Senior Executive Position)
- Director, National Center for Medical Rehabilitation Research
    - Theresa Cruz, Ph.D. (Senior Executive Position)
- Director, Division of Intramural Population Health Research
    - Jagteshwar Grewal, Ph.D. (Acting)
- Director, Office of Science Policy, Reporting, and Program Analysis
    - G. Stéphane Philogene, Ph.D.
- Chief, Office of Legislation and Public Policy
    - Vacant
- Director, Office of Global Health
    - Vesna Kutlesic, Ph.D.
- Director, Office of Health Equity
    - Charisee Lamar, Ph.D.
- Director, Office of Communications
    - Paul William

# NICHD WORKFORCE SNAPSHOT[1]

Eunice Kennedy Shriver National Institute of Child Health and Human Development

## Federal Employee Onboard (Headcount) Trending

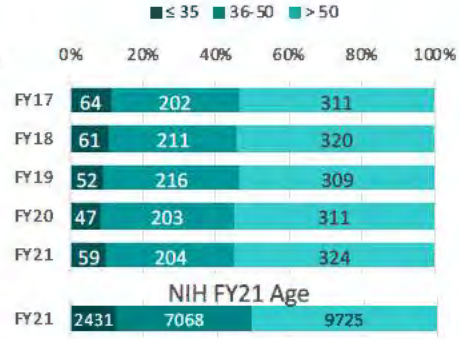

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



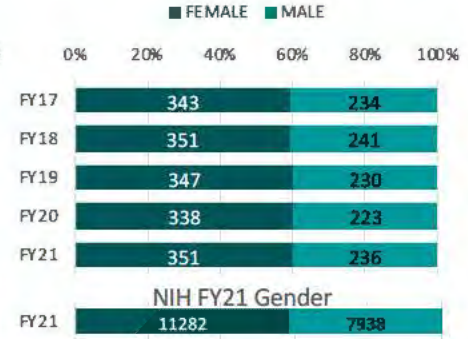

## Age Trending




## NIH FY21 Age



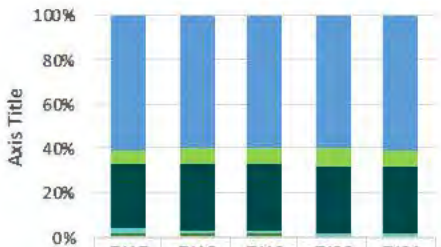

## Gender Trending




## NIH FY21 Gender




## Pay Plan Trending[2]

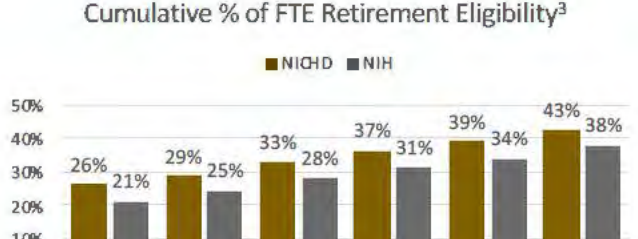



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 354 | 352 | 342 | 336 | 356 |
| EI | 34 | 41 | 42 | 43 | 46 |
| T42 | 165 | 178 | 174 | 168 | 172 |
| SES | 13 | 13 | 11 | 9 | 11 |
| CC | 11 | 8 | 8 | 5 | 2 |

## NIH FY21 Pay Plan


## Accession & Separation Trending


## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NICHD = 8.07 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

**Budget Summary**
(Dollars in [redacted] (b) (5)

| NIDA | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 1,077.488 | 1,457.724 |
| Less (specify sources) | | |
| Total Budget Authority | 1,077.488 | 1,457.724 |
| FTE | 383 | 382 |

## NIDA MISSION

The mission of the National Institute on Drug Abuse (NIDA) is to advance science on the causes and consequences of drug use and addiction and apply that knowledge to improve individual and public health. Since its establishment in 1974, NIDA-supported research has transformed our understanding of substance use and addiction and how to prevent and treat them. With continued Congressional support for the NIH Helping to End Addiction Long-term℠ (HEAL) Initiative, NIDA is poised to accelerate progress against addiction. Major NIDA-led initiatives under HEAL, include:

- The HEALing Communities Study (HCS), a multisite research study testing the implementation of evidence-based interventions in 67 communities across 4 states.
- The Justice Community Opioid Innovation Network (JCOIN), which is testing strategies to expand effective substance use disorder (SUD) treatment and care in partnership with local and state justice systems and community-based treatment providers.
- An expansion of the National Drug Abuse Treatment Clinical Trials Network, which has produced 26 study protocols and 70+ research studies examining treatment delivery, engagement, retention, duration, and support for people with opioid use disorder (OUD).
- Developing new medications for OUD and overdose, an effort that currently supports 63 targeted studies and has led to 8 IND applications.
- Nine studies aimed at developing culturally-tailored interventions for preventing opioid misuse and OUD among vulnerable older adolescents and young adults.
- HEALthy Brain and Child Development Study (HEALthy BCD), which will establish a large cohort of pregnant women to examine brain and cognitive development during early childhood (see below).

NIDA's Office of Translational Initiatives and Program Innovations (OTIPI) takes research discoveries in prevention, detection, and treatment of SUD into candidate health applications for commercialization. OTIPI manages NIDA's Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs, uses novel fit-for-purpose funding authorities such as prizes and open competitions, and establishes teaching programs that equip scientists with the competence to translate advances into tangible solutions. Many of these efforts take the form of innovative new technology applications, from mobile apps that help patients find open beds in addiction treatment facilities or connect to support communities, to sophisticated medical devices.

NIDA supports a robust epidemiological research program that has been instrumental in tracking the shifting landscape of drug use in the United States. The Monitoring the Future study, which surveys teenage drug use, and the Population Assessment of Tobacco and Health (PATH) study, which assesses

patterns of tobacco and nicotine use, have provided timely information on the alarming increase in vaping among adolescents and young adults. Data from these studies have had important policy impacts, informing Juul Labs' 2019 decision to stop selling mint JUUL pods in the United States and the FDA's January 2020 policy prioritizing enforcement against certain flavored cartridge-based vaping products that appeal to kids

## NIDA BUDGET

NIDA's FY 2020 enacted budget was $1.457 billion and included over $266 million for the HEAL initiative. The following table summarizes NIDA's operating budgets from FY 2008-16 by program/division.

**NICHD Budget by Program**
(Dollars in Millions)

| NIDA Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Actual |
|---|---|---|---|---|---|
| Division of Basic Neuroscience and Behavioral Research | 363.553 | 410.901 | 456.078 | 452.177 | |
| Division of Epidemiology, Services and Prevention Research | 320.608 | 303.379 | 311.853 | 323.147 | |
| Division of Therapeutics and Medical Consequences | 169.866 | 162.029 | 157.959 | 133.544 | |
| Center for the Clinical Trials Network | 41.281 | 39.106 | 40.122 | 39.743 | |
| Office of Translational Initiatives and Program Innovations | - | - | - | 37.988 | |
| Opioid Crisis/HEAL | - | - | 250.0 | 257.843 | 266.321 |
| Intramural Research | 90.356 | 90.561 | 93.483 | 96.233 | |
| Research Management and Support | 63.394 | 64.870 | 64.879 | 67.540 | |
| **Total** | **1,049.058** | **1,070.846** | **1,374.374** | **1,408.215** | **266.321** |

## NIDA PRIORITY ISSUES

**Addiction and Overdose Crisis:** More than 67,300 people died from drug overdose in the United States in 2018. While overdose-involved death rates decreased between 2017-2018, provisional CDC data indicate that they rose 4.6 percent in 2019. Deaths involving synthetic opioids, cocaine, and methamphetamine—as well as a combination of these drugs—have continued to increase. The COVID-19 pandemic is exacerbating these trends, with drug use and drug overdoses increasing sharply since the pandemic began. NIDA plays a lead role in the NIH HEAL Initiative (see above) through which it is supporting an extensive portfolio of research to prevent and treat opioid misuse and addiction, and the Institute is prioritizing research to address the growing stimulant use disorder crisis, including research to develop effective pharmacotherapies for stimulant use disorder (See NIH Top Issue "Addiction and Overdose Crisis" and NIDA Issue Paper "Emerging Stimulant Use Crisis").

**Intersection of COVID-19 and Substance Use Disorder (SUD:** COVID-19 presents challenges to people with SUD and in recovery. People with SUD are more susceptible to COVID-19 and its complications.

Social distancing, in addition to increasing stress that can contribute to substance misuse, has challenged access to SUD treatment and recovery supports. The pandemic has had a negative effect on research, including HEAL-funded programs, which were impacted by the closure of research universities, justice settings, and other study sites. NIDA issued a Notice of Special Interest (NOSI) to solicit research on risks and outcomes for COVID-19 in individuals with SUD, through which it is funding nearly 80 research projects, including projects examining the impact of COVID-related policy changes on access to SUD treatment.

**Impact of Socioeconomic Status and Racial Inequity on Substance Use Outcomes:** Substance use disorders arise from many interacting biological and environmental factors, including social determinants of health. These include low socioeconomic status (SES), which is a strong driver of health disparities. Low SES is associated with profound impacts on the cognitive, social, and brain development of children and exacerbates health disparities over the course of life. The impacts of racial inequities also drive health disparities, especially related to drug use and addiction. Difficulties in accessing care based on race/ethnicity persist, and the impacts of drug use continue to disproportionately affect racial/ethnic minority communities.

**Impact of scheduling psychoactive substances on scientific research and medications development:** NIDA continues to be concerned about the challenges of conducting research on substances in Schedule I of the Controlled Substance Act (e.g., cannabis, psilocybin, and certain fentanyl analogues), and the placement of new substances in Schedule I (e.g., kratom, other fentanyl analogues). Obtaining or modifying a schedule I research registration involves significant administrative challenges that can deter scientists from pursuing research on these compounds and hamper our understanding of their adverse and therapeutic potential. NIDA has worked with the HHS, FDA, DEA, and ONDCP to ensure that legislation to add fentanyl analogues to Schedule I would include provisions to facilitate research with these drugs, worked with HHS to ensure that regulatory efforts to schedule kratom would include provisions to facilitate kratom research, and provided technical assistance on bills that would facilitate research with cannabis, including products sold in state dispensaries.

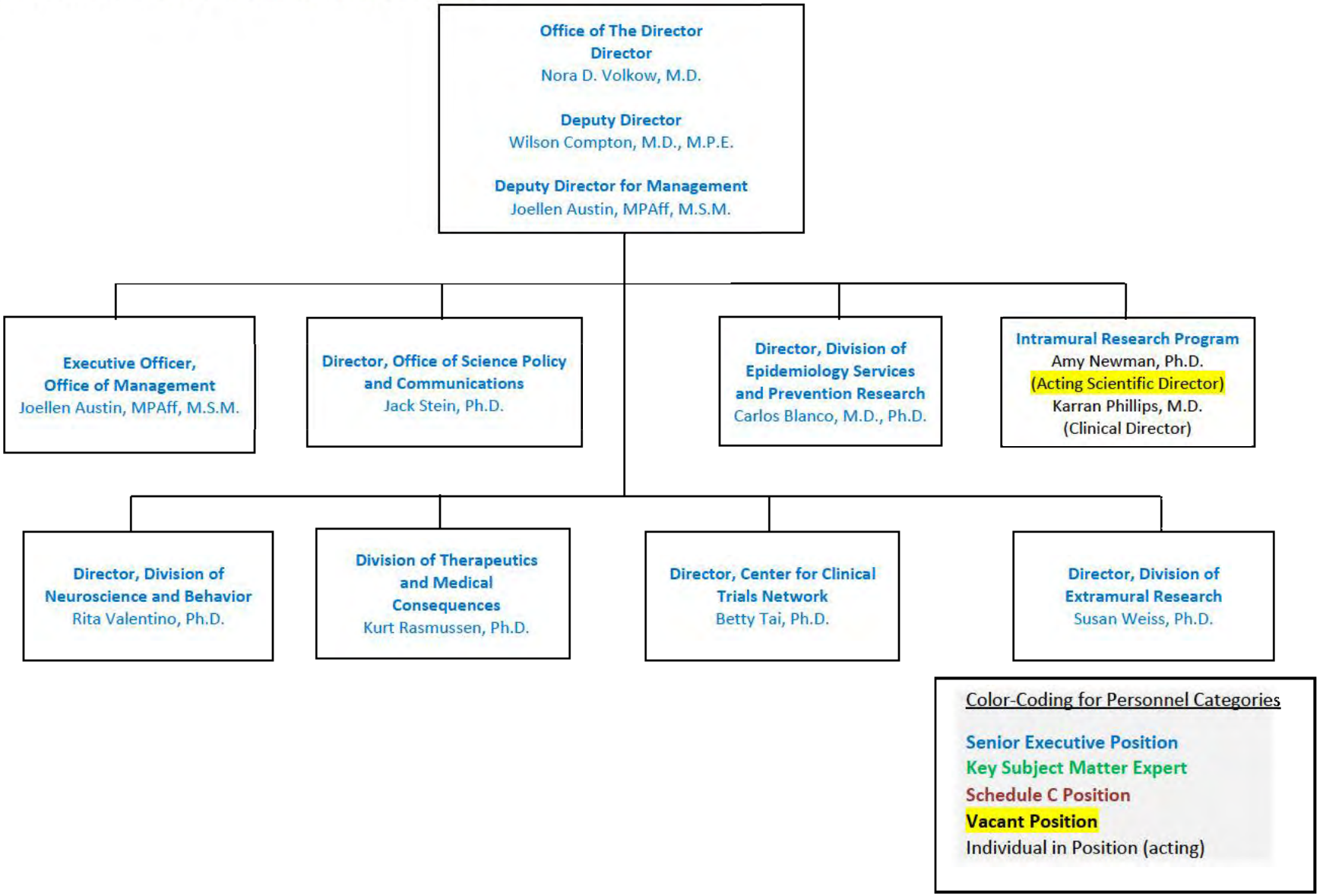
## NIDA SIGNIFICANT CHANGES

- **NIDA Intramural Research Program.** Beginning in 2018, NIDA's Intramural Research Program (IRP) began reinvigorating its clinical program by hiring three new clinical investigators and establishing the NIDA Translational Research Initiative (TRI), which designs and implements clinical research protocols in collaboration with intramural investigators at NIDA, other NIH ICs, and extramural investigators. The TRI supports NIDA's mission to improve individual and public health by translating basic biobehavioral research findings into preventions and tangible treatments for SUD and associated diseases, and also supports the institute's cross-cutting goal of increasing the real-world relevance of research. In 2020, the IRP created the Translational Addiction Medicine Branch (TAMB), which conducts translational research that spans pre-clinical, animal benchwork, to humans in clinical research settings, with the goal to put into practice treatments applicable to diverse patient populations. The TAMB also develops novel addiction treatments and precision medicine approaches, including work on the intersection between addiction, health disparities, and patients with mental health and other medical comorbidities.
- **Adolescent Brain Cognitive Development Study.** NIH renewed its commitment to the Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of child health and development ever conducted in the United States. With $290 million in new funding for 7 years, investigators will be able to collect data for the full 10-year duration of the study.

Following nearly 12,000 children, the study, which is led by NIDA, will help us understand how the experiences of adolescence shape brain, cognitive, and social development. ABCD has already released two sets of anonymized high-quality baseline data to the research community via the National Institute of Mental Health Data Archive. More than 60 research papers have been published using these data, leading to a better understanding of the association between certain traits and experiences (e.g., sleep, body mass index, neighborhood deprivation, screen time) and brain physiology and other outcomes.

- **HEALthy Brain and Child Development Study.** NIDA, along with several other NIH ICOs, has made a significant investment in the HBCD Study. Modeled on the ABCD study, HBCD is expected to enroll women during their second trimester of pregnancy or after birth of their baby and will include mothers whose babies were exposed pre- or perinatally to opioids and other substances, women from comparable high-risk environments who did not use substances during pregnancy, and pregnant women from lower risk environments. HBCD will help researchers understand normal child brain development, as well as the long-term impact of pre- and postnatal exposure to drugs and other environmental and genetic influences on brain development and other health outcomes. Because of the timing of this project, it may also be possible to determine the direct or indirect long-term impact of SARS-CoV2 on neural development. NIH has invested $15 million in Phase 1 of the HBCD study, which was funded to determine feasibility of the project and to identify potential barriers to the successful implementation of this large, complex study. HBCD is expected to launch in the Fall 2021, and its anticipated costs are ~$437 million to follow the participants to age 10.

## NIDA ORGANIZATIONAL CHART AND WORKFORCE



**National Institutes on Drug Abuse**

Office of the Director

- Director, Nora Volkow (Senior Executive Position)
- Deputy, Wilson Compton M.D., M.P.E. (Senior Executive Position)
- Deputy Director for Management, Joellen Austin, MPAff, M.S.M. (Senior Executive Position)

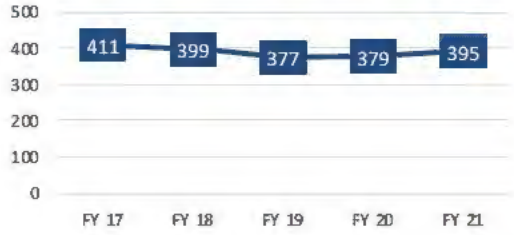
The following offices report directly to the NIDA Director:

- Executive Officer, Office of Management
    - Joellen Austin, MPAff, M.S.M. (Senior Executive Position)
- Director, Office of Science Policy and Communications
    - Jack Stein, Ph.D. (Senior Executive Position)
- Director, Division of Epidemiology Services and Prevention Research
    - Carlos Blanco, M.D., Ph.D. (Senior Executive Position)
- Scientific Director, Intramural Research Program
    - Amy Newman, Ph.D. (Acting; Senior Executive Position)
- Clinical Director, Intramural Research Program
    - Karran Phillips, M.D.
- Director, Division of Neuroscience and Behavior
    - Rita Valentino, Ph.D. (Senior Executive Position)
- Director, Division of Therapeutics and Medical Consequences
    - Kurt Rasmussen, Ph.D. (Senior Executive Position)
- Director, Center for Clinical Trials Network
    - Betty Tai, Ph.D. (Senior Executive Position)
- Director, Division of Extramural Research
    - Susan Weiss, Ph.D. (Senior Executive Position)

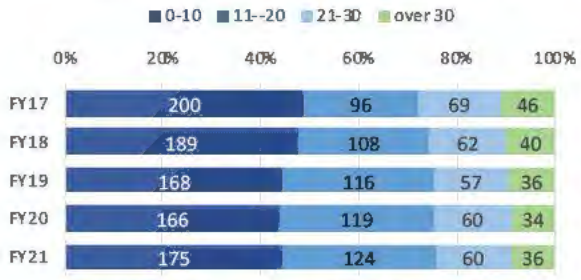
National Institute on Drug Abuse

# NIDA WORKFORCE SNAPSHOT[1]

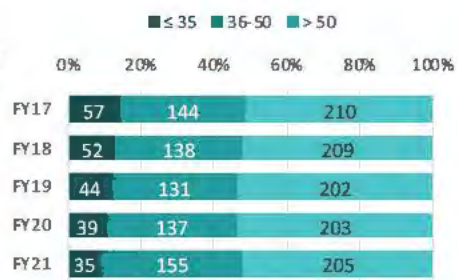
## Federal Employee Onboard (Headcount) Trending



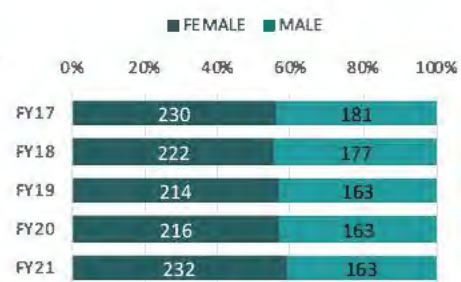

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending

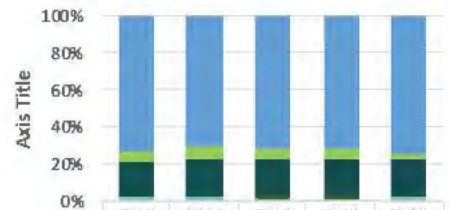



## NIH FY21 Federal Length of Service (Yr.)


## NIH FY21 Age

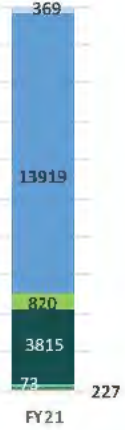

## NIH FY21 Gender


## Pay Plan Trending[2]

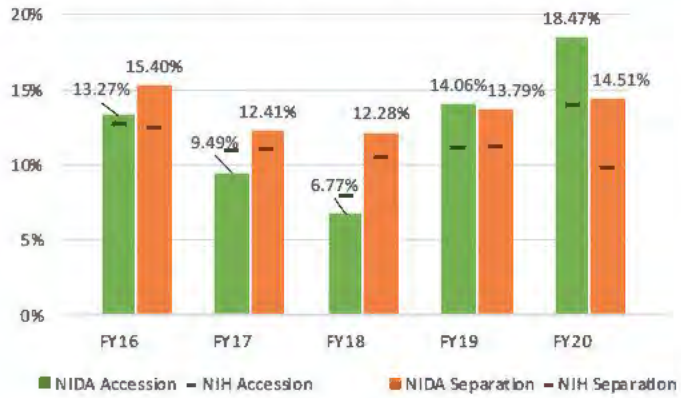



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 299 | 283 | 271 | 273 | 293 |
| EI | 27 | 28 | 23 | 23 | 14 |
| T42 | 78 | 80 | 75 | 75 | 80 |
| SES | 2 | 2 | 2 | 2 | 2 |
| CC | 5 | 6 | 6 | 6 | 6 |

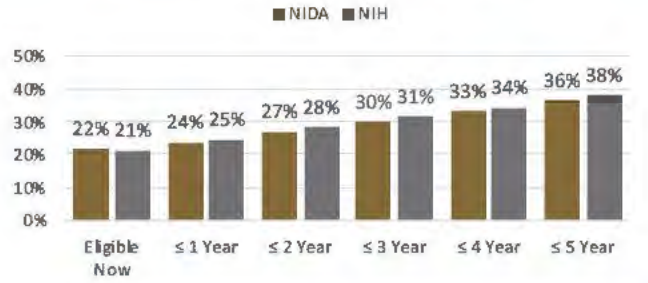
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIDA = 6.63 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

**Budget Summary**
(Dollars in Millions)

| NIDCD | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 422.311 | 490.692 | |
| Less (specify sources) | | | |
| Total Budget Authority | $22.311 | 490.692 | |
| FTE | 137 | 140 | |

## NIDCD MISSION

Approximately one in every six Americans will experience a communication disorder during his or her lifetime. For these individuals, the basic components of communication (sensing, interpreting, and responding) can be extremely challenging. To address these concerns, Congress established the National Institute on Deafness and Other Communication Disorders (NIDCD) in October 1988. Its mission is to support both basic and clinical research focused on understanding the normal processes and disorders of human communication. The NIDCD manages a broad portfolio of basic, translational, clinical, and public health research focused on human communication and associated disorders in three program areas: hearing and balance; taste and smell; and voice, speech, and language.

Recently, the NIDCD supported research advances in the following areas of deafness and other communication disorders:

- The key sensory protein responsible for hearing and balance, TMC1, was identified in 2018, ending a 40-year quest by scientists. Now researchers are using gene therapy to target the TMC1 gene mutation in animal models to restore hearing and balance function. These efforts may one day translate into gene therapies for people with this gene mutation.
- Researchers have identified a receptor—Neuropeptide Y-like receptor 7—that, when activated, prevents mosquitos from seeking human blood meals. Scientists hope to develop ways to deliver molecules that activate this receptor to mosquitos to prevent human blood-seeking and prevent subsequent mosquito-borne illnesses.
- Scientists have identified mutations in genes in people around the world who stutter. About 20-25 percent of children who stutter will continue into adulthood. Overall, about one percent of adults stutter. Understanding the genetic causes of stuttering and the parts of the brain that are affected, allows researchers to identify targets for future treatments.

## NIDCD BUDGET

**Spending by NIDCD Activity**

(Dollars in Million)

| NIDCD Activity | FY 2016 | FY 2017 | FY 2018 | FY 2019 | FY 2020 |
|---|---|---|---|---|---|
| **Hearing and Balance** | 258.792 | 268.151 | 269.544 | 274.002 | 286.215 |
| **Taste and Smell** | 61.531 | 63.551 | 68.189 | 65.793 | 70.551 |
| **Voice, Speech, and Language** | 101.988 | 104.175 | 121.143 | 133.193 | 133.193 |
| **Total** | 422.311 | 435.877 | 458.876 | 472.988 | 490.692 |

## NIDCD PRIORITY ISSUE

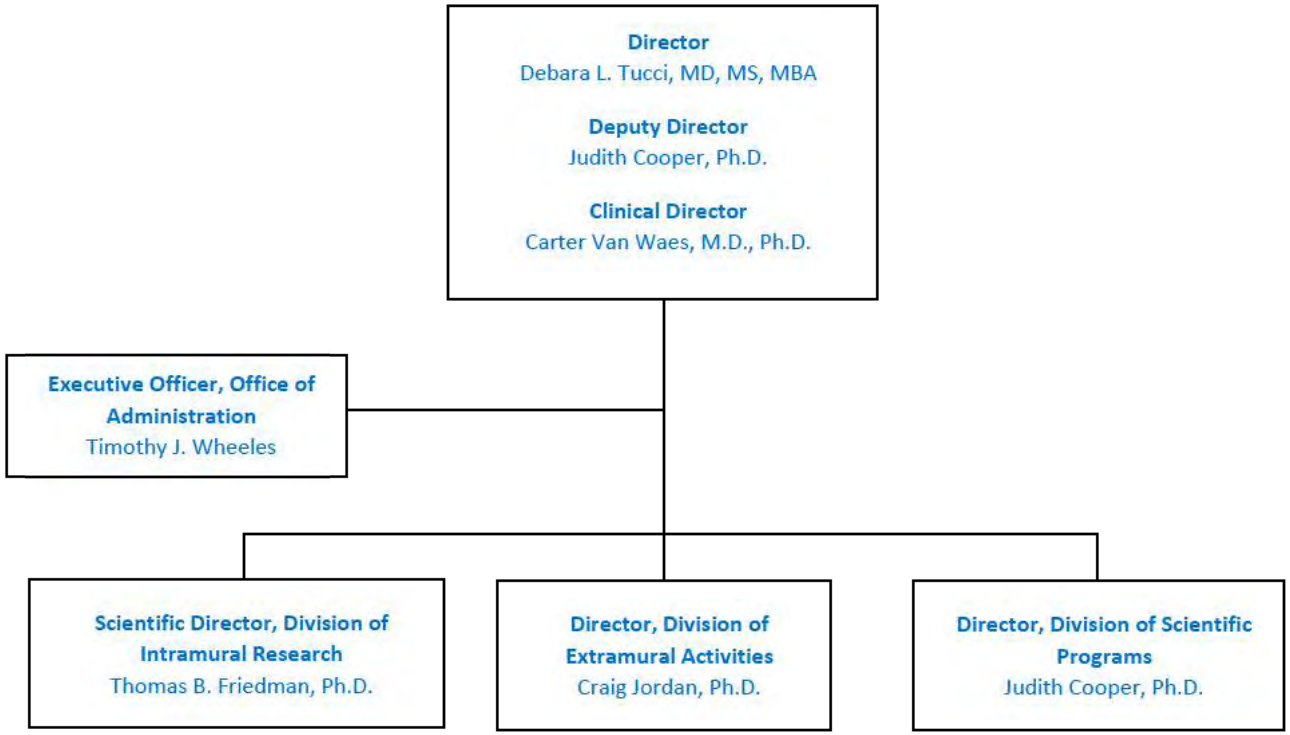
**Research Drives Changes to Make Hearing Health Care More Accessible and Affordable:** NIDCD co-sponsored an effort with other Federal agencies and the Hearing Loss Association of America for the National Academies of Sciences, Engineering, and Medicine (NASEM) to issue a consensus report to help transform hearing health care in the United States. Hearing aids and other assistive devices can significantly improve the quality of life for many people, but only one in four adults who could benefit from hearing aids has ever used these devices. In June 2016, NASEM released the consensus study report—which included a recommendation for the FDA to create and regulate a new category of over-the-counter (OTC) hearing devices, which could improve access to affordable hearing loss interventions for adults with mild-to-moderate hearing loss. These regulations are expected to be released in early 2021.

## NIDCD SIGNIFICANT CHANGES

NIDCD's budget has sustained steady growth over the past few years: FY 2016, 4.4 percent; FY 2017, 3.3 percent; FY 2018, 5.3 percent; FY 2019, 3.1 percent. Although Congress appropriates large amounts of funds to support NIH research initiatives such as COVID-19, the BRAIN Initiative, *All of Us*, and opioid research, the dedicated funding for these initiatives do not directly impact NIDCD's budget in comparison to other NIH ICs.

As the new NIDCD director, Dr. Tucci is leading an effort to develop a new strategic plan to set new research opportunities for the future. NIDCD will continue its long-standing support of scientific training and career development to build a new cadre of scientists in our mission areas. Development of an inclusive and diverse workforce is a priority of the institute. In addition, the NIDCD is placing high priority in research to determine whether smell loss can predict disease severity or other neurological consequences of COVID-19 disease.

## NIDCD ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**National Institute on Deafness and Other Communication Disorders**

- Debara L. Tucci, M.D., MS, MBA (Senior Executive Position)
- Deputy Director, Judith Cooper, Ph.D. (Senior Executive Position)
- Clinical Director, Carter Van Waes, M.D., Ph.D. (Senior Executive Position)

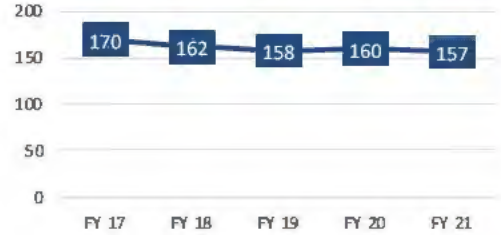
The following offices report directly to the Director:

- Executive Officer, Office of Administration
    - Timothy J. Wheeles, M.A. (Senior Executive Position)
- Acting Scientific Director, Division of Intramural Research
    - Thomas B. Friedman, Ph.D. (Senior Executive Position)
- Director, Division of Extramural Activities
    - Craig Jordan, Ph.D. (Senior Executive Position)
- Director, Division of Scientific Programs
    - Judith Cooper, Ph.D. (Senior Executive Position)

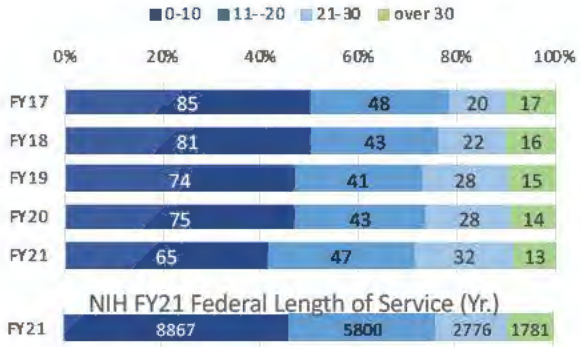
National Institute on Deafness and Other Communication Disorders

# NIDCD WORKFORCE SNAPSHOT[1]

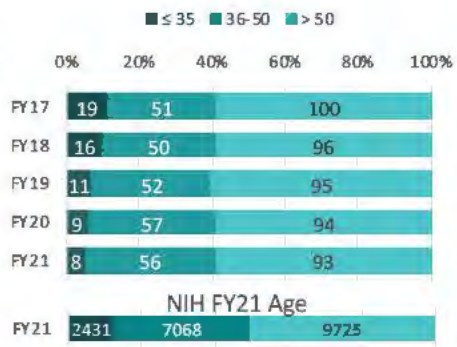
## Federal Employee Onboard (Headcount) Trending



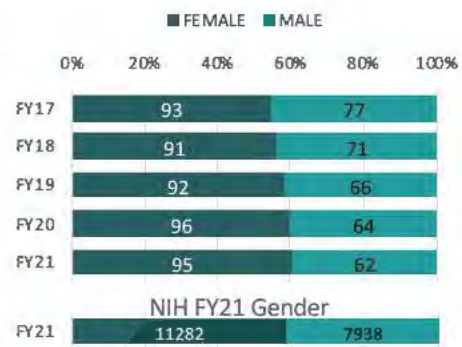

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



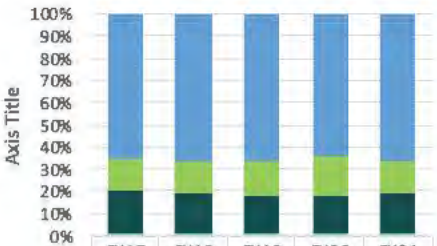

## NIH FY21 Age




## NIH FY21 Gender



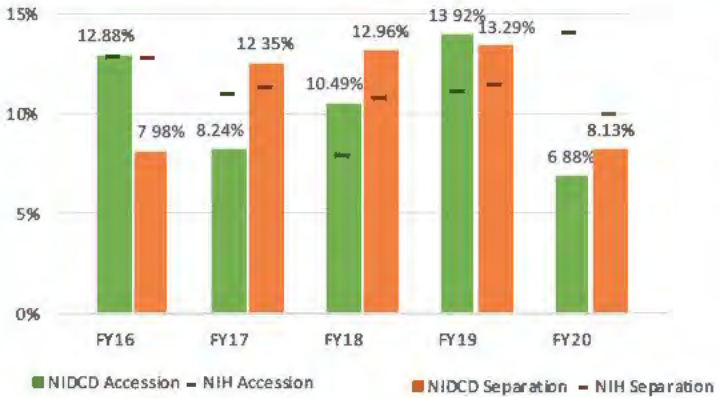

## Pay Plan Trending[2]



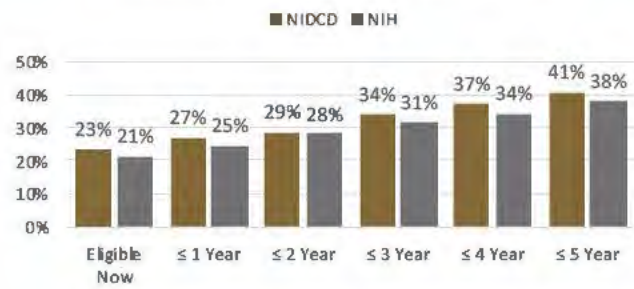

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 111 | 107 | 104 | 102 | 104 |
| EI | 25 | 23 | 26 | 28 | 22 |
| T42 | 32 | 30 | 26 | 28 | 29 |
| SES | 1 | 1 | 1 | 1 | 1 |
| CC | 1 | 1 | 1 | 1 | 1 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIDCD = 7.62 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

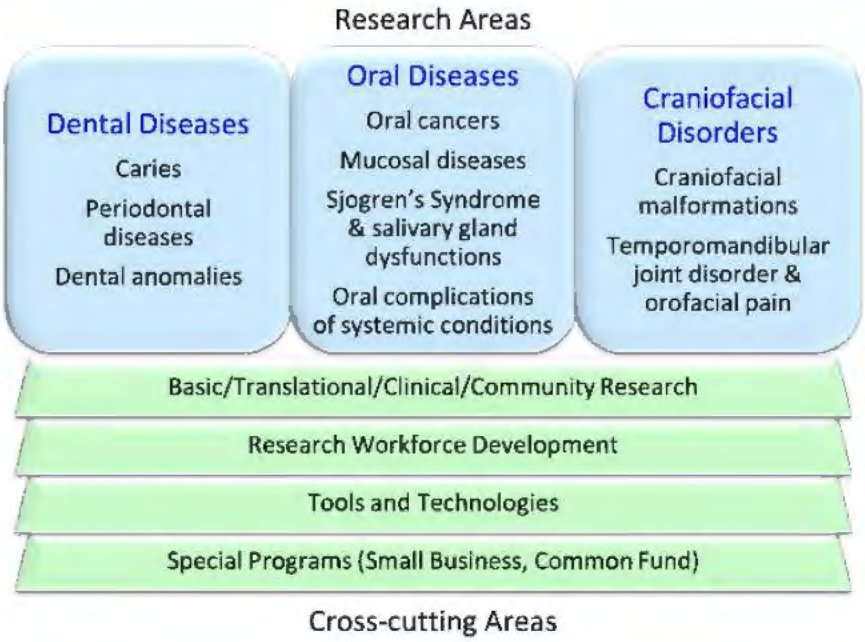
**Budget Summary**
(Dollars in Milli

| NIDCR | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 415.582 | 477.679 | |
| Less (specify sources) | | | |
| Total Budget Authority | 415.582 | 477.679 | |
| FTE | 228 | 235 | |

## NIDCR MISSION

The oral health of Americans has improved dramatically in the past half-century, gains due in large part to research supported and conducted by the National Institute of Dental and Craniofacial Research (NIDCR). One of the first of the 27 NIH ICs to be established, NIDCR was formed in 1948 to address the epidemic of tooth decay affecting the Nation. Seventy years later, NIDCR continues to be a catalyst for driving breakthrough discoveries, transforming research to knowledge and therapies, and enhancing oral health for all people.

NIDCR supports a diverse portfolio of research areas focusing on dental, oral, and craniofacial (DOC) diseases and disorders (see figure). NIDCR supports a continuum from basic to clinical research, to implementing evidence-based findings in communities. NIDCR invests in many cross-cutting areas such as advancing novel tools and technologies, health disparities research, and developing a diverse research workforce. In FY 2019, NIDCR funded more than 850 grants at approximately 200 institutions across 42 states. We also supported 360 individuals through training and career development awards. We support 6,500 researchers who provide essential evidence-based information so that clinicians, including 200,000 U.S. dentists, can more effectively help improve the oral health of the nation.




NIDCR is committed to ensuring that oral health is always considered in the context of overall health, as the health of the teeth, mouth, and craniofacial region are essential to a person's overall health and

well-being. We equip oral health practitioners with the methods, tools, and technologies they need to act as key participants in an integrated health care team. NIDCR's research and research training align with emerging personalized health care efforts through our support of genomics and data science, and the development, adoption, and integration of emerging technologies, such as digital data tools and machine learning. We promote trans-NIH and multidisciplinary research collaborations to bring diverse talent together to work on scientific challenges and implement novel modes of engagement to enhance communication between clinicians and scientists to spur new research. We encourage public-private partnerships, including support of domestic small businesses, to speed the progress of research and development toward the creation of clinical methods, tools, and products to improve public health.

NIDCR contributes to shared research interests of other NIH ICOs, as well as with other OPDIVs within HHS and across the Federal Government. These areas of interest include orofacial pain and temporomandibular joint disorders (TMJDs), non-opioid analgesics, regenerative medicine, oral cancer, microbiome, craniofacial disorders, bone health, and aging. We collaborate extensively with other ICOs, in addition to a variety of outside stakeholders on matters related to public health including the use of fluoride, and emerging scientific and public health challenges like vaping and e-cigarettes, HPV-associated oral cancer, and COVID-19.

## NIDCR BUDGET

**Budget Authority by Activity**
(Dollars in Millions)

| NIDCR Activity | FY 2016 Actual* | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating |
|---|---|---|---|---|---|
| **Extramural Research:** | | | | | |
| Oral and Craniofacial Biology | 180.057 | 190.772 | 204.688 | 220.293 | 228.471 |
| Clinical Research | 67.201 | 64.048 | 71.554 | 69.803 | 72.394 |
| Genetics and Genomics | 54.804 | 58.639 | 55.583 | 54.041 | 56.047 |
| Behavioral and Social Sciences | 18.591 | 17.551 | 18.495 | 16.879 | 17.505 |
| **Subtotal, Extramural** | 320.653 | 331.010 | 350.320 | 361.016 | 374.417 |
| **Intramural Research** | 65.912 | 66.800 | 68.299 | 70.363 | 72.826 |
| **Research Management & Support** | 26.256 | 26.987 | 28.064 | 29.265 | 30.436 |
| **TOTAL** | 412.821 | 424.797 | 446.683 | 460.644 | 477.679 |

*FY 2016 Actual includes a reduction of $2.8M for the AIDS and ZIKA transfers.

## NIDCR PRIORITY ISSUES

**Emerging Public Health Challenges:** NIDCR is building on its foundational investments in basic and translational oral health research to address current public health challenges. The most pressing current efforts focus on:

- COVID-19: Responding to the global pandemic by funding immediate, high-impact intramural and extramural research to: reduce the risk of SARS-CoV-2 transmission in dental practices; measure viral load in oral secretions and the effect of masks on reducing transmission; develop handheld sensors to detect SARS-CoV-2 in saliva; and improve oral health behavior, care, and access for low-income urban families.

- Opioid use and orofacial pain: Discovering and testing safer, non-addictive pain medications and interventions to improve pain treatments and decrease opioid use and misuse and developing approaches to advance pain management strategies by dental practitioners.
- Electronic cigarettes and vaping: Characterizing the effects of vaping and e-cigarettes on oral health, including the risk for oral cancer and other oral diseases.
- HPV-associated oral cancers: Addressing increasing prevalence of HPV+ head and neck cancer by improving and accelerating diagnosis of oral HPV infection, exploring the feasibility of oral HPV screening in dental settings, and examining the efficacy of HPV vaccines in preventing HPV+ oral cancer.

**Health Disparities**: Although major improvements in oral health have been made for the U.S. population, certain segments of the population continue to experience disproportionate and unacceptable burdens of oral diseases. NIDCR is working to reduce oral health disparities, such as the increased incidence of tooth decay, periodontal disease, tooth loss, and oral cancer, in populations where these diseases are observed at higher rates. NIDCR's Multidisciplinary and Collaborative Research Consortium to Reduce Oral Health Disparities in Children established several community-based and medical-dental partnerships that are currently testing novel interventions to remove barriers preventing access to oral care in vulnerable populations. NIDCR also collaborates with NIGMS's Native American Research Centers for Health to fund research on the impact of prenatal vitamin D supplementation on early childhood dental decay.

**Temporomandibular Joint Disorders:** At least 10 million people in the United States are estimated to be affected by temporomandibular joint disorders (TMJDs), a diverse group of conditions that cause jaw joint and muscle dysfunction and pain. To tackle the complex clinical features and biology of TMJDs and find effective interventions, NIDCR established a trans-NIH, multi-council TMJD working group. They will advise on implementing recommendations from the Congressionally requested and NIH/NIDCR-supported National Academies of Science, Engineering & Medicine report "Temporomandibular Disorders: Priorities for Research and Care."

**Workforce Diversity**: The NIDCR-supported intramural and extramural biomedical workforce does not accurately reflect the diversity of the American people. To increase oral health research workforce diversity, and therefore the quality of scientific research produced, NIDCR funds a Mentoring Network to Support a Diverse Dental, Oral and Craniofacial Research Workforce and launched the NIDCR Director's Postdoctoral Fellowship to Enhance Diversity in Dental, Oral, & Craniofacial Research. In the future NIDCR will support a Predoctoral to Postdoctoral Transition Award for a Diverse Dental, Oral, and Craniofacial Research Workforce

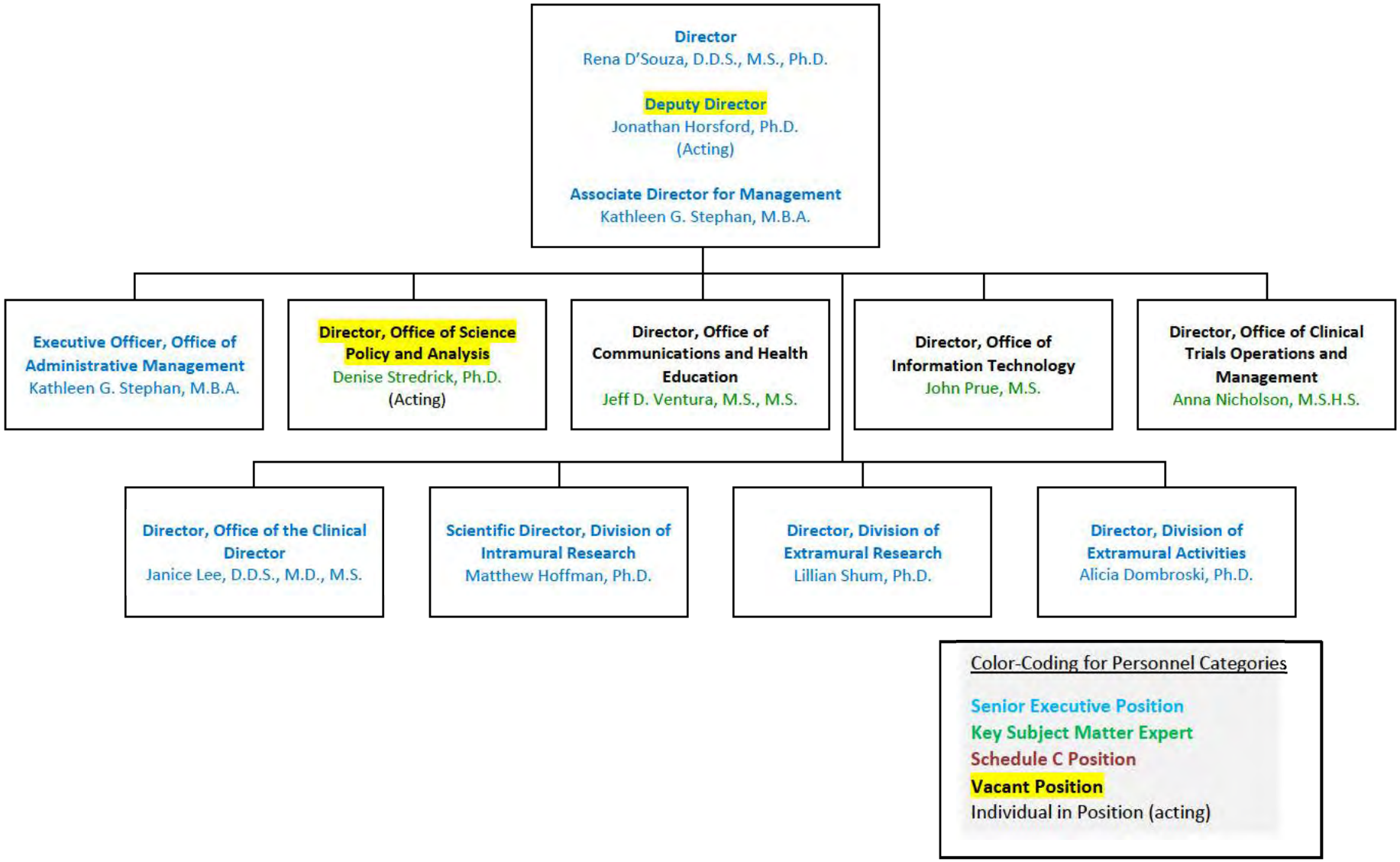
## NIDCR SIGNIFICANT CHANGES

In September 2020, NIH selected Dr. Rena N. D'Souza as NIDCR's next Director. A licensed dentist and well-established researcher in the field of genetics, Dr. D'Souza joins NIDCR from the University of Utah, Salt Lake City where she served as assistant vice president for academic affairs and education for health sciences. Dr. D'Souza is renowned for her research in craniofacial development, genetics, tooth development and regenerative dental medicine. She is a champion of diversity in the biomedical research workforce, and she is committed to inclusion, equity, and diversity.

NIDCR funds research that uses innovative approaches that maximize investment value. A few significant changes include:

- Expanding data science – We are increasing our investment in data science research and training, such as advancing the use of machine learning/artificial intelligence to improve the utility of large DOC datasets. We are also applying universally accepted data principles to ensure the reusability of data. Additional data science opportunities include the optimization of clinical procedures and assessment of treatment outcomes; building and strengthening infrastructures that collect and disseminate research and health data; and advancing strategies to ensure long-term sustainability of data repositories.
- Advancing regenerative medicine – We significantly bolstered support of our Tissue Engineering and Regenerative Medicine Program, which aims to develop strategies to replace or regenerate DOC tissues using bioengineering and stem cell biology-based approaches. To address the lag in translating basic research into products that can be safely and effectively used in people, the Dental, Oral, and Craniofacial Tissue Regeneration Consortium (DOCTR-C), now in its third phase, is focusing on the validation, manufacturing, and preclinical testing of the most promising products to ready them for submission for FDA approval.
- Enhancing the Intramural Research Program
    - NIDCR is committed to increasing the diversity of its research workforce and fostering the next generation of researchers by providing ample opportunities for gaining leadership experience. In the past three years, the intramural program recruited five Stadtman Investigators and two Lasker Clinical Investigators, and created diversity fellowships for post-baccalaureates and post-doctoral fellows.
    - To provide leadership opportunities, the intramural program established committees advising the Scientific Director, reinstated annual PI workshops organized by a rotating group of Investigators, and started a trainee-led seminar series.
    - To better serve the community of trans-NIH investigators conducting clinical research within the NIH Clinical Center, and to ensure oral health is an integral component of study volunteers' overall health, NIDCR expanded access to its intramural dental clinic. Between 2015 and 2019 the dental clinic saw a 60 percent increase in study participant volume and supported 23 different clinical trials.

## NIDCR ORGANIZATIONAL CHART AND WORKFORCE



**National Institute of Dental and Craniofacial Research**

Office of the Director

- Director, Rena D'Souza, D.D.S., M.S., Ph.D. (Senior Executive Position)
- Deputy Director, Jonathan Horsford, Ph.D. (Acting) (Senior Executive Position; Vacant)
- Associate Director for Management, Kathleen G. Stephan, M.B.A. (Senior Executive Position)

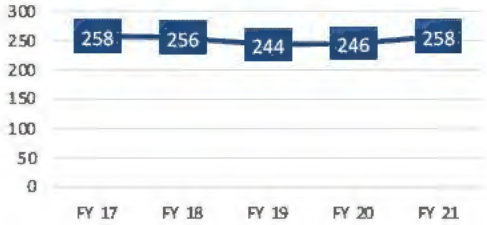
The following positions report directly to the NIDCR Director:

- Director, Office of Science Policy and Analysis
    - Denise Stredrick, Ph.D. (Acting; Subject Matter Expert)
- Director, Office of Communications and Health Education
    - Jeff Ventura, M.S., M.S. (Subject Matter Expert)
- Director, Office of Information Technology
    - John Prue, M.S. (Subject Matter Expert)
- Director, Office of Clinical Trials Operations and Management
    - Anna Nicholson, M.S.H.S. (Subject Matter Expert)
- Director, Office of the Clinical Director (Senior Executive Position)
    - Janice Lee, D.D.S., M.D., M.S.
- Scientific Director, Division of Intramural Research (Senior Executive Position)
    - Matthew Hoffman, B.D.S., Ph.D.
- Director, Division of Extramural Research (Senior Executive Position)
    - Lillian Shum, M.D., Ph.D.
- Director, Division of Extramural Activities (Senior Executive Position)
    - Alicia Dombroski, Ph.D.

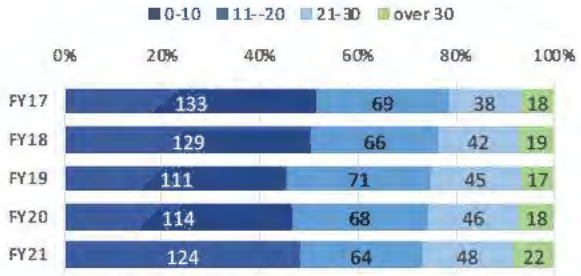
National Institute of Dental and Craniofacial Research

# NIDCR WORKFORCE SNAPSHOT[1]

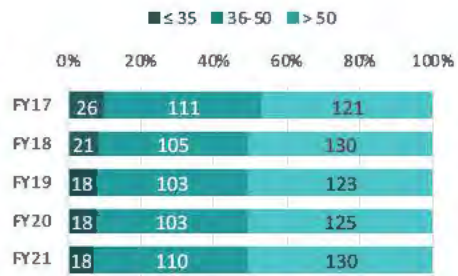
## Federal Employee Onboard (Headcount) Trending



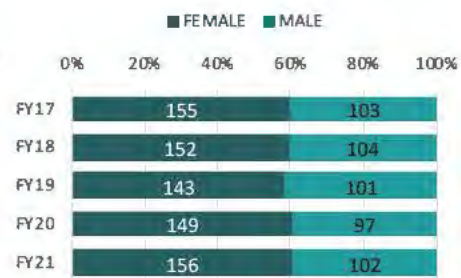

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending

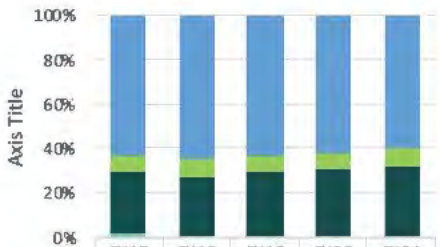



## NIH FY21 Federal Length of Service (Yr.)


## NIH FY21 Age


## NIH FY21 Gender


## Pay Plan Trending[2]




| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 162 | 166 | 153 | 153 | 154 |
| EI | 21 | 20 | 20 | 17 | 21 |
| T42 | 71 | 67 | 68 | 74 | 81 |
| SES | 1 | 1 | 1 | 1 | 1 |
| CC | 3 | 2 | 2 | 1 | 1 |

## NIH FY21 Pay Plan


## Accession & Separation Trending


## Cumulative % of FTE Retirement Eligibility[3]


Average time FTEs stayed past retirement eligibility
NIDCR = 6.67 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

**Budget Summary**
(Dollars in Millions)

| NIDDK | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 1,968.357 | 2,264.314 | |
| Less (specify sources) | | | |
| Total Budget Authority | 1,968.357 | 2,264.314 | |
| FTE | 643 | 660 | |

## NIDDK MISSION

Established in 1950, the National Institute of Diabetes and Digestive Kidney Disease (NIDDK). NIDDK supports and conducts research to address some of the most chronic, common, and costly diseases and conditions affecting the U.S. population, as well as other conditions that are less widespread but still devastating. Guided by the NIDDK Director's core principles, the Institute serves people who have, or are at risk for, obesity, diabetes, kidney, liver, and digestive diseases, and other diseases and conditions; healthcare providers, who use research findings in practice; community members who use research results to inform health-related programs and policies; the general public; and the numerous scientists at universities, medical centers, and small businesses across the country who receive NIDDK funding for their research. Many NIDDK mission diseases place disparate burdens on minority groups and people with limited resources. These disparities have been exacerbated by the ongoing novel coronavirus pandemic, with increased rates of COVID-19 and disproportionately poor outcomes in people with obesity, diabetes, and/or other diseases. NIDDK remains firmly committed to alleviating such health disparities through research.

NIDDK directs most of its funding extramurally to support investigator-initiated research. The Institute also funds other research efforts through solicitations in areas of scientific opportunity or challenge. As is the case across NIH, NIDDK uses a statutory two-stage peer-review process to make awards. NIDDK also supports scientists in its intramural laboratories in Bethesda, Maryland and Phoenix, Arizona. NIDDK collaborates and coordinates with other NIH ICOs and other Federal agencies to advance research and its translation into improved public health. To inform research planning, NIDDK seeks input from expert researchers, scientific organizations, healthcare providers, patient advocates, and the public.

NIDDK has a leadership role in many collaborative NIH efforts, for example, the type 2 diabetes component of the Accelerating Medicines Partnership (AMP-T2D). NIDDK also co-leads NIH Common Fund programs including: one to explore how physical activity benefits health; another to study the "druggable genome"; and one to accelerate development of therapeutic devices that modulate electrical activity in nerves to improve organ function. The NIDDK chairs the Diabetes Mellitus Interagency Coordinating Committee (DMICC) and other statutory committees and leads and/or participates in other interagency groups.

**Major NIDDK Programs:**

- **The Diabetes, Endocrinology, and Metabolic Diseases program** – funds basic, clinical, and translational research on diabetes, cystic fibrosis, obesity, and other metabolic and endocrine

diseases. NIDDK funds additional studies through a special mandatory funding program for type 1 diabetes research.

- **The Digestive Diseases and Nutrition program** – funds basic, clinical, and translational research on diseases of the esophagus, stomach, intestines, liver, and pancreas. The program also supports research on obesity and studies related to nutrition and nutritional disorders.
- **The Kidney, Urologic, and Hematologic Diseases program** – funds basic, clinical, and translational research on diseases of the kidneys and urinary tract, and research on disorders of the blood and blood-forming organs.
- **The Intramural Research Program** – supports NIDDK scientists conducting disease research at the Bethesda campus, as well as scientists studying obesity and type 2 diabetes in American Indians and other populations at its Phoenix site. Intramural scientists also study structures of biological molecules and conduct other research to understand basic biological processes.

Across its programs, NIDDK supports research training and career development for the next generation of scientists. NIDDK also supports information and outreach efforts to bring science-based knowledge to diverse audiences of patients, healthcare providers, and the public.

**NIDDK Research Activities, Advances, and Accomplishments**

NIDDK research has led to tremendous progress on multiple fronts in health and disease. The landmark Diabetes Prevention Program (DPP) has improved health and may now be helping reduce government spending. The NIDDK-led DPP showed that people at high risk for developing type 2 diabetes could reduce their risk through either a lifestyle intervention (diet and exercise) aimed at modest weight loss or with the drug metformin. A successful NIDDK-funded study testing delivery of the lifestyle intervention at YMCAs led to creation of the CDC-led National DPP to deliver the intervention in communities. CMS estimated the approach would yield net savings and better health and began the Medicare DPP benefit in 2018.

A trial conducted by the NIDDK's Type 1 Diabetes TrialNet was the first to show that, with early preventive treatment targeting the immune system, clinical type 1 diabetes can be delayed by 2 or more years among people who are at high risk. NIDDK-supported research has also contributed to several FDA-approved technologies that are giving people with type 1 diabetes new options for managing their disease with less burden. Research supported in part by NIDDK led to recent FDA approvals of drugs that treat specific mutant versions of the CFTR protein that cause cystic fibrosis, potentially yielding dramatic health improvement for about 90 percent of people with the disease. Studies of living donor liver transplantation and living kidney donation have provided important information for patients and potential donors. NIDDK-funded studies have revealed benefits and risks of bariatric surgery for treating obesity and related conditions in adolescents and adults. Studies through NIDDK-led research networks have led to a better understanding of, and new treatment approaches for, pediatric liver diseases (e.g., the ChiLDReN Network) and novel insights into urologic chronic pelvic pain syndromes (e.g., the MAPP Research Network. In conjunction with NIH's HEAL Initiative, NIDDK has funded the Hemodialysis Opioid Prescription Effort (HOPE) consortium to address opioid use among individuals with end-stage renal disease (ESRD) undergoing hemodialysis. ChiLDReN Network) and novel insights into urologic chronic pelvic pain syndromes (e.g., the MAPP Research Network). In conjunction with NIH's HEAL Initiative, the NIDDK has funded the Hemodialysis Opioid Prescription Effort (HOPE) consortium to address opioid use among individuals with end-stage renal disease (ESRD) undergoing hemodialysis.

Other NIDDK-supported research continues progress toward understanding, preventing, and treating diseases across the Institute's mission: Studies of the gut microbiome are illuminating its effects on

health and disease. More personalized approaches to treatment are becoming possible with new insights into genetic and other factors that contribute to disease—e.g., an NIDDK-supported study found that a combination of clinical, genetic, and immunologic tests can predict response to standard medical therapy for children newly diagnosed with a form of inflammatory bowel disease (IBD). Personalized treatments could also emerge from targeted efforts to understand heterogeneity of disease, such as through the NIDDK's Kidney Precision Medicine Project. Ongoing research to develop three-dimensional "chips" that replicate the structure and function of human organs/tissues in a laboratory setting could help accelerate drug discovery and ultimately yield new therapeutics.

## NIDDK BUDGET

**Budget Authority by Activity**
(Dollars in Millions)

| NIDDK Activity | FY 2016 Enacted | FY 2017 Enacted | FY 2018 Enacted | FY 2019 Enacted | FY 2020 Enacted |
|---|---|---|---|---|---|
| Diabetes, Endocrinology, and Metabolic Diseases | 643.530 | 663.554 | 692.662 | 700.209 | 731.636 |
| Digestive Diseases and Nutrition | 482.533 | 494.838 | 551.023 | 586.963 | 612.476 |
| Kidney, Urologic, and Hematologic Diseases | 439.377 | 452.421 | 453.375 | 459.102 | 475.202 |
| Type 1 Diabetes *Mandatory appropriation* | 150.000 | 139.650 | 150.000 | 150.000 | 150.000 |
| Intramural Research Program | 184.430 | 189.637 | 199.877 | 206.830 | 215.000 |
| Research Management & Support | 68.487 | 70.145 | 73.860 | 76.719 | 80.000 |
| Total | 1,968.357 | 2,010.245 | 2,120.797 | 2,179.823 | 2,264.314 |

## NIDDK PRIORITY ISSUES

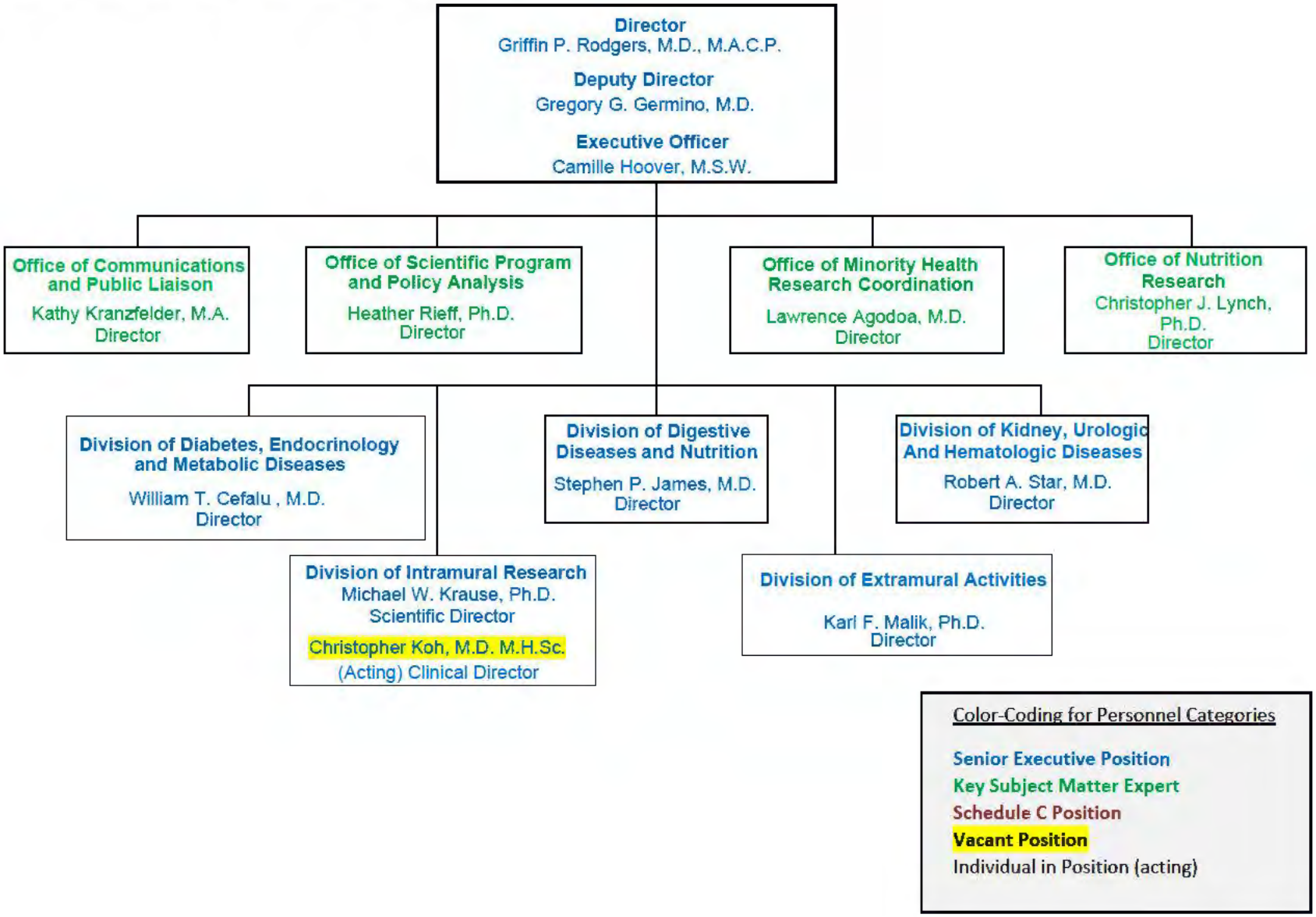
The Special Statutory Funding Program for Type 1 Diabetes Research: is a special mandatory appropriation ($150 million/year) that supports research on the prevention, treatment, and cure of type 1 diabetes and its complications. The current authorization will expire after December 11, 2020. Unless the Program is reauthorized by Congress, NIDDK will have to scale back or curtail many currently supported research efforts.

HHS National Viral Hepatitis Action Plan implementation group: Through its role in the Trans-NIH Committee on Viral Hepatitis and the HHS National Viral Hepatitis Action Plan implementation group, NIDDK works with other NIH Institutes and Federal agencies to support the current HHS priority on cure and elimination of viral hepatitis and its sequelae, such as liver cirrhosis and cancer.

## NIDDK SIGNIFICANT CHANGES

The Office of Nutrition Research (ONR) will be moving from NIDDK to the DPCPSI within NIH OD during the first quarter of FY 2021. This move will elevate attention to and ensure a coordinated approach to nutrition research across NIH.

## NIDDK ORGANIZATIONAL CHART AND WORKFORCE



**National Institute of Diabetes and Digestive and Kidney Diseases**
Office of the Director

- Director, Griffin P. Rodgers, M.D., M.A.C.P. (Senior Executive Position)
- Deputy Director, Gregory G. Germino, M.D. (Senior Executive Position)

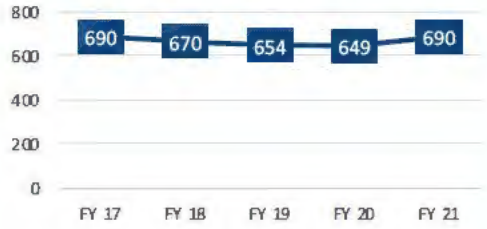
The following Divisions and Offices report directly to the Director:

- Executive Officer
    - Camille Hoover, M.S.W. (Senior Executive Position)
- Director, Office of Communications and Public Liaison
    - Kathy Kranzfelder, M.A. (Key Subject Matter Expert)
- Director, Office of Scientific Program and Policy Analysis
    - Heather Rieff, Ph.D. (Key Subject Matter Expert)
- Director, Office of Minority Health Research Coordination
    - Lawrence Agodoa, M.D. (Key Subject Matter Expert)
- Director, Office of Nutrition Research
    - Christopher J. Lynch, Ph.D. (Key Subject Matter Expert)
- Director, Division of Diabetes, Endocrinology, and Metabolic Diseases
    - William T. Cefalu, M.D. (Senior Executive Position)
- Director, Division of Digestive Diseases and Nutrition
    - Stephen P. James, M.D. (Senior Executive Position)
- Director, Division of Kidney, Urologic, and Hematologic Diseases
    - Robert A. Star, M.D. (Senior Executive Position)
- Scientific Director, Division of Intramural Research
    - Michael W. Krause, Ph.D. (Senior Executive Position)
- Acting Clinical Director, Division of Intramural Research
    - Christopher Koh, M.D., M. H. Sc (Senior Executive Position)
- Director, Division of Extramural Activities
    - Karl F. Malik, Ph.D. (Senior Executive Position)

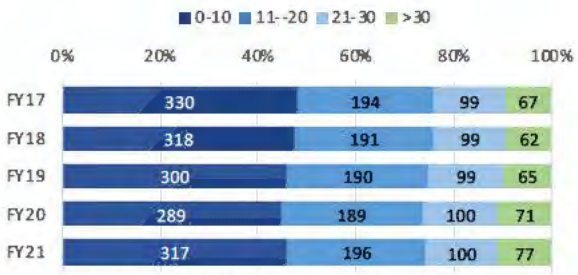
National Institute of Diabetes and Digestive and Kidney Diseases

# NIDDK WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

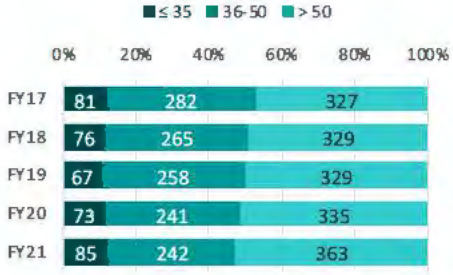



## Federal Length of Service (Yr.) Trending

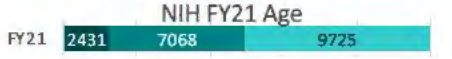



## NIH FY21 Federal Length of Service (Yr.)

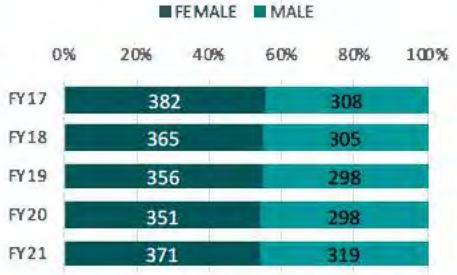

## Age Trending




## NIH FY21 Age

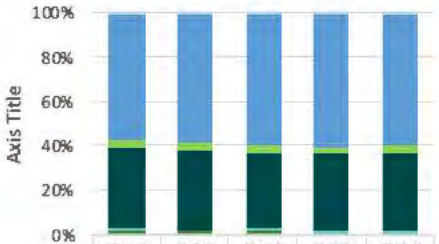



## Gender Trending



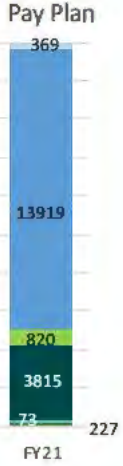

## NIH FY21 Gender


## Pay Plan Trending[2]

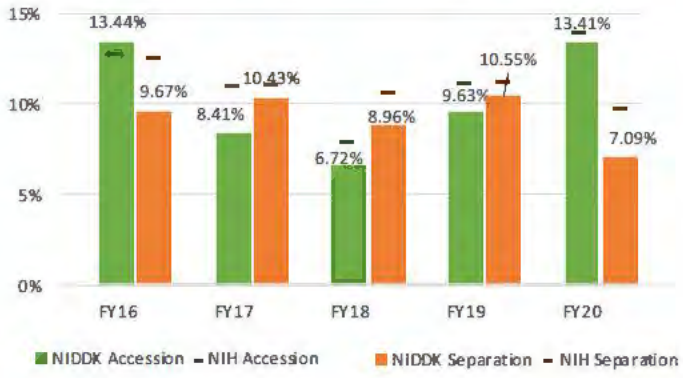



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 1 | 1 | 1 | 1 | 1 |
| GS | 396 | 388 | 388 | 391 | 412 |
| EI | 22 | 23 | 22 | 20 | 23 |
| T42 | 251 | 242 | 226 | 224 | 243 |
| SES | 6 | 6 | 6 | 5 | 4 |
| CC | 14 | 10 | 11 | 8 | 7 |

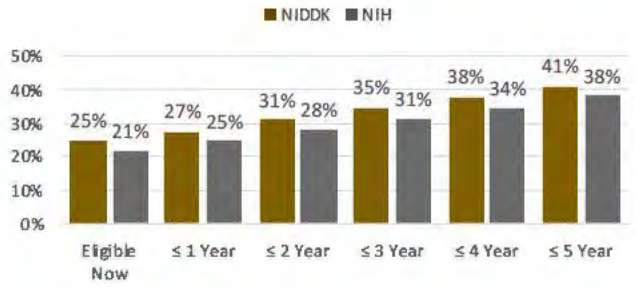
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIDDK = 5.55 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.

[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS

[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

**Budget Summary**
(Dollars in Millions)

| IC Name | FY 2016 Enacted | FY 2020 Actual[1] | (b) (5) |
|---|---|---|---|
| Total Program Level LHHS Appropriation | 693.702 | 802.482 | |
| Total Program Level Superfund Appropriation | 77.349 | 80.993 | |
| Less (specify sources) | | | |
| Total Budget Authority | 771.051 | 883.475 | |
| FTE | 642 | 630 | |

[1]Supplemental funds in the amount of $10 million were pro
Preparedness and Response Supplemental Appropriations Act, 2020." Funds are to be used "for worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other workers who are at risk of exposure to coronavirus through their work duties." Of the supplemental funding provided, $6.277 million was obligated in FY 2020.

[2]The FY 2021 LHHS Appropriation House Level does not include $51.648 million in emergency funding to NIEHS to be used for lost productivity due to the coronavirus.

## NIEHS MISSION

The National Institute of Environmental Health Sciences (NIEHS) was established in 1966 as the Division of Environmental Health Sciences; in 1969, it was elevated to a full institute within NIH. NIEHS's statutory purpose is to conduct and support research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly. NIEHS research thus covers all diseases and conditions that could be caused or affected by exposure to environmental agents, defined broadly. This research is used to inform policy and help people in America and worldwide live healthier lives through prevention and diagnosis of environmentally related adverse health outcomes.

NIEHS is located in Research Triangle Park (RTP), North Carolina, geographically distant from the main NIH campus. Both its Division of Intramural Research (DIR) and its Division of Extramural Research (DER) and Training (the component that manages extramural grant funding) are located there.

Some unique programs featured at NIEHS:

- **NIEHS Clinical Research Branch** – translates basic laboratory findings in environmental health to improving health in humans. The Clinical Research Unit on the NIEHS North Carolina campus provides infrastructure, staffing, and assumes a core laboratory function in support of NIEHS intramural investigators. NIEHS Environmental Autoimmunity Group is based at the NIH Clinical Center in Bethesda, Maryland, so NIEHS clinical studies have a presence at both sites.
- **Division of the National Toxicology Program (DNTP)** – is the NIEHS component of the interagency National Toxicology Program (NTP), along with FDA's National Center for Toxicological Research (NCTR) and CDC's National Institute for Occupational Safety and Health. The NIEHS Director serves as the Director of NTP. The NIEHS DNTP's activities include laboratory research, toxicology testing, and oversight of NTP communications, database, website, and advisory groups.

- **Superfund Basic Research Program and Worker Training Program** – The NIEHS Hazardous Substance Basic Research and Training Program (Superfund Research Program [SRP]) provides practical, scientific solutions to protect health, the environment, and communities. SRP works to learn more about ways to protect the public from exposure to hazardous substances, such as industrial solvents, arsenic, lead, and mercury. A related program, the Worker Training Program (WTP), was created through the Superfund Amendments and Reauthorization Act of 1986 to provide health and safety training for thousands of workers who may be involved in handling hazardous materials (HAZMAT) or in responding to emergency releases of HAZMAT. These workers gain new skills on how to safely handle, remove, and contain hazardous waste. More recently, the WTP has developed and provided health and safety resources for workers who may be at risk of exposure to COVID-19.

## NIEHS BUDGET

**Budget Authority by Activity**
(Dollars in Millions)

| NIEHS Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual[1] | FY 2020 Actual[2] |
|---|---|---|---|---|---|
| **Extramural Research** | | | | | |
| **Fundamental Research** | 203.798 | 198.536 | 197.674 | 201.930 | 210.023 |
| **Exposure Research** | 67.773 | 72.157 | 89.770 | 108.124 | 112.458 |
| **Translational Research and Special Populations** | 92.482 | 100.855 | 106.188 | 100.683 | 104.719 |
| **Predictive Toxicology** | 84.388 | 89.216 | 90.881 | 92.020 | 95.708 |
| **Training and Education** | 25.455 | 23.825 | 23.276 | 19.454 | 20.234 |
| **Subtotal, Extramural** | 473.896 | 484.589 | 507.789 | 522.211 | 543.142 |
| **Intramural Research** | 192.483 | 201.133 | 213.187 | 220.393 | 230.027 |
| **Research Management & Support** | 26.194 | 26.947 | 28.402 | 29.362 | 29.313 |
| **TOTAL, DIRECT** | 692.573 | 712.669 | 749.378 | 771.966 | 802.482 |
| **NIEHS SUPERFUND (DOI)** | | | | | |
| **Detail** | | | | | |
| **Superfund Research** | 49.075 | 49.161 | 49.165 | 50.660 | 52.663 |
| **Worker Training Program** | 28.177 | 28.176 | 28.177 | 28.328 | 28.330 |
| **TOTAL, SUPERFUND** | 77.252 | 77.337 | 77.342 | 78.988 | 80.993 |
| **Grand Total** | 769.825 | 790.006 | 826.720 | 850.954 | 883.475 |

[1] NIEHS received $1 million in a Disaster Relief Supplemental appropriation

[2] Supplemental funds in the amount of $10 million were provided to NIEHS in accordance with the "Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020." Funds are to be used "for worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other workers who are at risk of exposure to coronavirus through their work duties." Of the supplemental funding provided, $6.277 million was obligated in FY 2020.

## NIEHS PRIORITY ISSUES

**Genes and Environment in Biomedical Research:** Health is the product of both one's genes and one's environment. NIEHS is working to identify the environmental factors in the equation—the sum of a person's chemical, dietary, psychosocial, and other exposures through air, water, food, and elsewhere. NIEHS is investing in efforts develop and apply new technologies to measure more exposures and to determine how they interact with a person's genes, both directly and indirectly. The goal is to enable incorporation of assessment of environmental factors across a wider range of NIH research including the groundbreaking effort known as the *All of Us* Research Program.

**Environmental Health Disparities Research:** NIEHS is engaged in research to understand and address the disparate health impacts of environmental hazards on disadvantaged and diverse communities. New directions for this research include better integration of research across scientific disciplines and more in-depth evaluation of social determinants of health.

**Innovation in Toxicology Research and NIEHS/DNTP:** Among its responsibilities, the NIEHS Division of the NTP (DNTP) works to develop and apply new and improved methods and approaches that advance toxicology and better assess health effects from environmental exposures. NIEHS/DNTP is a key partner in the interagency Toxicology Testing in the 21$^{st}$ Century (Tox21) program which has developed high-throughput, cell-based approaches to characterizing the biological activity of chemicals and drugs. These and other efficient, predictive, and economical systems for assessing the effects of chemical substances on human health were envisioned in the seminal National Research Council report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*.

**Clinical and Computational Science Building (CCSB):** NIEHS has increasingly prioritized data- and computational-driven science across all NIEHS scientific programs. The construction of a 125,000 square foot research building on the NIEHS campus at RTP, NC will facilitate the co-location of all NIEHS scientists involved in clinical, computational, and data sciences. The CCSB will provide critical infrastructure by replacing the aging, modular Clinical Research Unit (CRU) which is past its design lifespan and vulnerable to severe thunderstorms, tornadoes, and hurricanes common in the region. The CCSB is mission-critical for NIEHS since computational and data science methods have become foundational to environmental health and biomedical research. The enhanced integration of computational and data science research with clinical research will accelerate translational efforts promoting novel discovery, methods development, and opportunities for cross training of analytical, clinical, and environmental health sciences experts.

**Litigation hold related to Aqueous Film-Forming Foam (AFFF) Multi-District Litigation (MDL):** The majority of the lawsuits are products liability cases against the AFFF manufacturers, but several lawsuits also include claims against the United States regarding its use and disposal of AFFF.

**EPA Litigation Hold** for which one individual within NIEHS/NTP is affected – the EPA IRIS Risk Assessment of Chloroprene (Litigation Hold notice date 9/23/2016).

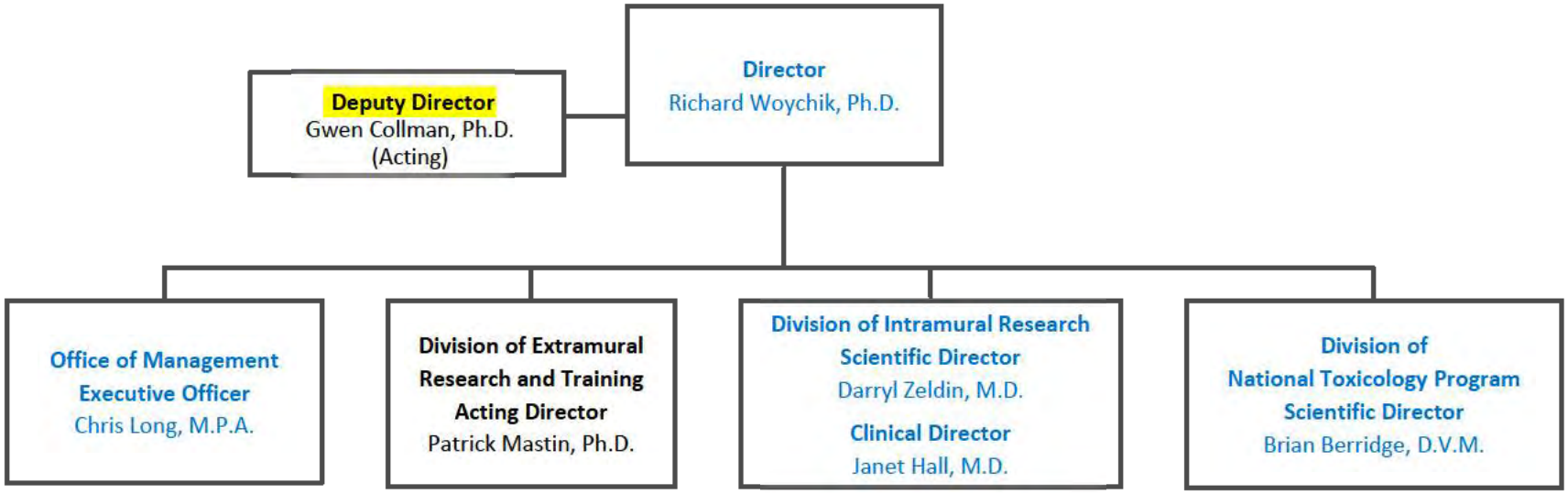
## NIEHS SIGNIFICANT CHANGES

The Labor, HHS portion of the NIEHS budget over this period has increased at an average 3.7 percent each FY. While this rate of increase has consistently fallen below that of NIH as a whole, the NIEHS's inconsistent rate of increase can be linked to Congress' provision of funds to targeted research priorities such as Alzheimer's Disease, opioid research, Cancer Moonshot, BRAIN, the *All of Us* Research Program, development of a universal flu vaccine, and combating antibiotic-resistance. The NIEHS/LHHS increase

rate has been consistent with other institutes and centers who have also not received such targeted funding in their appropriations.

The Interior and Environment (Superfund) portion of the NIEHS budget was flat for much of this period until receiving a 2.1 percentage increase in FY 2019. The FY 2020 enacted budget provided an additional $2 million (+2.5 percent) in targeted funds to support research on polyfluoroalkyl substances (PFAS) and other emerging contaminant concerns by the Superfund Research Program. Support for continued growth of the Superfund appropriation is further demonstrated by proposal of an equivalent increase at the FY 2021 House level.

## NIEHS ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**National Institute of Environmental Health Sciences**

Office of the Director

- Director, Richard Woychik, Ph.D. (Senior Executive Position)
- Deputy Director, Gwen W. Collman, Ph.D. (Acting)

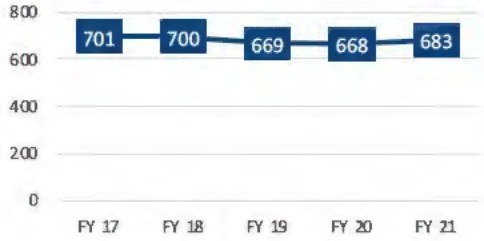
These offices report directly to the Director

- Office of Management
    - Chris Long, M.P.A. (Senior Executive Position)
- Division of Extramural Research & Training
    - Patrick Mastin, Ph.D. (Acting)
- Scientific Director, Division of Intramural Research
    - Darryl C. Zeldin, M.D. (Senior Executive Position)
- Clinical Director, Division of Intramural Research
    - Janet Hall, M.D. (Senior Executive Position)
- Scientific Director, Division of National Toxicology Program
    - Brian Berridge, D.V.M. (Senior Executive Position)

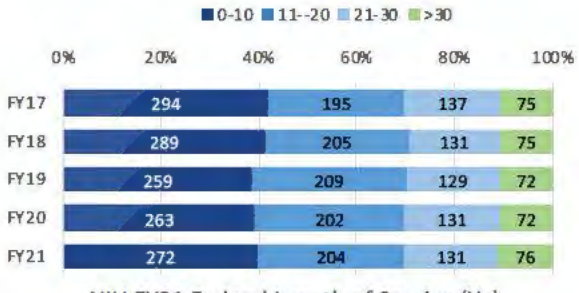
National Institute of Environmental Health Sciences
*Your Environment. Your Health.*

# NIEHS WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

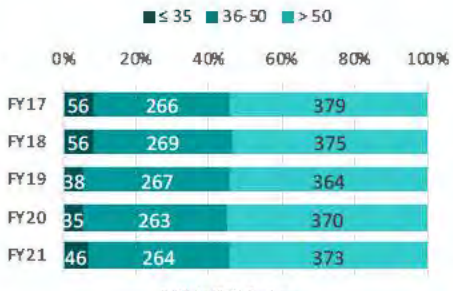



## Federal Length of Service (Yr.) Trending

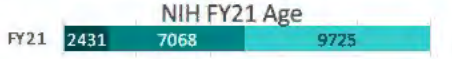



## NIH FY21 Federal Length of Service (Yr.)

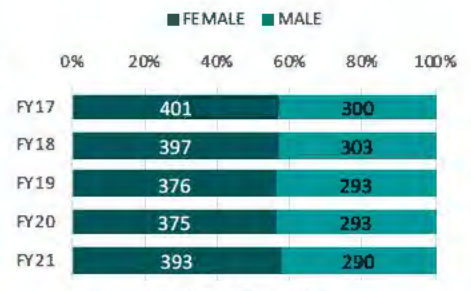

## Age Trending




## NIH FY21 Age

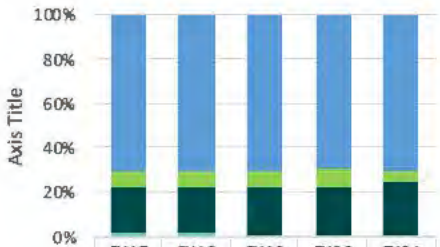



## Gender Trending



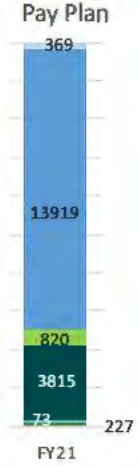

## NIH FY21 Gender


## Pay Plan Trending[2]

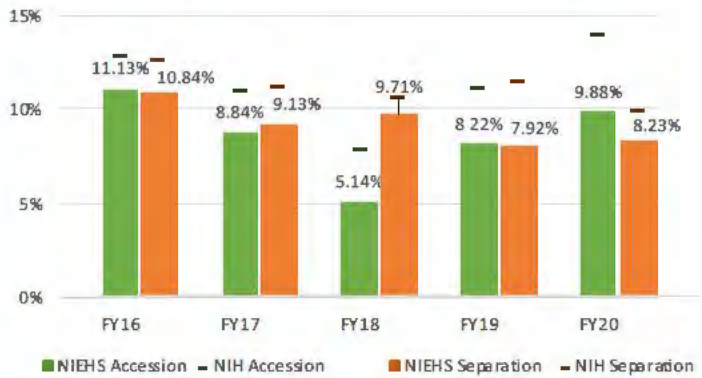



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 491 | 490 | 470 | 461 | 477 |
| EI | 51 | 51 | 53 | 55 | 40 |
| T42 | 150 | 150 | 139 | 145 | 158 |
| SES | 2 | 2 | 1 | 1 | 1 |
| CC | 7 | 7 | 6 | 5 | 6 |

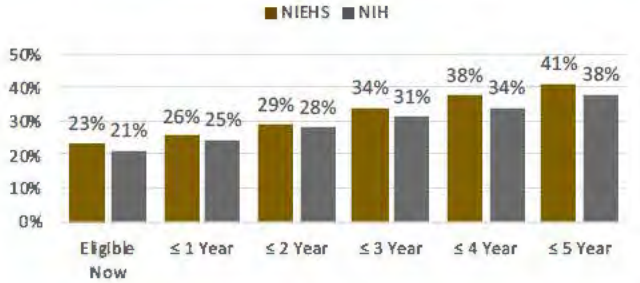
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIEHS = 5.74 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

**Budget Summary**
(Dollars in Millions)

| NIGMS | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 2,512.073 | 2,937.218 |
| Less (specify sources) | 780.000 | 1,230.821 |
| Total Budget Authority | 1,732.073 | 1,706.397 |
| FTE | 183 | 184 |

(b) (5)

## NIGMS MISSION

The National Institute of General Medical Sciences (NIGMS) was established in 1962 with a $124.6 million budget. In FY 2020, the Institute's budget was $2.937 billion. The vast majority of this money goes into local economies through grants to individual investigators at universities, medical schools, hospitals, and other research institutions throughout the country. NIGMS has always taken its role as a steward of taxpayer dollars seriously and has thus attempted to invest its resources in a manner that reflects its commitment to scientific impact and productivity, diversity, efficiency, and accountability.

NIGMS supports fundamental research that increases understanding of biological processes that lay the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS-funded scientists investigate how living systems work at a range of levels, from specific molecules and cells to tissues, whole organisms, and populations. The Institute also supports research in certain clinical areas, primarily those affecting multiple organ systems. To assure the vitality and continued productivity of the research, NIGMS provides leadership in training the next generation of scientists, in enhancing the diversity of the scientific workforce, and in developing institutional research capacities throughout the country.

NIGMS uses three major means to advance its mission:

- Grants that support scientific research at colleges, universities, medical schools, research institutes, and small businesses in areas related to NIGMS' mission. This effort includes promoting the ability of individual investigators to pursue new research directions, novel scientific insights and innovative ideas to optimize the likelihood of making important scientific discoveries and advances.
- Training and education awards that support the development of a diverse, multidisciplinary biomedical research workforce.
- Programs that support the development of and widespread access to high-quality research resources and technologies and that build capacity in under-resourced institutions and states.

## NIGMS BUDGET

The FY 2020 enacted budget for NIGMS is $2.9 billion. NIGMS supports fundamental biomedical research that feeds advances in scientific understanding, medicine, and technology. By defining the mechanisms of health and disease, providing targets for drug development, and developing new technologies, NIGMS-funded basic research is a critical driver of the U.S. economy. NIGMS supports more than 4,000 investigators and 5,000 research grants, helping to maintain a healthy research enterprise in every state in the nation as well as in U.S. territories. In addition, NIGMS is dedicated to boosting opportunities for

new and early career investigators to establish independent biomedical research programs and thus provides leadership in training the next generation of scientists.

**Budget Authority by Activity**
(Dollars in Millions)

| NIGMS Activity | FY 2016 Enacted | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Plan |
|---|---|---|---|---|---|
| **Extramural Research** | | | | | |
| **Detail** | | | | | |
| **Cell Biology and Biophysics** | 526.078 | 546.164 | 0 | 0 | 0 |
| **Biophysics, Biomedical Technology, and Computational Biosciences** | 252.926 | 288.772 | 522.123 | 549.307 | 572.066 |
| **Genetics and Molecular, Cellular, and Developmental Biology** | 525.571 | 554.874 | 833.115 | 842.773 | 877.691 |
| **Pharmacology, Physiology and Biological Chemistry** | 449.444 | 465.907 | 599.478 | 575.934 | 599.796 |
| **Training, Workforce Development and Diversity** | 326.636 | 314.035 | 320.212 | 323.908 | 337.328 |
| **Division for Research Capacity Building** | 360.339 | 400.871 | 427.256 | 448.604 | 467.191 |
| ***Institutional Development Award (IDeA) (non-add)*** | *320.840* | *333.361* | *350.575* | *361.573* | *386.573* |
| **Subtotal, Extramural** | 2,440.994 | 2,570.624 | 2,702.183 | 2,740.526 | 2,854.072 |
| **Intramural Research** | 3.747 | 3.676 | 3.588 | 3.979 | 4.145 |
| **Research Management & Support** | 67.333 | 71.852 | 75.254 | 77.375 | 79.000 |
| **TOTAL** | 2,512.073 | 2,646.152 | 2,781.024 | 2,821.880 | 2,937.218 |

## NIGMS PRIORITY ISSUES

Laboratory Safety: Ensuring the safety of NIGMS trainees and other laboratory staff is of utmost importance to the Institute. Thus, NIGMS is providing supplements to training grants for developing curricular materials related to laboratory safety.

Regional and National Resources: NIGMS is committed to supporting the development, maintenance, and accessibility of high-quality technologies and research resources, including laboratory and computational tools and technologies as well as reagent, biological and database resources.

Diversity of the Biomedical Research Workforce: NIGMS has recognized the historical need for enhanced diversity and representation in the biomedical research enterprise and has thus maintained a strong commitment to the principles of equity, diversity, and inclusion.

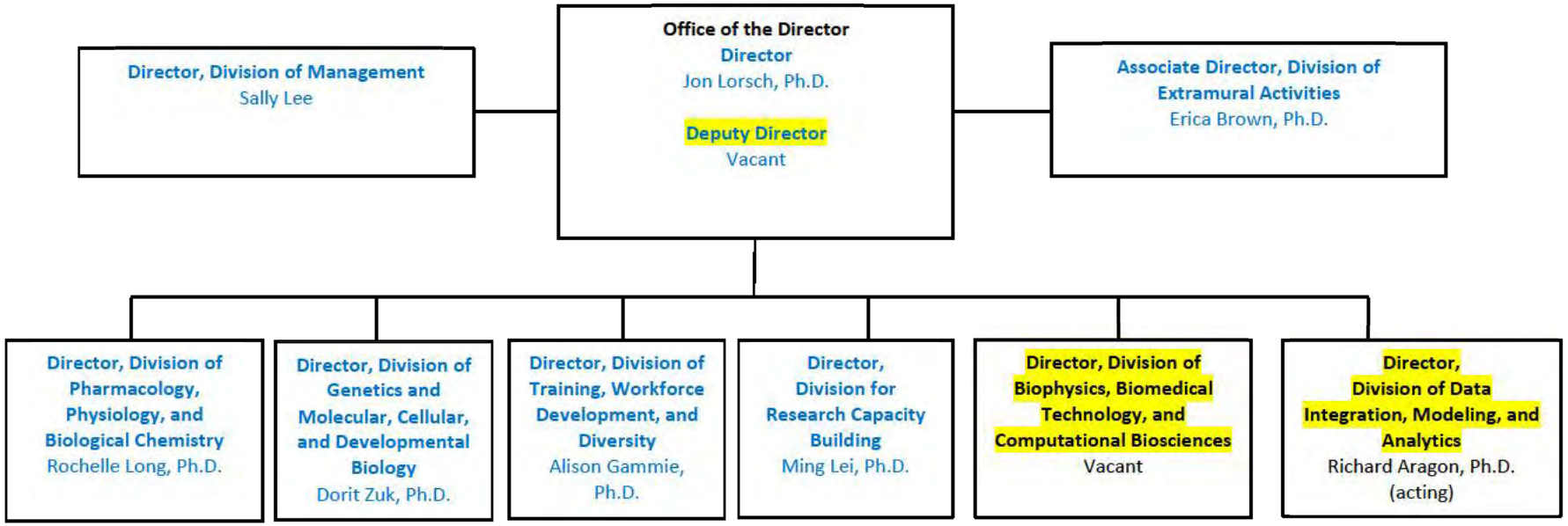
## NIGMS SIGNIFICANT CHANGES

Beginning in FY 2015, the NIGMS Budget Authority was reduced by roughly one-third. To keep the Institute's funding consistent with historical levels, the appropriators used Public Health Service (PHS) Evaluation Financing to replace the reduced NIGMS Budget Authority.

NIGMS has had several noteworthy changes in its operations:

- Division of Research Capacity Building (DRCB) – Formerly the Center for Research Capacity Building (CRCB), DRCB became a division in 2018 in order to better address the needs of NIGMS' research capacity building programs, including the Institutional Development Award (IDeA), the Support for Research Excellence (SuRE, formerly SCORE); and the Native American Research Centers for Health (NARCH). DRCB also houses the Science Education Partnership Awards (SEPA) program and oversees the STTR Regional Technology Transfer Accelerator Hubs for IDeA States. DRCB consists of the Networks and Development Programs Branch and the Research Advancement Programs Branch.
- Division of Data Integration, Modeling, and Analytics (DIMA) – Formerly the Office of Program Planning, Analysis, and Evaluation, DIMA became a division in January of 2020 commensurate with its increased capacity of serving as NIGMS' central nexus for all data-driven discussions, decisions, and actions. DIMA serves the Institute's Director, Deputy Director, Senior Staff, Scientific Divisions, and Program Staff by providing robust, timely, accurate, and contextually appropriate data and information that aid in the efficient administration of all NIGMS programs and in the proper stewardship of taxpayer resources. DIMA consists of the Data Modeling and Analytics Branch and the Data Integration and Dissemination Branch.
- Division of Cell Biology – In FY 2019, NIGMS received approval to re-organize, eliminating the Division of Cell Biology. Functional components of this Division were integrated into the Division of Genetics and Molecular, Cellular, and Developmental Biology.

## NIGMS ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories
Senior/Scientific Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position(acting)

**National Institute of General Medical Sciences**

Office of the Director

- Director, Jon Lorsch, Ph.D. (Scientific Executive Position)
- Deputy Director, Vacant (Scientific Executive Position)

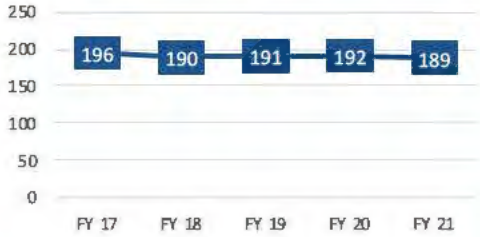
The following offices report directly to the Director:

- Director, Division of Extramural Activities
  - Erica Brown, Ph.D. (Scientific Executive Position)
- Director, Office of Administrative Management
  - Sally Lee (Senior Executive Position)
- Director, Division of Pharmacology, Physiology, and Biological Chemistry
  - Rochelle Long, Ph.D. (Scientific Executive Position)
- Director, Division of Genetics and Molecular, Cellular, and Developmental Biology
  - Dorit Zuk, Ph.D. (Scientific Executive Position)
- Director, Division of Training, Workforce Development, and Diversity
  - Alison Gammie, Ph.D. (Scientific Executive Position)
- Director, Division for Research Capacity Building
  - Ming Lei, Ph.D. (Scientific Executive Position)
- Director, Division of Biophysics, Biomedical Technology, and Computational Biosciences
  - Vacant (Scientific Executive Position)
- Director, Division of Data Integration, Modeling, and Analytics
  - Richard Aragon, Ph.D. (Acting; Scientific Executive Position)

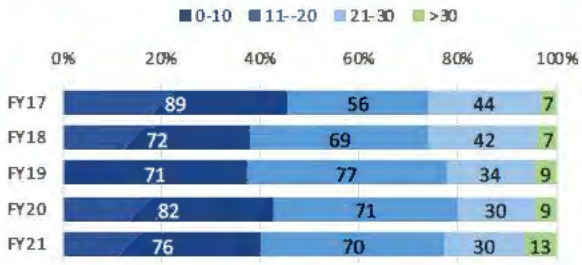
National Institute of General Medical Sciences

# NIGMS WORKFORCE SNAPSHOT [1]

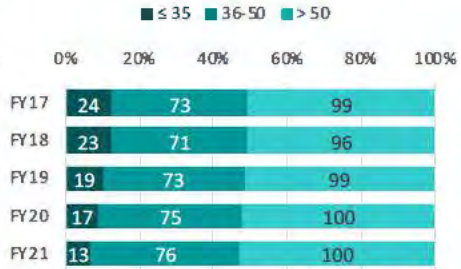
## Federal Employee Onboard (Headcount) Trending



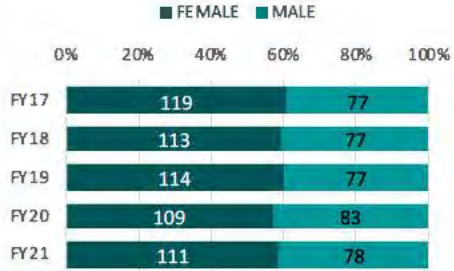

## Federal Length of Service (Yr.) Trending




## Age Trending

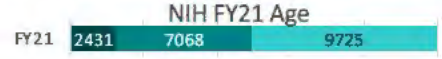



## Gender Trending



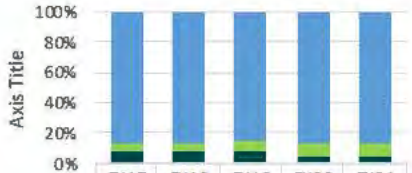

## NIH FY21 Federal Length of Service (Yr.)


## NIH FY21 Age




## NIH FY21 Gender

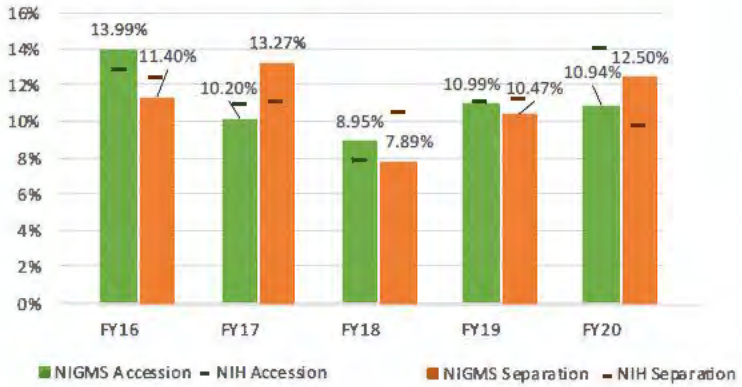

## Pay Plan Trending[2]



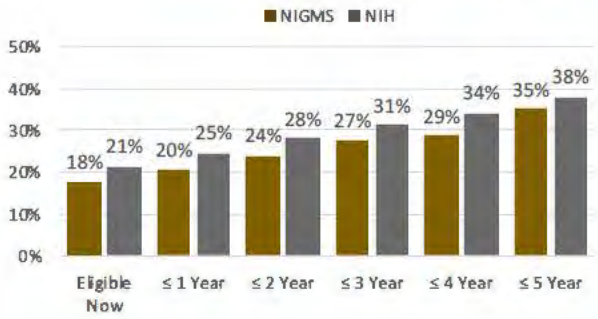

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 169 | 165 | 162 | 166 | 164 |
| EI | 11 | 11 | 15 | 16 | 15 |
| T42 | 16 | 13 | 13 | 9 | 9 |
| SES | 0 | 1 | 1 | 1 | 1 |
| CC | 0 | 0 | 0 | 0 | 0 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIGMS = 6.44 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

**Budget Summary**
(Dollars in Millions)

| NIMH | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 1,548.4 | 2,038.4 | |
| Less (HIV/AIDS Transfers) | 29.7 | 4.6 | |
| Less (Unobligated Balance) | | 2.0 | |
| Total Budget Authority | 1,518.7 | 2,045.0 | |
| FTE | 541 | 563 | |

## NIMH MISSION

On July 3, 1946, President Truman signed the National Mental Health Act, establishing the National Institute of Mental (NIMH) to address the mental health needs of returning veterans. NIMH since expanded and is the largest funder of research on mental disorders in the world. NIMH determines priorities based on scientific opportunity, Congressional mandates, and public health need. NIMH makes funding decisions with input from peer-review of grant applications and guidance from the National Advisory Mental Health Council. The NIMH Strategic Plan for Research outlines the scope of NIMH's major research programs. These programs range from understanding basic pathophysiology; to identifying causes and trajectories of mental illnesses; to developing innovative treatment and prevention strategies and ensuring public health impact. NIMH-funded basic research has led to discoveries including a strong genetic risk for schizophrenia; the first treatment specifically for postpartum depression; an effective medication for treatment-resistant depression; and a high-tech support system to slow the degradation of tissue in postmortem brains. The new Sensorimotor domain was added to the Research Domain Criteria (RDoC) initiative, NIMH's dynamic framework for investigating the nature of mental health and illness in terms of varying degrees of function and dysfunction in general psychological/biological systems. Translating scientific discovery to service delivery, NIMH also funds services research on effective interventions for children and adults. For example, NIMH supports pioneering advances in treatment for first episode psychosis (FEP), and mobile mental health that capitalizes on accessible technology.

## NIMH BUDGET

NIMH's FY 2020 enacted budget was $2,038.4 million, plus $4.6 million HIV/AIDS via transfer and $2.0 million unobligated balance to equal a total budget authority of $2,045.0 million. Budget Highlight Include Cures funding, NIMH's Brain Research to Advance Innovative Neurotechnologies (BRAIN) Initiative budget increased from $169.0 million in FY 2019 to $199.0 million in FY 2020.

**Budget Authority by Activity**
(Dollars in Millions)

| | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| **Extramural Research:** | | | |
| **Neuroscience and Basic Behavioral Science[1]** | 554.2 | 842.0 | |

| | | | (b) (5) |
|---|---|---|---|
| **Services and Intervention Research** | 147.1 | 157.7 | |
| **Translational Research** | 391.1 | 503.4 | |
| **AIDS Research** | 149.8 | 173.6 | |
| **Office of the Director** | 28.4 | 62.7 | |
| **Subtotal, Extramural Research** | 1,270.5 | 1,739.4 | |
| **Intramural Research** | 170.9 | 210.7 | |
| **Research Management & Support** | 77.2 | 94.8 | |
| **Total** | 1,518.7 | 2,045.0 | |

[1]Neuroscience and Basic Behavioral Science include the BRAIN Initiative and

## NIMH PRIORITY ISSUES

**Suicide Prevention:** Suicide is the tenth leading cause of death overall in the United States, with over 48,000 people dying by suicide each year. NIMH is committed to supporting research to improve the ability to identify who is at risk for suicide and develop effective treatments for at-risk individuals. As the government lead in the National Action Alliance for Suicide Prevention's Prioritized Research Agenda for Suicide Prevention, NIMH has helped shape priorities in suicide prevention research. Because many suicide decedents in the United States have accessed healthcare services in the 12 months preceding death, healthcare systems can play a vital role in identifying individuals at risk and preventing suicide attempts. NIMH research has identified a growing number of evidence-based suicide prevention tools that can be implemented in the healthcare system, such as the Ask Suicide-Screening Questions (ASQ) tool, a screening tool that takes only 20 seconds to administer, and Safety Planning, an approach that reduces access to lethal means, identifies coping strategies to decrease risk of suicidal behavior, and lists people and resources that could help in crisis. Also, emergency departments (ED) have begun using telehealth to address the shortage of ED-based mental health providers. NIMH is supporting these efforts through research to identify feasible approaches to telehealth-supplied suicide prevention practices. Additionally, NIMH Intramural Research Program (IRP) researchers discovered that the new medication esketamine is effective against treatment-resistant forms of depression—one of the main risk factors for suicide—and are working to understand the neurobiological underpinnings of suicide. NIMH continues to support research to identify who is most at risk for suicide, understanding the causes of suicide risk, developing interventions, and testing the effectiveness of suicide prevention services in real-world settings. NIMH also seeks to increase uptake of those practices known to be effective by working collaboratively with key stakeholders on practice, policy, and advocacy. Partnerships like these are essential for the uptake of evidence-based suicide prevention practices that save lives.

**Mental Health Disparities:** The challenges of developing effective and transformative treatments for mental illnesses are compounded by disparities in access to mental health care, which further disadvantage members of underrepresented and underserved groups and increase the burden of mental illnesses on individuals, families, and communities. NIMH supports a research agenda aimed at understanding and reducing mental health disparities. In 2018, NIMH formed the new Office for Disparities Research and Workforce Diversity (ODWD), to prioritize and coordinate research on delivering effective treatment to underserved communities, including people living in rural areas and racial, ethnic, and sexual and gender minorities. In collaboration with the NIMH Center for Global Mental Health Research, ODWD is encouraging research to better understand the genetic, neurobiological, psychosocial, and environmental mechanisms/or factors that underlie mental health disparities through the Ending Disparities in Mental Health (EDIfy-MH) program.

**Psychosis and schizophrenia:** Schizophrenia is a serious mental illness (SMI) and one of the top 15 leading causes of disability worldwide. The disorder is characterized by alterations in a person's thoughts, feelings, and behaviors, which can include a loss of contact with reality known as psychosis. Delaying the start of treatment is often associated with poorer response and significantly worse long-term outcomes. Detection and intervention before psychosis develops, when individuals are at clinical high risk for psychosis, could attenuate, postpone, or even prevent the transition to psychosis, and improve individuals' clinical and functional outcomes. NIMH supports research aimed at early identification and prevention of psychosis. For example, the NIMH-funded Recovery After an Initial Schizophrenia Episode (RAISE) project showed that services research can speed implementation of coordinated specialty care (CSC) for early psychosis in community settings by optimizing the organization and delivery of current treatments. NIMH followed up on the RAISE project findings by establishing the Early Psychosis Intervention Network (EPINET). EPINET aims to create an early psychosis "learning healthcare system," where data that are routinely collected in CSC programs as part of clinical practice drive continuous improvement in patient care and scientific discovery. NIMH support for schizophrenia research is also focused on translating genetic associations into causal disease mechanisms. For example, NIMH encourages research to develop and apply resources and tools for the large-scale and systematic genetic fine-mapping of serious mental illnesses and related traits. This Fall, NIMH joined other NIH Institutes to launch the Accelerating Medicines Partnership – Schizophrenia to focus on discovering better ways to identify and treat individuals at high risk for developing psychosis.

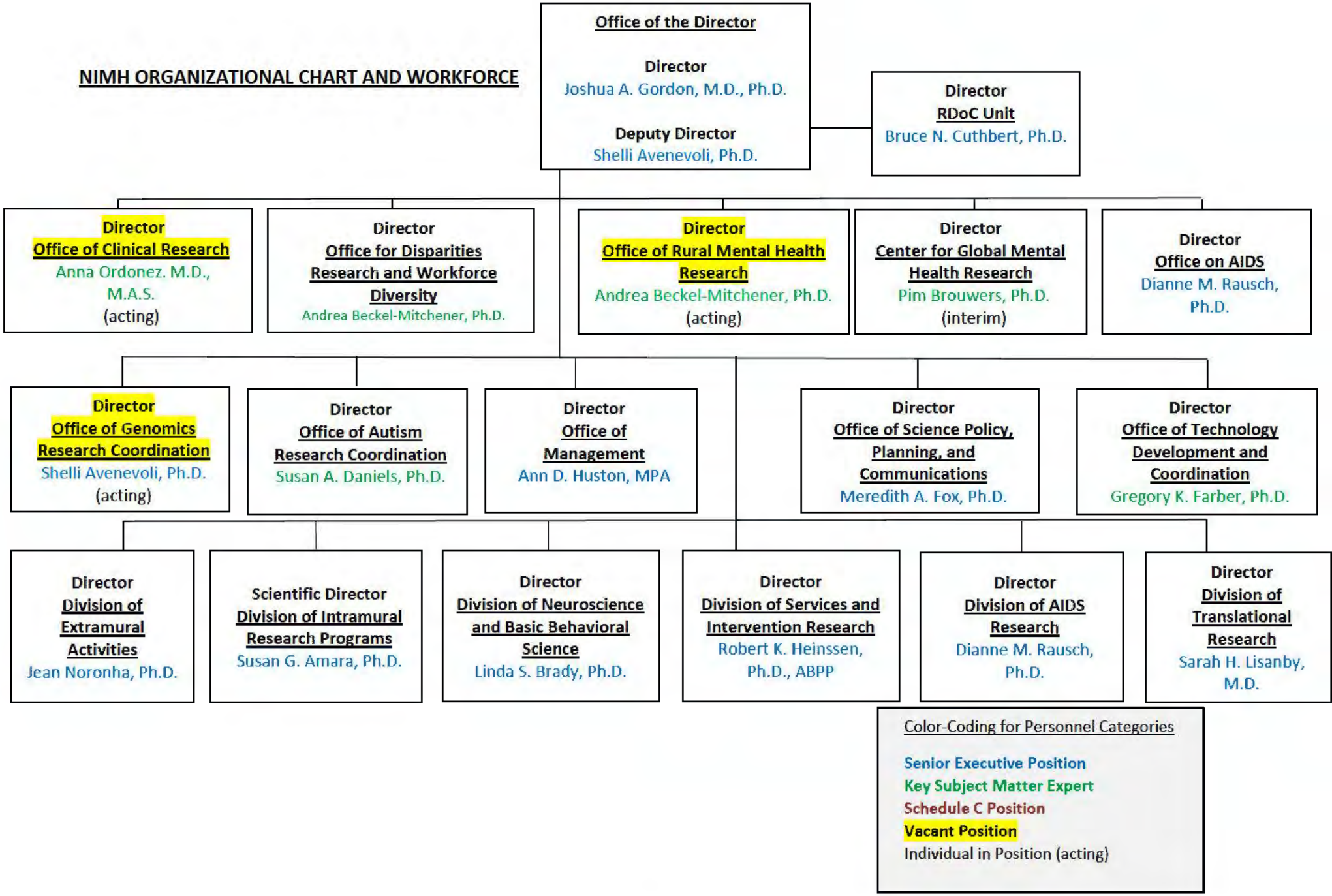
**Autism Spectrum Disorder (ASD):** An estimated 1 in 54 eight-year old children in the United States have ASD, a developmental disorder that affects social communication and behavior. NIMH chairs the Congressionally authorized NIH Autism Coordinating Committee (ACC) to promote the quality and pace of ASD research across NIH. The NIMH Director also chairs the Interagency Autism Coordinating Committee (IACC), a Federal advisory committee composed of Federal and public members. NIMH supports a wide spectrum of ASD research including services research across the lifespan (e.g., the Autism Centers of Excellence) and resources to support research (e.g., the National Database for Autism Research (NDAR) and human biobanks). Recognizing that early screening and diagnosis of ASD is critical to optimizing outcomes, NIMH supports research projects to develop and validate screening tools that can be implemented in the general population and in community settings to detect signs of ASD in the first year of life. The identification of biomarkers is another essential aspect of NIMH's efforts to improve early identification of ASD. For example, through the Autism Biomarker Consortium for Clinical Trials, NIMH co-funds a multi-site study of preschool (3-5 years) and school aged (6-11 years) children with and without ASD to test the utility of specified biomarkers for future use to improve clinical trials.

**Computational Neuroscience:** NIMH is dedicated to supporting computational approaches that integrate knowledge about mental illnesses gained at genetic, molecular, cellular, circuit, behavioral, and healthcare system levels. Advances in analysis of single-cell technologies hold promise for mapping the molecular and cellular diversity of the brain, and new ways to measure multiple molecular features that control genes (multi-omics) allow deeper biological understanding from large collections of brain tissues and genetic data. Computational methods can be used to integrate precise genomic information provided by single-cell approaches with multi-omic information gathered from adult brain tissue samples. NIMH is supporting an initiative that encourages researchers to develop new, or adapt existing approaches to inform integrative analyses of single-cell and tissue multi-omic datasets from brain samples to achieve new insights into the biology of mental illnesses.

## NIMH SIGNIFICANT CHANGES

NIMH does not have any Significant Changes to report.

# NIMH ORGANIZATIONAL CHART AND WORKFORCE



**National Institute of Mental Health**

National Institute of Mental Health

- Director, Joshua A. Gordon, M.D., Ph.D. (Scientific Executive Position)
- Deputy Director, Shelli Avenevoli, Ph.D. (Senior Executive Position)

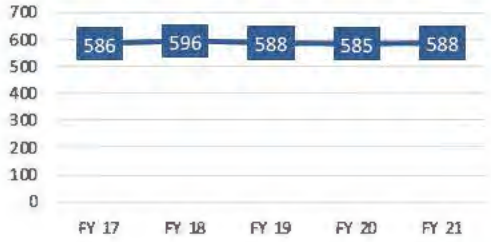
The following offices report directly to the Director:

- Director of the Research Domain Criteria (RDoC) Unit
  - Bruce N. Cuthbert, Ph.D. (Scientific Executive Position)
- Director of the Office of Clinical Research
  - Anna Ordonez, M.D., M.A.S. (Acting)
- Director of the Office for Disparities Research and Workforce Diversity
  - Andrea Beckel-Mitchener, Ph.D.
- Director of the Office of Rural Mental Health Research
  - Andrea Beckel-Mitchener, Ph.D. (Acting)
- Interim Director of the Center for Global Mental Health Research
  - Pim Brouwers, Ph.D.
- Director of the Office on AIDS
  - Dianne M. Rausch, Ph.D. (Scientific Executive Position)
- Director of the Office of Genomics Research Coordination
  - Shelli Avenevoli, Ph.D. (Acting)
- Director of the Office of Autism Research Coordination
  - Susan A. Daniels, Ph.D.
- Director of the Office of Management
  - Ann D. Huston, M.P.A. (Senior Executive Position)
- Director of the Office of Science Policy, Planning, and Communications
  - Meredith A. Fox, Ph.D. (Scientific Executive Position)
- Director of the Office of Technology Development and Coordination
  - Gregory K. Farber, Ph.D.
- Director of the Division of Extramural Activities
  - Jean Noronha, Ph.D. (Scientific Executive Position)
- Scientific Director of the Division of Intramural Research Programs
  - Susan G. Amara, Ph.D. (Scientific Executive Position)
- Director of the Division of Neuroscience and Basic Behavioral Science
  - Linda S. Brady, Ph.D. (Scientific Executive Position)
- Director of the Division of Services and Intervention Research
  - Robert K. Heinssen, Ph.D., ABPP (Scientific Executive Position)
- Director of the Division of AIDS Research
  - Dianne M. Rausch, Ph.D. (Scientific Executive Position)
- Director of the Division of Translational Research
  - Sarah H. Lisanby, M.D. (Scientific Executive Position)

National Institute of Mental Health

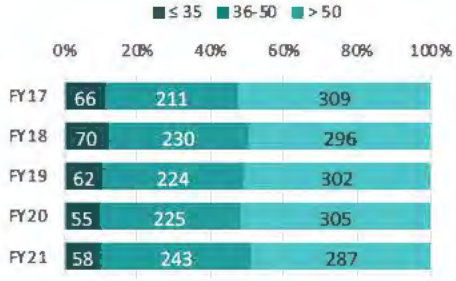
# NIMH WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

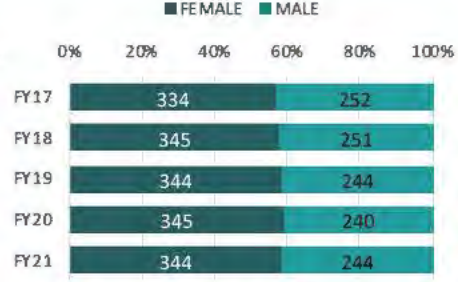



## Federal Length of Service (Yr.) Trending


## Age Trending



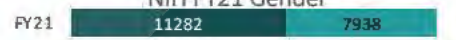

## Gender Trending



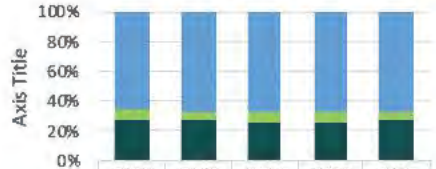

## NIH FY21 Federal Length of Service (Yr.)


## NIH FY21 Age


## NIH FY21 Gender



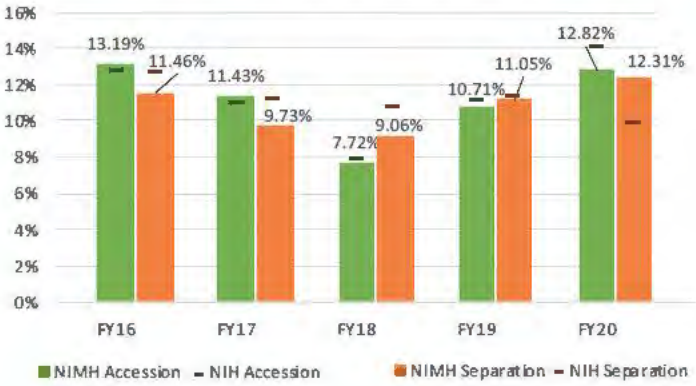

## Pay Plan Trending[2]



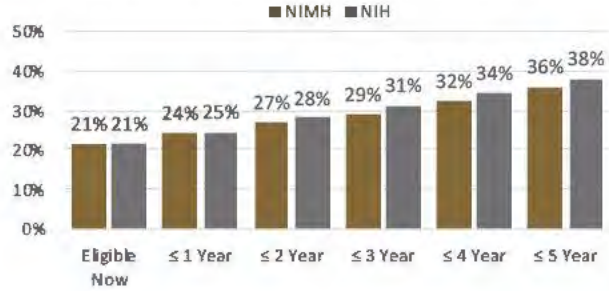

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 383 | 403 | 400 | 394 | 400 |
| EI | 44 | 29 | 38 | 42 | 29 |
| T42 | 154 | 160 | 147 | 146 | 157 |
| SES | 3 | 3 | 3 | 3 | 2 |
| CC | 2 | 1 | 0 | 0 | 0 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NIMH = 5.03 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

**Budget Summary**
(Dollars in Mi

(b) (5)

| NIMHD | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 280.680 | 335.812 |
| Less (specify sources) | | |
| Total Budget Authority | 280.680 | 335.812 |
| FTE | 64 | 68 |

## NIMHD MISSION

The National Institute on Minority Health and Health Disparities (NIMHD) guides the fields of both minority health (MH) and health disparities (HD) research by supporting investigator-initiated research projects, community-based participatory research (CBPR), Centers of Excellence programs, research infrastructure development, and training initiatives. NIMHD's work touches the lives of millions of Americans burdened by disparities in health outcomes and racial and ethnic minority group status, residing in rural areas, being of low socioeconomic status, and other population groups subject to discrimination.

NIMHD leads the development of the NIH's MH and HD research priorities as outlined in legislation (Sec 10334, Affordable Care Act). Specifically, in collaboration with other NIH ICOs, NIMHD plans, reviews, coordinates, and evaluates minority health and health disparities research activities and budgets across NIH.

In 1990, the Office of Minority Programs (OMP) was established in the NIH Office of the Director and in 1993, became the Office of Research on Minority Health. The National Center on Minority Health and Health Disparities (NCMHD) was established by the passage of the Minority Health and Health Disparities Research and Education Act of 2000 (P.L. 106-525) on November 22, 2000. NIMHD was re-designated as an Institute by the Patient Protection and Affordable Care Act (P.L. 111-148) on March 23, 2010.

Recent accomplishments by the NIMHD include the launch of the Social Epigenomics Research Initiative on Minority Health and Health Disparities, which supports and accelerates human epigenomic investigations focused on identifying and characterizing the mechanisms by which social experiences at various stages in life affect gene function and influence health trajectories or modify disease risk in racial and ethnic minority and other populations with health disparities. Research from the *Social Adversities, Epigenetics, and the Obesity Epidemic* study seeks to understand the mechanisms by which social adversity confers risk for obesity in youth. Another programmatic accomplishment is the Collaborative Minority Health and Health Disparities Research with Tribal Epidemiology Centers, in which *the Impact of Navajo Nation Tax on Junk Food* study is examining the impact of the Healthy Diné Nation Act (HDNA) passed in November 2014, which imposes an 8.2 percent tax on junk food and distributes the revenue among local governments to support and develop local wellness projects. A third program, the Specialized Centers of Excellence on Minority Health and Health Disparities, supports transdisciplinary, multi-level research and provides research opportunities for post-doctoral fellows, junior faculty, and

other ESIs. One NIMHD-funded Center, the *New York University Center for the Study of Asian American Health (CSAAH)* aims to understand, address, and reduce Asian American health disparities.

## NIMHD BUDGET

NIMHD's FY 2020 Enacted funding level, in the amount of $335,812,000, is $22.6 million (or 6.7 percent) above the FY 2019 Enacted funding level ($313,211,000). NIMHD's congressionally appropriated funds are utilized to fund various research programs and facets of the agency, such as, but not limited to, research grants, Research Centers in Minority Institutions (RCMI) program, and operational support. The increased level of funding contributed to NIMHD's continuing effort in increasing its research project grant (RPG) portfolio through providing additional opportunities to the research community and allocating resources to investigator-initiated research projects and other health disparity-specific research programs in an effort to broaden the Institute's research portfolio. By advancing the scientific understanding of mechanisms that lead to health disparities, NIMHD will maximize its impact on improving minority health and reducing health disparities.

In FY 2020, the Research Centers in Minority Institutions (RCMI) program was allocated $75,000,000, which is 15.8 percent above the FY 2019 allocation. RCMI provides grants to institutions that award doctoral degrees in the health professions or health-related sciences and have a significant enrollment of students from racial and ethnic minority groups that are underrepresented in biomedical sciences. The program is funded from NIMHD's base funding.

**Budget Authority by Activity**
(Dollars in Millions)

| NIMHD Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Enacted |
|---|---|---|---|---|---|
| Integrative Biological and Behavioral Sciences | 84.947 | 135.500 | 53.375 | 50.358 | 52.964 |
| Community Health and Population Sciences | 68.560 | 47.706 | 69.788 | 46.797 | 47.968 |
| Clinical and Health Services Research | 70.712 | 73.423 | 34.967 | 67.589 | 66.519 |
| Research Centers on Minority Health and Health Disparities | 14.395 | 8.778 | 95.790 | 96.271 | 107.658 |
| Training and Career Development | | | 26.255 | 25.979 | 28.003 |
| Subtotal, Extramural | 256.614 | 263.408 | 280.176 | 286.995 | 303.112 |
| Intramural Research | 5.848 | 5.216 | 4.114 | 5.113 | 7.500 |
| Research Management & Support | 17.831 | 19.046 | 20.107 | 21.104 | 25.200 |
| TOTAL | 280.293 | 287.670 | 304.396 | 313.211 | 335.812 |

## NIMHD PRIORITY ISSUES

There are four priority issues for NIMHD, two of which have also been identified as top issues at the NIH level. These include *Health Disparities Research in the Biomedical Enterprise*, with a focus on health disparities research in communities, rural health and the importance of social determinants of health; and *Inclusion of Underrepresented populations in research*. More information on these top issues is included in the overall NIH issues section. The other two issues relate to *Chronic health care outcomes*

*post disaster*; and *Community-engaged interventions to promote healthy lifestyles and manage chronic disease*.

## NIMHD SIGNIFICANT CHANGES

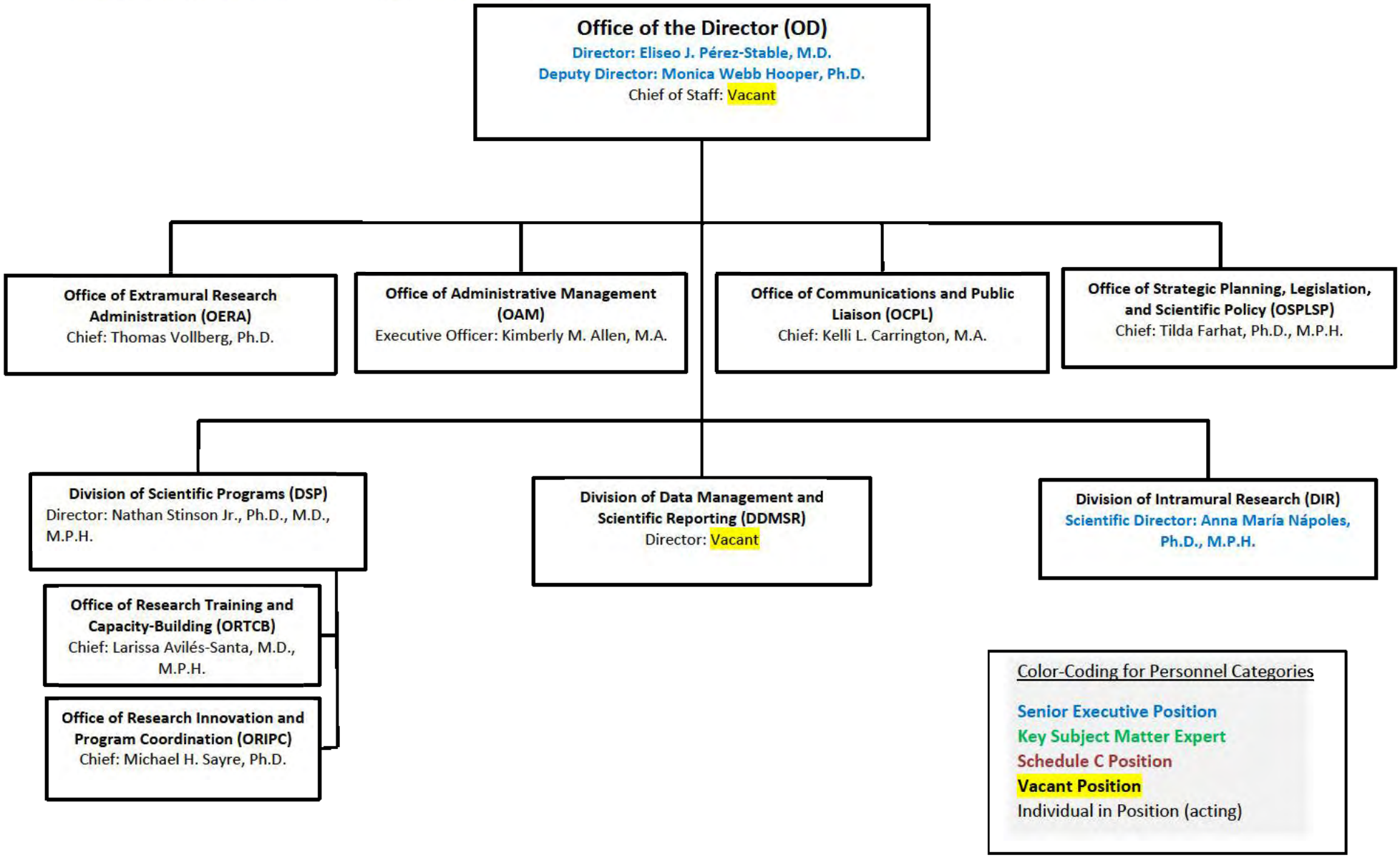
In 2017, Dr. Anna Maria Napoles became the second NIMHD Scientific Director.

In 2017, NIMHD established three extramural research interest areas: Community and Health Services Research, Integrative Biological and Behavioral Research, and Community Health and Population Sciences.

In 2018, the NIMHD Minority Health and Health Disparities Research Framework was released.

In 2020, Dr. Monica Webb-Hooper became the second NIMHD Deputy Director.

## NIMHD ORGANIZATIONAL CHART AND WORKFORCE



**National Institute on Minority Health and Health Disparities**

- Office of the Director
  - Director, Eliseo J. Pérez-Stable, M.D. (Senior Executive Position)
  - Deputy Director, Monica Webb Hooper, Ph.D. (Senior Executive Position)
  - Chief of Staff, Vacant

The following Divisions/Offices report directly to the Director, NIMHD:

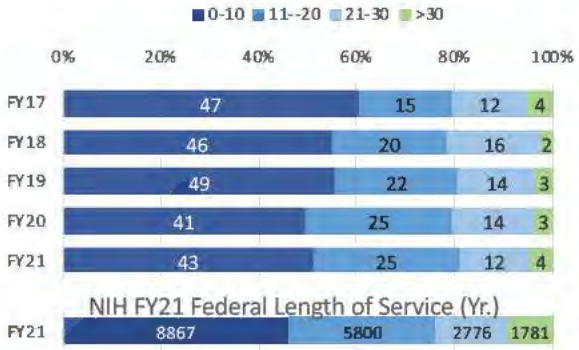
- Office of Administrative Management
  - Executive Officer, Kimberly M. Allen, M.A.
- Division of Scientific Programs
  - Director, Nathaniel Stinson, Ph.D., M.D., M.P.H
- Division of Intramural Research
  - Scientific Director, Anna María Nápoles, Ph.D., M.P.H. (Senior Executive Position)
- Division of Data Management and Scientific Reporting
  - Director, (Vacant)
- Office of Extramural Research Administration
  - Chief, Thomas Vollberg, Ph.D.
- Office of Strategic Planning, Legislation, and Scientific Policy
  - Chief, Tilda Farhat, Ph.D., M.P.H.
- Office of Communications and Public Liaison (OCPL)
  - Chief, Kelli L. Carrington, M.A.

National Institute on Minority Health and Health Disparities

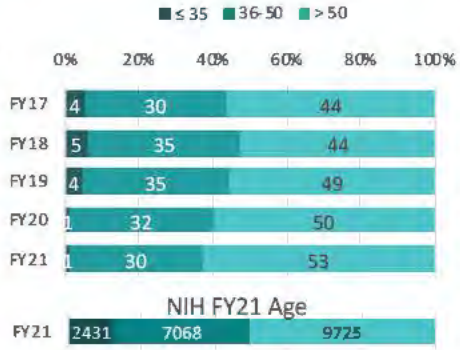
# NIMHD WORKFORCE SNAPSHOT [1]

## Federal Employee Onboard (Headcount) Trending

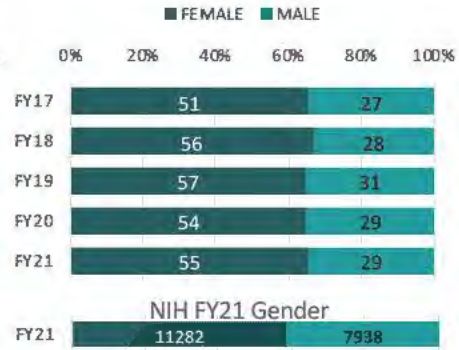

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



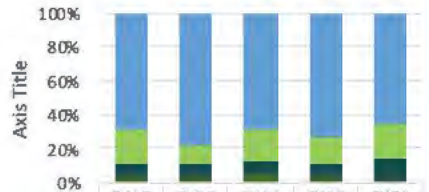

## NIH FY21 Age




## NIH FY21 Gender

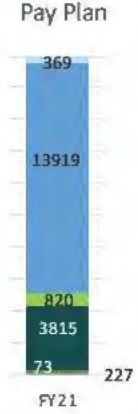



## Pay Plan Trending[2]

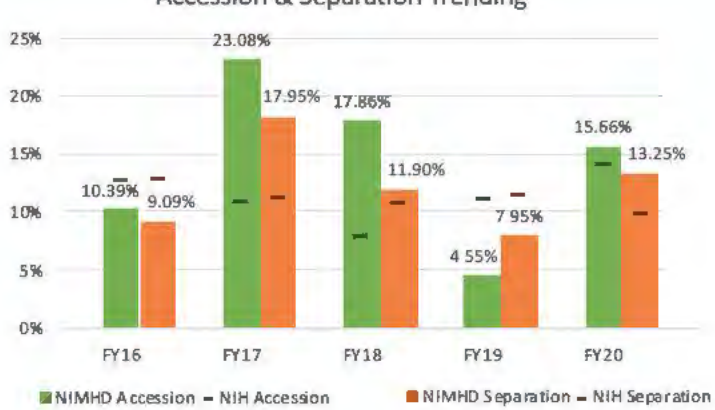



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 53 | 65 | 60 | 60 | 55 |
| EI | 16 | 10 | 17 | 13 | 17 |
| T42 | 6 | 6 | 7 | 7 | 10 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 3 | 3 | 4 | 3 | 2 |

## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]


Average time FTEs stayed past retirement eligibility
NIMHD = 7.75 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

**Budget Summary**
(Dollars in Mil

(b) (5)

| NINDS | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 1,692.832 | 2,376.577 |
| Less (specify sources ) | | |
| Total Budget Authority | 1,692.832 | 2,376.577 |
| FTE | 520 | 532 |

## NINDS MISSION

The National Institute of Neurological Disorders and Stroke (NINDS) was established in 1950 and is the nation's largest funder of neuroscience research. NINDS supports and conducts research to understand the brain and nervous system and to improve diagnosis, prevention, and treatment for common and rare neurological diseases that affect millions of Americans. The NINDS Extramural Research Program supports neuroscience research through grants and contracts to academic institutions, medical centers, research institutes, and small businesses. NINDS identifies promising research through peer review of investigator-initiated proposals and solicits proposals for public health needs and exceptional opportunities. The NINDS Intramural Research Program and ten other Institutes conduct basic and clinical neuroscience research in over 150 laboratories on the NIH campus, creating a rich environment for innovative, multidisciplinary studies and for research training. NINDS is also a leading partner in Trans-NIH Neuroscience Initiatives, including the NIH BRAIN Initiative, the NIH Blueprint for Neuroscience Research, research on Alzheimer's Disease Related Dementias (ADRD), the NIH Pain Consortium, and the NIH HEAL[SM] Initiative to address the opioid crisis.

The Division of Neuroscience (DON) is the largest part of the NINDS extramural program, supporting research on the normal brain, spinal cord, and nerves of the body; neurological disease mechanisms; and the early development of diagnostics and treatments. Such basic neuroscience research drives progress in public and private sectors and is a major NINDS priority. Investigator-initiated research is the foundation of NINDS basic research, and NINDS also promotes fundamental research through a targeted initiative. Other DON programs support research resources, core facilities, and scientific conferences. The Division of Extramural Activities (DEA) leads NINDS extramural support for research training and career development, workforce diversity, and enhancing research rigor and reproducibility.

The Division of Translational Research (DTR) leads milestone-driven programs that support therapy development for neurological disorders, including small molecule drugs, biologic therapies, and devices, as well as biomarkers to aid in clinical trials. NINDS has driven past advances such as the first enzyme replacement therapies and several drugs for epilepsy. Recent successes include the first gene-targeted and disease modifying treatments for spinal muscular atrophy and muscular dystrophy, and new biologic and drug therapies have entered clinical trials for Parkinson's disease, ALS, and other conditions. NINDS programs are also advancing technology for brain computer interfaces and brain stimulation therapies for Parkinson's disease, epilepsy, spinal cord injury, and other conditions.

The Division of Clinical Research (DCR) supports clinical research infrastructure and large-scale clinical research. NINDS clinical trials led to the first emergency treatment for stroke, and in 2018, showed that brain imaging can identify stroke patients who can benefit from brain clot removal far longer after stroke than once thought possible. Recent studies have also informed care for epilepsy and traumatic brain injury and shed light on the role of vascular risk factors in dementia. NINDS innovations to improve clinical research efficiency are used widely across NIH. Current NINDS clinical networks are the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) for early phase studies; StrokeNet for stroke trials; Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) led jointly with NHLBI; and Early Phase Pain Investigation Clinical Network (EPPIC-Net), part of the NIH HEAL initiative.

## NINDS BUDGET

Extramural research, including funding through DEA, DON, DCR, and DTR, accounted for approximately 87 percent of the total NINDS budget in FY 2020. Other budget components are DIR; Research, Management, and Support (RMS); and funds for NINDS activities within the NIH HEAL℠ Initiative.

**Budget Authority by Activity**
(Dollars in Millions)

| NINDS Activity | FY 2016 Enacted | FY 2017 Enacted | FY 2018 Enacted | FY 2019 Enacted | FY 2020 Enacted |
|---|---|---|---|---|---|
| Division of Clinical Research | 141.643 | 130.122 | 128.646 | 116.378 | 156.363 |
| Division of Extramural Activities | 75.536 | 96.859 | 84.517 | 100.225 | 93.663 |
| Division of Neuroscience | 1,178.446 | 1,229.495 | 1,333.687 | 1,353.137 | 1,445.884 |
| Division of Translational Research | 64.280 | 75.704 | 81.460 | 106.341 | 129.703 |
| Division of Intramural Research | 165.878 | 172.615 | 181.936 | 191.214 | 200.748 |
| Research Management & Support | 67.050 | 73.893 | 77.884 | 80.670 | 83.896 |
| Helping to End Addition Long-term (HEAL) | - | - | 213.900 | 240.843 | 266.321 |
| TOTAL NINDS | 1,692.832 | 1,778.688 | 2,102.030 | 2,188.808 | 2,376.577 |

## NINDS PRIORITY ISSUES

**NIH BRAIN Initiative—BRAIN 2.0:** The NIH BRAIN Initiative began in 2014, ramped up to $500 million in FY 2020 with funds from regular appropriations and the 21st Century Cures Act. A BRAIN Director is now in place, and an external BRAIN 2.0 group assessed progress and reported in 2019 that the Initiative is advancing so well on its original priorities that that it could invest in larger, transformative projects. These projects will create a comprehensive parts list of cell types in the human brain, wiring diagrams of the complete mouse brain and long-range nerve pathways in primate (including human) brains, and an armamentarium of tools to access brain cells and circuits. Although focused initially on the normal brain, the extent to which BRAIN is opening avenues for progress against human disease is encouraging.

**COVID-19 — Neurological consequences and post-COVID symptoms:** NINDS supports infrastructure to collect data on neurologic manifestations of COVID-19 and has funded five grant supplements to gather

clinical, imaging, and other data. No clear evidence shows that SARS-CoV-2 infects the brain, but it can cause blood clots throughout the body, which can lead to stroke. After COVID-19 recovery, rare cases of acute necrotizing hemorrhagic encephalopathy, acute disseminated encephalomyelitis, anti-NMDA receptor encephalitis, transverse myelitis, and Guillain Barré Syndrome have been reported and may relate to the immune response to the virus targeting the nervous system. NINDS is monitoring reports of persistent fatigue, pain, cognitive slowing (or "brain fog"), and other symptoms weeks after infection in some people; and is working with other NIH Institutes to identify and address post-COVID disability.

**Myalgic encephalomyelitis/Chronic fatigue syndrome (ME/CFS) research:** In October 2015, NIH announced actions to advance ME/CFS research. Since then, 23 NIH ICOs have coordinated ME/CFS research through the Trans-NIH ME/CFS Working Group. In 2017, NIH established ME/CFS Collaborative Research Centers and continues to fund these centers to improve understanding of the causes of ME/CFS. A recent publication from an intramural ME/CFS study that conducted outpatient focus groups provides qualitative assessments of post-exertional malaise, a central feature of ME/CFS. Some COVID-19 patients are experiencing chronic fatigue similar to ME/CFS that can linger months after infection. So-called long-haulers (individuals with chronic post-COVID-19 symptoms) and ME/CFS advocates call for research to follow people with chronic post-COVID-19 symptoms. NIH funding opportunities continue to stimulate ME/CFS research, and strategic planning for ME/CFS research will begin in Fall 2020.

**Gene-Based Therapies for Ultra-Rare Neurological Disorders:** About 45 percent of rare diseases are neurological disorders, and 90 percent of rare childhood disorders have major neurological effects. Most rare diseases have a genetic origin; in many cases, the causal mutations are unique to very small numbers of people, sometimes to a single patient. Combined, rare diseases represent a large medical need; but few have FDA-approved treatments, and the small number of patients with each condition limits incentives for commercial investment and presents challenges for research and regulatory approval. NINDS is establishing the Ultra-rare Gene Therapy Network (URGenT) to support the development of state-of-the-art gene-based therapies for ultra-rare diseases, which affect one or less than one in 50,000 people.

**Human Fetal Tissue Research:** In June 2019, HHS announced new policies regulating the use of HFT in research. The policies have implications across biomedical research, including neuroscience research supported by NINDS and the NIH BRAIN Initiative. Many neurological disorders with life-long burden are due to abnormal brain development. HFT has been used to study human neurological diseases and aspects of normal and abnormal brain development that are unique to humans and cannot be understood solely by studies in animal or cell models. The neuroscience community is concerned that restricting research using ethically sourced fetal tissue will limit important opportunities for progress.

## NINDS SIGNIFICANT CHANGES

In FY 2016**,** as part of the National Plan to Address Alzheimer's Disease**,** NINDS and NIA worked together to support research on Alzheimer's Disease (AD), and Alzheimer's Disease Related Dementias (ADRD), to set national research priorities, and since FY 2017, to produce an annual budget estimate for NIH AD/ADRD initiatives. With additional appropriations to NIA, NIH AD research funding grew nearly 4.5-fold from FY 2015 to FY 2020. NIA provides a portion of its AD funds to NINDS for ADRD research, and since FY 2016, both institutes use an extended payline for these areas to fund more meritorious applications. In 2020, NIA and NINDS launched an intramural center for ADRD research to take advantage of the unique resources of the NIH intramural research program.

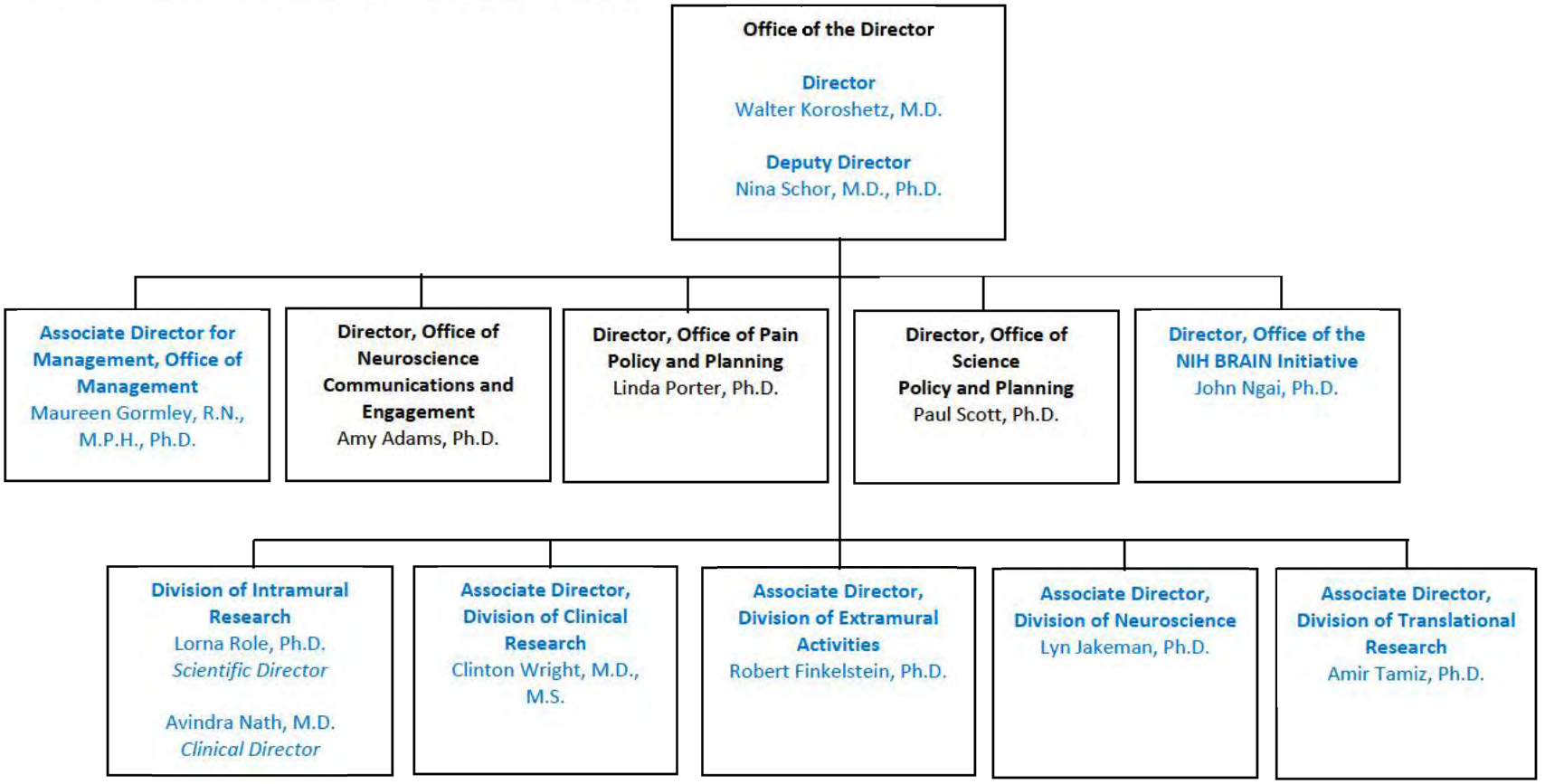
August 2016, NINDS hired an Associate Director for Management (ADM), filling a new position to oversee NINDS-wide process improvement and leadership development. The ADM led efforts to enhance supervisors' skills to lead effectively, launch an executive coach training program, and establish a peer advisory network to prevent harassment. In addition, internal reorganizations have integrated scientific program and administrative leadership. NINDS received an Organizational Excellence and Impact Award from the national Organizational Development network for these multi-year efforts.

September 2016, NINDS implemented a new divisional structure for its extramural research program, establishing the Division of Neuroscience (DON), Division of Extramural Activities (DEA), Division of Translational Research (DTR), and the Division of Clinical Research (DCR).

April 2018, the NIH HEAL Initiative launched as an aggressive trans-agency effort to provide scientific solutions to the national opioid overdose crisis, including improved treatments for pain and opioid use disorder. The crisis of opioid misuse, addiction, and overdose affects people of all ages in communities nationwide. Opioid medications are prescribed for many of the 50 million Americans with chronic pain yet are not effective for all people. The HEAL Initiative augments ongoing NIH investments, including the discovery and testing of non-addictive alternatives to opioids. NINDS leads HEAL Initiative programs to advance the preclinical discovery and development of new medications and devices to treat acute and chronic pain conditions, and to evaluate the effectiveness of therapies through the clinical trial pipeline. NINDS funded $773M through HEAL programs in FY 2018 to FY 2020.

February 2019, Dr. Lorna Role became the Scientific Director of the NINDS Intramural Research Program, replacing Dr. Alan Koretsky who had served as Scientific Director since 2006. Dr. Role has worked to enhance shared resources for neuroscience research, promote collaboration across disciplines, and enhance research training and initiatives for improving workforce diversity.

## NINDS ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**National Institute of Neurological Disorders and Stroke**

Office of the Director

- Director, Walter Koroshetz, M.D. (Senior Executive Position)
- Deputy Director, Nina Schor, M.D., Ph.D. (Senior Executive Position)

The following offices report directly to the NINDS Director:

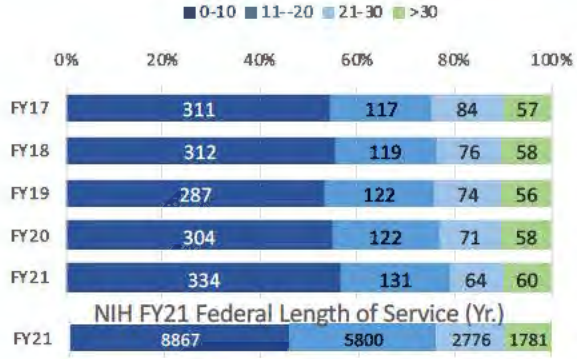
- Associate Director for Management, Office of Management
    - Maureen Gormley, R.N., M.P.H., Ph.D. (Senior Executive Position)
- Director, Office of Neuroscience Communications and Engagement
    - Amy Adams, Ph.D.
- Director, Office of Pain Policy and Planning
    - Linda Porter, Ph.D.
- Director, Office of Science Policy and Planning
    - Paul Scott, Ph.D.
- Director, Office of the NIH Brain Initiative
    - John Ngai, Ph.D. (Senior Executive Position)
- Scientific Director, Division of Intramural Research
    - Lorna Role, Ph.D. (Senior Executive Position)
- Clinical Director, Division of Intramural Research
    - Avindra Nath, M.D. (Senior Executive Position)
- Associate Director, Division of Clinical Research
    - Clinton Wright, M.D., M.S. (Senior Executive Position)
- Associate Director, Division of Extramural Activities
    - Robert Finkelstein, Ph.D. (Senior Executive Position)
- Associate Director, Division of Neuroscience
    - Lyn Jakeman, Ph.D. (Senior Executive Position)
- Associate Director, Division of Translational Research
    - Amir Tamiz, Ph.D. (Senior Executive Position)

National Institute of Neurological Disorders and Stroke

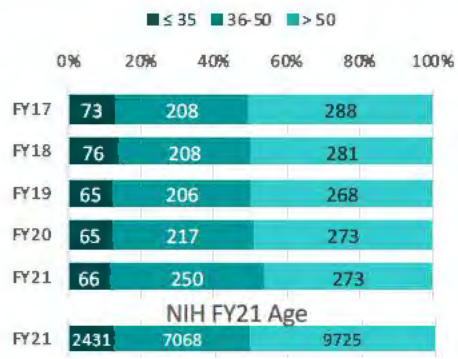
# NINDS WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

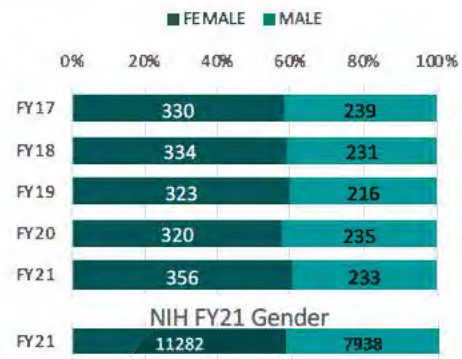

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



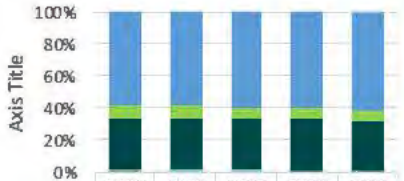

## NIH FY21 Age




## NIH FY21 Gender

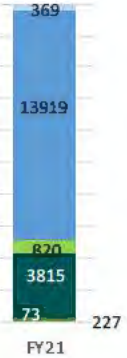



## Pay Plan Trending[2]

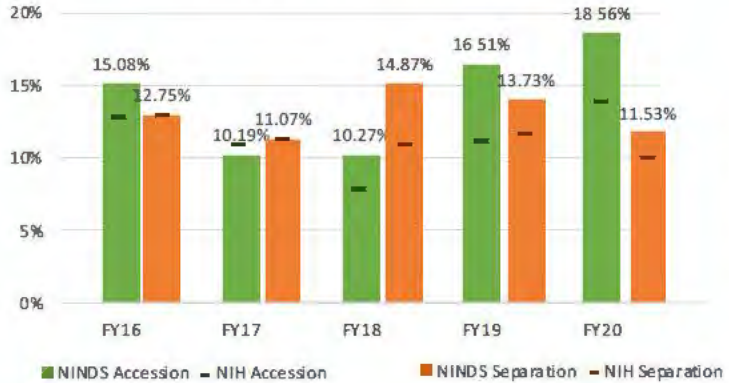



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 1 | 1 | 1 | 1 | 1 |
| GS | 331 | 329 | 321 | 328 | 359 |
| EI | 43 | 45 | 36 | 41 | 40 |
| T42 | 184 | 182 | 174 | 180 | 185 |
| SES | 2 | 2 | 2 | 1 | 1 |
| CC | 8 | 6 | 5 | 4 | 3 |

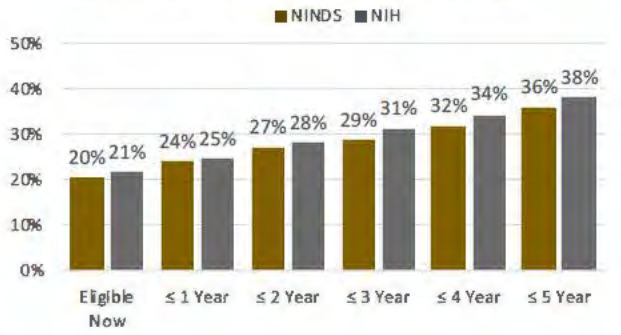
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NINDS = 5.75 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

**Budget Summary**
(Dollars in Millions)

| NINR | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 146.485 | 169.113 | |
| Less (specify sources) | | | |
| Total Budget Authority | 146.485 | 169.113 | |
| FTE | 96 | 96 | |

## NINR MISSION

Since 1986, the National Institute of Nursing Research (NINR) has served as the primary Federal resource for the support of nursing science. In this capacity, NINR plays a major role in guiding the agenda for the field of nursing science in the United States, science that builds the evidence base for clinical practice, improves quality of life, and promotes and improves the health of individuals, families, and communities. In October 2020, Dr. Shannon N. Zenk joined NIH as the new director of NINR.

NINR-supported scientists provide a critical link between the research and practice settings, leading multidisciplinary studies to generate new evidence and translating those findings into practice. NINR fulfills a unique role within NIH by supporting primarily clinical research that is focused on individuals and their caregivers across the lifespan and health spectrum, and not on any particular disease or organ system. NINR-supported science seeks to: better understand and manage adverse symptoms; develop strategies to promote health and prevent illness; enhance self-management of chronic conditions; and improve end-of-life and palliative care. NINR also supports training fellowships and awards to train a transdisciplinary, innovative, and diverse nursing science workforce. NINR collaborates with numerous partners at NIH in support of NINR-led and other trans-NIH research initiatives.

NINR's extramural research programs primarily fund investigator-initiated research and training at schools of nursing and other academic institutions, as well as hospitals and small businesses. NINR's intramural research program at NIH collaborates with other NIH ICs, as well as other Federal departments, to study topics such as traumatic brain injury and cancer treatment-induced fatigue. NINR's research programs in symptom science improve quality of life for individuals and families by identifying effective strategies to manage symptoms of acute and chronic illness, and by contributing to a better understanding of underlying biological mechanisms of symptoms such as pain, fatigue, and sleep disturbance. NINR's intramural Symptom Science Center promotes research on understanding the mechanisms of symptoms to improve patient outcomes, and trains new investigators in this research area. The Center is led by NINR but promotes collaborations across the intramural and extramural communities of NIH. The NINR End of-Life and Palliative Care research program supports science to develop strategies to prevent or reduce the symptoms of advanced illness, such as pain, distress, and other physical and psychosocial symptoms. As part of this program, NINR supports the Palliative Care Research Cooperative (PCRC) group, currently a network of over 550 interdisciplinary scientists in over 170 research sites across the United States, to build the science of end-of-life and palliative care.

NINR's training programs prepare the next generation of nurse scientists through research fellowships and innovative training opportunities such as a Summer Genetics Institute and Methodologies

Bootcamp. The 2020 Bootcamp, held virtually for the first time, allowed over 1,000 registrants to learn about the latest applications of artificial intelligence to the healthcare environment.

## NINR BUDGET

Investigator-initiated research projects, support for new investigators, research training, and career development are the Institute's highest priorities. Of the NINR FY 2020 enacted budget of $169.113 million, 79 percent is used to support grant activities. Research Project Grants comprise 67 percent, or $112.9 million of the NINR budget. Five percent of our budget, or $7.7 million, is used to support the Ruth L. Kirschstein National Research Service Award training program, the second highest percent of total budget dedicated to this program at NIH. This level of support allows NINR to sustain the development of a highly qualified research workforce. Other grant activities include Centers at four percent, or $5.9 million, and Other grants at four percent, or $5.9 million.

NINR maintains a strategic balance between solicitations issued to the extramural community in high-priority areas of research, and funding made available to support investigator-initiated projects. Scientific reviews, with recommendations from the National Advisory Council for Nursing Research, inform the level of recommended support for all research applications.

The Intramural Research Program accounts for eight percent, or $14.2 million while the Research, Management and Support mechanism share of the budget stands at about ten percent, or $16.7 million.

**Budget Authority by Activity FY 2016-2020**

(Dollars in Millions)

| NINR Activity | 2016 Enacted | 2017 Enacted | 2018 Enacted | 2019 Enacted | 2020 Enacted |
|---|---|---|---|---|---|
| Symptom Science | 27.705 | 23.632 | 26.676 | 28.520 | 29.489 |
| Self-Management | 14.060 | 17.767 | 22.042 | 21.108 | 21.825 |
| Wellness | 39.927 | 38.125 | 36.076 | 40.399 | 41.771 |
| 21st Century Nurse Scientists | 13.418 | 12.590 | 14.717 | 16.728 | 17.296 |
| Promoting Innovation | 9.399 | 11.224 | 11.687 | 9.851 | 10.186 |
| End-of-Life and Palliative Care | 16.960 | 18.843 | 17.424 | 17.042 | 17.621 |
| Subtotal, Extramural | 121.470 | 122.182 | 128.623 | 133.648 | 138.187 |
| Intramural Research | 9.405 | 11.861 | 12.791 | 13.485 | 14.216 |
| Intramural Personnel | 3.878 | 4.518 | 4.800 | 5.342 | 5.146 |
| Intramural Non-personnel | 5.527 | 7.343 | 7.991 | 8.143 | 9.071 |
| Research Management & Support | 15.610 | 15.894 | 16.248 | 16.036 | 16.710 |
| RMS Personnel | 10.721 | 10.341 | 10.536 | 9.845 | 10.358 |
| RMS Non-personnel | 4.889 | 5.553 | 5.712 | 6.190 | 6.352 |
| TOTAL | 146.485 | 149.937 | 157.662 | 163.169 | 169.113 |
| Total Personnel | 14.599 | 14.859 | 15.336 | 15.187 | 15.504 |
| Total Non-personnel | 131.886 | 135.078 | 142.326 | 147.982 | 153.609 |

## NINR PRIORITY ISSUES

(b) (5)

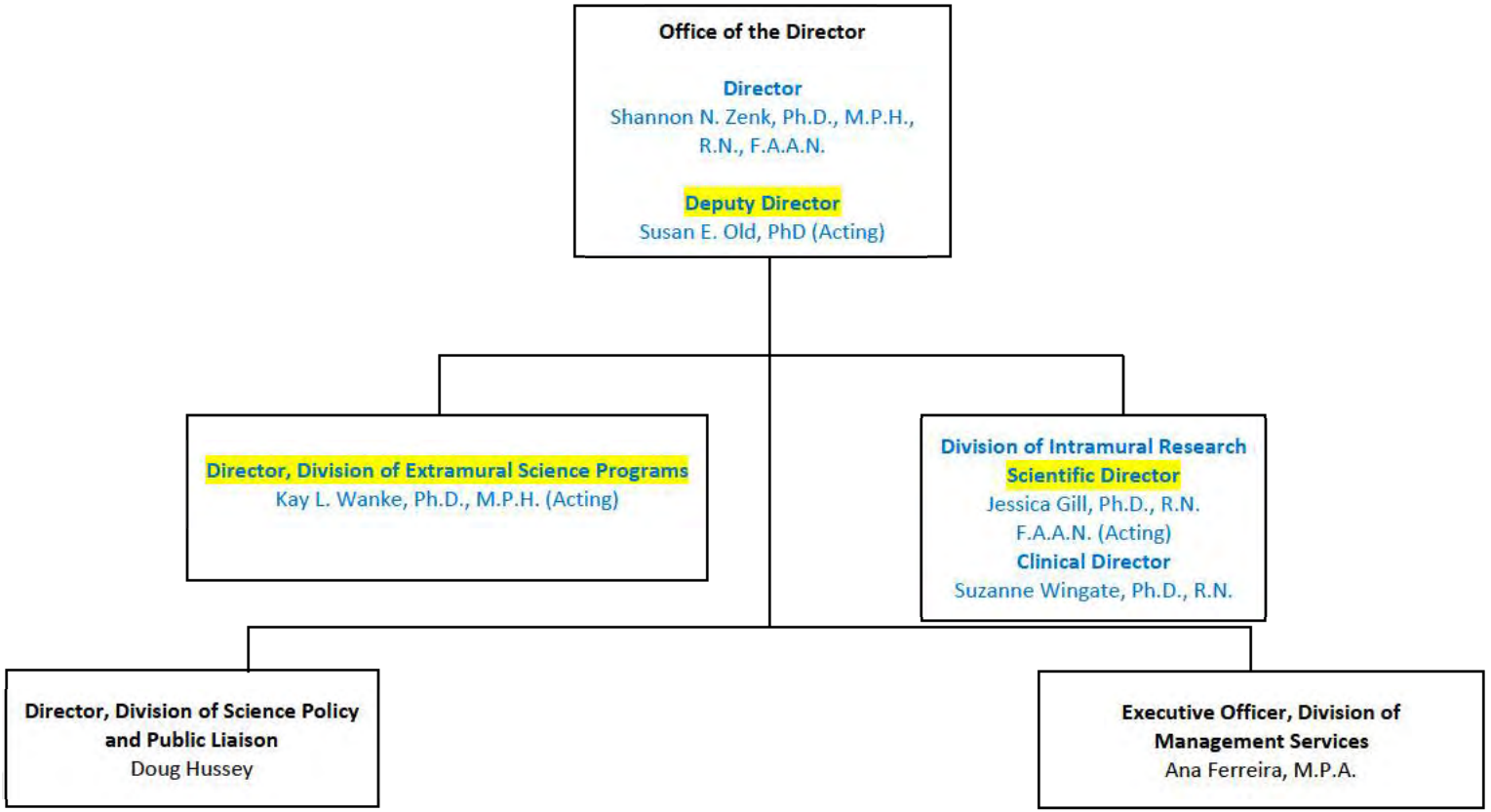
(b) (5)

**Senior Leadership Vacancies**: The Institute's senior leadership has been in transition for the last few years due to retirements and departures for other opportunities. Currently, three top positions (Deputy Director, Scientific Director, Extramural Director) are occupied by individuals in acting roles, with an additional senior leader retiring in December 2020. NINR is implementing a phased plan to fill these positions and address future succession planning.

## NINR SIGNIFICANT CHANGES

Between FY 2016 and the present, NINR's appropriation has tracked closely with the overall increases and decreases in NIH's total appropriation and that of most other ICs. There have been no significant changes to NINR's appropriation during that time period outside of those overall trends.

## NINR ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

212

**National Institute of Nursing Research**

Office of the Director

- Director, Shannon N. Zenk, Ph.D., M.P.H., R.N., F.A.A.N. (Senior Executive Position)
- Deputy Director, Susan E. Old, Ph.D. (Acting)

The following divisions report directly to the NINR Director:

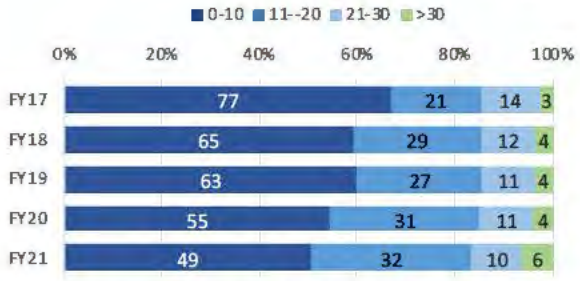
- Director, Division of Extramural Science Programs
    - Kay L. Wanke, Ph.D., M.P.H. (Acting; Senior Executive Position)
- Scientific Director, Division of Intramural Research
    - Jessica Gill, Ph.D., R.N., F.A.A.N (Acting; Senior Executive Position)
- Clinical Director, Division of Intramural Research
    - Suzanne Wingate, Ph.D., R.N. (Senior Executive Position)
- Director, Division of Science Policy and Public Liaison
    - Doug Hussey
- Executive Officer, Division of Management Services
    - Ana Ferreira, M.P.H.

National Institute of Nursing Research

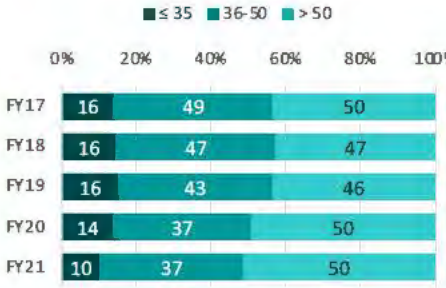
# NINR WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

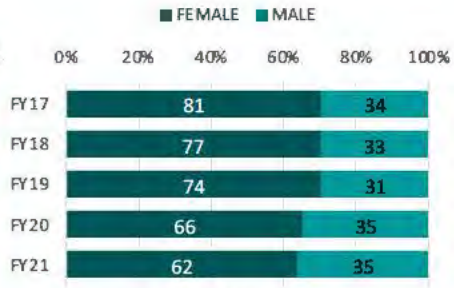

## Federal Length of Service (Yr.) Trending



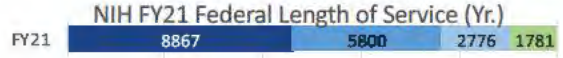

## Age Trending



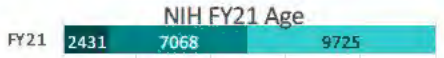

## Gender Trending



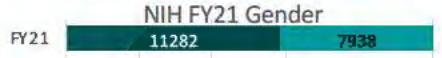

## NIH FY21 Federal Length of Service (Yr.)



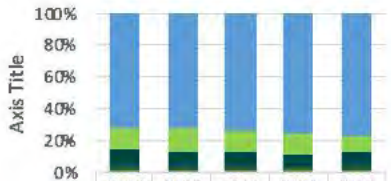

## NIH FY21 Age




## NIH FY21 Gender



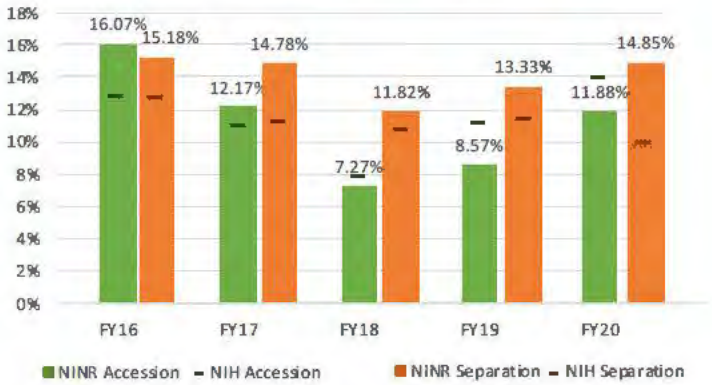

## Pay Plan Trending[2]



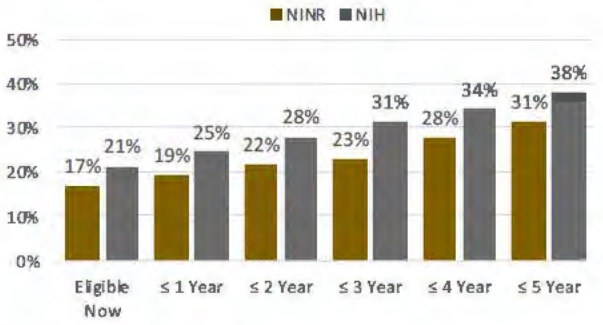

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 83 | 80 | 77 | 76 | 74 |
| EI | 15 | 15 | 14 | 14 | 11 |
| T42 | 14 | 12 | 11 | 8 | 9 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 3 | 3 | 3 | 3 | 3 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NINR[4] = 1.43 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.
[4] Two of the 13 NINR retirement actions from FY16-20 occurred before the staff reached retirement eligibility.

# NATIONAL LIBRARY OF MEDICINE (NLM)

**Budget Summary**
(Dollars in Millions)

| NLM | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 394.664 | 456.911 | |
| Less (specify sources) | | | |
| Total Budget Authority | 394.664 | 456.911 | |
| FTE | 811 | 741 | |

## NLM MISSION

The National Library of Medicine (NLM) is a leader in biomedical and health data science research and the world's largest biomedical library. NLM's research and information services play a pivotal role in translating biomedical research into practice. NLM conducts and funds research and research training in biomedical information science, informatics, data analytics, and data science to advance computational biology and computational health science. In addition, NLM develops, supports, and sustains biomedical information services that make the full range of biomedical information—literature, research data, software tools, data standards—findable, accessible, interoperable, and reusable. Every day, NLM sends and receives more than 130 terabytes of data through critical resources such as PubMed, PubMed Central, GenBank, ClinicalTrials.gov, and the database of Genotypes and Phenotypes (dbGaP). Millions of researchers, clinicians, students, educators, and the general public use NLM services every day to support scientific discovery, health care delivery, and public health decision making. There is not a biomedical discovery, public health advance, or clinical care action in the past 30 years that has not benefited from NLM resources.

Congressional authorization language, as relevant now as it was 65 years ago, charges NLM to acquire, organize, preserve, and make available a wide range of materials to "assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health." It also charges NLM to support research and development in medical library science; processing, storing, retrieving, and distributing biomedical and health information; and technologies that bridge research and clinical applications of data and information. NLM authorization legislation also charges it to establish Regional Medical Libraries. These libraries coordinate what is currently an 8,200-member Network of the National Library of Medicine (NNLM) that provides local training and community engagement to improve access to health information to people across the country. NLM is also a leader in NIH's efforts to build a diverse workforce for data-driven research and health.

NLM's research and information resources are essential to advancing NIH's mission and activities. NLM's focus on data and information-related research and substantial investment in developing and sustaining information services for biomedical data, literature, and genomic sequences is unique among NIH Institutes and Centers. NLM leverages these special capabilities with partners to advance key priorities of other components of NIH and the HHS. For example, NLM is leading NIH's efforts to promulgate the use of health information technology standards in clinical research, building on NLM's deep expertise in terminology and data exchange standards that support interoperability among EHRs. NLM also leverages the NNLM to support NIH's *All of Us* Research Program by developing and deploying

health information resources to support outreach to populations in rural, urban, and medically underserved areas.

## NLM BUDGET

In FY 2020, more than 80 percent of NLM's $457 million budget supported its intramural programs. The largest share of the intramural budget supports the development and extension of NLM's heavily used biomedical information and data services; the balance supports intramural research. NLM's extramural program supports grants for biomedical informatics research; information resources to reduce health disparities; and scholarly works in the history, philosophy, and ethics of biomedicine. NLM's extramural program also supports university-based research training in biomedical informatics for 200 pre- and post-doctoral students per year. It also supports the Regional Medical Libraries that coordinate the activities of the NNLM. In FY 2020, NLM received $10 million in supplemental CARES Act funding to support activities to improve the quality of clinical data for research and care, accelerate research including phenotyping, image analysis, and real-time surveillance, and to enhance access to COVID-19 literature and molecular data resources.

**Budget Authority by Activity**
(Dollars in Millions)

| NLM Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Budget |
|---|---|---|---|---|---|
| Extramural Program: Biomedical Informatics Research | 26.129 | 30.055 | 32.783 | 36.706 | 40.050 |
| Informatics Resources/Training for Biomedicine and Health | 18.842 | 14.212 | 17.615 | 16.837 | 15.732 |
| Health Information for Health Professionals and the Public (NNLM) | 11.952 | 12.000 | 11.911 | 11.570 | 11.132 |
| Sub-Total, Extramural | 56.923 | 56.267 | 62.309 | 65.113 | 66.914 |
| Intramural Programs | 323.799 | 335.272 | 346.969 | 353.247 | 369.381 |
| Research Management and Support | 14.352 | 14.710 | 15.510 | 19.775 | 20.616 |
| Total, NLM | 395.074 | 406.249 | 424.788 | 438.135 | 456.911 |

## NLM PRIORITY ISSUES

**Accelerate research and training in informatics, data science, AI:** NLM's longstanding investments in research and training focus on novel approaches to collecting, analyzing, and learning from biomedical data across data types and disease areas. NLM must quickly ramp up its intramural and extramural research programs to meet growing needs for new analytical methods and models and streamline its university-based research training programs to meet the information and training needs of an increasingly diverse population.

Grow research literature and data services in a sustainable way: As biomedical research becomes more data-intensive and NIH establishes broader expectations for the management and sharing of data from NIH-supported research, NLM must fund sustainable technical and financial approaches to meet the demand for information services that is growing at a rate that outpaces growth in research budgets. Long-term roadmaps, resources, and strategies will be needed to manage growth and accelerate data driven discovery.

**NLM reorganization and personnel:** NLM is implementing a multi-phase reorganization to improve operational efficiencies, expand its research capacity, and support its Strategic Plan, 2017-2027. As part of this reorganization, NLM plans to recruit three senior-level positions during 2021.

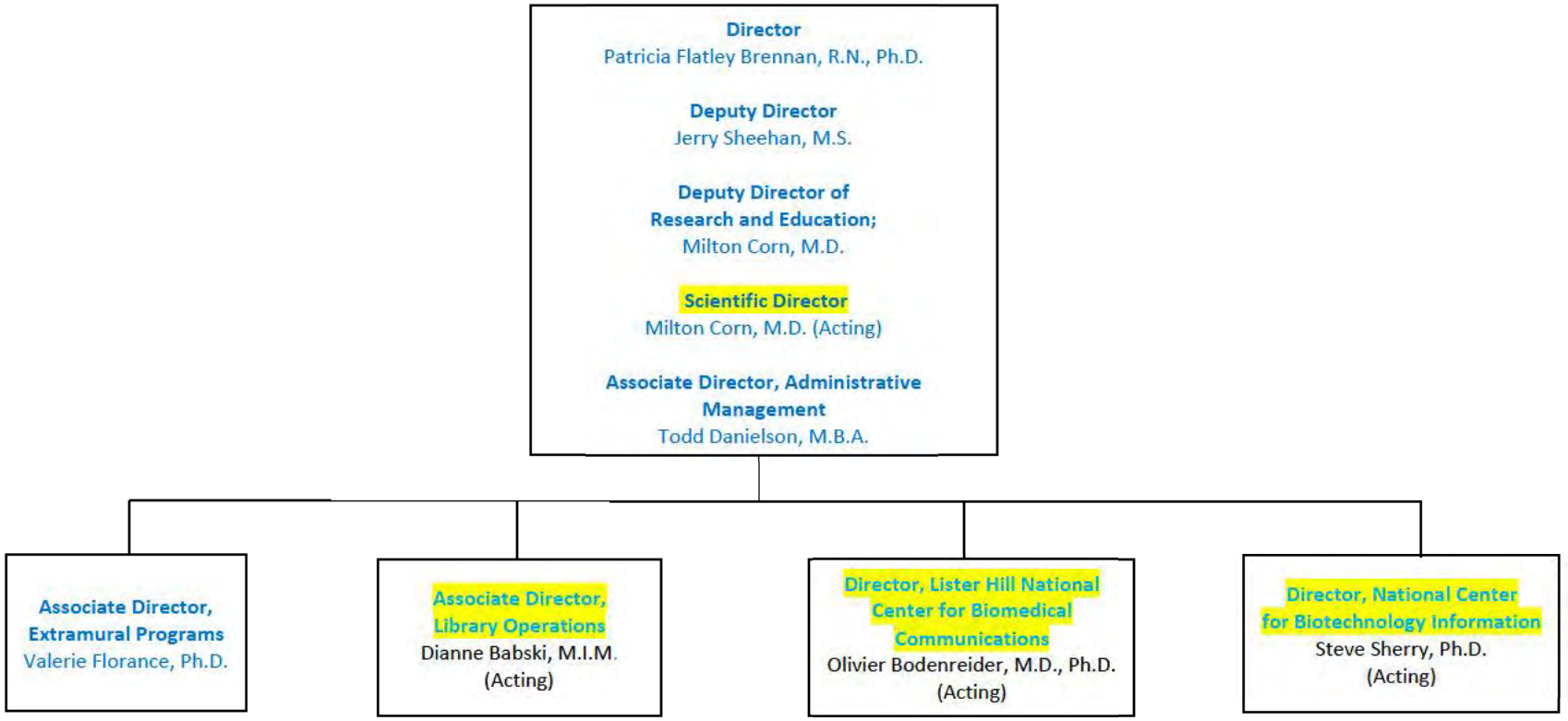
**Modernize the NLM infrastructure:** NLM must maintain the integrity and robustness of its physical and IT infrastructures in order to preserve NLM's collections, support new ways of working among staff, and sustain heavily used biomedical information services, even as NLM makes greater use of cloud-based IT infrastructure. NLM is making needed investments to renovate its facilities and data center in collaboration with relevant NIH offices.

**Support public accountability and open science:** NLM is the entity responsible for systems, such as PubMed Central and ClinicalTrials.gov, that make important biomedical research information and data publicly accessible in support of regulatory and policy requirements. NLM must ensure that technical platforms and quality review procedures can accommodate growing workloads and support emerging needs and functions, such as linking publications to associated data and ensuring the quality of data and information released prior to peer review and publication.

## NLM SIGNIFICANT CHANGES

Following creation of its Strategic Plan, 2017-2027, NLM enhanced investments in its intramural and extramural research programs to accelerate advances in biomedical discoveries through data-driven research. By improving the efficiency and effectiveness of its information services and securing additional NIH support, NLM was able to expand funding for its extramural programs by almost 18 percent between FY 2016 and FY 2020. To support new regulatory requirements and the NIH policy for clinical trial registration and results reporting that took effect in 2017, NLM boosted funding and staffing for its ClinicalTrials.gov program. It also transitioned several of its information services to cloud-based platforms, including the fast-growing Sequence Read Archive (SRA) of genomic data. NLM launched a multi-phase reorganization that eliminated one division and integrated important toxicological and environmental health information onto priority NLM platforms to improve performance and efficiency. It consolidated its outreach and training programs and transferred audiovisual production into its communications office. Research management and support grew as reorganization efforts transitioned some functions into the Office of the Director. With a decline in Federal staff, NLM increased its reliance on contractors to maintain its efforts and bolster its responsiveness.

## NLM ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**National Library of Medicine**

Office of the Director

- Director, Patricia Flatley Brennan, R.N., Ph.D. (Senior Executive Position)
- Deputy Director, Jerry Sheehan, M.S. (Senior Executive Position)
- Deputy Director of Research and Education, Milton Corn, M.D (Senior Executive Position)
- Scientific Director, Milton Corn, M.D. (Acting; Senior Executive Position)
- Associate Director for Administrative Management, Todd Danielson, M.B.A. (Senior Executive Position)

The following positions report directly to the Director:

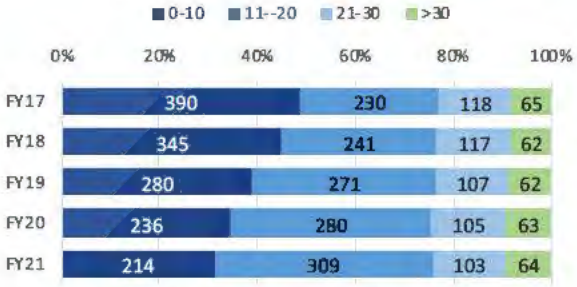
- Associate Director, Extramural Programs
    - Valerie Florance, Ph.D. (Senior Executive Position)
- Associate Director, Library Operations
    - Dianne Babski, M.I.M. (Acting; Senior Executive Position)
- Director, Lister Hill National Center for Biomedical Communications
    - Olivier Bodenreider, M.D., Ph.D. (Acting; Senior Executive Position)
- Director, National Center for Biotechnology Information
    - Steve Sherry, Ph.D. (Acting; Senior Executive Position)

U.S. National Library of Medicine

# NLM WORKFORCE SNAPSHOT [1]

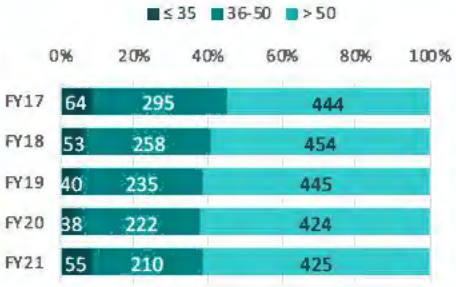
## Federal Employee Onboard (Headcount) Trending


## Federal Length of Service (Yr.) Trending



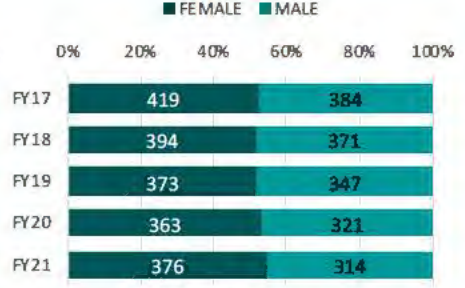

## NIH FY21 Federal Length of Service (Yr.)


## Age Trending



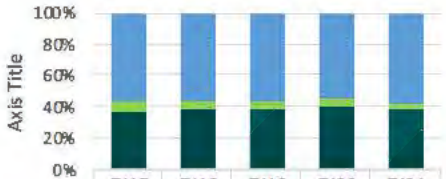

## NIH FY21 Age


## Gender Trending




## NIH FY21 Gender

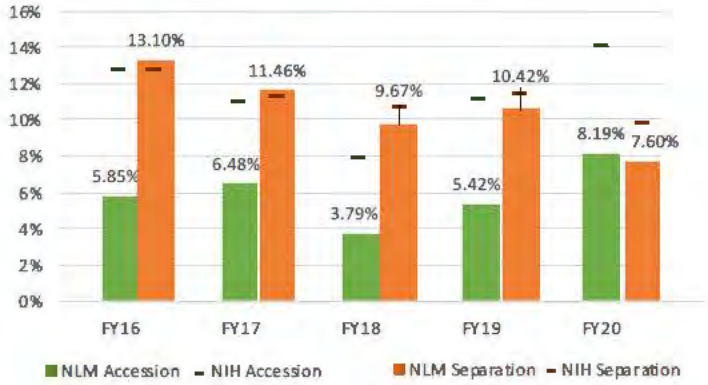

## Pay Plan Trending[2]




| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 458 | 434 | 409 | 379 | 395 |
| EI | 48 | 41 | 31 | 33 | 26 |
| T42 | 291 | 283 | 273 | 266 | 264 |
| SES | 5 | 6 | 6 | 5 | 4 |
| CC | 1 | 1 | 1 | 1 | 1 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]


Average time FTEs stayed past retirement eligibility
NLM = 6.27 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# CLINICAL CENTER (CC)

**Budget Summary**
(Dollars in Millions)

| CC | FY 2016 Enacted | FY 2020 Enacted | (b) (5) |
|---|---|---|---|
| Total Program Level | 444.612 | 572.246 | |
| Less (specify sources ) | | | |
| Total Budget Authority | 444.612 | 572.246 | |
| FTE | 1,879 | 1,844 | |

## CC MISSION

The Clinical Center (CC) is the research hospital of NIH. The CC is a component of the NIH's intramural program and supports the 17 Institutes conducting clinical research protocols on the NIH campus located in Bethesda, Maryland. As the country's largest hospital devoted entirely to clinical research, the CC is a national resource that makes it possible to rapidly translate scientific observations and laboratory discoveries into new approaches for diagnosing, treating, and preventing disease. The "bench-to-bedside" concept adopted upon opening of the CC in 1953, locates patient care units in close proximity to basic research laboratories. This specialized hospital design facilitates interaction and collaboration among clinician researchers and enables the CC to provide a model environment for patient care and safety, clinical research, and training.

**Patient Care and Safety:** With patients from across the United States and abroad, the CC-patient relationship differs from the traditional provider-consumer affiliation in several distinct ways. Viewed as partners in medical discovery, all care is provided at no charge to the patient. Excellence in patient care is not only a requirement to assure the safest and highest quality treatment but is also a key imperative to sustain compliance to the requirements of clinical research. Since opening, over 570,000 patients have participated in clinical research at the CC. In FY 2020, the CC admitted 3,074 patients, accounting for 31,196 inpatient days. Additionally, 61,586 outpatient visits occurred in FY 2020. This is lower than our typical patient load, but this decrease is due to the ongoing COVID-19 pandemic.

**Clinical Research:** The CC maintains a strong and stable clinical research infrastructure for the intramural research program. The 1,488 active protocols at the CC are comprised of 748 (50 percent) clinical trials and 612 (41 percent) natural history studies. Rounding out the portfolio, there are 52 (3 percent) screening and 20 (1 percent) training protocols. In addition to providing clinical services to the Institutes with clinical programs on the NIH campus, the CC supports its own independent research portfolio, which has been critical for recruitment and retention of the best clinicians into the clinical research environment.

**Training:** Training the next generation of biomedical researchers and clinician-scientists is a core function of the CC. As the sponsoring institution for graduate medical training programs accredited by the Accreditation Council for Graduate Medical Education, the American Board of Medical Specialties, and the United Council for Neurologic Subspecialties, the CC fosters the development of a broad investigator base through clinical residency and fellowship training at the NIH. In addition, the CC has an extensive portfolio of courses and programs accessible for students and other trainees from the intramural program, academic medical centers, and private industry, both domestic and international.

Two main buildings comprise the CC. The Mark O. Hatfield Clinical Research Center (CRC) opened in 2005. The 870,000 square foot facility houses 200 inpatient beds, 93 day hospital stations, critical care facilities and research labs, and connects to the original Warren G. Magnuson Clinical Center, which houses the ambulatory care research facility (ACRF), 13 clinics, 11 operating rooms, and imaging facilities.

## CC BUDGET

The FY 2020 budget for the CC is $572.246 million with an additional one-time increase in funding for our response to the COVID-19 epidemic of $14.213 million. It is important to note that unlike most of the Institutes and Centers at the NIH, the CC does not receive an appropriation. The Institutes centrally fund the CC via a "school tax." This school tax is based on each Institute's percentage of the total intramural research budget.

**Budget Authority by Activity**
(Dollars in Millions)

| CC Activity | FY 2016 Enacted | FY 2017 Enacted | FY 2018 Enacted | FY 2019 Enacted | FY 2020 Enacted |
|---|---|---|---|---|---|
| **Management Fund** | 444.612 | 455.32 | 499.24 | 531.74 | 572.246 |
| **FTE** | 1,879 | 1,859 | 1,859 | 1,844 | 1,844 |

## CC PRIORITY ISSUES

**Upgrading outdated facilities**: Although the CRC opened in 2005, several CC departments, including Radiology and Imaging Sciences, Laboratory Medicine, Transfusion Medicine, Positron Emission Tomography, and Perioperative Medicine (operating rooms), remain in the Warren G. Magnuson Clinical Center, where the infrastructure needs improvement. To support the intramural clinical research enterprise and improve patient care, the CC needs updated facilities.

**Ensuring the CC continues to focus on its work as a high reliability organization**: Patients and their families are full partners in the research enterprise. Risks related to a therapy that has never been used in humans for the first time may be unavoidable. CC staff will be relentless in anticipating preventable harm, applying a systems approach to eliminate risks whenever possible, and mitigating those that remain.

**Improving the funding model of the CC**: Over the years, NIH has discussed several possible solutions, including a line item, but a formal decision has yet to be made.

**Continuing to enhance clinical capabilities**: In the last few years, the Clinical Center has expanded its capacity in several ways, ranging from tripling the capacity of cellular engineering to implementing brand new pediatric observation beds and the new pediatric hospitalist service. In the future, it will be necessary for the Clinical Center to continue to evolve to best meet the needs of our patients, guided by the NIH Clinical research program.

## CC SIGNIFICANT CHANGES

In the last few years, we have introduced significant changes to governance of the Clinical Center (separating the oversight of *clinical research science* from the CEO's oversight of *operational and hospital administrative management*); established a new CC Mission and strategic aims; revised our Guiding Principles; and integrated a new CC Research Hospital Board (CCRHB). The CC organizational

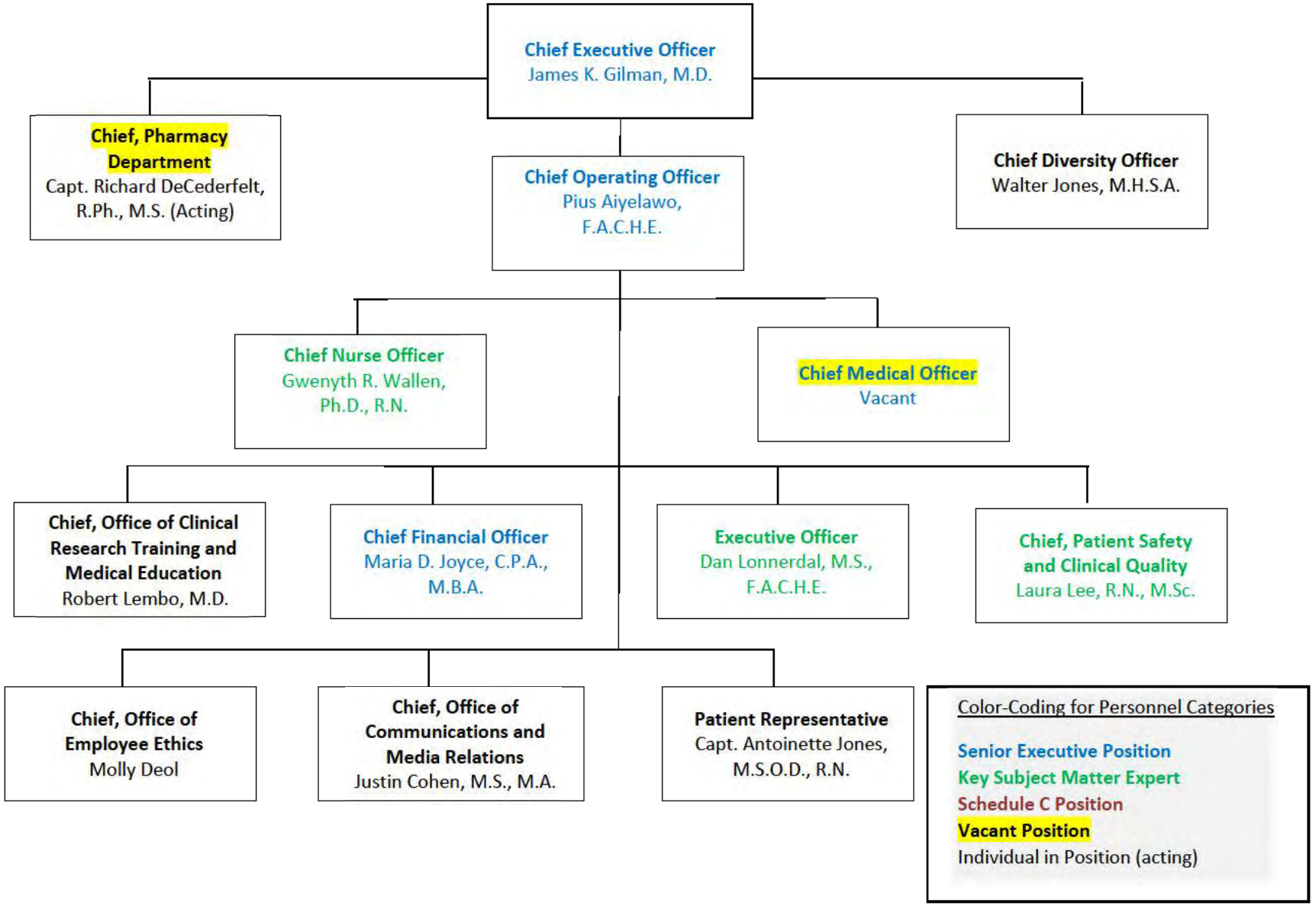
chart supports the new governance model. These changes have been grounded in an unwavering commitment by the CC workforce to fortifying a culture and practice of safety and quality.

In 2017, a documentary produced by the Discovery channel titled, First in Human, showcased the powerful real-life experiences of doctors, researchers, staff, patients and their caregivers in the CC. The three-episode series was filmed over the course of a year. The series title, First in Human, captures the essence of the CC. Since its beginning, the CC has served as a global leader in the conduct of Phase 1 clinical research trials, which is the first stage of research testing in humans. The CC has specialized resources and infrastructure to support such studies. Indeed, many of the great scientific discoveries made at the CC began as first-in-human Phase 1 trials.

The CC also recently established the CC Research Support & Operational Compliance Office as a resource to investigator efforts to ensure rigor and reproducibility of research, reduce administrative burden, and engage in proactive risk management practices. Quarterly Morbidity & Mortality (M&M) Conferences for all CC and IC clinical staff engaged in patient care were introduced in 2017. M&M Conferences in U.S. hospitals originated more than 100 years ago. They have evolved to address various aspects of patient care such as complications, adverse events, death, medical errors, omissions, and system problems. At the CC, unique patient care aspects related to clinical research studies are also included in M&Ms. Since 2017, these CC sessions have been extremely well attended and have promoted excellent dialogue and follow up among multidisciplinary professionals throughout the organization.

An FDA inspection in 2015 found that the NIH pharmacy infrastructure and processes fell short of contemporary industry practices. T his FDA finding has triggered a determined effort to provide aseptic processing areas approaching those in commercial pharmaceutical manufacturing facilities. The first project—the interim intravenous admixture unit (iIVAU)—was opened in April of 2017. It provides clean room capabilities for both hazardous and non-hazardous medications. Modern HVAC systems and automated building control systems ensure that the areas where drugs are prepared are maintained under carefully controlled conditions. However, the real solution of a permanent IVAU is nearing completion, with construction currently ongoing.

## CC ORGANIZATIONAL CHART AND WORKFORCE



**National Institutes of Health Clinical Center**

- Chief Executive Officer, James K. Gilman, M.D. (Senior Executive Position)

The following offices report directly to the Chief Executive Officer:

- Chief Operating Officer
  - Pius Aiyelawo, F.A.C.H.E. (Senior Executive Position)
- Chief Diversity Officer
  - Walter Jones, M.H.S.A.
- Chief, Pharmacy Department
  - CAPT Richard DeCederfelt, R.Ph., M.S. (Acting)

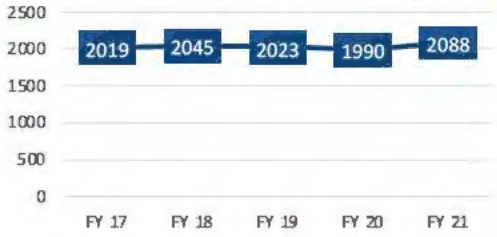
The following senior leaders report to the Chief Operating Officer:

- Chief Financial Officer
  - Maria D. Joyce, C.P.A., M.B.A. (Senior Executive Position)
- Chief Nurse Officer
  - Gwenyth R. Wallen, Ph.D., R.N. (Key Subject Matter Expert)
- Chief Medical Officer (Senior Executive Position)
  - Vacant
- CC Executive Officer
  - Dan Lonnerdal, M.S., F.A.C.H.E. (Key Subject Matter Expert)
- Chief, Office of Patient Safety and Clinical Quality
  - Laura Lee, R.N., M.S.C.
- Chief, Office of Clinical Research Training and Medical Education
  - Robert Lembo, M.D.
- Chief, Office of Employee Ethics
  - Molly Deol
- Chief, Office of Communications and Media Relations
  - Justin Cohen, M.S., M.A.
- Patient Representative
  - Capt. Antoinette Jones, M.S.O.D., R.N.

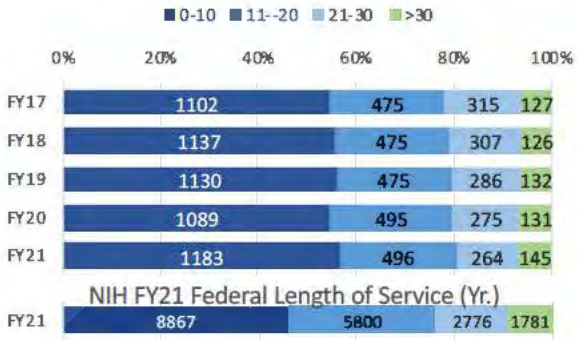
NIH Clinical Center
America's Research Hospital

# CC WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending



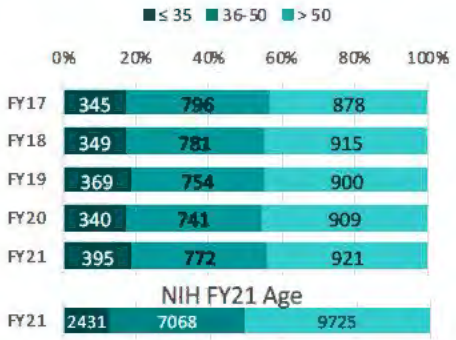

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



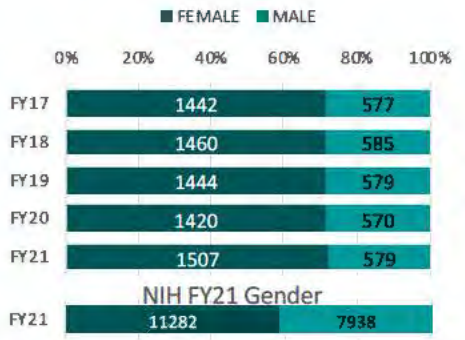

## Age Trending




## NIH FY21 Age



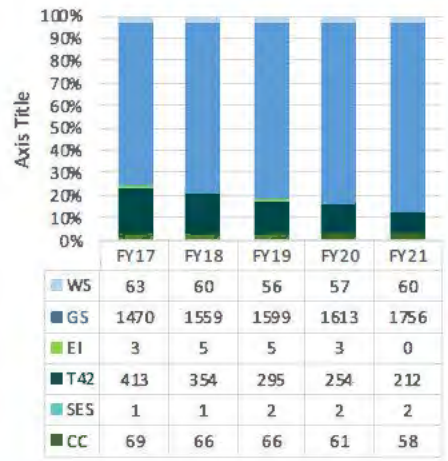

## Gender Trending




## NIH FY21 Gender

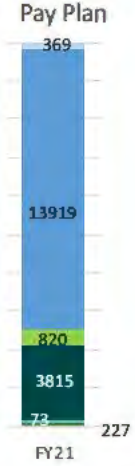



## Pay Plan Trending[2]

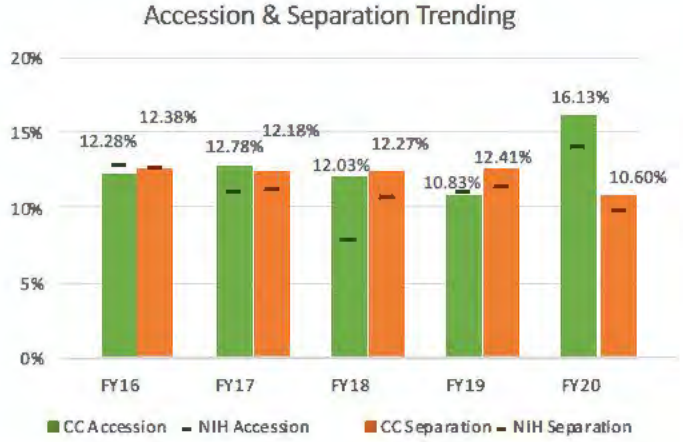



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 63 | 60 | 56 | 57 | 60 |
| GS | 1470 | 1559 | 1599 | 1613 | 1756 |
| EI | 3 | 5 | 5 | 3 | 0 |
| T42 | 413 | 354 | 295 | 254 | 212 |
| SES | 1 | 1 | 2 | 2 | 2 |
| CC | 69 | 66 | 66 | 61 | 58 |

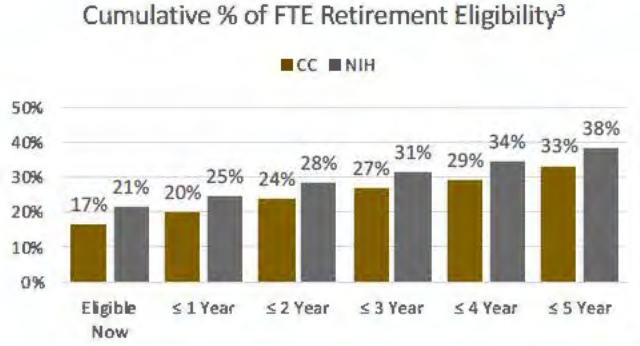
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
CC = 4.93 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# CENTER FOR INFORMATION TECHNOLOGY (CIT)

## Budget Summary

(Dollars in Mi

(b) (5)

| CIT | FY 2016 Enacted | FY 2020 Enacted |
|---|---|---|
| Total Program Level | 274.510 | 331.335 |
| Less (specify sources) | | |
| Total Budget Authority | 274.510 | 331.335 |
| FTE | 290 | 234 |

## CIT MISSION

The Center for Information Technology (CIT) manages NIH's core information technology (IT) infrastructure and provides enterprise-level IT systems, solutions, and services to all ICOs and the OD. CIT's services include networking, scientific computing, software and systems engineering, enterprise systems, desktop and mobile device support, data storage, and staff support and training. Modernizing the NIH IT infrastructure, cyber security, and delivering high quality, innovative day-to-day IT services are CIT's top three priorities.

Unlike the ICs that receive an appropriation from Congress, CIT is funded by the NIH Management Fund (MF) and Service and Supply Fund (SSF). The use of CIT services is discretionary and varies by NIH IC. In addition, CIT's Office of Scientific Computing Services (OSCS) supports and enables intramural research at NIH by providing advanced computing technologies to the NIH Intramural Research Program.

## CIT BUDGET

CIT supports NIH's core IT infrastructure and provides enterprise-level information technology systems, solutions, and services to all 27 ICs and the NIH Office of the Director.

Approximately 12 percent of CIT's budget is spent on salaries and benefits for Federal staff, 54 percent is spent on IT professional services, 22 percent is spent on equipment and maintenance, and the remaining 12 percent is spent on software and other expenses. CIT's budget increase has been due to NIH capital investments to modernize the NIH IT infrastructure, improve cybersecurity, and deliver high quality, innovative day-to-day IT services to the NIH biomedical research community.

NIH benefits from economies of scale and other cost efficiencies through an enterprise approach for IT infrastructure and services. For example, CIT has achieved cost savings in the millions by negotiating and establishing enterprise-level contracts for IT equipment and commercial software that are available to all ICs. CIT is also able to provide higher quality services at a lower cost for core enterprise-level IT infrastructure capabilities, such as network services, high performance computing, and data storage.

## Budget Authority by Activity

(Dollars in Millions)

| CIT Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Actual |
|---|---|---|---|---|---|
| SSF CJ | 274.505 | 267.627 | 306.259 | 288.589 | 331.335 |

## CIT PRIORITY ISSUES

**Sustaining a Modern IT infrastructure to Enable Science**: NIH's ability to make continued advances in research and discovery is critically dependent on having the right technologies, systems, and tools to support mission priorities. Support from NIH leadership enabled many significant improvements in NIH's IT infrastructure and capabilities over the last five years, and NIH now has a stronger foundation for future research and discoveries. For example, CIT maintains a state-of-the-art, 100 gigabit network to connect researchers around the world as they generate new frontiers in biomedical research. CIT's OSCS provides significant resources to support computationally intensive (HPC) research programs in the NIH Intramural Research Program. CIT also operates the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative which allows NIH to explore the use of cloud environments to streamline NIH data use by partnering with commercial providers. STRIDES provides cost-effective access to industry-leading partners to help advance biomedical research. Today's investigators require high-quality, high-scale computational resources to conduct high-impact, transformative research. Given the Federal fiscal environment, NIH will be faced with hard choices as it balances the need for new innovative capabilities with what is required to sustain a robust and healthy IT infrastructure. Predictable and sustained funding is required for NIH to be able to continue to provide the state-of-the art computational resources that are needed to attract and retain a world-class biomedical workforce.

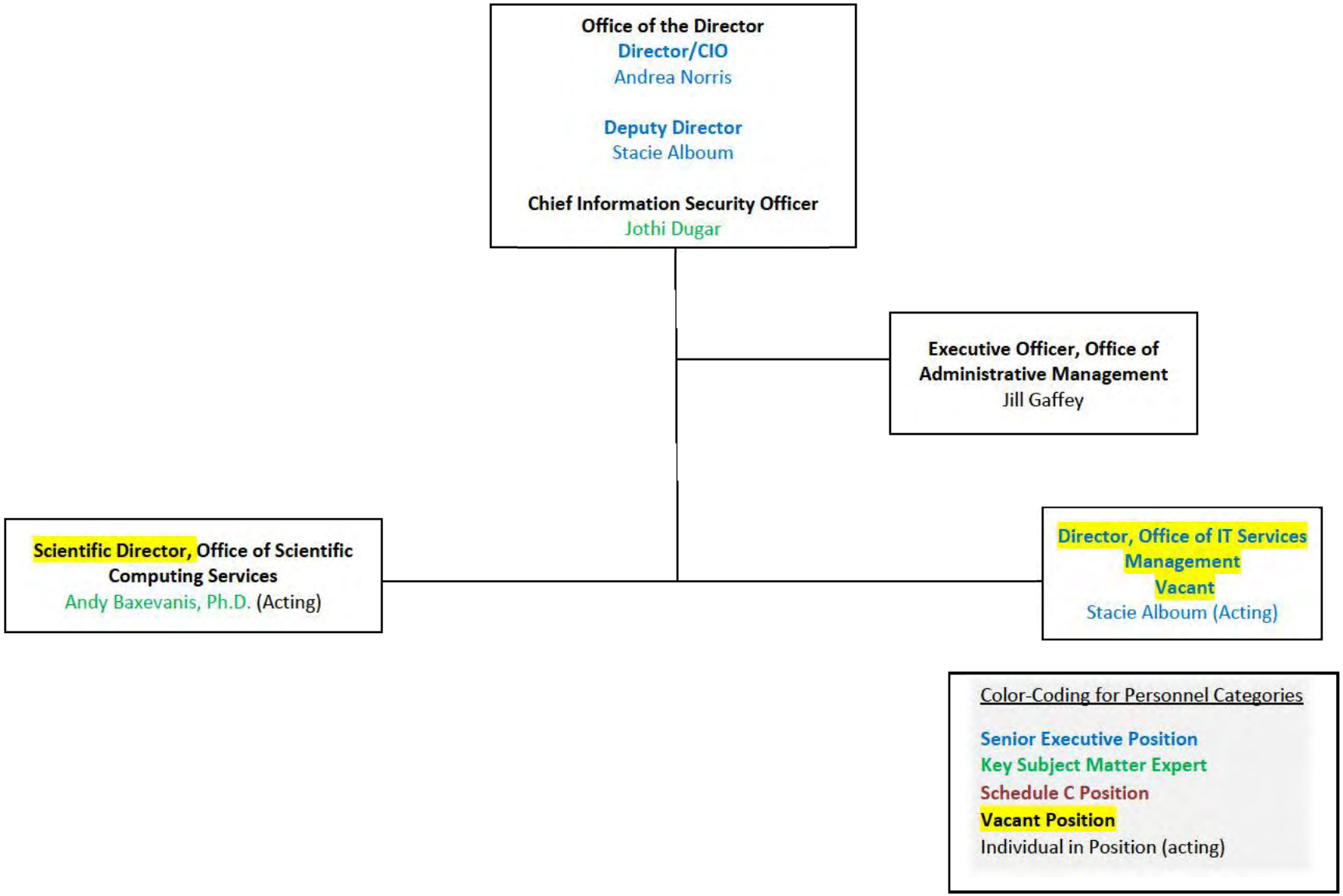
**Cybersecurity**: Protecting NIH's information and systems is one of our most important technology challenges. Like other Federal agencies and large organizations, NIH must respond to an increasing volume of cyber threats and security vulnerabilities NIH inspects, secures, and transits almost 8,000 terabytes of scientific data a day through its network supporting 100+ research labs and facilities and approximately 200 terabytes of data to research collaborators around the world through the Internet. NIH has almost 3,000 public facing systems and web sites, and almost 100,000 different devices routinely connect to the NIH network. NIH has a comprehensive security program to protect NIH information and assets and comply with Federal laws and policies. NIH takes a proactive, risk-based approach to implementing cohesive security while recognizing the open, collaboration nature of the research enterprise. We need to make sure we are making the right risk-based decisions and continuing to learn from our experiences. Open collaboration and data sharing are critical to the NIH mission; we expect cybersecurity challenges will continue to grow over the next five years.

**Delivering High Quality, Cost-Effective Systems and IT Services**: In addition to supporting a robust IT infrastructure, CIT is focused on providing access to innovative systems and tools and assuring high quality day-to-day services for NIH researchers, program managers, administrators, and management staff. For example, NIH staff use collaboration capabilities such as virtual meetings, desktop videoconferencing, and video streaming to support research and administrative operations. These tools facilitate collaboration in geographically distributed workplaces and help to enhance communication in today's constrained travel budget environment. These tools have provided critical support for NIH during the COVID-19 pandemic, enabling staff to work remotely in support of the nation's public health response to the novel coronavirus. ICs are finding it difficult to retain the staff resources and skills needed to provide increasingly complex technologies, and it is becoming cost prohibitive for them to maintain IC-unique IT commodity-like services and infrastructure. Adoption of more innovative approaches that incorporate industry best practices at the enterprise level will result in improved staff productivity at lower costs. Providing a more robust environment and a more seamless IT experience for staff and stakeholders in a cost-effective way will remain a high priority issue.

## CIT SIGNIFICANT CHANGES

There are extensive oversight and operational requirements for Federal IT that continue to have a significant impact on NIH, as well as operational and policy requirements brought on by the pandemic. CIT bears significant responsibility for implementing and operating NIH's cybersecurity infrastructure. The constantly evolving threat landscape requires new approaches to defending against and mitigating threats to NIH's most critical data and assets. CIT has also invested increased effort in remote access and virtual collaboration tools to enable NIH's response to the coronavirus pandemic to continue while many staff are working remotely. NIH works in collaboration with the OMB and Department leadership to execute IT management statutory and policy responsibilities. Federal and Department-level changes in policy, as well as the nation's public health landscape, will continue to affect NIH IT planning, program management, and operational flexibilities.

## CIT ORGANIZATIONAL CHART AND WORKFORCE



**Center for Information Technology**

Office of the Director

- Director/Chief Information Officer, Andrea Norris, M.B.A. (Senior Executive Position)
- Deputy Director, Stacie Alboum, M.B.A. (Senior Executive Position)
- Chief Information Security Officer, Jothi Dugar

The following offices report directly to the Director:

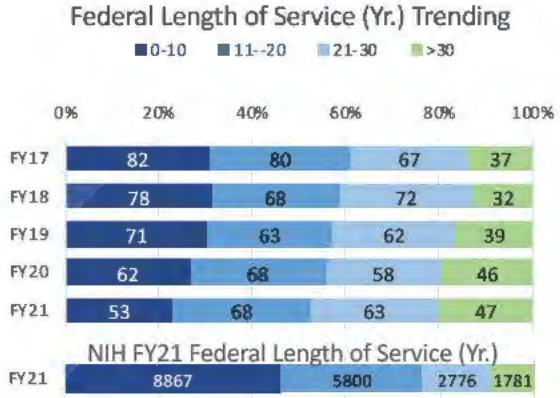
- Executive Officer, Office of Administrative Management
    - Jill Gaffey, M.B.A.
- Scientific Director, Office of Scientific Computing
    - Andy Baxevanis, Ph.D. (Acting)
- Director, Office of IT Services Management
    - Stacie Alboum, M.B.A. (Acting; Senior Executive Position)

NIH Center for Information Technology

# CIT WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending

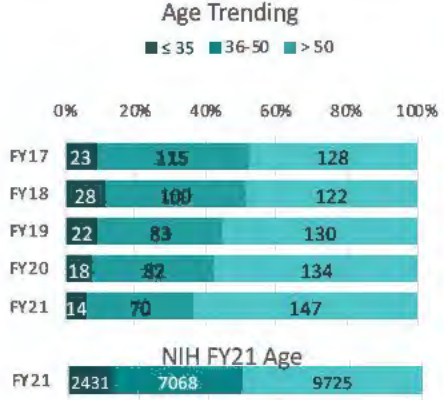

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



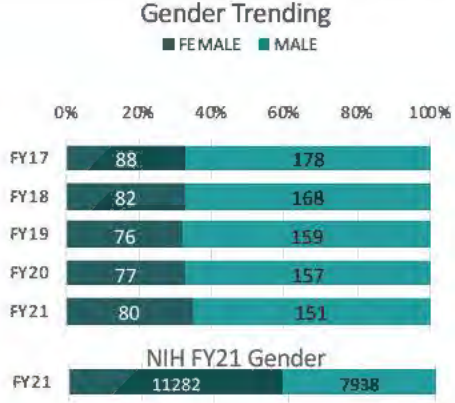

## Age Trending




## NIH FY21 Age



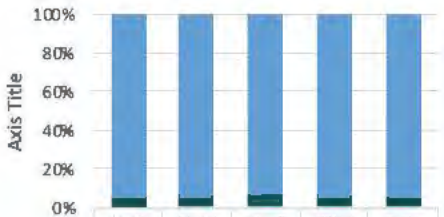

## Gender Trending




## NIH FY21 Gender

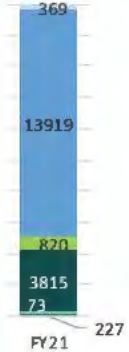



## Pay Plan Trending[2]

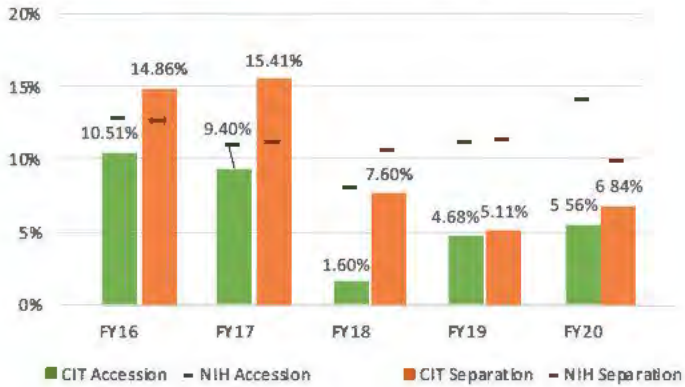



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 252 | 236 | 220 | 220 | 218 |
| EI | 0 | 0 | 0 | 0 | 0 |
| T42 | 13 | 12 | 12 | 11 | 11 |
| SES | 1 | 2 | 3 | 3 | 2 |
| CC | 0 | 0 | 0 | 0 | 0 |

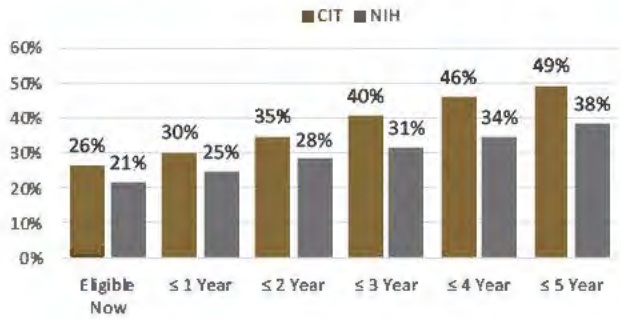
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
CIT = 5.66 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# CENTER FOR SCIENTIFIC REVIEW (CSR)

**Budget Summary**
(Dollars in Millions)

| CSR | FY 2016 Enacted | FY 2020 Enacted | FY 2021 President's | FY 2021 House | FY 2021 Senate |
|---|---|---|---|---|---|
| Total Program Level | 128.222 | 140.893 | (b) (5) | | |
| Less (specify sources ) | 0 | 0 | | | |
| Total Budget Authority | 128.222 | 140.893 | | | |
| FTE | 388 | 409 | | | |

## CSR MISSION

Since 1946, the Center for Scientific Review's (CSR) key mission has been to see that NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. It is this system of peer review that has provided the foundation for scientific and medical advancements the United States is known for.

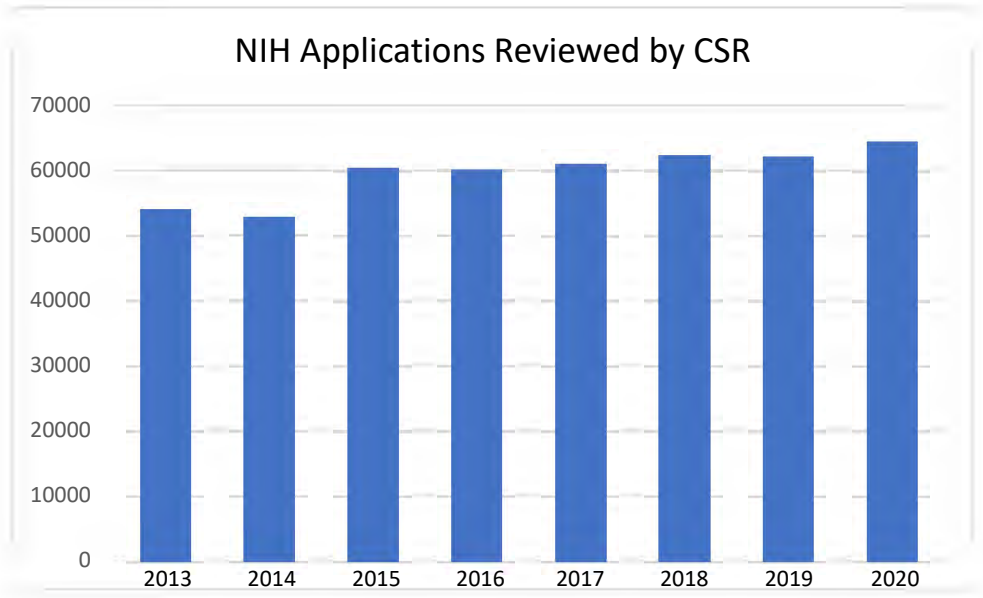
In addition to handling the receipt of all NIH grant applications, CSR receives and processes grant applications from CDC, National Institute for Occupational Safety and Health (NIOSH), Agency for Healthcare Research and Quality (AHRQ), Administration for Children and Families (ACF), and special projects for the Office of the Secretary HHS (OS/HHS). CSR reviews ~75 percent of NIH grant applications and also applications for joint NIH-NSF initiatives, joint NIH-DOE initiatives, the Global Alliance for Chronic Disease, the FDA Tobacco Regulatory Science Research Program, CDC, NIOSH, and ACF Small Business Innovation Research applications, and initiatives at the request of OS/HHS.

CSR employs a large staff of Ph.D. scientists who manage review in more than 1,600 review meetings per year, engaging more than 18,000 individuals across the United States. CSR leads all other NIH ICOs in efficiency and timeliness in completion of peer review. The work of CSR is central to the disbursement of ~ $39.2 billion annually across the United States for medical research and does so with less than 0.4 percent of the NIH budget.

To maintain and improve the peer review process that allows NIH to identify the most promising research, CSR's recent efforts are focused on:

- **Evaluation of the quality of review and reviewers** – making peer review groups nimble enough to adapt to rapidly evolving and increasingly multidisciplinary scientific fields. The Evaluating Panel Quality in Review (ENQUIRE) process was launched in 2019. ENQUIRE is a systematic, continuous, data-driven process to ensure that scientific scope of peer review groups evolve with emerging fields and are optimized to accurately identify high impact research.
- **Reviews of high-profile trans-NIH initiatives** – including RadX℠, HEAL, and INCLUDE.
- **Response to the COVID-19 pandemic** – converting all peer review meetings from in-person to virtual, to ensure that NIH peer review continued uninterrupted. This was achieved due to the foresight in acquiring/testing the FedRAMP-certified Zoom platform as early as mid-2019 and purchasing 650 licenses in preparation for an emergency.
- **Simplifying NIH peer review criteria** – to reduce administrative burden and refocus reviewer attention on the important questions of scientific impact and merit.

- **Adopted a data-driven approach** – to improve processes, inform decision-making, and to ensure peer review is functioning in a manner that instills public trust. Technological developments include use of text mining algorithms to inform ENQUIRE and use of machine learning/artificial intelligence to identify patterns indicating potential review integrity violations.
- **Broadening input by increasing diversity among reviewers** – geographic diversity, academic rank, race/ethnicity, and gender to better identify high impact science.




## CSR BUDGET

CSR is funded through the MF rather than through a direct appropriation. CSR's request is reviewed by the Extramural Activities Working Group (EAWG) committee and then approved by the Management and Budget Working Group committee. Budget requirements are highly dependent on the number of grant applications reviewed by CSR. Normally, ~80 percent of applications are reviewed in face-to-face meetings. Cost per application has been constant in inflation-adjusted dollars. Cost per application was $2,326 in FY 2016 and was $2,300 in FY 2019.

In March of FY 2020, CSR transitioned all meetings to electronic formats in response to the COVID-19 pandemic, which resulted in reduced costs. CSR reviewed approximately 49 percent of applications face-to-face. Some costs, normally for peer review meetings, were used to facilitate the transition including additional Cisco and Zoom licenses to run video meetings and laptops for telework. CSR was also able to provide $5.221 million in support to the clinical center. Cost per application has decreased to $1,894 as a result. Cost per application is expected to return to close to $2300 of FY 2019 once the pandemic no longer impacts operations and face-to-face review meetings resume.

**Budget Authority by Activity**
(Dollars in Millions)

| CSR Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Planned | FY 2020 Actual |
|---|---|---|---|---|---|---|
| Personnel | 71.282 | 75.243 | 76.715 | 79.051 | 84.884 | 82.975 |
| Review | 38.228 | 40.89 | 43.125 | 42.617 | 40.029 | 15.44 |
| Operations | 17.767 | 15.383 | 16.777 | 18.131 | 16.655 | 22.235 |
| Total | 127.277 | 131.516 | 136.617 | 139.799 | 141.568 | 120.65 |

## CSR PRIORITY ISSUES

**Adjustments to work practices resulting from COVID-19**: It is anticipated that CSR will transition back to holding some portion of review meetings in person. The return to in-person meetings involves unknowns of potential long-term economic changes such as the cost of air travel, meeting rooms, and hotel rooms for reviewers who travel to a review meeting.

**Ensuring the Quality and Efficiency of NIH Peer Review:**

- Continued evaluation of the function and scope of peer review groups using ENQUIRE. ENQUIRE was launched in 2019 and continues evaluating about 40 chartered review groups each year.
- CSR made initial recommendations to simplify the review criteria to reduce burden on reviewers and, more importantly, refocus review on the questions of significance and impact. CSR will continue to lead this effort and will also focus on review criteria for clinical trials applications.
- CSR is exploring ways to reduce potential biases in review. In collaboration with the NIH Common Fund, CSR will pilot a multi-stage, partially blinded review. CSR has piloted bias awareness training that includes scenarios of biases such as for the familiar and the "Matthew" effect. CSR is refining this training and plans to make it available for all ~18,000 reviewers who serve each year. These actions haves the potential to benefit NIH; reducing the influence of potential biases should allow for more accurate identification of high impact science.
- CSR is developing a Review Integrity Strategic plan as well as artificial intelligence tools to identify patterns of collaboration, publication, and conduct that could identify breaches in the integrity of the peer review process. CSR will continue to lead efforts to preserve the integrity of peer review through proactive and reactive steps.
- CSR is developing innovative solutions to allow efficient peer review while maintaining or improving its quality. Examples include an electronic system to process nominations and approvals for FACA committee membership and a tool that relies on artificial intelligence to adjust automated referral of grant applications as the scientific scope of peer review groups change. CSR will further refine these tools and make them available across the NIH.

## CSR SIGNIFICANT CHANGES

**Management Processes**

Management changes include regular input sought from employees regarding significant organizational or policy changes, regular engagement through 1:1 meetings with leadership, increased transparency in decision making and hiring practices, and increased collaboration across division and role.

Greater numbers of teleworking staff have lowered costs and office space requirements, increased staff morale and efficiency, and enabled peer review to continue without interruption regardless of the challenge—from severe weather to COVID-19.

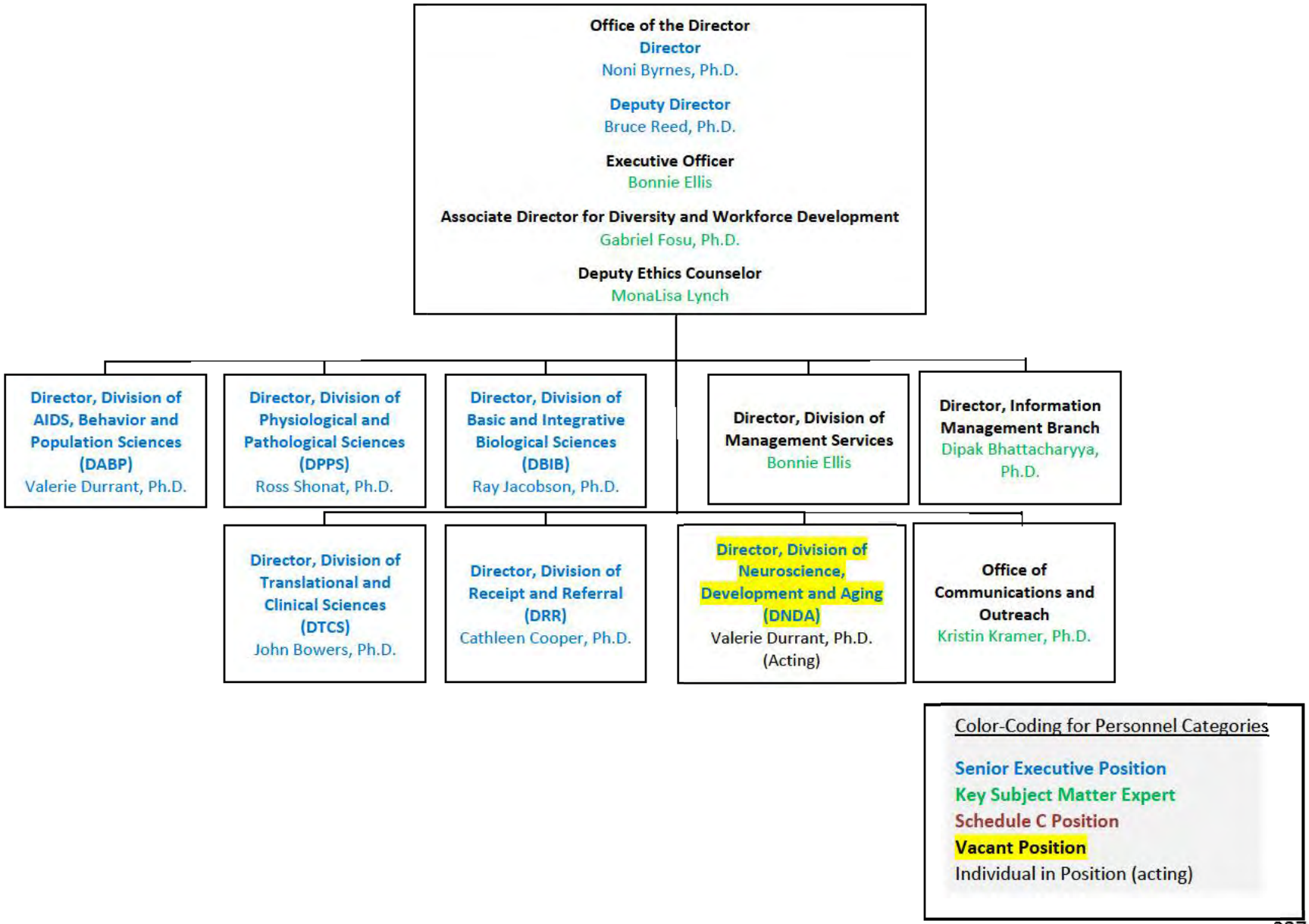
Expanded development and use of remote review meetings has reduced travel-related costs, enabled CSR to recruit much needed reviewers who could not travel to review meetings, and allowed CSR to continue peer review during the COVID-19 pandemic.

**Changes in Operations**

A new Office of Communications & Outreach was established in 2019 to increase communication and engagement with the external scientific community, with NIH extramural programs, and within CSR.

The Information Management Branch has taken on an increasingly important role as many CSR decisions and recommendations around peer review quality and efficiency are driven by data and development of innovative tools.

## CSR ORGANIZATIONAL CHART AND WORKFORCE






237

**Center for Scientific Review**

Office of the Director

- Director, Noni Byrnes, Ph.D. (Senior Executive Position)
- Deputy Director, Bruce Reed, Ph.D. (Senior Executive Position)
- Executive Officer, Bonnie Ellis, M.B.A. (Key Subject Matter Expert)
- Associate Director for Diversity and Workforce Development, Gabriel Fosu, Ph.D. (Key Subject Matter Expert)
- Deputy Ethics Counselor, MonaLisa Lynch, M.A. (Key Subject Matter Expert)

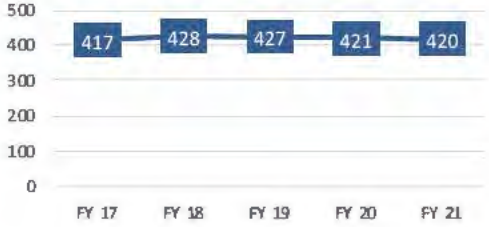
The following offices report directly to the Director:

- Division of AIDS, Behavior and Population Sciences (DABP)
    - Valerie Durrant, Ph.D. (Senior Executive Position)
- Division of Basic and Biological Sciences (DBIB)
    - Ray Jacobson, Ph.D. (Senior Executive Position)
- Division of Management Services (DMS)
    - Bonnie Ellis (Key Subject Matter Expert)
- Division of Neuroscience, Development and Aging (DNDA)
    - Valerie Durrant, Ph.D. (Acting)
- Division of Physiological and Pathological Sciences (DPPS)
    - Ross Shonat, Ph.D. (Senior Executive Position)
- Division of Receipt and Referral (DRR)
    - Cathleen Cooper, Ph.D. (Senior Executive Position)
- Division of Translational and Clinical Sciences (DTCS)
    - John Bowers, Ph.D. (Senior Executive Position)
- Office of Communications and Outreach
    - Kristin Kramer, Ph.D. (Key Subject Matter Expert)
- Information Management Branch
    - Dipak Bhattacharyya, Ph.D. (Key Subject Matter Expert)

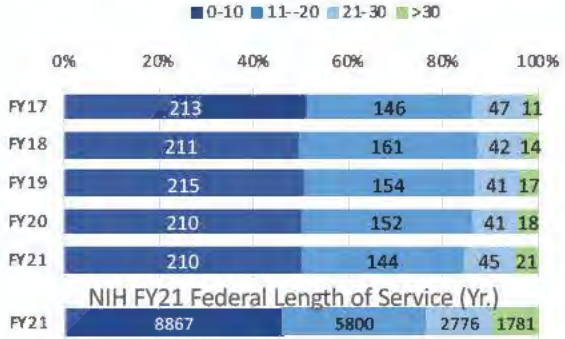
# CSR WORKFORCE SNAPSHOT [1]

Center for Scientific Review

## Federal Employee Onboard (Headcount) Trending



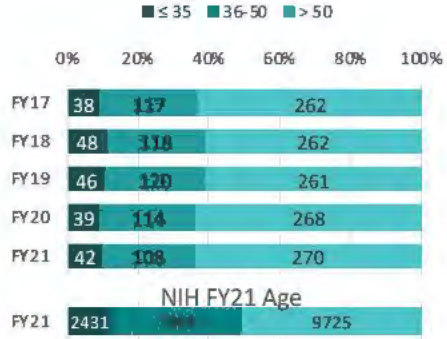

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



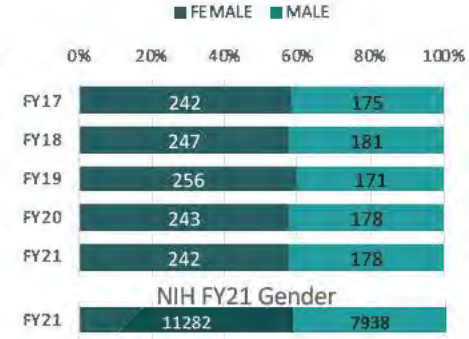

## Age Trending




## NIH FY21 Age



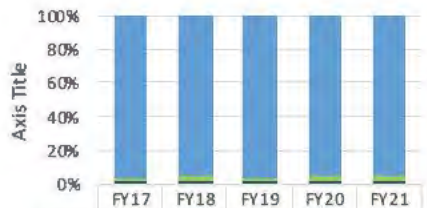

## Gender Trending




## NIH FY21 Gender



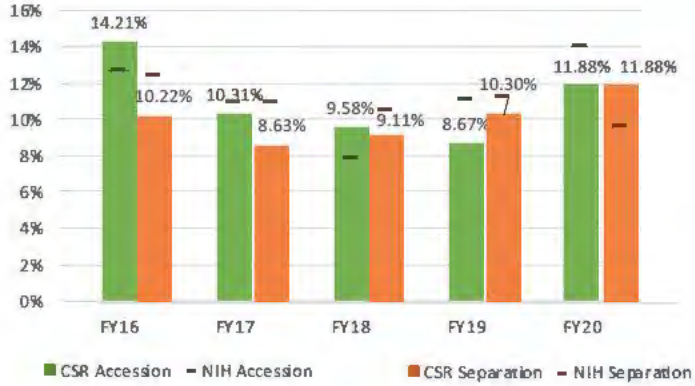

## Pay Plan Trending[2]



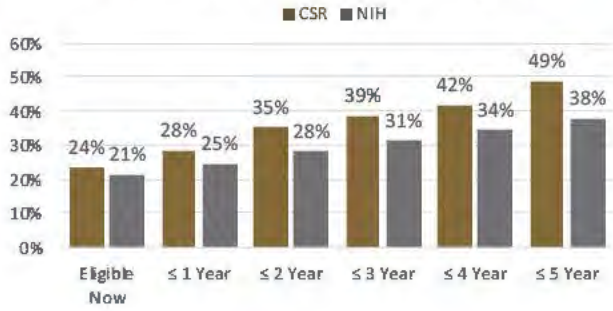

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 399 | 409 | 410 | 402 | 401 |
| EI | 9 | 9 | 9 | 12 | 11 |
| T42 | 9 | 10 | 8 | 7 | 8 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 0 | 0 | 0 | 0 | 0 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
CSR = 5.99 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES (FIC)

**Budget Summary**
(Dollars in Millions)

| FIC | FY 2016 Enacted | FY 2020 Enacted | FY 2021 President's Budget | FY 2021 House Level | FY 2021 Senate Level |
|---|---|---|---|---|---|
| Total Program Level | 70.447 | 80.827 | (b) (5) | | |
| Less (specify sources) | | | | | |
| Total Budget Authority | 70.447 | 80.827 | | | |
| FTE | 62 | 61 | | | |

## FIC MISSION

Established in 1968, the Fogarty International Center (FIC) supports and facilitates global health research conducted by United States and international investigators and trains the next generation of scientists to address global health challenges. Specifically, Fogarty invests in the global scientific workforce through research and research training programs built on collaborations between research institutions in the U.S. and low- and middle-income countries. These investments reap significant long-term benefits. For example, Fogarty-supported trainees from decades ago are now senior investigators on NIH-funded studies, contributing to cutting edge advances in globally relevant science. In addition to their scientific leadership, former Fogarty trainees inform health policies in the United States and other countries and train the next generation of global health leaders. FIC programs encompass a wide range of diseases and needs, including HIV/AIDS and EIDs; non-communicable diseases; environmental health, trauma and injury and harnessing mobile technology to improve health. This diverse portfolio represents a unique role for FIC at NIH, leading the development and implementation of programmatic initiatives that cut across the missions of individual Institutes and Centers. In addition, FIC's distinct mission of global health research training ensures that all of NIH can harness scientific talent worldwide to combat health threats in the United States and abroad.

Finally, Fogarty serves as a focal point for international activities at the NIH, working with the NIH OD and across the ICOs to help advance global health research agendas, develop trans-NIH cooperative activities, establish agreements between NIH and foreign institutions, and represent the NIH international research agenda within the USG.

Select Programs:

- **Leadership in Trans-NIH Initiatives** – In collaboration with other ICOs total, Fogarty has played a pivotal role in the development and implementation of the NIH Common Fund's Harnessing Data Science for Health Discovery and Innovation in Africa program (DSI-Africa), which will leverage data science technologies to develop solutions to the continent's most pressing public health problems through a robust ecosystem of new partners from academic, government and private sectors. In the next decade, rapid advances in data science are expected to transform biomedical and behavioral research and lead to improved health for individuals and populations. While data science applications are largely undeveloped in Africa, there are opportunities to utilize data science to impact health outcomes on the continent and around the world, including in the United States.

- **Harnessing Technology** – Digital and mobile technologies are among the most exciting and promising innovations in global health. Accordingly, Fogarty invested recent increases in its appropriations in the Mobile Health: Technology and Outcomes in LMICs (mHealth) program, which supports research on the use of mobile phones, tablets, and other wireless devices to improve health in low-resource settings. Grantees in this program, which is also supported by eight other NIH ICOs, have already developed low-cost technologies with the potential for impact in the United States. These types of leapfrogging technologies are crucial to improving health outcomes in low-resource settings here in the United States and abroad.
- **Infectious Diseases Portfolio – Training and Modeling** – FIC supports unique and critical efforts to address the threat of infectious diseases by building research capacity, which enables other NIH Institutes to conduct and support vital research. FIC's HIV Research Training Program has produced some of the world's leading scientific experts on the disease and has led to numerous advances that have benefited patients globally and in the United States. FIC's Global Infectious Disease (GID) program continues to build a critical mass of in-country scientists to conduct independent infectious diseases research. Finally, FIC's in-house scientists in the Division of International Epidemiology and Population Studies (DIEPS) use data-driven modeling and innovative computational tools to study of the spread of disease and guide polices to mitigate the impact of infectious disease transmission and prepare for future pandemics. The COVID-19 crisis has demonstrated that this team is a valuable resource for NIH during epidemic or pandemic outbreaks. For example, during the COVID-19 crisis from December 2019 to September 2020, DIEPS has authored 15 publications on the pandemic, with 12 additional manuscripts submitted or in preparation.

## FIC BUDGET

The FIC FY 2020 enacted budget level was $80.827 million, including an extramural budget of $62.161 million with $57.878 million in grants and $4.282 million in Research and Development contracts. FIC supported a total of 283 extramural grants in FY2020, including 68 Research Project Grant (RPG) awards and 215 in Other Research related grants. FIC's Research Management and Support budget (RMS) was $18.666 million in FY 2020 for the operation of FIC and to support trans-NIH initiatives.

**Budget Authority by Activity**
(Dollars in Millions)

| FIC Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Plan |
|---|---|---|---|---|---|
| Extramural Research | | | | | |
| Research Capacity Strengthening | 36.892 | 37.241 | 32.174 | 38.193 | 39.533 |
| Development of Human Resources for Global Health Research | 8.628 | 10.244 | 11.121 | 11.960 | 12.379 |
| International Collaborative Research | 8.449 | 8.112 | 14.757 | 9.901 | 10.248 |
| Subtotal, Extramural Research | 53.969 | 55.597 | 58.052 | 60.053 | 62.161 |
| Intramural Research | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| Research Management & Support | 16.050 | 16.255 | 17.503 | 17.868 | 18.666 |
| Total | 70.019 | 71.852 | 75.555 | 77.921 | 80.827 |

## FIC PRIORITY ISSUES

**Global health research**: NIH plays a pivotal role in global health research. It is critical that NIH leadership continue uninterrupted so that cutting-edge science can continue to inform the prevention, diagnosis and treatment of diseases that span the globe and affect our own population. Strengthening global health research capacity in the U.S. and in low- and middle-income countries, as well as identifying and supporting strategic collaborative initiatives with organizations in high-income countries, are integral to addressing complex health challenges that know no borders and are prevalent worldwide. The COVID-19 pandemic illustrates the need for skilled researchers with experience in global settings who can fight diseases wherever they originate or continue to be an international threat.

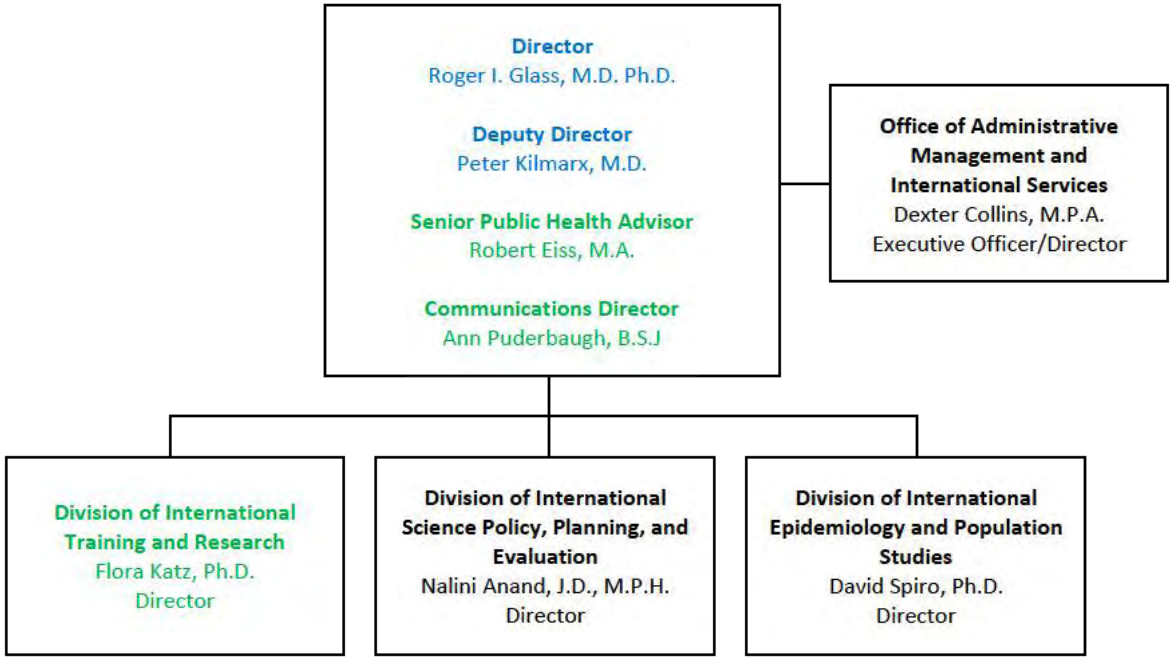
**HHS Coordination**: FIC serves as point of contact for USG Interagency issues that require coordination with NIH and other Operational Divisions of the HHS. The expected exit of the United States from the World Health Organization (WHO) will impact technical interactions and long- standing partnerships involving NIH and is a topic of attention and discussion.

**General Data Protection Regulation (GDPR)**: FIC has a lead advisory role in addressing international data sharing and other impediments that emerged with the enactment of GDPR, which regulates the processing of personal data of residents in the European Union and European Economic Area (EEA). The regulation took effect in 2018, applies extraterritorially, and creates new obligations for organizations that collect, use, and share across borders personal data of EU residents. As a result of sanctions and restrictions on data sharing under GDPR, NIH has encountered delays and significant difficulties in data transfers to the United States—ranging from genomic studies to multi-site clinical trials.

## FIC SIGNIFICANT CHANGES

None identified

## FIC ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**John E. Fogarty International Center for Advanced Study in the Health Sciences**

Office of the Director

- Director, Roger I. Glass, M.D., Ph.D. (Senior Executive Position)
- Deputy Director, Peter Kilmarx, M.D. (Senior Executive Position)
- Senior Public Health Advisor, Robert Eiss, M.A.
- Communications Director, Ann Puderbaugh, B.S.J.

The following divisions report directly to the Director:

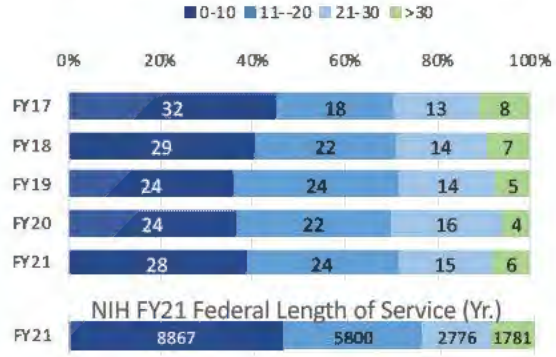
- Executive Officer/Director, Office of Administrative Management and International Services
    - Dexter Collins, M.P.A.
- Director Division of International Relations
    - Christine Sizemore, Ph.D.
- Director Division Training and Research
    - Flora Katz, Ph.D. (Senior Executive Position)
- Director Division of International Science Policy Planning, and Evaluation
    - Nalini Anand, J.D., M.P.H.
- Director Division of International Epidemiology and Population Studies
    - David Spiro, Ph.D.

# FIC WORKFORCE SNAPSHOT[1]

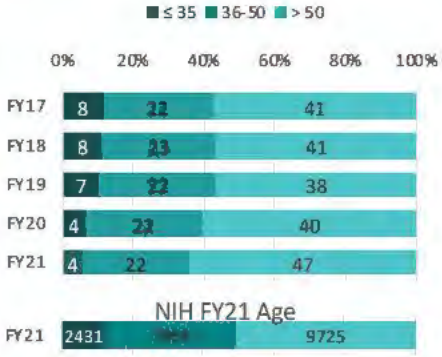
Fogarty International Center

## Federal Employee Onboard (Headcount) Trending

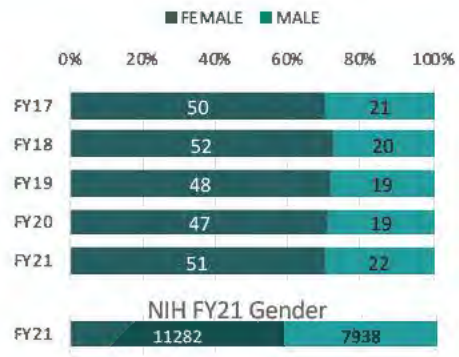

## Federal Length of Service (Yr.) Trending




## Age Trending




## Gender Trending




## NIH FY21 Federal Length of Service (Yr.)



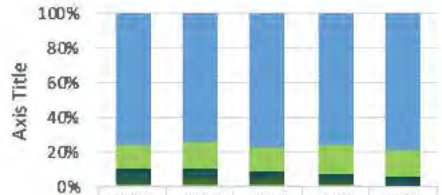

## NIH FY21 Age




## NIH FY21 Gender

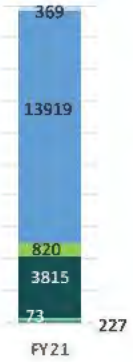



## Pay Plan Trending[2]

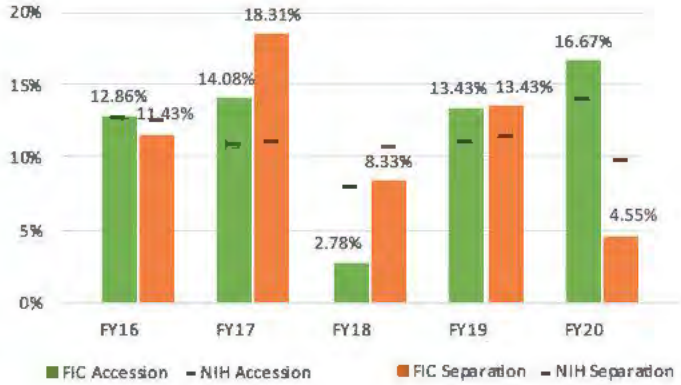



| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 54 | 54 | 52 | 50 | 57 |
| EI | 10 | 11 | 9 | 11 | 12 |
| T42 | 5 | 4 | 3 | 3 | 4 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 2 | 3 | 3 | 2 | 0 |

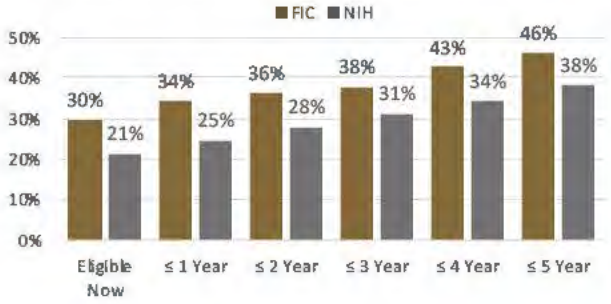
## NIH FY21 Pay Plan




## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
FIC = 4.27 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

**Budget Summary**
(Dollars in Millions)

| NCATS | FY 2016 Enacted | FY 2020 Enacted | FY 2021 President's Budget | FY 2021 House Level | FY 2021 Senate Level |
|---|---|---|---|---|---|
| Total Program Level | 685.417 | 832.888 | (b) (5) | | |
| Additional (CARES Act) | 0 | 36.000 | | | |
| Total Budget Authority | 685.417 | 868.888 | | | |
| FTE | 142 | 167 | | | |

## NCATS MISSION

The National Center for Advancing Translational Sciences (NCATS) was established on December 23, 2011, as part of the Consolidated Appropriations Act, 2012 (P.L. 112-74), to develop, demonstrate, and disseminate innovations that reduce, remove, or bypass system-wide bottlenecks in the translational research process. Rather than targeting a disease or fundamental science, NCATS focuses on what is common across diseases and the translational spectrum, supporting translation on a system-wide level as a scientific and operational problem.
NCATS's definitions:

- **Translation** is the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes.
- **Translational science** is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

The translation of a basic discovery to an improvement in public health requires cross-disciplinary teams of scientists, clinicians, and other stakeholders with wide-ranging expertise and perspectives. Serving as a catalyst for translational science, NCATS supports innovative collaborations across scientific disciplines and organizations, including academia, industry, and patient organizations. NCATS can rapidly adapt to serve medical and societal needs, including those of underrepresented or underserved populations, and to pivot to apply translational technologies to emerging issues.
Significant activities:

- NCATS produces a biennial report of its accomplishments. The most recent report covers calendar years 2017-2018.
- NCATS developed and released a new 5-year strategic plan in Fall 2016. The plan is organized around the conceptual themes of translational science, collaborations, training and stewardship. NCATS is working to update the plan in 2021.

**National COVID Cohort Collaborative (N3C):** The N3C Data Enclave is a centralized, secure, national clinical data resource with powerful analytics capabilities that the research community can use to study COVID-19, including potential risk factors, protective factors, and long-term health consequences. The N3C is a partnership among the NCATS-supported Clinical and Translational Science Awards (CTSA) Program hubs and the National Center for Data to Health (CD2H), with overall stewardship, including the data, by NCATS.

**Platform Vectors for Gene Therapy (PaVe-GT):** The goal of the PaVe-GT pilot program is to test the ability to significantly increase the efficiency of gene therapy trial startup by using a standardized process, with the same capsid and manufacturing methods, for four different rare diseases. PaVe-GT is funded under NCATS's innovative Cures Acceleration Network (CAN) authority, which has the goal to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials.

**NCATS Pharmaceutical Collection (NPC):** The NPC is a comprehensive, publicly accessible collection of approved molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of diseases and interventions. Over the past 10 years, researchers used the NPC to study an array of pathways and disease models, generating an unparalleled amount of data for such viruses that cause Ebola, Zika, Hepatitis C, Malaria, and, most recently, SARS-CoV-2, the virus that causes COVID-19. A number of projects produced drugs with new potential uses that have entered clinical trials, or have shown activity in testing, for several diseases and viruses.

## NCATS BUDGET

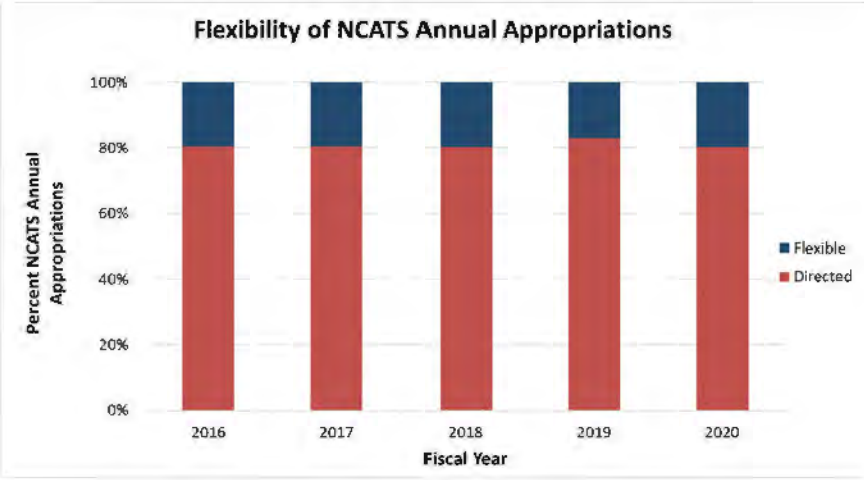
In accordance with appropriation language, NCATS's annual appropriation is divided into three distinct allotments (in addition to the Small Business Innovation Research and Small Business Technology Transfer allotment set-aside). The Clinical and Translational Science Activities allotment is the largest of these, representing approximately 69 percent of the NCATS budget. The CAN allotment supports that program and must be specifically appropriated, per authorization language; up to 20 percent of the amount appropriated for CAN may be used for OTA. The Re-Engineering Translational Sciences allotment supports all other NCATS activities. Legislation sets spending "floors" for the CTSA Program and spending "ceilings" for CAN. Recently, NCATS has also received funding from NIH's HEAL initiative and from the CARES Act for activities directed to the COVID-19 pandemic.

**Budget Authority by Activity**
(Dollars in Millions)

| NCATS | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating |
|---|---|---|---|---|---|
| Clinical and Translational Science Activities | 499.305 | 514.971 | 541.504 | 557.813 | 578.151 |
| Cures Acceleration Network | 25.788 | 25.039 | 25.773 | 44.487 | 49.100 |
| Reengineering Translational Sciences | 159.273 | 164.238 | 173.333 | 201.303 | 205.637 |
| Helping End Addiction Long-term | 0 | 0 | 13.497 | 43.894 | 0 |
| Coronavirus Aid, Relief, and Economic Security Act (CARES Act) | 0 | 0 | 0 | 0 | 36.000 |
| Total | 684.366 | 704.248 | 754.107 | 847.497 | 868.888 |

## NCATS PRIORITY ISSUES

**Strengthening and Streamlining the Nation's Capacity to Conduct Clinical Trials:** NCATS supports both preclinical and clinical programs that work to address translational science roadblocks to develop treatments more quickly and effectively. NCATS's authorization language restricts the Center's support of clinical trials to Phase II (trials designed to test drugs for efficacy and side effects in a limited number of patients) or Phase III for a treatment for a rare disease, after confirming that no similar research is being conducted. The restriction on NCATS's ability to support Phase III clinical trials constrains the Center's ability to partner with external researchers in academia or industry to fulfill its mission of addressing important translational roadblocks. Having these restrictions removed would greatly benefit NCATS's work to carry out its mission to improve the efficiency of clinical trial research and identify more effective scientific and operational solutions to speed the development of potential treatments.




**Increasing Budgetary Flexibility to Meet Translational Science Needs:** Currently, the annual budgetary appropriation to NCATS contains directives and restrictions that provide limited flexibility for the Center to address priority translational science needs and opportunities. Allowing NCATS greater flexibility, similar to other NIH ICs, in allocating its financial resources would ensure that its funds are used to support the highest-quality translational science and be able to address urgent needs.

**Addressing Roadblocks to Repurposing Existing Therapeutics:** Developing a brand-new therapeutic takes significant time, money, and effort. Many fail, due to bottlenecks in the therapeutic development process, and more knowledge needs to be gained about why. Translation of a promising molecule into an approved drug often takes one to two decades, if successful at all. It is crucial to advance strategies to reduce this time frame, decrease costs, and improve success rates. One such strategy is drug repurposing, which involves evaluating whether existing drugs or already studied compounds can be evaluated for a different purpose than originally thought and can shorten the time to clinical evaluation in patients. NCATS has made progress in using repurposing as a vehicle to test process improvements to address translational roadblocks. Repurposing a potential drug or compound has a number of complexities that involve different stakeholders, including but not limited to: access to potential therapeutics (industry), prioritizing candidates (potential researchers, computational scientists, funders), intellectual property rights, reimbursement (payors), prescribing behaviors (clinical practice), and business models to stimulate interest in conducting the research and pursuing development of potential treatments. NCATS continues to explore these issues to determine which may be within its mission to address directly or ways to convene different stakeholders to address together.

**Rare Diseases:** There are over 7,000 rare diseases, each defined as affecting fewer than 200,000 persons in the United States. But, taken as a whole, they affect approximately 30 million people in the U.S. New awareness and appreciation on the impact of rare diseases is greatly needed. Most rare diseases are genetic (around 80 percent) and with recent substantial advances in genetic science are potentially

treatable. Therefore, there needs to be greater access to early genetic/genomic testing; greater application of gene therapy or other "targeted" (sometimes referred to as "precision medicine") approaches; and, a shift in strategy to studying, and developing treatments for, many rare diseases at time. Augmented resources for several strategies are needed.

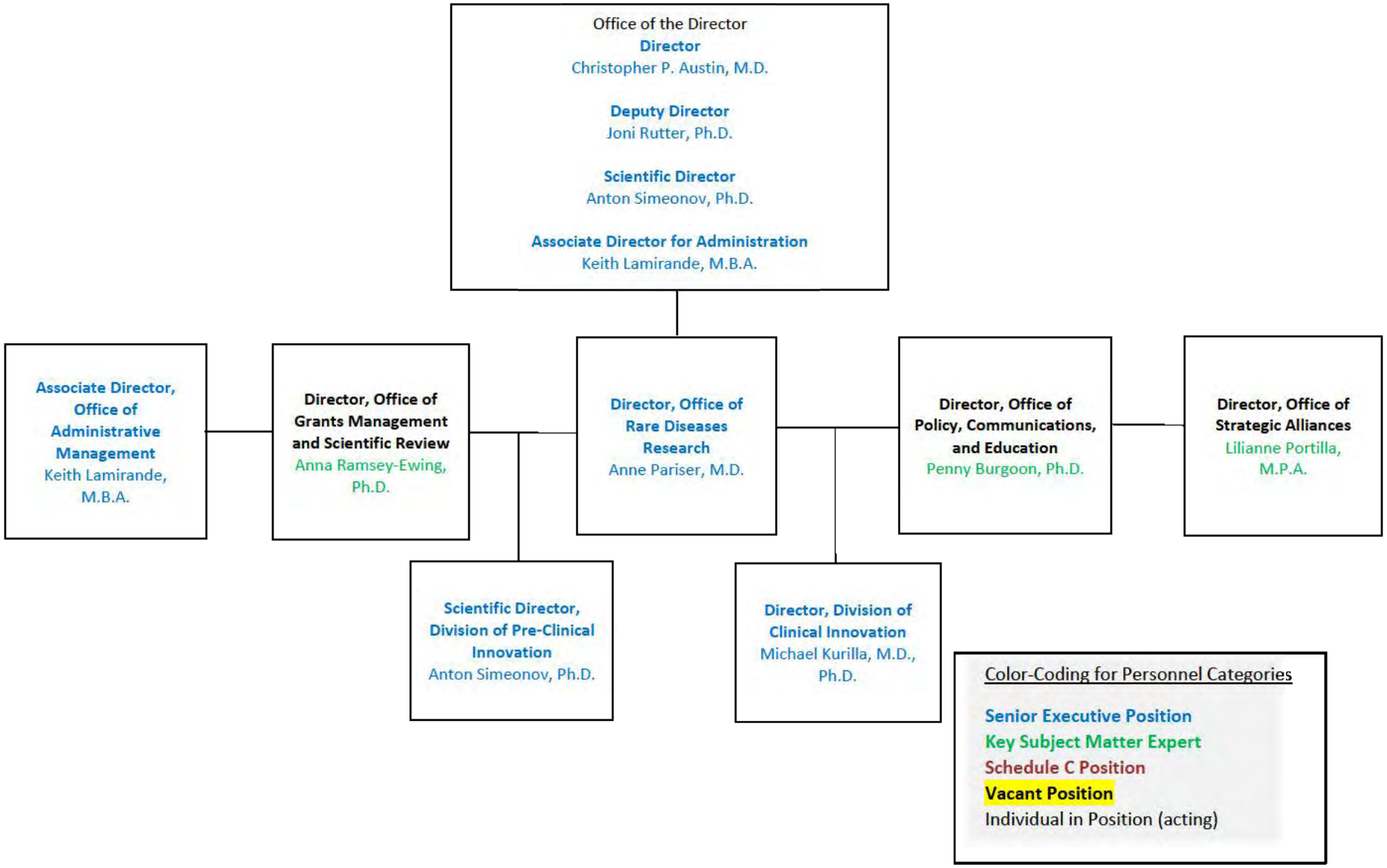
## NCATS SIGNIFICANT CHANGES

NCATS was established 10 years ago (2011) and had its first permanent Director appointed 9 years ago (2012). In that time frame, there has been significant growth and maturity of its programs, along with the establishment of several new programs. Key to NCATS growth has been increased funding for the CTSA Program and the diversification of the program to support several innovative initiatives, such as the Trial Innovation Network (TIN) and the CTSA Clinical Innovation Awards (CCIAs).
NCATS also began receiving sufficient funding in FY 2016 to enable the use of Other Transaction Authority (OTA) within the CAN. OTA allows NCATS to make research awards that are not the typical NIH grant, contract, or cooperative agreement. Instead, the Center can more nimbly add or subtract specific expertise, tools, technologies, and approaches to achieve scientific goals. This flexible research authority also lowers certain regulatory and policy barriers, making it possible to attract nontraditional partners and form novel arrangements to bring innovative ideas and new technologies to solving the biggest challenges in translational science. OTA has been used since 2016 to support the Biomedical Data Translator Program.

The 21st Century Cures Act (P.L. 114-255, 12/13/2016) changed NCATS annual report to a biennial report and modified its restriction on supporting clinical trials, allowing support for all Phase II clinical trials and support for Phase III clinical trials on rare diseases and conditions. (See Issue Paper titled "Strengthening and Streamlining the Nation's Capacity to Conduct Clinical Trials" for a more information.)

NCATS has been working to change the way research on rare diseases is conducted, from working on them one at a time to many at a time, and the perception that rare diseases don't affect many people. Rare diseases are estimated to affect over 30 million U.S. citizens and have a significant impact on the economy. (See Top Issue "Rare Diseases" for more information).

## NCATS ORGANIZATIONAL CHART AND WORKFORCE



**National Center for Advancing Translational Sciences**

Office of the Director

- Director, Christopher P. Austin, M.D. (Senior Executive Position)
- Deputy Director, Joni Rutter, Ph.D. (Senior Executive Position)
- Scientific Director, Anton Simeonov, Ph.D. (Senior Executive Position)
- Associate Director for Administration, Keith Lamirande, M.B.A. (Senior Executive Position)

The following divisions report directly to the Director:

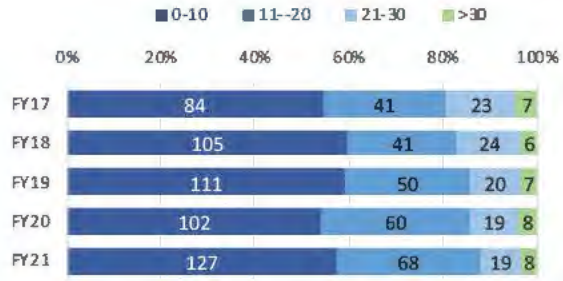
- Associate Director, Office of Administrative Management
    - Keith Lamirande, M.B.A. (Senior Executive Position)
- Director, Office of Grants Management and Scientific Review
    - Anna Ramsey-Ewing, Ph.D. (Key Subject Matter Expert)
- Director, Office of Rare Diseases Research
    - Anne Pariser, M.D. (Senior Executive Position)
- Director, Office of Policy, Communications, and Education
    - Penny Burgoon, Ph.D. (Key Subject Matter Expert)
- Director, Office of Strategic Alliances
    - Lilianne Portilla, M.P.A. (Key Subject Matter Expert)
- Scientific Director, Division of Pre-Clinical Innovation
    - Anton Simeonov, Ph.D. (Senior Executive Position)
- Director, Division of Clinical Innovation
    - Michael Kurilla, M.D., Ph.D. (Senior Executive Position)

National Center for Advancing Translational Sciences

# NCATS WORKFORCE SNAPSHOT[1]

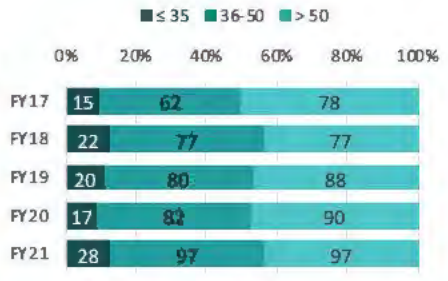
## Federal Employee Onboard (Headcount) Trending


## Federal Length of Service (Yr.) Trending

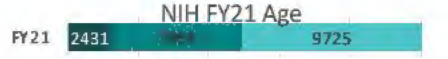



## NIH FY21 Federal Length of Service (Yr.)

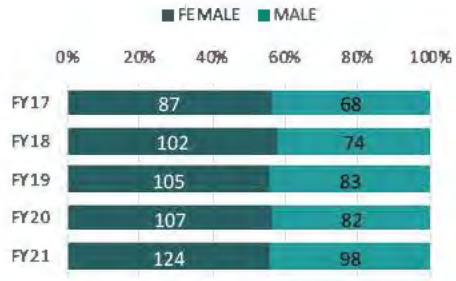

## Age Trending



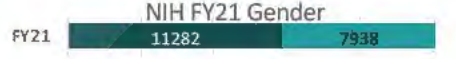

## NIH FY21 Age




## Gender Trending




## NIH FY21 Gender

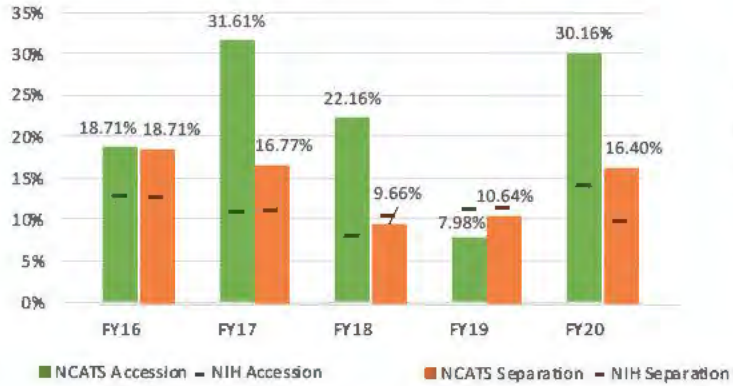



## Pay Plan Trending[2]

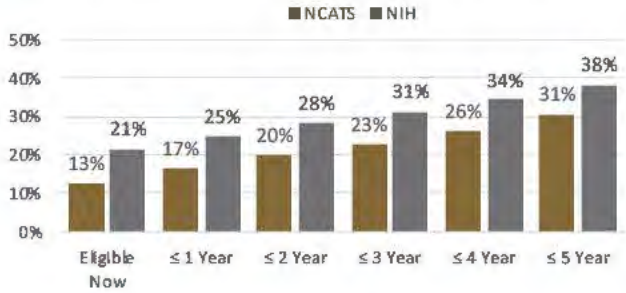

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 103 | 129 | 124 | 125 | 150 |
| EI | 11 | 6 | 17 | 16 | 8 |
| T42 | 39 | 39 | 44 | 43 | 60 |
| SES | 1 | 1 | 1 | 1 | 1 |
| CC | 1 | 1 | 2 | 4 | 3 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NCATS = 4.94 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] **CC**=CC; **SES**=ES, EX, SL, RS; **T42**=RF, RG, AD; **EI**=EI; **General Schedule (GS)**=GS, GM, GP, GR; **Federal Wage System (WS)**=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

**Budget Summary**
(Dollars in Millions)

| NCCIH | FY 2016 Enacted | FY 2020 Enacted | FY 2021 President's Budget | FY 2021 House Level | FY 2021 Senate Level |
|---|---|---|---|---|---|
| Total Program Level | 130.789 | 151.877 | (b) (5) | | |
| Less (specify sources) | | | | | |
| Total Budget Authority | 129.941 | 151.877 | | | |
| FTE | 72 | 75 | | | |

## NCCIH MISSION

The National Center for Complementary and Integrative Health (NCCIH), established in October 1998, is the lead Federal agency for rigorous scientific research on the fundamental mechanisms, usefulness, and safety of complementary and integrative health practices, including dietary, psychological, and physical approaches that may have originated outside of conventional medicine. This diverse group of health practices includes natural products, such as dietary supplements, plant-based products, and probiotics, as well as mind and body approaches, such as yoga, massage therapy, meditation, mindfulness-based stress reduction, spinal manipulation, and acupuncture. These approaches are considered complementary because they are used in conjunction with conventional medicine. Integrative health care seeks to bring conventional and complementary approaches together in a safe, coordinated way to improve clinical care for patients, health promotion, and disease prevention.

NCCIH, formerly known as the National Center for Complementary and Alternative Medicine (NCCAM), was created 20 years ago to facilitate the study and evaluation of complementary and alternative medical practices and to disseminate the resulting information to the public. At that time, the use of these practices was growing in popularity and availability, but little was known about their safety and efficacy. In addition, patients rarely discussed their use of complementary approaches with their doctors, and some used these approaches as an alternative to conventional medical care. This created potential problems for patients as some complementary approaches such as natural products can interfere with prescribed medications. In addition, some individuals may use approaches that are safe and effective for some conditions, but not for others. For example, evidence suggests that acupuncture may be effective for back and neck pain, but not for hip osteoarthritis. NCCIH was created to address this scientific and public health need. In the last twenty years, NCCIH has worked to advance the position that these complementary therapies should be "integrated" with and not used as an "alternative" to conventional medicine. The name of the center was changed in 2014 from NCCAM to NCCIH to reinforce this position. The Center has helped build the scientific infrastructure needed to conduct rigorous scientific research of complementary health approaches. The Center has expanded the scientific knowledge base around these practices and established resources to disseminate this information to the public—ultimately impacting their use.

**Who We Serve: Americans' Use of Complementary and Integrative Approaches** – Many complementary products and practices are in widespread use by the public. Data from the 2012 National Health Interview Survey shows that about 1 in 3 American adults (33 percent) used complementary health approaches, as did about 1 in 9 children age 4 to 17 (12 percent). Mind and body

approaches in widespread use included yoga (14 percent of adults; 8 percent of children in the 2017 National Health Interview Survey), chiropractic or osteopathic manipulation (8 percent of adults; 3 percent of children), meditation (14 percent of adults; 5 percent of children in 2017), and massage therapy (7 percent of adults; 0.7 percent of children). Natural products (dietary supplements other than vitamins and minerals), such as fish oil, glucosamine, probiotics, and melatonin, were used by 18 percent of adults and 5 percent of children—generally to promote overall health and wellness. Chronic pain—back pain, headache, musculoskeletal pain—is the other dominant health condition driving use.

**How We Operate: Setting Research Priorities and Enhancing Stewardship** – NCCIH research spans the continuum of basic, mechanistic, translational, efficacy, effectiveness, and implementation science research. Most of the research supported by the Center is developed through investigator-initiated proposals. Proposals undergo rigorous peer review prior to funding. While the grant application stream is robust, NCCIH has one of the lowest funding rates of all NIH ICs.

NCCIH is committed to funding research in areas that will maximize impact on health and health care. Consistent with this principle, NCCIH has made pain management a major emphasis in its solicitation of research proposals. A 2016 review by NCCIH scientists of U.S.-based clinical trials published in the *Mayo Clinic Proceedings* suggests that some of the most popular complementary health approaches, such as yoga, tai chi, and acupuncture, appear to be effective tools in helping manage common pain conditions. Another important area of focus is on "real world effectiveness" studies of integrative health approaches that bring conventional and complementary approaches together in a coordinated way, particularly for management of pain and other symptoms. As part of its 2020-2021 Strategic Planning Process, NCCIH is expanding its focus on whole person research and on multi-modal interventions. Finally, as a responsible steward of its publicly provided resources, NCCIH is highly selective in the choice of topics for major clinical trials. Decisions about which large-scale trials to support must be based on the strength, reliability, and reproducibility of signals from clinical experience and preliminary, smaller pilot studies, as well as on evidence of scientific plausibility obtained from mechanistic studies. Adequate methods and tools to accurately and effectively measure clinical outcomes are equally important, whether studying a mind and body practice or a natural product. For example, NCCIH has a strict natural product integrity policy to ensure that natural products used in NCCIH-supported research are fully identified, characterized, and standardized.

## NCCIH BUDGET

**Budget Authority by Activity**
(Dollars in Millions)

| NCCIH Activity | FY 2016 Actual | FY 2017 Actual | FY 2018 Actual | FY 2019 Actual | FY 2020 Operating Plan |
|---|---|---|---|---|---|
| **Extramural Research** | | | | | |
| Clinical Research | 53.569 | 50.270 | 54.346 | 92.108 | 95.617 |
| Basic Research | 47.167 | 54.124 | 57.322 | 19.337 | 20.074 |
| Training | 3.896 | 3.839 | 2.969 | 4.170 | 4.789 |
| **Subtotal, Extramural** | 104.632 | 108.233 | 114.637 | 115.614 | 120.480 |
| **Intramural Research** | 8.709 | 9.058 | 9.606 | 11.606 | 12.535 |
| **Research Management & Support** | 16.6 | 17.098 | 17.441 | 18.740 | 18.863 |
| **TOTAL** | 129.941 | 134.389 | 141.684 | 145.961 | 151.877 |

## NCCIH PRIORITY ISSUES

**Nonpharmacologic strategies for pain management:** In 2017, NCCIH partnered with the DoD, DVA, and seven other ICOs at NIH to launch the NIH-DoD-VA Pain Management Collaboratory (PMC). The PMC seeks to support the development, implementation, and testing of cost-effective, large-scale, real-world research on nonpharmacologic approaches for pain management and related conditions in military and veteran health care delivery organizations.

**Role of cannabis in pain management**: Cannabis is a unique source of phytochemicals, containing over 100 cannabinoids and terpenes, each with its own pharmacology. The cannabinoid THC is the most widely studied and is responsible for the plant's addictive and psychoactive effects; however very few of the other cannabinoids and terpenes have been extensively studied. NCCIH recently funded nine new research awards that will investigate the potential pain-relieving properties and mechanisms of actions of the diverse phytochemicals in cannabis, including both minor cannabinoids (non-THC) and terpenes. This investment of approximately $15 million over 5 years will strengthen the evidence regarding cannabis components and whether they have potential roles in pain management.

**Safety and efficacy of natural products***:* NCCIH (together with the NIH Office of Dietary Supplements (ODS) and in partnership with the FDA) maintains interest determining both the safety and efficacy of natural products and their interactions with other drugs. For example, the Centers for Advancing Research on Botanicals and Other Natural Products (CARBON) Program, launched in 1999 in collaboration with the NIH ODS, promotes collaborative and transdisciplinary research on the safety, effectiveness, and mechanisms of action of botanical dietary supplements that have a high potential to benefit human health. The CARBON Program is comprised of three Botanical Dietary Supplements Research Centers, and two Centers for Advancing Natural Products Innovation and Technology. NCCIH has also established new standards for rigor and reproducibility within the field. For example, NCCIH established a natural product integrity policy and quality control program for the study of herbal medicines, dietary supplements, and probiotics. This policy requires all proposed research projects to submit information on the source, composition, and process of production of the product it plans to study. This information is reviewed by experts to ensure that product quality is adequate to yield definitive and reproducible research results. Product information has been evaluated for more than 500 research projects since the policy was established in 2006.

## NCCIH SIGNIFICANT CHANGES

NCCIH is spearheading an effort to establish an Intramural Pain Research Center within the NIH Clinical Center (CC). This evolving, multidisciplinary initiative will help identify specific pain mechanisms, determine the efficacy of non-opioid treatments, and predict individual patient response to therapies and outcomes. Initial efforts have focused on the urgent need to develop a pain phenotyping and brain imaging platform to support project-specific initiatives and serve the many patients at the Clinical Center who are experiencing intractable pain associated with their disease and/or treatment. The Pain Research Center also plans to collect a wide range of measures related to pain, thus allowing NIH medical community to quantify patients' pain and target it with effective novel non-opioid interventions.

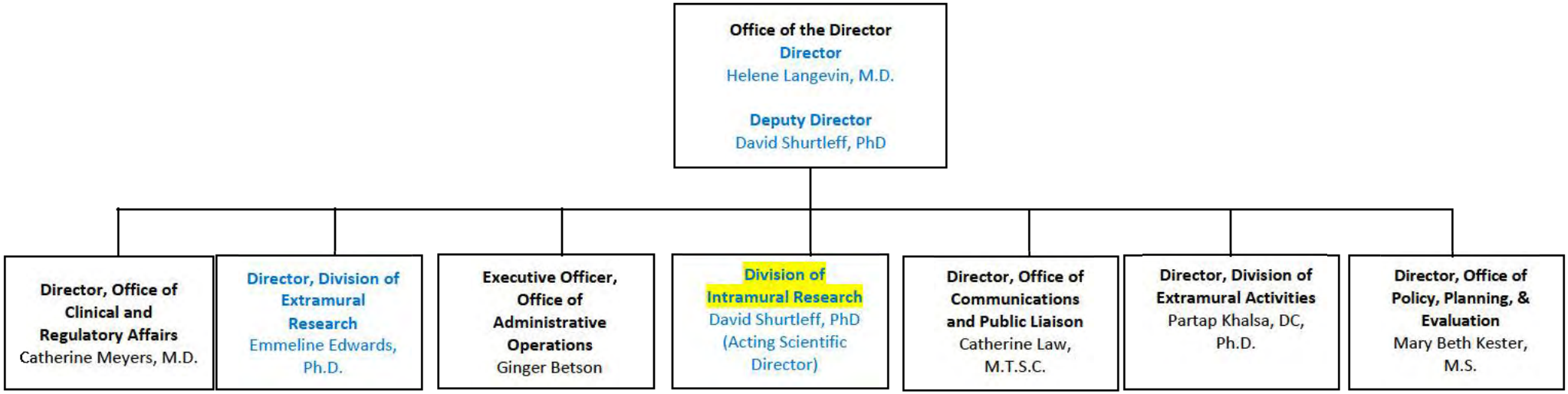
NCCIH is leading major extramural initiatives investing in pragmatic clinical trials of nonpharmacologic approaches for pain management. Pragmatic clinical trials are human effectiveness trials that can be embedded into standard healthcare. These studies are beneficial because they are conducted in a real-world setting with a real-world distribution of patients.

NCCIH is leading the NIH-Department of Defense-Veterans Affairs Pain Management Collaboratory (PMC). This partnership between NCCIH and other Federal agencies supports research evaluating the efficacy of nonpharmacologic pain management approaches within the military and veteran healthcare systems and investigating how these approaches could be integrated into the healthcare systems.

NCCIH is leading the HEAL initiative's Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) program, which seeks to take interventions and treatment guidelines that have already been shown to work for specific pain conditions and integrate them into healthcare delivery systems. Recent decades have seen an overreliance on the prescription of opioids for chronic pain, which has contributed to an epidemic of opioid overdose deaths and addiction.

As part of its Strategic Planning efforts for FY 2021 - 2026, NCCIH is actively planning for the future of the research enterprise. The Center is strengthening a consideration of "whole person" health with research on multimodal approaches to care. A whole person health framework provides critical insights and opportunities to expand and build on NCCIH's current research portfolio on natural products and mind and body approaches. By deepening NCCIH's scientific understanding of the connections that exist across domains of human health, NCCIH can better understand how conditions interrelate, define multimodal interventions that address these problems, and deepen how NCCIH supports patients through the full continuum of their health experience, including the return to health.

## NCCIH ORGANIZATIONAL CHART AND WORKFORCE




Color-Coding for Personnel Categories

Senior Executive Position
Key Subject Matter Expert
Schedule C Position
Vacant Position
Individual in Position (acting)

**National Center for Complementary and Integrative Health**

Office of the Director

- Director, Helene Langevin, M.D. (Senior Executive Position)
- Deputy Director, David Shurtleff, Ph.D. (Senior Executive Position)

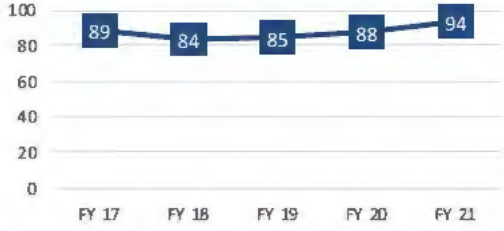
The following Divisions/Offices report directly to the Director:

- Director, Division of Extramural Research
  - Emmeline Edwards, Ph.D. (Senior Executive Position)
- Scientific Director, Division of Intramural Research
  - David Shurtleff, Ph.D. (Acting; Senior Executive Position)
- Clinical Director, Division of Intramural Research
  - Maryland Pao, M.D. (Acting; Senior Executive Position )
- Director, Division of Extramural Activities
  - Partap Khalsa, D.C., Ph.D.
- Executive Officer, Office of Administrative Operations
  - Ginger Betson
- Director, Office of Clinical and Regulatory Affairs
  - Catherine Meyers, M.D.
- Director, Office of Communications and Public Liaison
  - Catherine Law, M.T.S.C.
- Director, Office of Policy, Planning, and Evaluation
  - Mary Beth Kester, M.S.

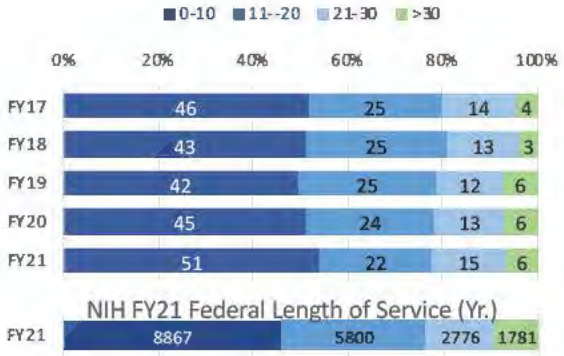
National Center for Complementary and Integrative Health

# NCCIH WORKFORCE SNAPSHOT[1]

## Federal Employee Onboard (Headcount) Trending



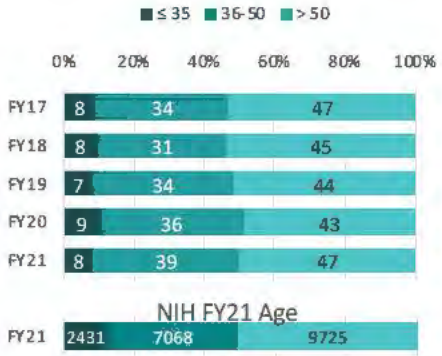

## Federal Length of Service (Yr.) Trending




## NIH FY21 Federal Length of Service (Yr.)



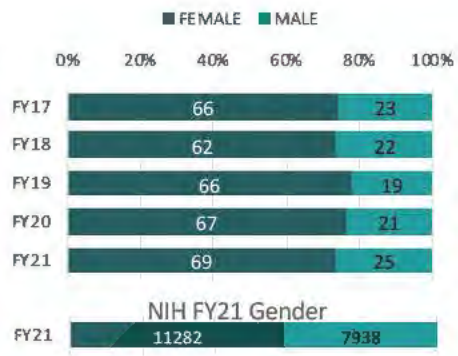

## Age Trending




## NIH FY21 Age



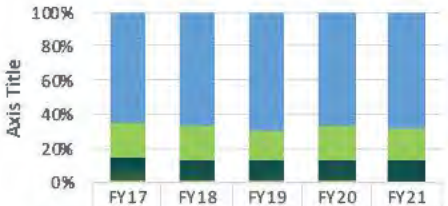

## Gender Trending




## NIH FY21 Gender



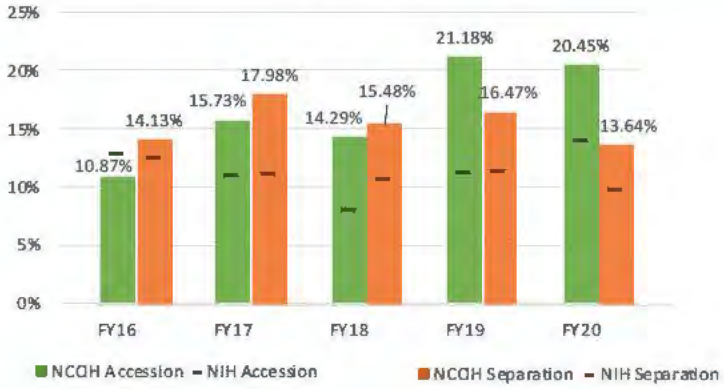

## Pay Plan Trending[2]



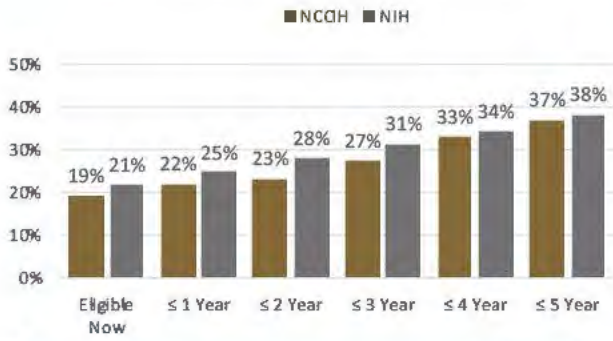

| | FY17 | FY18 | FY19 | FY20 | FY21 |
|---|---|---|---|---|---|
| WS | 0 | 0 | 0 | 0 | 0 |
| GS | 58 | 56 | 59 | 59 | 64 |
| EI | 18 | 17 | 15 | 18 | 18 |
| T42 | 10 | 9 | 9 | 9 | 11 |
| SES | 0 | 0 | 0 | 0 | 0 |
| CC | 3 | 2 | 2 | 2 | 1 |

## NIH FY21 Pay Plan


## Accession & Separation Trending




## Cumulative % of FTE Retirement Eligibility[3]




Average time FTEs stayed past retirement eligibility
NCCIH = 4.04 years
NIH = 5.54 years

[1] Onboard data is headcount as of October 1st for each fiscal year.
[2] CC=CC; SES=ES, EX, SL, RS; T42=RF, RG, AD; EI=EI; General Schedule (GS)=GS, GM, GP, GR; Federal Wage System (WS)=WG, WL, WS
[3] Retirement eligibility calculated as of 10/1/2020.

# OVERSIGHT

The NIH Office of Management Assessment (OMA) within the Office of Management (OM), Office of the Director (OD) provides central coordination and liaison functions for all Office of Inspector General (OIG) and Government Accountability Office (GAO) audits and reviews performed over NIH programs.

## OFFICE OF THE INSPECTOR GENERAL (OIG)

Inspector General (IG)**:** The OIG and the IG Biography can be found online at the HHS Office of the Inspector General Website.

**Top Issues and Recent Reports**

For OIG reviews, OMA works closely with the HHS Office of the Assistant Secretary for Financial Resources (ASFR). With respect to NIH issues, the OIG:

- protects the integrity of HHS programs through audits, investigations, and inspections to help identify, prevent, and mitigate fraud, waste, abuse, mismanagement, and conflicts of interest;
- reports program and management problems and recommends corrective actions to the Secretary of HHS and to Congress in the interest of maintaining good management and maximizing efficiency and effectiveness.

Since January 20, 2017, there have been 33 OIG reports discussing and/or assessing NIH programs and NIH has closed 37 OIG recommendations included in those reports. As of September 21, 2020, NIH has 34 open OIG recommendations included in those reports. Reports that merit special attention are listed below, including those on topics with continued Congressional interest and those with open recommendations directed to NIH.

Final OIG reports meriting special attention (in reverse chronological order):

1. NIH Should Improve Its Stewardship and Accountability Over Hardware and Software Assets (FY 2020)
    - Issued September 2020 – contains seven recommendations.
    - NIH takes seriously and acknowledges its role as a responsible steward of programs and resources.
2. NIH Should Improve Preventative and Detective Controls to More Effectively Mitigate the Risk of Compromise (FY20) *[report contains restricted, sensitive information, OIG limited report distribution]*
    - Cybersecurity will continue to be of interest to the Department, the Administration, and Congress.
3. The National Cancer Institute Needs to Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants (FY20)
    - Zero of two recommendations implemented.
4. The National Eye Institute Generally Had Adequate Procedures To Assess An Applicant's Risk During The Pre-Award Process (FY20)
    - Zero of two recommendations implemented.
5. NIH Has Acted to Protect Confidential Information Handled by Peer Reviewers, But Could Do More (FY20)
    - Zero of four recommendations implemented.
    - Research Integrity and Foreign Influence is a top issue for the agency.
6. NIH Submitted OIG Clearance Documents for Just Over One-Half of Its Audit Recommendations, and the Remaining 225 Recommendations Were Unresolved as of September 30, 2016 (FY20)
    - Zero of two recommendations implemented.

7. NIH Had Information Technology Controls Weaknesses Surrounding Its Electronic Health Record System (FY20)
    - Three of three recommendations implemented.
    - Cybersecurity will continue to be of interest to the Department, the Administration, and Congress.
8. NIH Has Limited Policies, Procedures, and Controls In Place For Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations (FY19)
    - Zero of three recommendations implemented.
    - Congress is interested in the means for managing and minimizing conflicts of interest for institutions and investigators.
9. Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations (FY19)
    - Zero of two recommendations implemented.
    - Research integrity and foreign influence are top issues for the agency.
10. NIH Has Made Strides In Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More (FY19)
    - Zero of two recommendations implemented.
    - Congress is interested in the means for managing and minimizing conflicts of interest for institutions and investigators.
11. NIH Could Improve Its Monitoring To Ensure that an Awardee of the *All of Us* Research Program had Adequate Cybersecurity Controls to Protect Participants' Sensitive Data (FY19)
    - One of one recommendation implemented.
    - The *All of Us* Research Program is a top issue for the agency.
12. Opportunities Exist for the NIH to Strengthen Controls in Place to Permit and Monitor Access to Its Sensitive Data (FY19)
    - Six of six recommendations implemented.
    - Foreign Influence is a top issue for the agency.
13. NIH Did Not Always Administer Superfund Appropriations During FY 2015 In Accordance With Federal Requirements (FY18)
    - Two of four recommendations implemented.

## GOVERNMENT ACCOUNTABILITY OFFICE (GAO)

For GAO reviews, OMA works with the HHS Office of the Assistant Secretary for Legislation (ASL). With respect to NIH issues, the GAO:

- provides oversight of Federal programs and insight into ways to make government more efficient, effective, ethical, and equitable;
- issues reports, testimonies, and legal decisions to Congress and issues guidance on the use of internal or management controls to ensure effective and efficient government operations;
- annually identifies Federal agency programs with fragmented goals or activities. Past issues involving NIH include:
    - In 2020, fragmentation Public Access to Research Results, based on report GAO-20-81 (see #23 in table below). In 2020, GAO determined that NIH partially addressed the action by building consensus on issues and processes to implement leading practices that enhance and sustain collaboration across Federal agencies.
    - In 2019, fragmentation Patent Licensing at Federal Labs, based on report GAO-18-327 (see #27 in table below). In 2019, GAO determined that NIH addressed the action by collecting and disseminating written materials detailing aspects of the processes used to help establish license financial terms.

- In 2017, fragmentation Administrative Requirements on Research, based on report GAO-16-573 (see #29 in table below). In 2020, GAO determined that NIH addressed the action by participating in several interagency efforts to identify areas for standardizing administrative requirements for Federal research grants.

**High Risk List**

GAO does not consider NIH to be a High-Risk Operating Division of HHS. Since January 20, 2017, there have been 96 GAO reports discussing and/or assessing NIH programs issued, and NIH has closed 27 GAO recommendations included in those reports. As of September 21, 2020, NIH has 10 open GAO recommendations included in those reports. Reports that merit special attention are listed below, including those on topics with continued Congressional interest and those with open recommendations directed to NIH.

Final GAO reports meriting special attention (in reverse chronological order):

1. COVID-19 Monitoring and Oversight (FY20)
    a. COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions
    b. COVID-19 Contracting: Observations on Federal Contracting in Response to the Pandemic
    c. COVID-19: Opportunities to Improve Federal Response and Recovery Efforts
    - No recommendations addressed to NIH.
    - Infectious diseases will continue to be of immediate concern to Congress.
    - Pandemic Preparedness and COVID-19 Research are top issues for the agency.
2. Federal Advisory Committees: Actions Needed to Enhance Decision-Making Transparency and Cost Data Accuracy (FY20)
    - Just issued – contains one recommendation.
3. Survivors of Childhood Cancer: Factors Affecting Access to Follow-up Care (FY20)
    - Childhood cancer will continue to be an immediate concern to Congress.
4. Genetic Services: Information on Genetic Counselor and Medical Geneticist Workforces (FY20)
    - Genetics will continue to be a concern to Congress.
5. Native American Youth: Agencies Incorporated Almost All Leading Practices When Assessing Grant Programs Addressing Delinquency (FY20)
    - Health Disparities Research and Rural Health are top issues for the agency.
6. Sexual Harassment in STEM Research: Agencies Have Taken Actions, but Need Complaint Procedures, Overall Plans, and Better Collaboration (FY20)
    - Zero of two recommendations implemented.
    - Diversity, Inclusion, Equity and Culture is a top issue for the agency.
7. Maternal Mortality: Trends in Pregnancy-Related Deaths and Federal Efforts to Reduce Them (FY20)
    - Maternal Morbidity and Mortality is a top issue for the agency.
8. Drug Control: The Office of National Drug Control Policy Should Develop Key Planning Elements to Meet Statutory Requirements (FY20)
    - Drug pricing will continue to be of interest to the Department, the Administration and Congress.
9. Cloud Computing Security: Agencies Increased Use of Federal Authorization Program, but Improved Oversight and Implementation Needed (FY20)
    - Zero of four recommendations implemented.
    - Cybersecurity is a top issue for the agency.
10. Federal Research: Additional Actions Needed to Improve Public Access to Research Results (FY20)
    - Zero of two recommendations implemented.

11. Animals Use in Research-Federal Agencies Should Assess and Report on Their Efforts to Develop and Promote Alternatives (FY19)
    - Animal use in research will continue to be of interest to Congress.
12. Small Business Innovation Research (SBIR)
    - SBIR: Few Agencies Made Awards to Small Businesses Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Funds, or Private Equity Firms (FY19)
    - SBIR: Many Agencies Took Longer to Issue Small Business Awards than Recommended Report to Congressional Committees (FY19)
    - SBIR: Additional Actions Needed to Implement Fraud, Waste, and Abuse Prevention Requirements (FY17)
    - SBIR: Most Agencies Met Spending Requirements, but DOD and EPA Need to Improve Data Reporting (FY17)
    - Small business research programs continue to be of interest to Congress.
13. NIH Research: Actions Needed to Ensure Workforce Diversity Strategic Goals Are Achieved (FY18)
    - One of one recommendation implemented.
    - Diversity, Inclusion, Equity and Culture is a top issue for the agency
14. Federal Research: Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions (FY18)
    - One of one recommendation implemented.
    - Patent licensing will continue to be of interest to the Department, the Administration and Congress.
15. Youth with Autism: Federal Agencies Should Take Additional Action to Support Transition-Age Youth (FY17)
    - One of two recommendations implemented.
    - Autism will continue to be of interest to the Department, the Administration and Congress.
16. FEDERAL RESEARCH GRANTS: Opportunities Remain for Agencies to Streamline Administrative Requirements (FY16)
    - Three of three recommendations closed.
    - Congress often hears from Federally funded investigators on the burden associated with meeting administrative requirements of grants.

**Duplication Reports**

GAO hasn't identified any NIH programs as "duplicative." Instead, GAO tagged three programs with potentially fragmented goals/activities. Duplication/fragmentation/overlap show up in the same annual GAO report that most people refer to as GAO's duplication report.

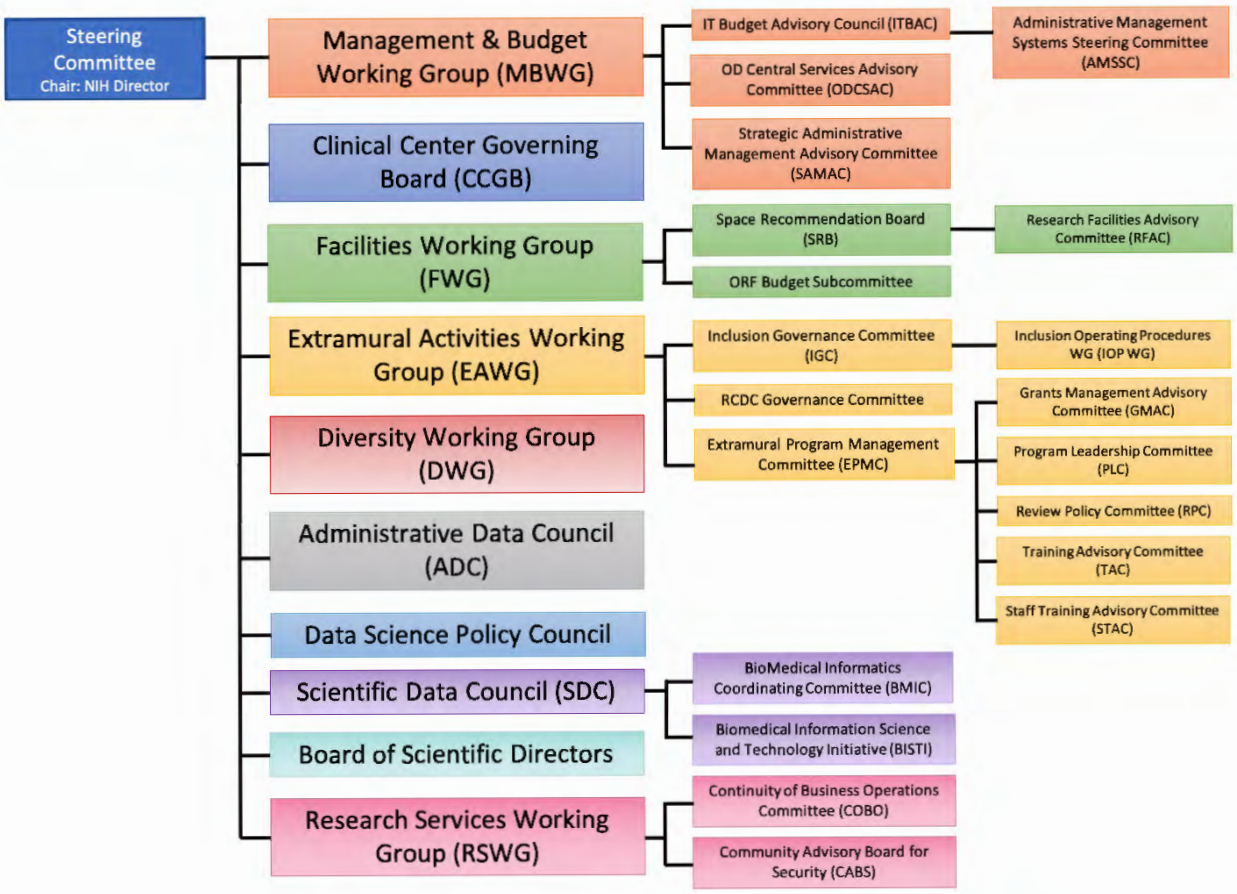
1. In 2020, fragmentation Public Access to Research Results, based on report GAO-20-81. In 2020, GAO determined that NIH partially addressed the action by building consensus on issues and processes to implement leading practices that enhance and sustain collaboration across Federal agencies.
2. In 2019, fragmentation Patent Licensing at Federal Labs, based on report GAO-18-327. In 2019, GAO determined that NIH addressed the action by collecting and disseminating written materials detailing aspects of the processes used to help establish license financial terms.
3. In 2017, fragmentation Administrative Requirements on Research, based on report GAO-16-573. In 2020, GAO determined that NIH addressed the action by participating in several interagency efforts to identify areas for standardizing administrative requirements for Federal research grants.

# GOVERNANCE

**KEY STRUCTURES AND DECISION-MAKING PROCESSES**

The Steering Committee (SC), chaired by the NIH Director, provides oversight for, but does not manage, functions common to NIH Institutes and Centers (ICs). The SC's ten subcommittees (listed below) make corporate policy and resource recommendations to the Steering Committee. The NIH Principal Deputy Director coordinates science policy, legislation, and communication issues and brings those issues directly to the Steering Committee for consideration.

- **The Administrative Data Council (ADC)** recommends strategies and policies for trans-NIH information and information technology supporting extramural, intramural, and administrative functions. They provide recommendations and oversight of investments in NIH's IT infrastructure and in enterprise-wide systems, applications, and tools with strategic importance, high dollar value, or significant impact on the NIH mission.
- **The Board of Scientific Directors** provides advises the SC on intramural-related activities. i Specifically, they develop, review, and recommend policies affecting the IRPs of the NIH Institutes and Centers to the Deputy Director for Intramural Research.
- **The Clinical Center Governing Board (CCGB)** was created in response to recommendations from the NIH Scientific Management Review Board, to position the Clinical Center as a national resource and address obstacles to developing and sustaining an optimal environment for clinical research at the agency.
- **The Data Science Policy Committee (DPSC)** provides a forum for trans-NIH data science policy development and oversight. The DSPC is intended to address the growing policy challenges and opportunities associated with 'big data' and data science in biomedical research, thereby promoting maximum public benefit from data utilization in a manner that fulfills the agency's principles toward responsible stewardship of data.
- **The Diversity Working Group (DWG)** provides advice on diversity and inclusion issues affecting the intramural and extramural research communities and the NIH workforce.
- **The Extramural Activities Working Group (EAWG)** focuses primarily on the Office of Extramural Research (OER), the Center for Scientific Review (CSR), and the extramural aspects of Office of Technology Transfer (OTT) and Contracts (R&D). They also provide governance for efforts aimed at restructuring and consolidating key administrative components associated with extramural research and training.
- **The Facilities Working Group (FWG)** advises on planning, acquisition, development, use of land and facilities, and advises the Director of the Office of Research Facilities (ORF) on operating policies and business strategy.
- **The Management and Budget Working Group (MBWG)** oversees the development of budgetary, human resource, management and organizational strategies, and provides recommendations to the SC on funding levels for several NIH components that do not receive appropriations, such as the Office of Research Services (ORS), ORF Development and Operations, Office of the Director (OD) Central Services, CSR, Center for Information Technology (CIT), IT Enterprise Systems, and the Clinical Center (CC).
- **The Research Services Working Group (RSWG)** advises the ORS Director on matters of program, policy, and budget.
- **The Scientific Data Council (SDC)** is a high-level advisory body for computational and quantitative research programs across NIH.




**Senior Biomedical Research and Biomedical Product Assessment Service (Not Yet Implemented)**
The 21st Century Cures Act expanded provisions of the Senior Biomedical Research Service (SBRS), under 42 U.S. Code § 237, as the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS). The law allows for up to 2,000 members (NIH allocated 1,261) to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.

HHS issued guidance in May 2020, which included essential information for NIH to move forward, such as the number of slots, delegation of pay, and other matters. NIH convened a working group to develop a position structure and policy guidance and established a committee that will conduct peer and pay review of potential candidates and make recommendations on policy decisions. NIH is working to implement these changes in early 2021.

**NIH Title 42 Compensation Review Committees**
"Title 42," as used in the employment context, refers to two specific appointment authorities under the Public Health Service Act, codified as 42 U.S.C. § 209(f) for "special consultants" and 42 U.S.C. § 209(g) for fellows and other appointees. NIH uses these authorities to appoint certain doctoral level scientists in the intramural and extramural programs, as well as senior scientific leaders (e.g., IC Directors). Because there is no statutory pay cap under either authority—overall limits are established by the Secretary of HHS—Title 42 provides NIH with greater pay flexibility and the ability to compete more effectively with the private sector than with other Federal employment mechanisms.
NIH has established two pay models to govern Title 42 pay setting for senior leaders and for other

Title 42 scientists (the IC Directors/NIH Deputy Directors Compensation Model and the NIH Title 42 Pay Model, respectively). The following review and oversight committees operate under these models to assure equity and consistency in pay setting across NIH, compliance with overarching Title 42 policies and requirements, and prudent stewardship of Federal funds and resources.

**NIH Compensation Committee (NCC)**
Chaired by the NIH Deputy Director for Management and composed of NIH senior and scientific Leaders, NCC exercises broad policy and oversight responsibility for the "NIH Title 42 Pay Model," advises the NIH Principal Deputy Director and Director on a variety of compensation policies and issues, oversees the activities of the IC Title 42 Standing Committees (see below), and reviews and makes recommendations on all individual pay requests requiring approval by the NIH Principal Deputy Director or Director.

**NCC Workgroups:** Special emphasis groups that operate under the purview of the NCC.

- NIH Clinical Compensation Panel (NCCP): Chaired by the NIH Deputy Director for Intramural Research and composed of senior physicians in NIH leadership positions. NCCP performs functions required by law relating to Title 38 compensation determinations, makes similar compensation recommendations for Title 42 clinicians in certain medical specialties, and fosters better "alignment" between Title 38 and Title 42 pay policies and individual pay decisions.
- NIH Distinguished Investigators Review Subcommittee (NDIRS): Chaired by the Deputy Director for Intramural Research and composed of highly accomplished NIH intramural senior investigators. NDIRS reviews intramural senior investigators nominated for the honorary designation of "NIH Distinguished Investigator" and advises on appropriate compensation for the select few (55 total, NIH-wide), at the highest level of achievement, who are granted this recognition by the NIH Director.

**IC T-42 Standing Committees**
High-level review committees established in each IC to advise the IC Director regarding Title 42 pay determinations for IC scientists and clinicians, including all requests requiring NCC review.

**NIH Performance Review Board**
A group of executives responsible for the review of Senior Executive Service (SES) and Senior Level / Scientific and Professional (SL/ST) performance plans, ratings, and performance recognition (pay increases and bonuses), as well as nominations for Individual Contribution and Presidential Rank awards. The names of individuals who serve on the NIH PRB must be published in the Federal Register before membership begins.

**Budget Process**
The NIH governance structure is used to formulate the internal central services budget; the process for developing the President's Budget is handled differently. The central services budgets consist of activities financed by the NIH Management Fund (MF) and Service and Supply Fund (SSF). These two funds support the three NIH Centers that do not receive direct appropriations from Congress—the NIH CC, CIT, and CSR, as well as administrative services that are funded through NIH-wide assessments. The MF is available for an additional year beyond the year when funds were collected; the SSF is available until expended for the purpose of what they were collected.

**NIH Central Services Budget Review and Approval**

- All budget requests are reviewed extensively before final recommendations are made to the NIH Director through the NIH SC/IC Directors.
    - MBWG makes funding recommendations on the requests of the EAWG, FWG, ITBAC, ORSAC, and OD CSAC (see table below).
    - CCGB makes funding recommendations for the CC budget as well as funding for Clinical Center Investment Fund.
    - ADC makes funding recommendations for strategic IT investments or Cybersecurity funded through the Capital Investment Fund (CIF).
    - Recommendations are coordinated among these three committees and a common presentation for all Central Services activities financed by the NIH SSF and MF are made to NIH Leadership.
- The role of the Committees in making priority funding recommendations is to balance service needs with the fiscal environment.

| Review Committee | Organizations Reviewed |
|---|---|
| **NIH Administrative Data Council (ADC)** | NIH Chief Information Officer (CIO) |
| **Extramural Activities Working Group (EAWG)** | CSR, Scientific Review and Evaluation Activities (SREA), OER |
| **Facilities Working Group (FWG)** | Office of Research Facilities (ORF), Leases, Utilities |
| **Information Technology Budget Advisory Committee (ITBAC)** | CIT, Enterprise Systems (non-strategic investment funding) |
| **Office of the Director Central Services Advisory Committee (OD CSAC)** | Office of the Director (other than OER, ORS, or ORF) |
| **Office of Research Services Advisory Committee (ORSAC)** | ORS |

**Risk Assessments**

Understanding the need to identify and manage risks, NIH incorporated Enterprise Risk Management (ERM) capabilities into its strategic planning, performance management, and resource allocations. The Office of Management Assessment (OMA) is responsible for maintaining and maturing the NIH ERM Program to meet the requirements and objectives of the Office of Management and Budget's (OMB) Circular A-123, *Management's Responsibility for ERM and Internal Control*, and the Federal Managers' Financial Integrity Act (FMFIA). OMA continually collaborates with the Department and its OPDIVs to advance the maturity of ERM within NIH and the Department.

NIH is committed to proactively managing risks that may impede the NIH mission. Such risks have the potential to affect patient and lab safety, the peer review process, laboratory animal welfare, conflict of interest disclosures, closeout of grant awards, data security, and more. Going forward, NIH is better prepared to respond to emerging risks that may undermine its research activities and are inconsistent with its research values and principles.

The NIH ERM Program requires each ICO to conduct an annual risk inventory assessment. ICOs identify, assess, and prioritize risks that have the potential to impact the achievement of their individual missions, strategic goals, and objectives. As needed, ICOs develop and document appropriate actions to address their top ERM risks. The ERM Program also requires each ICO to submit a supporting assurance

statement indicating that their internal controls reasonably ensure effective and efficient operations, compliance with applicable laws and regulations, and reliable financial reporting.

The NIH ERM Program also conducts NIH-wide internal control assessments and improper payment risk assessments on selected program areas. OMA aggregates and analyzes all risk data in conjunction with other available information to support the annual NIH FMFIA Statement of Assurance and the biennial update to the NIH ERM Risk Profile. The NIH ERM Risk Profile reflects the current environment and designates top ERM risks at the NIH level. The NIH Director certifies the NIH FMFIA Statement of Assurance and submits it to HHS for summary inclusion in the annual Agency Financial Report.

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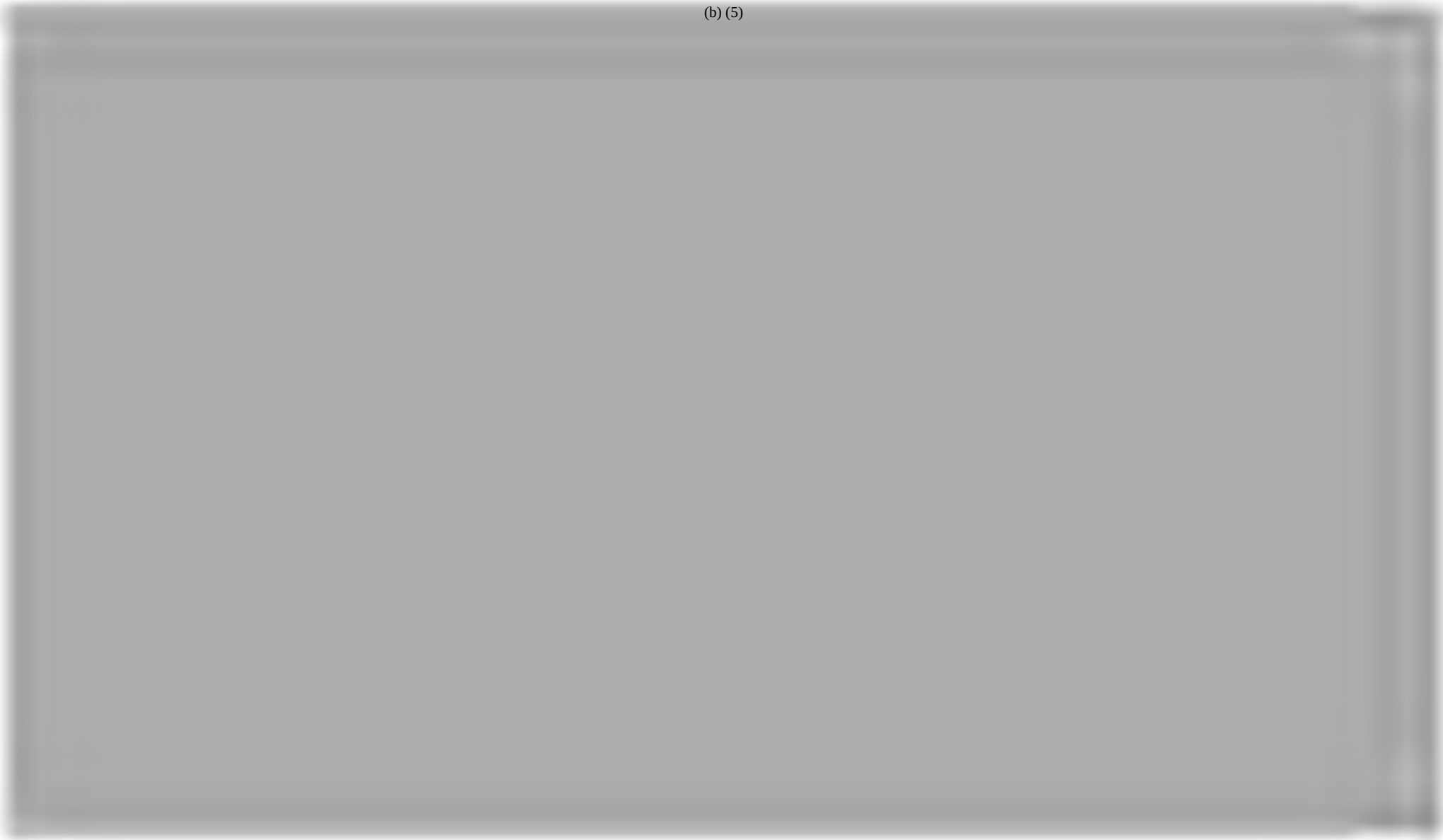

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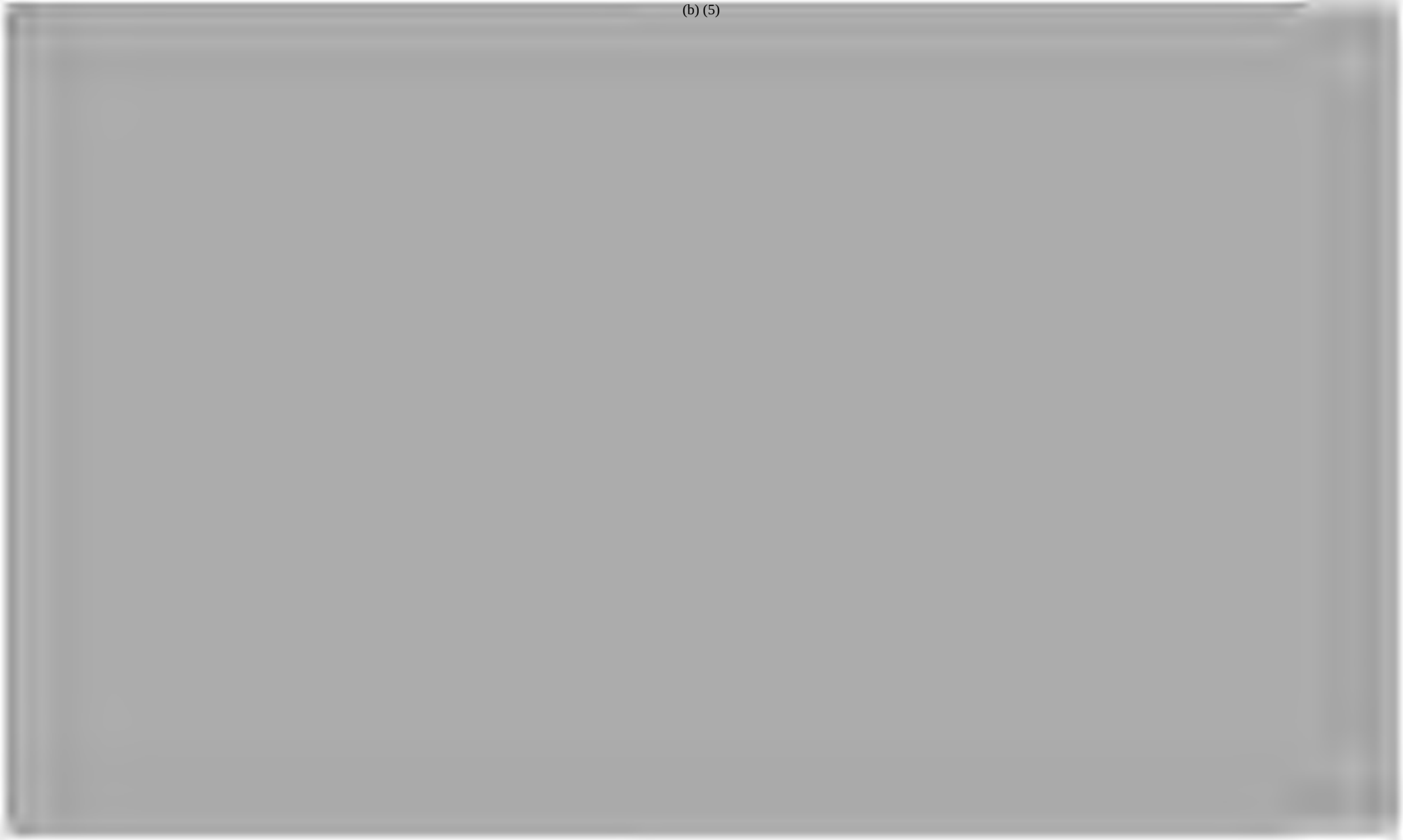

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## PARTICIPATION IN ENTERPRISE GOVERNMENT ACTIVITIES

| Name | NIH Representative |
|---|---|
| **Interdivision Councils** | |
| Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) | Kathleen (Cathy) Conry-Cantilena |
| Advisory Committee on Breast Cancer in Young Women (ACBCYW) | Dr. Jung-Min Lee, NCI |
| Advisory Committee on Heritable Disorders in Newborns and Children | Dr. Melissa Parisi, NICHD |
| Advisory Committee for Organ Transplantation (ACOT) | Dr. Nancy Bridges, NIAID |
| Agency Research Integrity Liaison Officer (ARILO) | Dr. Lawrence A. Tabak, Principal Deputy Director, NIH |
| Advisory Council on Alzheimer's Research, Care, and Services | Dr. Richard Hodes, NIA |
| Advisory Council on Blood Stem Cell Transplantation | Dr. Nancy L. Difronzo, NHLBI |
| Advisory Council for the Elimination of Tuberculosis | Dr. Mamodikoe Makhene, NIAID |
| Autoimmune Diseases Coordinating Committee (ADCC) | Dr. Ellen Goldmuntz, NIAID |
| Behavioral and Social Sciences Research Coordinating Committee | Dr. William Riley, OD/DPCPSI/OBSSR |
| Best Pharmaceuticals for Children Act (BPCA) Working Group | Dr. Huiqing Li, NHLBI<br>Dr. Rohan Hazra, NICHD |
| Blood, Organ, and Tissue Safety Executive Committee (BOTSEC) | CC (vacant) |
| Board of Scientific Counselors of the CDC's National Center for Injury Prevention and Control | Dr. Valerie Maholmes, NICHD |
| CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment | Dr. Paul Gaist, OD/DPCPSI/OAR |
| Clinical Utilization Plan for Anthrax Medical Countermeasure Use in a Mass Casualty Event (CUPAC) Medical Countermeasures Workgroup | Dr. Christine Grady, CC |
| CMS-FDA-NIH Trilateral Leadership Council | Dr. Francis S. Collins, Director, NIH |
| CMS-NIH Senior Leadership Council | Dr. Francis S. Collins, Director, NIH |
| Community Preventative Services Task Force | Dr. Carrie Klabunde, OD/DPCPSI/ODP<br>Dr. Elizabeth Neilson, OD/DPCPSI/ODP (alternate) |
| Coordinating Committee for Research on Women's Health | Dr. Janine Clayton, OD/DPCPSI/ORWH |
| DoD Resuscitation and Transfusion Steering Committee | CC (vacant) |
| Department of State - Expert Task Force on Cervical Cancer Prevention | Dr. Vikrant Sahasrabuddhe, NCI |
| Diabetes Mellitus Interagency Coordinating Committee (DMICC) | Dr. Nicole Redmond, NHLBI<br>Dr. William Cefalu, NIDDK |

| Name | NIH Representative |
|---|---|
| **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) - Enterprise Governance Board (EGB)** | Dr. Michael Kurilla, NIAID |
| **Federal Collaboration on Health Disparities Research.** | Dr. Eliseo J. Pérez-Stable, NIMHD |
| **Federal Experts Security Advisory Panel** | Dr. Carrie Wolinetz and Dr. Chris Viggiani, OD/OSP; Dr. Dennis Dixon, NIAID |
| **Federal Health Information Technology Coordinating Council** | Dr. Clem McDonald, NLM |
| **Federal Interagency Workgroup on Autism Spectrum Disorder (FIWA)** | Dr. Alice Kau, NICHD |
| **Federal Interagency Workgroup on Child Abuse and Neglect (FEDIAWG)** | Dr. Layla Esposito, NICHD<br>Dr. Valerie Maholmes, NICHD |
| **Federal Interagency Workgroup on Improving Diagnostic Safety and Quality in Healthcare** | Dr. Michael Kurilla, NCATS |
| **Federal Interagency Workgroup on Teen Dating Violence** | Dr. Layla Esposito, NICHD |
| **Federal Lead Action Plan Workgroup** | Dr. Tracy King, NICHD |
| **Federal Partners in Bullying Prevention** | Dr. Layla Esposito, NICHD |
| **Federal Sudden Unexpected/Unexplained Infant Death (SUID) Sudden Infant Death Syndrome (SIDS) Workgroup** | Lorena Kaplan, NICHD |
| **Federal Supply and Demand of Isotopes** | Dr. Bruce Tromberg, NIBIB<br>Dr. Antonio Sastre, NIBIB |
| **Federal Steering Committee on Adverse Drug Events** | Dr. David K. Henderson, CC |
| **Federal Tuberculosis (TB) Task Force** | TBD |
| **Federal Working Group on Bone Diseases (FWGBD)** | Dr. Robert H. Carter, NIAMS<br>Dr. Kristy Nicks, NIAMS |
| **Federal Working Group on Dietary Supplements (FWGoDS)** | Dr. Joe Betz, OD/DPCPSI/ODS<br>Dr. Lawrence Brody, NHGRI<br>Dr. Charlotte Pratt, NHLBI<br>Dr. Derrick Tabor, NIMHD |
| **Future Advanced Computing Ecosystem (FACE) Committee** | Dr. Susan Gregurick, OD/DPCPSI/ODSS<br>Dr. Tara Schwetz, OD/IMOD |
| **Genomic Data Submission and Management (GDSM) Taskforce** | Dr. Nishadi Rajapakse, NIMHD |
| **Global Health Initiative (State Department's)** ***Maternal and Child Health Work Group*** | Dr. Janine Clayton, OD/DPCPSI/ORWH |
| **Global Health Security Initiative** | Bert Maidment, NIAID |
| **Healthy People Federal Interagency Working Group** | Dr. Elizabeth Neilson, OD/DPCPSI/ODP<br>Elizabeth Vogt, OD/DPCPSI/ODP (alternate)<br>Dr. Michael Mussolino, NHLBI |
| **Health Information Technology Advisory Committee (HITAC)** | Dr. Clem McDonald, NLM |
| **HHS Administrative and Management Domain IT Steering Committee** | Andrea Norris, OCIO/CIT |

| Name | NIH Representative |
|---|---|
| **HHS Biosafety and Biosecurity Coordinating Committee** | Dr. Carrie Wolinetz, OD/OSP; Debbie Wilson, OD/OIR |
| **HHS Biovigilance Committee** | CC (vacant) |
| **HHS CIO Council and CISO Council (HHS-wide)** | Andrea Norris, OCIO/CIT |
| **HHS Data Council** | Dr. Belinda Seto, OD/DPCPSI/ODSS<br>Dr. Doug Sheeley, OD/DPCPSI/OSC |
| **HHS-DOD-VA Initiative for Military and Veteran Pain Management Research** | Dr. Sue Marden, NICHD |
| **HHS Ending the HIV Epidemic Agency Priority Goal Team—Operational Leadership** | Dr. Maureen Goodenow, OD/DPCPSI/OAR |
| **HHS Evaluation & Evidence Policy Council** | Dr. Marina Volkov, OD/DPCPSI/OEPR<br>Rosanna Ng, OD/DPCPSI/OEPR<br>Dr. Sara Dodson, NINDS |
| **HHS ERM Council** | Dr. Alfred C, Johnson OD/OM |
| **HHS Healthcare Infection Control Practices Advisory Committee (HICPAC)** | Dr. David K. Henderson, CC |
| **HHS Innovation and Information Policy Council** | Dr. Marc Rohrbaugh, OD/OIR/OTT |
| **HHS LGBT Issues Coordinating Committee** | Dr. Karen Parker, OD/DPCPSI/SGMRO |
| **HHS-NASA Inter-Agency Agreement Working Group** | Dr. Christopher Austin, NCATS |
| **HHS Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children** | Dr. Rohan Hazra, NICHD |
| **HHS Panel on Antiretroviral Guidelines for Adults and Adolescents** | Dr. H. Clifford Lane, NIAID<br>Dr. Alice Pau, NIAID |
| **HHS Panel on Prevention and Treatment of Opportunistic Infections in HIV-exposed and HIV-infected Children** | Dr. Bill Kapogiannis, NICHD |
| **HHS Rural Health Taskforce** | Dr. Nathan Stinson, NIMHD |
| **HHS Steering Committee for the Prevention of Healthcare-Associated Infections** | Dr. David K. Henderson, CC |
| **HHS Tobacco Control Steering Committee** | Dr. Helen Meissner, OD/DPCPSI/ODP |
| **HHS Working Group on Implementation of the National Strategy for Countering Biological Threats** | Dr. Hugh Auchincloss, NIAID<br>Dr. Michael Kurilla, NIAID |
| **Intra-agency Select Agent and Toxin Technical Advisory Committee** | Dr. Jessica Tucker, OD/OSP |
| **Interagency Adult Literacy Research Group** | Dr. Brett Miller, NICHD |
| **Inter-agency Arctic Research Policy Committee (IARPC)** | Dr. Dottie Castille, NIMHD |
| **Interagency Autism Coordinating Committee (IACC)** | Dr. Joshua Gordon, NIMH<br>Dr. Alice Kau, NICHD |
| **Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC)** | NCI/NIEHS |
| **Interagency Collaborative to Advance Research in Epilepsy (ICARE)** | Dr. Walter Koroshetz, NINDS |
| **Interagency Committee on Disability Research (ICDR)** | Dr. Theresa Cruz, NICHD<br>Dr. Jennifer Jackson, NICHD |
| **Interagency Committee on Human Nutrition Research** | Dr. Christopher Lynch, NIDDK |
| **Interagency Committee on Smoking and Health** | Dr. Gary Gibbons, NHLBI |

| Name | NIH Representative |
|---|---|
| Interagency Committee on STEM Education | Dr. L. Tony Beck, NIGMS |
| Interagency Committee on the American Community Survey (ACS) | Dr. Juanita Chinn, NICHD<br>Dr. Rebecca Clark, NICHD |
| Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorder (ICCFASD) | Dr. Patricia Powell, NIAAA<br>Dr. Tracy King, NICHD |
| Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease | Dr. Griffin Rodgers, NIDDK (Chair) |
| Interagency Coordinating Committee on Newborn and Child Screening | Dr. Melissa Parisi, NICHD |
| Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) | Dr. Ralph Hingson, NIAAA |
| Intragency Coordinating Committee on Newborn and Child Screening | Dr. Nicole Kleinstreuer, NIEHS |
| Interagency Forum for Child and Family Statistics | Dr. Juanita Chinn, NICHD<br>Dr. Regina Bures, NICHD |
| Interagency Pain Research Coordinating Committee (IPRCC) | Dr. Walter Koroshetz, NINDS |
| Interagency Task Force for Trauma-Informed Care | Dr. Valerie Maholmes, NICHD |
| Interagency Task Force on Military and Veterans Mental Health (ITF) | Dr. Farris Tuma, NIMH<br>Dr. Susan Borja, NIMH |
| Interagency Task Force on the Arts and Human Development | Dr. Kathy Mann-Koepke, NICHD |
| Interagency Workgroup on Child Abuse and Neglect (FEDIAWG) | Dr. Christopher Sarampote, NIMH<br>Dr. Valerie Malhomes, NICHD<br>Dr. Cheryl Boyce, NHLBI |
| Interagency Workgroup on Coordinating Opportunities for Evaluating Dolutegravir and Neural Tube Defects Association | Dr. Rohan Hazra, NICHD<br>Dr. Jack Moye, NICHD |
| Interagency Work Group on Healthcare Quality | Dr. Carrie Wolinetz, OD/OSP |
| Joint Agency Nutrition (JAN) Working Group | Dr. Christopher Lynch, NIDDK |
| Joint Committee on the Research Environment (JCORE) | Dr. Mike Lauer, OD/OER<br>Dr. Tara Schwetz, OD/IMOD<br>Dr. Carrie Wolinetz, OD/OSP |
| Kidney Care Working Group | Dr. Robert Star, NIDDK |
| Kidney Interagency Coordinating Committee (KICC) | Dr. Susan Mendley, NIDDK<br>Dr. Diane Reid, NHLBI |
| Lower Limb Prosthetics Research Standards Working Group | Dr. Theresa Cruz, NICHD<br>Dr. Joe Bonner, NICHD |
| Lupus Federal Working Group (LFWG) | Dr. Robert H. Carter, NIAMS<br>Dr. Marie Mancini, NIAMS |
| Maryland Governor's Life Science Advisory Board | Dr. Christopher Austin, NCATS<br>Lili Portilla, NCATS |
| Multi-Agency Tissue Engineering Science Interagency Working Group | Dr. Christine Kelley, NIBIB<br>Dr. Martha Lundberg, NHLBI |
| Muscular Dystrophy Coordinating Committee (MDCC) | Dr. Robert H. Carter, NIAMS<br>Dr. Walter Koroshetz, NINDS<br>Dr. Melissa Parisi, NICHD |

| Name | NIH Representative |
|---|---|
| | Dr. James Kiley, NHLBI<br>Dr. Huiqing Li, NHLBI |
| **National Advisory Board on Medical Rehabilitation Research** | Dr. Ralph Nitkin, NICHD |
| **National Clinical Care Commission** | Dr. Barbara Linder, NIDDK |
| **National Collaborative on Childhood Obesity Research (NCCOR)** | Dr. Deborah Young Hyman, OD/DPCPSI/OBSSR (until 3/31)<br>Dr. Anrew Bremer, NICHD<br>Dr. Christina Stile, NICHD<br>Dr. Layla Esposito, NICHD<br>Dr. Charlotte Pratt, NHLBI |
| **National Committee on Vital and Health Statistics (NCVHS) (OS/ASPE)** | Dr. William Riley, OD/DPCPSI/OBSSR |
| **National Death Index Working Group** | Dr. Juanita Chinn, NICHD<br>Dr. Rebecca Clark, NICHD |
| **National Health Security Strategy Work Group** | Dr. Michael Kurilla, NIAID |
| **National Practitioner Data Bank (NPDB)** | Dr. David Henderson, CC |
| **National Science Advisory Board for Biosecurity (NSABB)** | Dr. Dennis Dixon, NIAID (ex-officio on behalf of Dr. Anthony Fauci)<br>Dr. Carrie Wolinetz, OD/OSP |
| **National Science and Technology Council (NSTC)** ***Committee on Science (NSTC-CoS)*** | Dr. Francis S. Collins, Director, NIH (co-chair) |
| **National Science and Technology Council Committee on Science** | Dr. Francis S. Collins, Director, NIH |
| **National Science and Technology Council Committee on Technology** | Dr. Mark Rohrbaugh, OD/OSP |
| **National Science and Technology Council Committee on Environment, Natural Resources, and Sustainability** | NIEHS |
| **National Science and Technology Council Committee on Homeland and National Security** | Dr. Michael Kurilla, NIAID<br>Dr. Chris Viggiani, OD/OSP |
| **National Science and Technology Council Committee on STEM Education** | Dr. L. Tony Beck, NIGMS |
| **National Science and Technology Council Committee on International Science and Technology Cooperation** | Robert Eiss, FIC |
| **National Science and Technology Council Life Sciences Subcommittee** | Dr. Carrie Wolinetz, OD/OSP |
| **National Science and Technology Council Machine Learning & Artificial Intelligence Subcommittee** | Dr. Patricia Brennan, NLM |
| **National Science and Technology Council Social, Behavioral, and Economic Sciences Subcommittee** | Dr. William Riley, OD/DPCPSI/OBSSR |
| **National Science and Technology Council Physical Sciences Subcommittee** | Dr. Bruce Tromberg, NIBIB |
| **National Science and Technology Council U.S. Group on Earth Observations (USGEO) Subcommittee** | Dr. John Balbus, NIEHS |
| **National Science and Technology Council Subcommittee for Ocean, Science and Technology** | Dr. Aubrey Miller, NIEHS |
| **National Science and Technology Council Subcommittee on Open Science** | Jerry Sheehan, NLM |

| Name | NIH Representative |
|---|---|
| National Science and Technology Council Subcommittee on Global Change Research | Dr. John Balbus, NIEHS |
| National Science and Technology Council Research Business Models Interagency Working Group | Dr. Mike Lauer, OD/OER |
| National Toxicology Program | Dr. Richard Woychik. NIEHS |
| National Toxicology Porgram Executive Committee | Dr. Richard Woychik. NIEHS |
| NIH and National Aeronautics and Space Administration (NASA) Collaboration on Space-Related Health Research | Dr. Bruce Tromberg, NIBIB |
| NIH-CMS Leadership Committee | Dr. Giffin Rodgers, NIDDK<br>Dr. Robert Star, NIDDK, co-chair of Evidence Generation Working Group |
| NIH-FDA Joint Leadership Council | Dr. Christopher Austin, NCATS |
| NIST-OSTP Lab-to-Market: Inter-Agency Work Group on Technology Transfer | Dr. Sury Vepa, NCATS |
| NIH-NASA Scientific Potential/Actual Collaborative Efforts (SPACE) Group | Dr. Christopher Austin, NCATS |
| Tobacco Regulatory Science Working Group | Dr. David Murray, OD/DPCPSI/ODP |
| Nutrition Research Coordinating Committee (NRCC) | Dr. Christopher Lynch, NIDDK<br>Dr. Charlotte Pratt, NHLBI |
| Office of Science and Technology Mo99 Stakeholders Working Group | |
| Office of Science and Technology Policy National Strategic Computing Initiative Committee | Dr. Susan Gregurick, OD/DPCPSI/ODSS |
| Office of Science and Technology Policy Networking Information Research and Development Committee | Dr. Susan Gregurick, OD/DPCPSI/ODSS |
| Patient Centered Outcomes Research Institute (PCORI) | Dr. Francis S. Collins, Director, NIH |
| Patient Centered Outcomes Research Trust Fund Leadership Council | Jerry Sheehan, NLM |
| Pediatric Prevention of Mother-to-Child Transmission (PMTCT) PEPFAR Working Group | Dr. Nahida Chakhtou, NICHD |
| Portfolio Analysis Community of Interest (PACOI) (government-wide committee) | Dr. George Santangelo, OD/DPCPSI/OPA |
| Post-traumatic Stress Disorder (PTSD)/Traumatic Brain Injury (TBI) Workgroup | Farris Tuma, NIMH |
| Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (CARB) | Dr. Dennis Dixon, NIAID |
| President's Task Force on Environmental Health Risks and Safety Risks to Children | Dr. Kimberly Thigpen Tart, NIEHS<br>Dr. Melissa Parisi, NICHD (Lead Exposures Subcommittee) |
| Prevention Research Coordinating Committee (PRCC) | Dr. Jacqueline Lloyd, OD/DPCPSI/ODP<br>Dr. Lawton Cooper, NHLBI<br>Dr. Josephine Boyington, NHLBI |
| Public Health and Emergency Medical Countermeasures Medical Countermeasures | Dr. Anthony Fauci, NIAID<br>Dr. Michael Kurilla, NIAID |

| Name | NIH Representative |
|---|---|
| **Enterprise (PHEMCE) Senior Council and Executive Committee** | Dr. Robert Tamburro, NICHD |
| **Science for Disaster Reduction** | Dr. Aubrey Miller, NIEHS |
| **Secretary's Advisory Committee on Human Research Protections** | Dr. Valery Gordon, OD/OSP |
| **Secretary's Operation Center/Continuity of Operations** | Michael Spillane, OD/ORS |
| **Secretary's Tribal Advisory Committee (STAC)** | Dr. Lawrence A. Tabak, Principal Deputy Director, NIH |
| **Sexual & Gender Minority Research Coordinating Committee** | Dr. Karen Parker, OD/DPCPSI/SGMRO |
| **Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)** | Lisa Kaeser, NICHD |
| **Toxics/Chemicals of Emerging Concern Working Group** | Dr. Christopher Weis, NIEHS |
| **Trans-NIH Plan for HIV-Related Research Coordinating Committees** | Dr. Emily Erbelding, NIAID<br>Dr. Maureen Goodenow, OD/DPCPSI/OAR |
| **Treating for Two Interagency Working Group (medications in pregnancy)** | NICHD |
| **Tribal Health Research Coordinating Committee** | Dr. David Wilson, OD/DPCPSI/THRO<br>Dr. Juliana Blome, OD/DPCPSI/THRO |
| **United States Government Children in Adversity Working Group** | Dr. Vesna Kutlesic, NICHD<br>Dr. Jenelle Walker, NICHD |
| **Urban Waters Federal Partnership** | Ms. April Bennett, NIEHS |
| **U.S. Global Change Research Program** | Dr. John Balbus, NIEHS |
| **U.S. Preventative Services Task Force** | Dr. Carrie Klabunde, OD/DPCPSI/ODP<br>Dr. Elizabeth Neilson, OD/DPCPSI/ODP (alternate)<br>Dr. George Mensah, NHLBI<br>Dr. Gina Wei, NHLBI |
| **Urology Interagency Coordinating Committee** | Dr. Tamara Bavendam, NIDDK |
| **Vaccines and Related Blood Products Advisory Committee, FDA** | Dr. Michael Kurilla, NCATS |
| **Viral Hepatitis Interagency Work Group** | Dr. Jay Hoofnagle, NIDDK |
| **White House National Security Council**<br><br>**Biological Select Agents and Toxins Interagency Policy Committee (IPC) and Sub-IPC**<br><br>**Countering Biothreats Interagency Policy Committee on Gene Editing and Synthesis** | <br><br>Dr. Lawrence A. Tabak, Deputy Director, NIH<br>Dr. Carrie Wolinetz, OD/OSP<br><br>Dr. Lawrence A. Tabak, Deputy Director, NIH<br>Dr. Carrie Wolinetz, OD/OSP |
| **Cross-Department Initiatives** | |
| **2020 Surgeon General's Report on Oral Health** | Dr. Tim Iafolla, NIDCR |
| **Accelerating Medicines Partnership** | Dr. Robert H. Carter, NIAMS<br>Dr. Richard Hodes, NIA<br>Dr. Norann Zaghloul, NIDDK<br>Dr. Debra Babcock, NINDS |
| **Advanced Anticonvulsant System Interagency Product Team** | Dr, David Jett, NINDS |
| **BRAIN Initiative®** | Dr. John Ngai, NINDS |

| Name | NIH Representative |
|---|---|
| | Dr. Walter Koroshetz, NINDS<br>Dr. Joshua Gordon, NIMH |
| **Cancer Moonshot** | Dr. Dinah Singer, NCI |
| **Center for Neuroscience and Regenerative Medicine (CNRM)** | Dr. Walter Koroshetz, NINDS |
| **Data sharing between CMS and NCI's SEER (Surveillance, Epidemiology, and End Results) Program, NIDDK's U.S. Renal Data System, and NHLBI's Research Cohorts** | NCI/NHLBI<br>Dr. Kevin Abbott, NIDDK |
| **Dental, Oral and Craniofacial Data Resource Center** | NIDCR |
| **Dietary Supplement Label Database (DSLD)** | Dr. Johanna Dwyer, OD/DPCPSI/ODS |
| **DOD Clinical & Rehabilitation Medicine Committee** | Dr. Michael Steinmetz, NEI |
| **DOD Congressionally Directed Medical Research Program (CDMRP)** | Dr. Eva Szabo, NCI (Lung Cancer Research Program)<br>Dr. Kristin Burns, NHLBI |
| **Federal Interagency Traumatic Brain Injury Research (FITBIR) Information System** | Dr. Patrick Bellgowan, NINDS |
| **HHS Combating Antibiotic-Resistant Bacteria (CARB) National Database of Resistant Pathogens Implementation Working Group** | Dr. Maria Giovanni, NIAID |
| **Interagency Chemical Risk Assessment Working Group** | Dr. David Jett, NINDS |
| **Interagency ME/CFS Working Group** | Dr. Walter Koroshetz, NINDS |
| **National Action Alliance for Suicide Prevention** | NIMH |
| **National Longitudinal Survey of Youth** | Dr. Regina Bures, NICHD |
| **National Survey of Family Growth** | Dr. Rosalind King, NICHD |
| **Native American Research Centers for Health** | Dr. Sheila Caldwell, NIGMS<br>Mona Puggal (MPH), NHLBI |
| **National Research Action Plan (NRAP) for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families** | Dr. Joshua Gordon, NIMH (co-chairs with DOD and VA) |
| **NIH-CDC-IDSA Guidelines for Treatment of HIV Related Opportunistic Infections Among Adults and Adolescents** | Dr. Henry Masur, CC |
| **OMB Interagency Council on Evaluation Policy** | Dr. Ajay Vatave, OD/DPCPSI/OEPR |
| **Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission** | Dr. Nahida Chaktoura, NICHD |
| **Presidential Advisory Council on HIV/AIDS (PACHA)** | Dr. Maureen Goodenow, OD/DPCPSI/OAR |
| **Precision Medicine Initiative** | Eric Dishman, OD |
| **Pregnancy and Birth to 24 months (P/B-24) Project** | Dr. Andrew Bremer, NICHD<br>Dr. Rosalind King, NICHD |
| **Preparedness Against Chemical Threats (PACT) Working Group** | Dr. David Jett, NINDS |

| Name | NIH Representative |
|---|---|
| **President's Emergency Plan for AIDS Relief (PEPFAR)** | Dr. Emily Erbelding, NIAID |
| **President's Management Agenda: Workforcee for the 21st Century** | Camille Hoover, NIDDK |
| **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)** | Dr. Michael Kurilla, NIAID |
| **SEARCH for Diabetes in Youth** | Dr. Barbara Linder, NIDDK |
| **Strategic Multisite Initiative for the Identification, Linkage and Engagement in Care of Youth with Undiagnosed HIV (SMILE in Caring for Youth)** | NIAID |
| **Tissue Chip for Drug Screening** | Dr. Dan Tagle, NCATS |
| **Tobacco Regulatory Science Program** | Dr. Helen Meissner, OD/DPCPSI/ODP |
| **Toxicology Testing in the 21st Century (Tox21)** | Dr. Anton Simeonov, NCATS<br>Dr. Warren Casey, NIEHS |

**Cross-department initiatives and funding**

NIH has been working across HHS to support the development of vaccines, therapeutics, basic research, and facilities in response to the COVID-19 pandemic. As of October 2020, NIH has obligated a total of $1.175 billion and disbursed $143 million. In addition, under OWS, NIH is implementing a number of major clinical trials on behalf of BARDA. This includes vaccine and therapeutic trials under the ACTIV public-private partnership.

**Shared Services**

HHS Trusted Internet Connection (TIC): The NIH Network is a high-speed, highly available network that interconnects NIH, the commodity internet, and the Internet2 research network. Among the NIH Network's most notable features is its security, achieved through secure Internet access for not only NIH, but for the entire Department, through the HHS Trusted Internet Connection (TIC). The HHS TIC is currently an HHS-wide shared service that is operated and maintained by NIH on behalf of HHS. It is a complex wide-area network that includes commercial network circuits and network equipment and controls implemented across the HHS OPDIVs. The HHS TIC network was established to respond to Federal mandates to improve the security of Federal networks, OMB M-08-05, "Implementation of Trusted Internet Connections." There are significant IT security requirements that must be supported by the HHS TIC network in order to comply with OMB and DHS mandates. Specifically, HHS Security must monitor, protect, and report on data sent to and from the Internet via the HHS TIC network using a wide range of security technologies.

To align with industry best practice, support for the HHS TIC is shifting from a shared service operated by NIH to an outsourced, managed service operated by a commercial provider. HHS is leveraging the Managed Trusted Internet Protocol Services (MTIPS) as part of the HHS award on the General Service Administration (GSA) Enterprise Infrastructure Solutions contract. This mission-critical solution will improve HHS' security posture and meet the external connection security needs of the department. MTIPS will include the requisite network transport to reach the MTIPS points-of-presence. MTIPS will enable HHS to adopt new security technologies and to better protect HHS from increased cyber threats, such as the recent Denial of Service (DoS) attacks, as well as to better meet all

DHS security compliance requirements [redacted] (b) (5)

Electronic Research Administration (eRA): Through eRA, NIH offers grants management services and solutions to 24 Institutes and Centers and other Federal agencies. Our mission is to provide reliable solutions (including announcement of funding opportunities, application, review, award management and oversight, and closeout) that promote efficient grants management and optimal business decisions for NIH and partner agencies, while minimizing administrative activities required of grant recipients in line with Federal and agency-specific regulations and policies. The HHS has designated eRA as one of two Grants Management Centers of Excellence serving agencies across DHHS and the Federal government. HHS has also designated eRA as one of its top 10 High-Value Assets.

Among the agencies served by eRA are SAMHSA, FDA, CDC, AHRQ, VA, DOE, and the Uniformed Services University. eRA works closely with GrantSolutions to develop certain services, such as a FOA Module.

In FY2019 (FY2020 data being finalized), eRA published 1757 Funding Announcements, processed 166,000 applications and awards, handled $35.5 Billion in award obligations, saw 870,000 registered and 243,000 active users, had 23.3 million log-ins, managed the activities of 63,100 reviewers and 3,576 review meetings, and added 7.12 million electronic documents.

National Institute of Health Information Technology Assistance and Assessment Center (NITAAC): The MOTAAC is an OMB designated Best In Class, Government Wide Acquisition Contract (GWAC) which provides the streamlined purchase of IT services, solutions and commodities to all Federal agencies. Housed within the Department of Health and Human Services at NIH, NITAAC offers a full service acquisition program through three GWACs; Chief Information Officers-Solutions and Partners (CIO-SP3), CIO-SP3 Small Business, and Chief Information Officers-Commodities and (CIO CS) as well as a full service Assisted Acquisition program, and one of three OMB mandatory sources for laptop and desktop buys through our Government-wide Strategic Solutions program (GSS). Task orders placed under the CIO-SP3 contracts result in a significant time savings and therefore, a significant cost savings to Federal agencies. Finally, NITAAC is a leader in customer relationship management with our ability to get back to any and all Federal customers within one hour.

**President's Management Agenda & ReImagine HHS**

As part of *ReImagine HHS* (RHHS) and supporting "Strategic Shift: Making HHS More Innovative and Responsive," the *Optimize NIH (ONIH)* initiative supported operational improvements in alignment with the President's Management Agenda (PMA). Over 350 NIH program volunteers across administrative business areas mitigated risks and improved performance. Teams implemented efficiencies and replaced paper-based processes with online capabilities which reduced administrative burden, created public and internal portals to improve accountability and minimize risks, launched dashboards for data-driven decisions, upgraded and integrated existing enterprise systems to reduce redundant reporting, and automated workflows for streamlined processing.

# POLICIES AND REGULATIONS

## OVERVIEW OF HISTORICAL POLICIES AND REGULATIONS

As the largest funder of biomedical and behavioral research, NIH has an important role in assuring that NIH supported and conducted research meets the highest ethical and scientific standards. NIH has an extensive set of policies and mandates governing the application, scientific review, terms, and conditions of awards. NIH also issues new policies and guidelines in response to scientific and public health developments, emerging societal or ethical concerns, Congressional directives, and Federal mandates. While the HHS Secretary has not delegated rulemaking authority to the NIH Director, NIH takes the lead for HHS in developing regulations relevant to NIH's mission.

NIH has policies concerning grant application and award, inclusion of women, minorities, and children in research, use of human stem cells in research, humane animal care and use of laboratory animals, data sharing, and research involving recombinant DNA. The roughly 22 regulatory actions developed by NIH in the last two decades relate to the administration of research grants, training programs, loan repayment programs, scientific peer review, the management of conflicts of interest, standards of care for chimpanzees in the federally-supported sanctuary system, and the conduct of persons and traffic on the NIH federal enclave.

In addition to NIH being a steward of the research enterprise, NIH awardees and investigators are also subject to regulations governing the conduct of research that are promulgated by other federal agencies. As such, NIH has important perspectives and insights to contribute to regulatory actions. NIH has provided perspectives on regulations and guidance of other HHS agencies (FDA, CDC, CMS, OCR, SAMHSA, HRSA) and other federal departments (EPA, USDA, NASA, DOD, DOT, DOL, DOJ, DEA, SBA).

## RECENTLY ADOPTED OR PENDING POLICIES AND REGULATIONS

**Recently Adopted Regulations**

- *Standards of Care for Chimpanzees Held in the Federally Supported Sanctuary System; Technical Amendment (Final Rule).* This final rule was published in the *Federal Register* on September 1, 2020. It updates references in the regulation regarding delegated authorities and activities of the National Center for Research Resources (NCRR)/NIH to read correctly as the Division of Program Coordination, Planning and Strategic Initiatives/Office of Research Infrastructure Programs (DPCPSI/ORIP). NCRR was dissolved in December 2011 and its authorities were delegated to DPCPSI. DPCPSI/ORIP now has the lead responsibility for coordinating all efforts on behalf of HHS concerning the sanctuary system for surplus chimpanzees from both federal and non-federal sources. Additionally, since the regulation was issued in 2008, the number of existing National Primate Research Centers has been reduced from eight to seven, as of 2015.
- *Privacy Act; Implementation (Final Rule).* This final rule was published in the *Federal Register* on April 3, 2018. It makes the exemptions that HHS/NIH proposed for a subset of records covered in a new Privacy Act system of records, System No. 09-25-0225, NIH Electronic Research Administration (eRA) Records (NIH eRA Records) effective. The new system covers records used in managing NIH research and development applications and awards throughout the award lifecycle. The listed exemptions are necessary to maintain the integrity of the NIH extramural peer review and award processes, and will enable the agency to prevent, when appropriate, those individual record subjects from having access to, and other rights under the Privacy Act with respect to, confidential source-identifying material in the records.

**Recently Adopted Policies**

- *Human Fetal Tissue (HFT) Research Policy.* In 2019, HHS announced that it would convene an Ethics Advisory Board (EAB) in FY 2020 to advise, consult with, and make recommendations to the HHS Secretary regarding the ethics of research involving HFT from elective abortions (as authorized in the Public Health Service Act) proposed in grant applications and contract proposals that were recommended for funding. HHS also announced that no new research would be conducted within the NIH Intramural Research Program (IRP) that required new acquisition of HFT from elective abortions. To implement the HHS policy position, NIH issued guidance for potential applicants alerting them of the newly required information for applications using HFT and the associated evaluation criteria. On February 20, 2020, HHS issued a Federal Register Notice establishing the FY 2020 EAB along with a call for nominations. The EAB met in July 2020 and was disbanded (as the statute required) in September 2020. Unless a new policy direction is provided, NIH intramural research using HFT from elective abortions will continue to be prohibited, and HHS will need to establish a new EAB for FY 2021. In that case, HHS needs to publish a Federal Register Notice in early February 2021 establishing a new EAB for FY 2021 and soliciting nominations. The meeting of the FY 2021 HFT EAB would be held in the summer of 2021. If there is a policy change, HHS and NIH will need to rescind and/or revise existing guidance to the research community (including the NIH IRP).
- *Amendments to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).* In an April 2019 Federal Register Notice, NIH amended the *NIH Guidelines*, to remove the requirement to register and report on human gene therapy protocols under the *NIH Guidelines* to the NIH and to refocus the NIH Recombinant DNA Advisory Committee (RAC), renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), to provide recommendations to the NIH Director on, and serve as a public forum for, the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. Robust oversight for human gene therapy research continues under the FDA, which has regulatory oversight of all such clinical trials. In addition, NIH-funded human gene therapy research remains subject to the usual NIH oversight that applies to all NIH-funded research, and oversight by local authorities such as Institutional Review Boards (IRBs) and Institutional Biosafety Committees (IBCs).
- *Update on NIH Extension Policy for Early-Stage Investigator Status (ESI).* NIH remains strongly committed to the Next Generation Researchers Initiative (NGRI) policy to fund more early-career investigators and to enhance biomedical research workforce diversity. NIH considers requests for extension of the ESI period for various reasons, including medical concerns, disability, extended periods of clinical training, natural disasters, active duty military service. Each of these requests is reviewed on a case-by-case basis. Because close to 50% of the ESI extension requests are related to childbirth, NIH will approve an ESI extension of one year for childbirth within the ESI period. The policy was published in the NIH Guide for Grants and Contracts in September 2018 (NOT-OD-20-011).
- *Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award.* NIH clarified expectations regarding change in status, including absence of Program Director/Principal Investigator (PD/PI) and other Key Personnel named in the Notice of Award (NoA) of NIH grants, as well as change in recipient institution. NIH expects that funded biomedical and behavioral research occurs within an environment that is safe, healthful, and conducive to high-quality work. Language was added to clarify that NIH recipients are expected to provide safe and healthful working conditions for their employees and foster

work environments conducive to high-quality research. The request for approval should include whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (e.g., due to concerns about harassment, bullying, retaliation, or hostile working conditions). The policy was published in the NIH Guide for Grants and Contracts in June 2020 (NOT-OD-20-124).

- *Update to GDS management of Summary Data.* The NIH Genomic Data Sharing (GDS) Policy, which applies to all large-scale genomic data generated from NIH-funded research, facilitates broad and responsible human genomic data sharing through NIH data repositories through a two-tiered system of unrestricted or controlled access. Genomic summary results (GSR) are generated from primary analyses of genomic research and convey information relevant to genomic associations with traits or diseases across datasets rather than associations specific to any one individual research participant. GSR was available only through controlled access in response to potential risks to participant privacy. Input from genomics and ethics experts obtained in 2018, however, indicated that the risks associated with making GSR more openly available were overstated, and the benefits of doing so outweighed the risks. Therefore, NIH updated its procedures to allow unrestricted access to GSR from most NIH-supported studies for research purposes in 2020.
- *Basic Experimental Studies with Humans.* The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information requires registration and results information submission to ClinicalTrials.gov for all clinical trials funded in whole or in part by NIH. Basic Experimental Studies with Humans (BESH) are a subset of clinical trials that also meet the definition of basic research. Registering and reporting results in ClinicalTrials.gov has posed a challenge for some types of BESH. NIH undertook an extensive effort to understand better and address concerns raised by the community. NIH issued a Request for Information (RFI), conducted an analysis of registration and results reporting of BESH studies, interviewed internal and external BESH researchers, and engaged relevant scientific societies and Congress. NIH took a number of steps to mitigate issues while working to develop an appropriate resolution, including releasing a series of specific FOAs designated for BESH, conducting educational outreach both internally and externally, and extending policy flexibilities allowing registration and results reporting on an alternative platform though September 24, 2021 for applicants submitting through BESH FOAs. Congressional staff have continually expressed interest in the issues surrounding BESH and have directed NIH to report no less than 60 days prior to moving forward with any new proposals. NIH is currently evaluating all options for resolving challenges, including potentially extending existing policy flexibilities.
- *Gain of Function (GOF) Policy*. In January 2017, the Office of Science and Technology Policy (OSTP) issued Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO Policy Guidance) requiring federal departments and agencies conducting, supporting, or planning to conduct or support the creation, transfer, or use of enhanced potential pandemic pathogens (PPPs) to develop appropriate review mechanisms. In December 2017, HHS released its Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework), which formalized a multidisciplinary Department-level review of individual, proposed research that is reasonably anticipated to create, transfer, or use enhanced PPPs to guide agency funding decisions and oversight. Two research proposals have completed review under this new framework. OSTP and HHS continue to consider ways to foster safety, security, and public transparency for such research, and a meeting of the National Science Advisory Board for Biosecurity was convened in January 2020 to discuss these issues.

## Pending or Expected Regulations

(b) (5)

## Pending or Expected Policies

(b) (5)

(b) (5)

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## OVERVIEW OF THE POLICY/REGULATION REVIEW AND ENFORCEMENT PROCESS

NIH has processes for policy development and review and processes for the development, review, and enforcement of regulations.

**Policy Review Process**

As part of its role in leading the agency's overall research agenda, the NIH Office of the Director (OD) coordinates the development and review of policies to ensure the appropriate stewardship of public funds and public confidence in NIH research enterprise. The Office of Extramural Research (OER), the Office of Intramural Research (OIR), and the Office of Management (OM) develop policies, respectively, for grantees, intramural investigators, and contractors. The Office of Science Policy (OSP) complements these efforts and plays an overarching role in policy development and review. OSP focuses generally on developing policies to address cross-cutting scientific, public health, ethical, legal, and societal issues and in key areas of emerging technologies, biosafety, biosecurity, technology transfer, data sharing, human subjects protections, and clinical and healthcare research.

The NIH Director and senior leadership review and approve policies, most of which are developed through an extensive consultation process involving both internal and external stakeholders. NIH typically uses the NIH Guide to Grants and Contracts and the Federal Register to solicit comments on proposals and to publish final documents. Using authorities in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, NIH can take enforcement actions for non-compliance, including termination of funding.

**Regulatory Review Process**

Rulemaking actions that are of relevance to NIH and its research mission may be initiated by NIH, but the actions are carried out on behalf of the Secretary because the NIH Director does not have authority to promulgate regulations. These pertain mainly to NIH research grants, training programs, LRPs, scientific peer review, the conduct of persons and traffic on the NIH federal enclave, conflicts of interest, standards of care for chimpanzees in the federally supported sanctuary system, clinical trials registration, and the submission of results information. These regulations are codified in titles 42 and 45 of the CFR. Historically, none of NIH's rulemaking actions have been considered major rules.

The regulatory review process is managed by the NIH Regulations Program (NIHRP) in the Division of Management Support (DMS), Office of Management Assessment (OMA), OM, OD. The program is staffed by the Acting NIH Regulations Officer, a program analyst, a senior business consultant, and a senior regulations consultant. The review/clearance steps involve the:

- NIH Regulations Officer;
- DMS Director;
- Director, OMA;
- Deputy Director for Management (DDM);
- Relevant IC or OD Office management and program officials;
- NIH Branch of the Office of the General Counsel, including the NIH Legal Advisor or

designee;
- Deputy Director for Extramural Research (DDER) or the Deputy Director for Intramural Research (DIDR), as appropriate; Associate Director for of Science Policy
- Principal Deputy Director, NIH;
- NIH Director.

Regulatory staff in the Executive Secretariat, Office of the Secretary, HHS (OS/ES) communicate with the Office of Information and Regulatory Affairs (OIRA) concerning prepublication review, as required under EO 12866, and with the Office of the Federal Register Office (OFR) concerning OFR editing and publication the regulations. Typically, the NIH Regulations Officer does not communicate directly with OIRA or OFR officials on regulations.

The NIH Regulations Officer and staff are also responsible for assembling and submitting NIH's section of the Regulatory Plan and the semiannual Unified Agenda for HHS. The DDM, who also serves as the NIH Regulatory Reform Officer (RRO) (a role created in 2017 as part of HHS's implementation of EO 13777 Enforcing the Regulatory Agenda) and the Principal Deputy Director are responsible for reviewing NIH's Unified Agenda submissions.

As required by EO 13563, Improving Regulation and Regulatory Review, the NIHRP periodically reviews existing regulations to ensure that the regulations and the requirements set forth in them are clear, transparent, minimally burdensome, up-to-date, and continue to be consistent with statutory requirements. As part of these retrospective reviews, NIH considers suggestions from the public about appropriate reforms to existing regulations relevant to NIH and carefully considers comments.

Executive Orders 13771, Reducing Regulation and Controlling Regulatory Cost, and 13771, Enforcing the Regulatory Agenda, which were issued in 2017 and serve as the primary drivers of the President's Regulatory Reform Agenda, place additional constraints on NIH rulemaking. EO 13771 requires the NIHRP to ensure that for every new "significant regulatory action" at least two prior regulations be identified for elimination. EO 13777 requires the NIHRP to review all existing regulations to identify possible deregulatory actions to reduce costs and burdens. The NIHRP coordinates with ICO review teams to conduct the reviews. The NIH Regulatory Reform Task Force (NIH RRTF) was established in 2017 to oversee all regulatory reform-related activities at NIH. The NIH RRO chairs the NIH RRTF and the NIHRP serves an Executive Secretary role in support of the RRTF. Proposed deregulatory actions are reviewed by the RRO and the RRTF prior to submission to the Department for consideration. The NIHRP is required to provide monthly reports of deregulatory actions to the Department.

OMA also coordinates the agency's review and clearance of regulatory proposals of other agencies and departments. The review process involves relevant subject matter experts in the ICOs. OD, particularly OSP, helps consolidate comments from multiple components and resolves differing perspectives as needed.

The process of obtaining OIRA approval for NIH to collect information from the public is managed by the Project Clearance Branch, Office of Policy for Extramural Research Administration (OPERA), OER.

**Enforcement Issues**

Compliance and enforcement are the responsibility of several NIH components. For the extramural program, the Division of Grants Compliance and Oversight (DGCO), OPERA, OER is the focal point for

advancing external compliance with policy and legislative mandates and enhance compliance oversight by recipient institutions. It has a proactive compliance and oversight program to assist grantees in complying with the terms and conditions of the NoA. Non-compliance with the terms and conditions of award can lead to one or more actions, including suspension and termination of funding, depending on the severity and duration of the non-compliance. DGCO also develops compliance guidance and provides direction and advice to IC extramural staff and recipient institutions on compliance issues (e.g., special award conditions, enforcement). For example, OPERA is currently developing compliance guidance for NIH-funded research subject to the new Clinical Trials Registration and Results Submission rule and the complementary NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.

The NIH Grant Appeals Officer has jurisdiction for review of recipient appeals of certain enforcement actions, including termination, in whole or in part, of a grant for non-compliance with the terms and conditions, withholding of a non-competing continuation award for non-compliance with the terms and conditions, cost disallowances, or determination that a grant is void (not authorized by statute or regulation, or fraudulently obtained).

For NIH funded research that is subject to HHS regulations governing research with animal subjects, the NIH Office of Laboratory Animal Welfare provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

For intramural research, important compliance oversight roles are carried out by the Division of Occupational Health and Safety, Office of Research Services, OM, and the Office of Human Subjects Research Protections and the Office of Research Support and Compliance (ORSC).

For NIH-funded research that is subject to HHS regulations governing research with human subjects, NIH works with the Office for Human Research Protections, which has regulatory responsibility for overseeing compliance with the HHS regulations.

The Division of Program Integrity in OMA is responsible for conducting reviews of allegations involving misuse of NIH grant or contractor funds, grantee or contractor conflicts of interest, and other misconduct or misuses of NIH resources by NIH employee or others doing business with NIH.

Risk management, audit liaison, and program integrity functions in OMA help assure enforcement of applicable regulations. Consistent with the Federal Managers' Financial Integrity Act and OMB Circular A-123, Management's Responsibility for Internal Control, OMA also maintains an internal control system to assure compliance with applicable laws and regulations and to achieve other objectives.

Regarding enforcement issues, NIH is continuing to address compliance issues related to the conduct of clinical research in the NIH Clinical Center. In May 2015, the FDA conducted an unannounced "for cause" inspection of two units within the NIH Clinical Center (CC) Pharmacy Department. The inspection revealed serious problems with facilities, personnel training, and SOPs, and the sterile production facility was immediately shut down. NIH has taken several steps to remedy the issues and create an organizational structure that fosters and supports the highest quality of patient safety and research support. One important outcome of these efforts is the new Clinical Center Research Hospital Board (CCRHB). The Board provides advice and recommendations to the NIH Director and CEO of the NIH

Clinical Center pertinent to maintaining excellence in hospital operations, safety and quality, regulatory compliance, clinical research, and hospital leadership performance oversight. Additionally, outside contractors specializing in quality assurance for manufacturing and compounding have been engaged to perform a systematic inspection of NIH sterile processing facilities. ORSC was established in 2016 to ensure that research conducted across all Institutes and Centers (ICs) adheres to the highest legal, professional, and ethical standards.

## SUMMARY OF LITIGATION

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Resolved Lawsuits: There are no lawsuits resolved since January 20, 2009 that significantly affect the NIH's operations.

# CONGRESSIONAL RELATIONS AND ISSUES

NIH has two layers of congressional relations:
(1) The Office of the Director includes the Office of Associate Legislative Policy and Analysis (OLPA), led by Adrienne Hallett. OLPA serves the NIH Director, the NIH Director's Executive Committee, and Institute and Center (IC) Directors across NIH. OLPA is the official conduit for all NIH communications to and from Capitol Hill.
(2) Each IC has legislative/policy staff that collaborate with OLPA and directly support their IC leadership. Depending on the size of the IC, the congressional interest in their area of research, and the individual IC Director's desire for information, each IC has between 1-4 legislative/policy staff.

## DIVISION RELEVANT COMMITTEES

**Senate**

Health, Education, Labor, and Pensions (HELP) Committee:

- Chair Lamar Alexander (R-TN) [retiring]; Ranking Member Patty Murray (D-WA).
- Principal majority staff Grace Graham, Andy Vogt, and Melissa Pfaff.
- Principal minority staff Nick Bath and Garrett Devenney.
- HELP Committee does their work almost exclusively at the full Committee level.
- Subcommittees may hold occasional hearings.

Appropriations Committee:

- Chair Richard Shelby (R-AL) [retiring]; Ranking Member Patrick Leahy (D-VT).
- Principal majority staff Shannon Hines.
- Principal minority staff Charles Kiefer.
- Appropriations does their work almost exclusively at the Subcommittee level.
    - The majority of NIH's budget is appropriated by the Subcommittee on Labor, HHS, Education, and Related Agencies (LHHS):
        - Chair Roy Blunt (R- MO); Ranking Member Patty Murray (D-WA).
        - Principal majority staff Laura Friedel.
        - Principal minority staff Alex Keenan.
    - A small part of NIH's budget is appropriated by the Subcommittee on Interior, Environment and Related Agencies:
        - Chair Lisa Murkowski (R-AK); Ranking Member Tom Udall (D-NM) [retiring].
        - Principal majority staff Emy Lesofski.
        - Principal minority staff Rachael Taylor.

Small Business Committee:

- Chair Marco Rubio (R-FL) ; Ranking Member Ben Cardin (D-MD).
- Principal majority staff Samantha Soco.
- Principal minority staff Kevin Wheeler.

**United States House of Representatives**

Energy and Commerce (E&C) Committee:

- Chair Frank Pallone (D-NJ); Ranking Member Greg Walden (R-OR) [retiring].
- Principal majority staff Tiffany Guarascio.
- Principal minority staff Ryan Long.

- Subcommittee on Health:
    - Chair Anna Eshoo (D-CA); Ranking Member Michael Burgess (R-TX).
    - Principal majority staff Joe Banez.
    - Principal minority staff Kristen Shatynski.
- Subcommittee on Oversight and Investigations:
    - Chair Diana DeGette (D-CO); Ranking Member Brett Guthrie (R-KY).
    - Principal majority staff Kevin Barstow and Kristin Seum.
    - Principal minority staff Alan Slobodin.

Appropriations Committee:

- Chair Nita Lowey (D-NY) [retiring]; Ranking Member Kay Granger (R-TX).
- Principal majority staff Shalanda Young.
- Principal minority staff Anne Marie Chotvacs.
- Appropriations does their work almost exclusively at the Subcommittee level.
    - The majority of NIH's budget is appropriated by the Subcommittee on Labor, HHS, Education, and Related Agencies:
        - Chair Rosa DeLauro (D-CT); Ranking Member Tom Cole (R-OK).
        - Principal majority staff Stephen Steigleder.
        - Principal minority staff Susan Ross.
    - A small part of NIH's budget is appropriated by the Subcommittee on Interior, Environment and Related Agencies:
        - Chair Betty McCollum (D-MN); Ranking Member David Joyce (R-OH).
        - Principal majority staff Rita Culp.
        - Principal minority staff Kristin Clarkson.

Small Business Committee:

- Chair Nydia Velázquez (D-NY); Ranking Member Steve Chabot (R-OH).
- Principal majority staff Megan Sunn.
- Principal minority staff Joe Hartz.

## OTHER MEMBERS WITH SPECIAL INTEREST OR SUBJECT MATTER EXPERTISE

NIH is fortunate to have many Members of Congress who act as champions for NIH's work. Caucuses with an interest in NIH run the gamut: disease-focused like the Crohn's and Colitis Caucus; science-oriented like the Caucus on Innovation; or subject-focused like the Caucus on Children's Health or the Caucus on Black Women and Girls. Many members have special interests because they or someone in their family has a particular condition.

Major Senate champions include:

- Senator Dick Durbin (D-IL) - introduced the first bill to provide mandatory dollars to NIH and started the bipartisan Caucus on NIH, which required joining members to commit to supporting additional funds for the agency.
- Senator Lindsay Graham (R-SC) - joined Senator Durbin in launching the Caucus on NIH but has had little interaction with NIH before or since.
- Senator Roy Blunt (R-MO) - strong supporter with a record of producing appropriations increases for NIH.
- Senator Jerry Moran (R-KS) - strong supporter, particularly on appropriations.

- Senator Patty Murray (D-WA) - strong advocate for NIH on both appropriations and the policies that support and improve science.
- Senator Susan Collins (R-ME) - drives allocation of more funds for Alzheimer's disease research and holds biennial hearings on juvenile diabetes.
- Senator Mitt Romney (R-UT) - strong ally in protecting peer review.

Major House champions include:

- Rep. Tom Cole (R-OK) - secured appropriations increases for NIH in the past and is vocal about continuing that momentum.
- Rep. Rosa DeLauro (D-CT) - introduced a bill providing mandatory funding for NIH.
- Rep. Anna Eshoo (D-CA) - strong supporter of biomedical engineering.
- Rep. Jim McGovern (D-MA) - strong interest in nutrition research.

Subject Matter Expertise:

- Rep. Andy Harris (R-MD) - a physician and former NIH grantee in the field of anesthesiology. He has been vocal in his criticism of the way NIH functions, particularly in funding AIDS research. He thinks of himself as a champion for NIH.
- The physicians in Congress have a particular interest in NIH though they've not been wholly supportive as a group. Rep. Burgess (R-TX) has visited the Bethesda campus many times and is consistently engaged. Rep. Phil Roe (R-TN) has taken a strong interest in clinical trial participation.

## REQUIRED AUTHORIZATION/APPROPRIATIONS REPORTS AND UPDATES TO CONGRESS

The primary authorizing report requirement of NIH is the NIH Triennial Report, which is required by section 403 of the Public Health Service Act and is sent to Congress every three years. The next report will be released in the fall of 2020. The prior report was issued in February of 2016; Appendix A of the 2016 report includes all of statutory requirements related to the report. In addition to the Triennial report, NIH is required to submit about 30 reports to Congressional authorizing committees. Report topics and frequency of submissions vary widely.

In addition, NIH receives many requests for research updates on particular diseases through the appropriations process. These updates function as a substitute for disease-specific earmarking. Each year, the legislative reports that accompany our appropriations bills contain several requests for reports on major NIH-wide topics such as stewardship of big data, a plan for the retirement of the remaining research chimpanzees, and efforts to encourage more physicians to become researchers.

Over the past few years, NIH has worked with Congress to modify the mandates for reports through a larger regular process: The Triennial Report for the authorizing mandates, and the annual Congressional Budget Justification for the appropriations requests. This has been successful in streamlining our reporting processes.

NIH leadership updates the authorizing and appropriations committees on our progress in addressing various topics such as the foreign influence investigations, the artificial intelligence/machine learning agenda, or other large initiatives, approximately once a quarter or whenever there is big news to report.

## KEY PENDING LEGISLATION

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NIH is working with Committee staff to resolve these issues.

**Oversight Committees and Subcommittees**

Since the public statements about the impact of undue foreign influence on biomedical research, the oversight landscape has broadened for NIH. The Committees asserting jurisdiction and investigating NIH's policies and practices in this space include our authorizing and appropriating Committees, as well as the Senate Homeland Security and Governmental Affairs Committee (HSGAC), the Senate Committee on the Judiciary, the House Committee on Science, Space and Technology, and the House Oversight and Government Reform Committee. Republicans are generally concerned that NIH may not have done enough to anticipate the threat, while some Democrats have expressed concern that NIH's response to the threat not include racial profiling. A report issued by HSGAC in 2019 showed NIH had the most sophisticated response in the Federal Government. The Senate Committee on Appropriations, however, maintains a $5 million set-aside in the Office of the Director for the OIG to conduct audits of NIH.

The Human Fetal Tissue Ethics Advisory Board has inspired oversight on both sides of the issue, including a rider on the House FY20 appropriations bill prohibiting funds for the board.

Finally, animal welfare in research is a perennial topic for congressional oversight. The oversight comes in the form of Chairman letters requesting documents and appropriations report language. In particular, there is a growing interest in the possibility of alternatives to animal research. There are a few Members still requesting documents about the transfer of chimpanzees to the Federal sanctuary.

**The Appropriations Committee**

The House and Senate Appropriations Subcommittees have taken a strong interest in NIH for many years and conduct an annual budget hearing for NIH. In the Senate, NIH is the only non-cabinet level agency to be given a hearing.

NIH has benefited from strong bipartisan support from the Appropriations Committees. However, NIH tends to secure higher increases when Republicans are in the majority. That is not due to a difference in support for NIH, but rather reflects the variety of other priorities in the bill. Most Democrats view NIH as one of many high priorities in the bill, whereas most Republicans view NIH as one of the few priorities in the bill. In the past four years, NIH has received steady annual increases ranging between $2 and 3 billion. Those increases have occurred under Republican and Democratic leadership in the House.

A key issue in appropriations is earmarking of disease funding. For many years, the pendulum has swung between Congress wanting to designate a particular amount for research on a particular disease and Congress declining to do so. Recently, the pendulum has swung towards a growing number of earmarks in our annual appropriations bill for disease-specific initiatives or other political priorities. For example, in 2018, the Appropriations Committee directed NIH to start the INCLUDE Initiative. NIH also has received funding directives for other items like firearms research, universal flu vaccine, chronic disease, and Alzheimer's disease research.

Interest in promoting specific disease areas also has varied by administration. For example, President Nixon created the National Cancer Institute in 1971, there was an effort to achieve the doubled NIH funding in 1998, and the Obama Administration proposed cancer and Alzheimer's disease initiatives. Most recently, the Trump Administration proposed Lyme disease and gene vector initiatives in 2019.

While there will always be pressure from advocates to commit specific appropriations for specific disease areas, and doing so polls well in the short-term, there are several important reasons why this approach is not the most effective:

- When the funding for particular disease research is determined by Congress, the decision becomes less about funding meritorious science and more about which patient advocacy group is more connected or more sympathetic.
- It is politically risky to take sides in a patient advocacy disease war. Very quickly, you have to choose between juvenile diabetes and arthritis, cancer and Alzheimer's disease, mental health and obesity. In addition, the advocates have started to further divide – not just by disease, but by patient groups. For example, pediatric cancer groups have been agitating quite strongly to divert cancer research funding from adult populations to pediatric populations. In the end, every dollar dedicated to a disease is scrutinized against every dollar to a different disease, putting NIH in a tough political position.
- More than half of the funding appropriated to NIH funds basic research, which is the pipeline for innovation and industry, but cannot be categorized in a disease-focused funding model. Even within the disease-focused work, it is not possible to predict the source of breakthroughs
- When setting a specific dollar amount for specific diseases or conditions, you have to spend it, even if the funding allocated is more robust than the number of qualified applications. You can easily end up funding questionable projects under this model.
- Innovation ebbs and flows, and funding for science must be flexible in order to take advantage of opportunities as they present themselves. On the opposite side, public health crises also impact funding models. If NIH funding were locked in statutorily mandated disease-based silos, it would be increasingly difficult for NIH to respond to a crisis like the coronavirus outbreak.

**Small Business and Science Committees**

Federal agencies with extramural research and development budgets that exceed $100 million are statutorily required to allocate 3.2 percent of their appropriated funds to grants to small businesses through the Small Business Innovation Research (SBIR) program. Agencies with extramural R&D budgets

that exceed $1 billion are required to reserve 0.45 percent for the Small Business Technology Transfer (STTR) program. In FY 2020, NIH committed over $1 billion for these two programs.

Statutory authority for the SBIR and STTR programs expires on September 30, 2022, but NIH expects the programs to be reauthorized. The Senate Small Business Committee has introduced legislation that would make the programs permanent while gradually increasing the "set-aside" for SBIR to 6.4 percent and STTR to one percent through FY 2024. Industry supports the set-aside increase, while the academy is opposed.

As the overall NIH budget increases, the amount NIH spends on the SBIR and STTR programs also increases. NIH supports the programs but would prefer that growth be accomplished through the growth of the agency as a whole.

## CONFIRMATION HEARING PREPARATION

NIH has two political appointee positions that are appointed by the President – the NIH Director and the NCI Director. Only the NIH Director position is confirmed by the Senate. The NIH Director confirmation process is managed exclusively by the Senate HELP Committee.

Confirmation of the NIH Director has generally happened fairly quickly after nomination.

- HELP generally holds a confirmation hearing, but not always. Hearings are historically friendly and quick.
- General themes for confirmation hearings include the nominee's vision for the agency and areas of interest from the patient advocacy community.
- Many of the questions at confirmation hearings are similar to the questions posed to NIH witnesses during annual appropriations hearings:
    - For Dr. Zerhouni in 2002, many of the questions involved stem cell and cloning research, but also security in a post-9/11 world, and the relationship between autism and thimerosal in vaccines.
    - For Dr. Varmus in 1993, some of the more focused questions included the Office of AIDS Research (established in law in 1988, statute strengthened in June 1993) and the lack of women in clinical trials.
    - Dr. Healy in 1991 was questioned on conflict of interest in science and priority setting.

| Director | Nomination Date | Hearing Date | Committee Vote | Confirmation Date | Vote Tally |
|---|---|---|---|---|---|
| Collins | 7/9/2009 | None | 8/4/2009 | 8/7/2009 | Voice vote |
| Zerhouni | 4/29/2002 | 4/30/2002 | 5/2/2002 | 5/2/2002 | Voice vote |
| Varmus | 10/4/1993 | 11/3/1993 | 11/10/1993 | 11/20/1993 | Voice vote |
| Healy | 2/19/1991 | 3/14/1991 | 3/20/1991 | 3/21/1991 | Unanimous consent |

## IMPLICATIONS OF CONTINUING RESOLUTIONS

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## IMPLICATIONS OF CHANGES IN NEW CONGRESS

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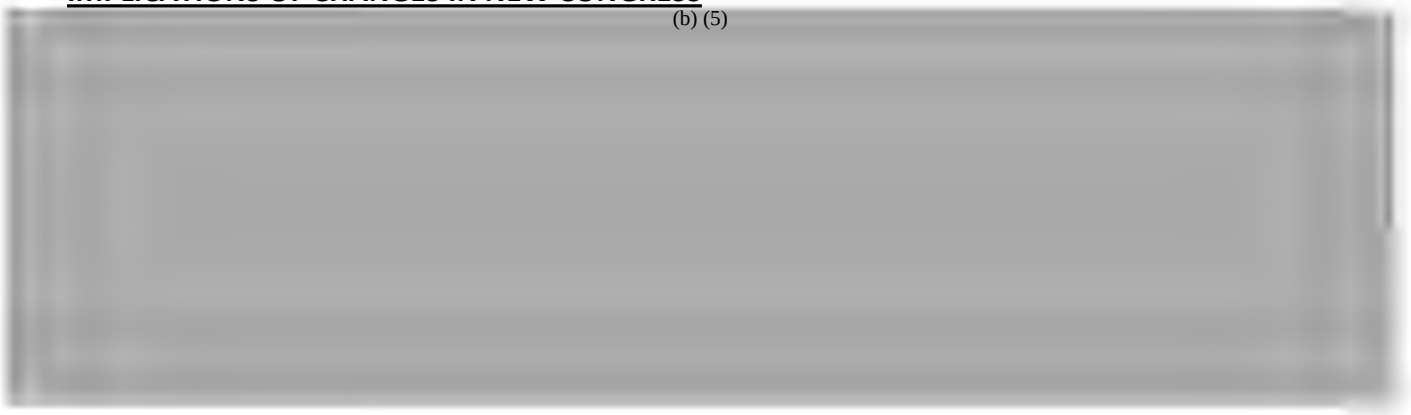

# EXTERNAL STAKEHOLDERS OVERVIEW AND ISSUES

## STAKEHOLDER GROUP OVERVIEW

NIH receives regular input from stakeholder organizations, including grantees, lawmakers, media, and nonprofit organizations, among others. NIH has a long-standing commitment to its many and varied audiences. Interaction with stakeholder organizations can increase the reach of NIH health communications and outreach programs. Interactions range from routine meetings to the establishment of novel programmatic initiatives and partnerships. Such programs allow for co-funding of research, provision of input into the design and scope of NIH research initiatives, and creation of new programs and collaborations.

Across NIH, stakeholder relations efforts are accomplished by individual Institutes and Centers (ICs), either acting alone or through cross-NIH collaboration, and as an integral part of the many programmatic responsibilities assigned to various offices within the NIH Office of the Director (OD). OD Offices with engagement efforts involving key agency stakeholders include OER, OIR, OCPL, OSP, and OLPA. Key offices within OER include the Office of Policy for Extramural Research Administration, Office of Laboratory Animal Welfare, Office of Research Information Systems, the Electronic Research Administration, and the Division of Communication and Outreach. Offices within OIR include the Office of Intramural Training and Education, Office of Technology Transfer, Office of Human Subjects Research, and the Office of Animal Care and Use. Another OD office with a strong interest in stakeholder engagement is the DPCPSI, which includes the Common Fund and several research-oriented offices with their own unique and important audiences. These offices include the Office of AIDS Research, the Office of Research on Women's Health, and the Office of Behavioral and Social Sciences Research, among others. Three relatively new offices within DPCPSI are the Tribal Health Research Office, the Sexual & Gender Minority Research Office, and the Office of Nutrition Research. NIH continues to evaluate how to reach a broad and diverse audience, and we are always searching for innovative ways to keep the public informed about the latest developments in science and medicine. Doing so advances the agency's mission: to enhance health, lengthen life, and reduce illness and disability.

In general, NIH stakeholders include:

- Grantees and other agency awardees;
- Congress and policy leaders;
- The media;
- Nonprofit organizations with an interest in disorders and conditions, as well as those with legislative and research components;
- Professional societies and scientific organizations;
- Clinical trial participants;
- Academia, including universities and teaching hospitals;
- Industry (e.g., pharmaceutical and biotech and bioengineering concerns);
- Executive Branch officials and agencies (including the Office of the Secretary within HHS, CDC, FDA, et al.);
- Philanthropists and foundations;
- State governments;
- The wider public at large, including individuals who are limited English proficient (LEP); and
- Unions representing NIH employees and contractors.

NIH promotes and benefits from dynamic and interactive communications with its many varied stakeholders, who: (1) help promote public understanding of the benefit of publicly funded research; (2) inform strategic research planning efforts; and (3) share and translate the results of medical research. The agency's stakeholders represent the public's voice on a wide range of issues falling under the NIH mission. Interactions with the NIH's many audiences have often proven essential to the development of responsible science policies.

**Institutes and Centers**

In addition to the programs and activities outlined below, IC stakeholder outreach and engagement programs include strategic partnerships and collaborations, such as community-based efforts, educational and outreach partnerships, and public health collaborations designed to help the agency reach target audiences and achieve health goals.

When appropriate, IC efforts extend to the inclusion of stakeholders in planning efforts, peer review programs, and co-funding arrangements. Several NIH ICs sponsor advocacy events organized on behalf of their nonprofit partners to build public trust and enhance transparency. A few ICs benefit from the emergence of groups based on the 'Friends' stakeholder organization model. They include the NIAMS Coalition, Friends of the National Library of Medicine (FNLM), Friends of NICHD, and other partner organizations that advocate for and support the IC with which they share an interest.

To support the agency's health communications goals, NIH reaches out to the public through a variety of congressionally mandated communications efforts, such as carefully designed campaigns aimed at raising public awareness of critical health issues. Certain efforts may target specific audiences, such as populations that are at greater risk for particular diseases. OCPL provides leadership and guidance and speaks for NIH as a whole, while individual IC communications clearinghouses provide educational materials and resources on a variety of IC-specific health-related topics. Communications teams across NIH share a similar challenge: identifying and selecting appropriate communication outlets for key audiences. Sometimes a communication effort is developed with the direct input of a specific stakeholder community. The result of these efforts is a broad-based communication program that uses the best of both traditional and new approaches to reach vast, ever-emerging audiences. An example of NIH's robust outreach programs is the agency's outreach to American Indian and Alaska Native communities (AI/AN). Formed in 2005, the Trans-NIH AI/AN Health Communications and Information Work Group provides a forum for health education and communications staff from NIH ICs to share strategies and communication approaches for developing and disseminating health information. This effort supports and augments the NIH Tribal Health Research Office, created under the NIH Division of Program Coordination, Planning, and Strategic Initiatives, mentioned above.

**Public Comment**

NIH routinely seeks to maximize agency interactions with its many stakeholder audiences by: (1) incorporating their input into NIH programs and issues as allowable and appropriate; (2) engaging in strategic, proactive planning; (3) facilitating the application of best practices for the agency's programs; and (4) entering into novel partnerships and agreements when possible. Public comment opportunities include input into the development of research policies and practices as appropriate and allowed, such as those in association with strategic research planning efforts. Public comment opportunities may take the form of simple outreach distributions to stakeholders as well as more formal channels and outlets, including Request for Information (RFI), Federal Register Notices, Notices of Proposed Rulemaking (NPRM), and Advance Notices of Proposed Rulemaking (ANPRM). One recent example is the 2019-2020 RFI inviting feedback on the NIH-Wide Strategic Plan for Fiscal Years (FYs) 2021-2025.

**Public-Private Partnerships**
Increasingly, NIH establishes partnerships among U.S. and overseas scientists, institutions, other agencies, industry, and nonprofits to advance research and training; foster communications; and identify opportunities for collaboration. One example of such an effort is the Accelerating Medicines Partnership (AMP), a public-private partnership that began in February 2014 and is ongoing. AMP is aimed at transforming the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics. For AMP, the NIH joined the FDA, 10 biopharmaceutical companies, and multiple nonprofit organizations to with the goal of increasing the number of new diagnostics and therapies reducing the time and cost for development.

**Global Reach**
Because of the NIH's role in: (1) controlling both infectious and non-communicable diseases; (2) fostering global health research and training; and (3) helping overseas nations develop a long-term research capacity, the agency finds itself with the formidable task of reaching global audiences. The principal NIH website—the agency's front door to the world—draws millions of unique visitors a month and provides 24/7 access to information about the agency's programs and activities. The NIH.gov site also provides a central home for many of the agency's social media features and outlets, including the main NIH Twitter feed, Facebook presence, YouTube accounts, the NIH GovDelivery account. The agency's ever-expanding social media presence includes a wide range of features and outlets sponsored by NIH ICs and program offices. In addition, the NIH Director's blog is a platform for the public to share views and thoughts on exciting research frontiers and cool advances in biomedical science.

Under the Office of the Director are several specialized blogs, such as Under the Poliscope, sponsored by the Office of Science Policy, and Open Mike, a series of communications aimed at connecting NIH Deputy Director for Extramural Research Dr. Michael Lauer with the agency's many grantees and other award recipients. These and other blogs offered by NIH continue to create engaged communities united by common interests and vested in a shared outcome, in this case, strong support for our nation's investment in biomedical research.

OCPL produces communication materials and programming for the agency's many audiences, including NIH staff, as well as the broad public spectrum. Products include the NIH Intranet; health information resource; and Spanish-language website, "Salud"; plus an array of publications, including the NIH Record, NIH Research Matters, and NIH News in Health.

Two additional features on the NIH website merit mention for their role in helping promote efficiency, transparency, and public trust between the agency and its stakeholders:

- The Impact of NIH Research website, designed to help the agency's many audiences discover more about how NIH: (1) provides value for the investment in publicly funded research; (2) influences the Nation's health; and (3) provides overall societal benefits, such as stimulating economic growth; and
- The Research Portfolio Online Reporting Tools (RePORT) , which provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research.

**Expanding Access**
NIH has worked to increase access to Federal programs and activities, and to ensure meaningful access to NIH-administered programs and activities for individuals who are LEP by implementing the agency's Language Access Plan (LAP). The focus of the LAP plan is to provide for communications in the preferred

language when an individual, such as a patient, has limited English proficiency. Of the 90 languages encountered by ICs in the development of accessible and effective health, science, and medical information for broad public dissemination, those most frequently encountered include Spanish, Chinese, French, Korean, and Brazilian Portuguese. Others include Afrikaans, Thai, Japanese, Hindi, Farsi, Italian, Russian, Arabic, Vietnamese, Navajo, Polish, and Tagalog. In addition, NIH makes information available through the NIH Clear Communication website and through IC efforts that reaffirm the agency's commitment to providing accessible materials and resources in an effort to help reach individuals with literacy challenges.

## SPECIAL INITIATIVES OR HOT TOPICS OF THE STAKEHOLDERS

### Opioid Research: the NIH HEAL Initiative

The Helping to End Addiction Long-term℠ Initiative, or NIH HEAL Initiative℠, is an aggressive, agency-wide effort to address the national opioid public health crisis. One highlight of the program is an annual investigators' meeting held for the benefit of participating HEAL research institutions. Information on the annual meeting is online at https://heal.nih.gov/news/events.

### Gene Therapy: Policy Streamlining

In 2018, NIH and FDA announced the two agencies' plan to streamline duplicative and burdensome oversight over gene therapy. As part of the streamlining effort, the NIH's longstanding Recombinant DNA Advisory Committee (RAC) will now focus on providing advice on safety and ethical issues associated with emerging biotechnologies. The NIH Director's statement outlining the proposal is available online at https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-streamlines-gene-therapy-oversight-charts-course-considering-emerging-technology. The two agencies also released the amended NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

### Local Issues: NIH in the Community

NIH functions as part of a larger community, and the larger community is considered a key stakeholder in NIH programs and activities. The agency enjoys strong, bipartisan support in Congress and is in regular communication with our local representatives, including U.S. Representative Jamie Raskin (Maryland's 8th District), U.S. Senator Chris Van Hollen and U.S. Senator Benjamin Cardin, both of whom have visited the campus in recent years. The agency coordinates planning and remediation with Montgomery County and Bethesda officials and stakeholders, focusing on traffic, noise, construction, waste, campus growth, security, and many other issues. NIH publishes its master plan online and maintains an Office of Community Liaison (OCL). OCL holds regular meetings for the benefit of local citizens, and minutes from meetings are made available on a dedicated website. NIH's interactions with local stakeholders extend to nearby facilities, such as the agency's buildings in Northern Montgomery County and Frederick, Maryland. NIH also coordinates research, planning, VIP events, and emergency operations with its neighbor, Walter Reed National Military Medical Center.

## RECENT ENGAGEMENTS WITH STAKEHOLDERS

Examples of agency engagement efforts directed at specific stakeholder constituencies follow.

### Patient Volunteers

For volunteer participants, NIH research often means hope and the promise of a diagnosis, treatment, or improved understanding. Volunteers in clinical research are more important than ever. An additional benefit is the role patient volunteers play in advancing science for the betterment of future generations.

The majority of NIH clinical research takes place under agency guidelines at teaching hospitals around the country and overseas. Many studies, however, take place at the NIH Clinical Center in Bethesda.

**Congress**
The OPLA has responsibility for agency interactions with members of Congress, their staff, and other key policymakers.

**Media**
The press, a major source of health information for the public, is an important transmission resource for NIH in ensuring that sound, research-based information is disseminated to the public. The OCPL is the central media contact at the NIH.

**Scientific Community**
A core constituency for any research organization is the scientific community, including laboratory investigators, academicians, and physician-investigators based at teaching hospitals, research centers, and universities around the country. Thousands of scientists from around the United States and overseas come to NIH for training and to work in NIH Intramural Research laboratories, most of which are on the NIH main campus in Bethesda, Maryland. These visitors include students, postdoctoral scholars, clinicians, and other trainees from around the world. More than 80 percent of the NIH's budget, however, is used to fund the NIH Extramural Program, which funds more than 300,000 research personnel at over 2,500 universities and research institutions.

NIH also works diligently to develop and deliver transparent and timely information about funding practices and policies to ensure that the engine of medical research discovery runs at top speed and that the scientific workforce's information needs are met. Several ICs have developed focused communications tools to help engage the scientific community, and grantees in particular. In addition, meetings, online comment opportunities, Federal Register notices, and RFIs are all well-established mechanisms for information sharing and public consultation with the biomedical research community.

Within OD, OCPL serves as the coordinating office for a network of designated Public Information Officers (PIO) based at university, academic medical centers, and other research institutions nationwide to ease communication, encourage collaboration, and coordinate publicity between NIH PIOs and communications staff at NIH-funded grantee and contracted institutions. The mission of the PIO network is to enhance knowledge exchange and improve the quality of information that reaches the public regionally. The PIO Network website houses events information, directories, a toolbox, and other resources for use by several hundred communications professionals located at academic institutions and teaching hospitals around the country.

**IRBs**
Institutional Review Boards (IRBs) play a critical role in review and approval of studies involving human research participants and evaluation of the potential benefits of research and risks to participants. NIH, primarily through the agency's Office of Science Policy and the Office of Extramural Research, manages relevant IRB policies, including issuing opportunities for public input into agency efforts aimed at revising and streamlining the review process for NIH-funded, multi-site clinical research studies in the United States, efforts ultimately designed to accelerate and advance clinical research. The Office of Science Policy also plays a pivotal role in relations with Institutional Biosafety Committees.

**Nonprofits and Professional Societies**
OD component offices and the majority of NIH ICs maintain open and productive relationships with public, private, and non-profit organizations concerned with biomedical research. The dialogue between NIH and nonprofits and professional societies—the agency's partners in biomedical research—is crucial to advancing research. Some nonprofits play an important role by offering research programs, including those programs that fund or co-fund research grants with the NIH.

**Foundations**
Because of the ever-evolving scientific landscape, NIH continues to develop its role in an ever-evolving stakeholder arena as well. NIH enjoys robust and growing stakeholder interest from philanthropists with an interest in medicine and science, venture capitalists, and foundations. For example, NIH has a close, collaborative relationship with the Bill & Melinda Gates Foundation. Another long-standing agency partner is the Foundation for the NIH (FNIH), which helps facilitate collaboration between and among NIH and leading public and private institutions. FNIH supports the mission of NIH by forming and facilitating public-private partnerships for biomedical research and training. Most recently, ACTIV, the public-private partnership led by the NIH and coordinated by the FNIH is a to develop a research strategy for prioritizing and speeding development of the most promising COVID-19 vaccines and treatments. These proposals must support the mission of NIH, foster innovation, facilitate creative discovery, and ensure a high rate of return.

**Unions**
The NIH workforce includes five diverse bargaining units which comprise 4.11 percent of the Federal employee population at NIH. The bargaining units include the following:

- American Federation of Government Employees, Local 2419 – 503 bargaining unit employees reside in the Office of Research Facilities, Office of Research Services and Clinical Center Nutrition Department. This unit is primarily comprised of wage-grade employees in the general maintenance and operations series (WG-4700), and includes contract specialists, events management personnel, food service workers, and emergency communications center personnel. These employees are located primarily in Bethesda, Maryland, and also work in Research Triangle Park, North Carolina, and Rocky Mountain Laboratories, Hamilton, Montana.
- American Federation of Government Employees, Local 2923 – 136 bargaining unit employees comprised of all nonprofessional employees of the National Institute of Environmental Health Sciences. These employees are located primarily in Research Triangle Park, North Carolina, with some in Bethesda, Maryland.
- Fraternal Order of Police – 47 bargaining unit employees comprised of all non-supervisory police officers at NIH. These employees are located primarily in Bethesda, Maryland, but also at the Rocky Mountain Laboratories in Hamilton, Montana.
- International Association of Fire Fighters, F-271 – 27 bargaining unit employees comprised of all non-supervisory employees in the GS-0081 series, Fire Protection and Prevention. All of these employees are located in Bethesda, Maryland.
- Public Service Employees Union, Local 572 – 12 bargaining unit employees comprised of housekeeping aids in the NIH Clinical Center, motor vehicle operators in the Office of Research Services, and various employees in the Division of Logistics Services.

Recent developments include successful contract negotiations with FOP, concluding in May 2020. The outcome of contract negotiations with AFGE L-2419 and AFGE L-2923 are pending the Federal Service Impasse Panel's decision.

The NIH Office of Human Resources (OHR) provides Labor Relations support to management for all five bargaining units. This Labor Relations support is provided by Employee & Labor Relations Specialists who also provide Employee Relations support to other areas of NIH.

## PERTINENT THIRD-PARTY REPORTS

In recent years, the NIH's reporting mandates have decreased in part thanks to improved agency transparency and the development of online resources designed to make available up-to-date research information. Chief among these is the NIH RePORT awards database.

Two key reports directed at Congress are the *NIH Strategic Plan* and *Triennial Report*. NIH is currently developing its next Strategic Plan, which covers the years FY 2021-2025. The Report is due to be released in December 2020. The 2016-2020 plan is available online. Note that individual NIH Institutes and Centers develop their own strategic plans, which can be found on their websites or in RePORT. Section 104 of the NIH Reform Act (PL 109-482) requires the NIH Director to submit a report to Congress that assesses "the state of biomedical and behavioral research," describes NIH activities and priorities. This report is called the Triennial Report and can be found online.

The NIH also submits annual "Reports to Congress" on a variety of topics focused on categorical spending and program planning. The 2021 reports are currently being prepared now and include Trisomy 21; Prematurity and; Maternal Mortality; the Impact of Racism on Public Health; Harassment Policies; Diversity at NIH Working Group and Strategic Plan; Participation of Pregnant and Lactating Individuals in COVID-19 Research; Male Reproductive Health; SARS-CoV-2 Pediatric Research Agenda; Gastroesophageal Reflux Disease (GERD); Lymphedema (LE); Use of Human Fetal Tissue in Research Diversity in Alzheimer's Disease Clinical Trials; Diversity at NIH Working Group and Strategic Plan; Unregulated Cosmetics; Addressing Youth Mental Health Disparities; Overdose Prevention Centers; Maternal-Fetal Transmission of Lyme Disease; Behavioral Research; Prematurity and Maternal Mortality; Post-Research Adoption of Animals in Extramural Research; Intramural Primate Research; Strengthening; Maternal Health Coordination; Animal Use in Research; Humane Research Alternatives; and Addressing Youth Mental Health Disparities.

Other topical Reports submitted to Congress are also linked to public law and mandates stemming from coordinating committees at the HHS level or higher (e.g., government-wide efforts). They include reports on Immune Diseases and Alzheimer's Disease research. They are available online at:

- The NIH Autoimmune Diseases Coordinating Committee: https://www.niaid.nih.gov/about/autoimmune-diseases-committee. The research report is available online as text or a PDF at: https://report.nih.gov/biennialreport/.
- NIH Bypass Budget Proposal for FY 2021 (report): https://www.nia.nih.gov/sites/default/files/2019-07/FY21-bypass-budget-report-508.pdf.

NIH's DPCPSI, organized within the OD, manages strategic planning and coordination of research and activities across the NIH. DPCPSI submits an annual report to Congress entitled, "Trans-NIH Research: Scientific Collaboration for the 21st Century," available online. In addition, NIH submits a Trans-Collaborations Report that highlights agency efforts carried out with its HHS partner agencies.

A listing of recent NIH-sponsored research reports can be found at https://www.ncbi.nlm.nih.gov/books/NBK4119/.

# CRISIS MANAGEMENT AND EMERGENCY RESPONSE

## EMERGENCY RESPONSE PLAN

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# ADMINISTRATIVE INFORMATION

## TRANSITION TEAM AND IMMEDIATE OFFICE STAFF CONTACT INFORMATION

| Name | Title | Email | Phone |
|---|---|---|---|
| **Lawrence A. Tabak, D.D.S., Ph.D.*** | Principal Deputy Director/First Assistant | lawrence.tabak@nih.gov | 301-496-2433 |
| **Tara A. Schwetz, Ph.D.*** | Associate Deputy Director | tara.schwetz@nih.gov | 301-496-2433 |
| **Courtney Aklin, Ph.D.*** | Senior Advisor | courtney.aklin@nih.gov | 301- 827-0196 |
| **Jordan Gladman, Ph.D.*** | Special Assistant to the Principal Deputy Director | jordan.gladman@nih.gov | 301-402-0689 |
| **Cyndi Burrus-Shaw** | Staff Assistant to the Principal Deputy Director | cyndi.burrus-shaw@nih.gov | 301-496-2433 |
| **Ayanna McManus** | Scheduler for the NIH Director | amcmanus@od.nih.gov | 301-496-2433 |
| **Gretchen Wood** | Staff Assistant to the NIH Director | woodgs@od.nih.gov | 301-496-4272 |
| **Patrice Allen-Gifford** | Director, Executive Secretariat | patrice.allen-gifford@nih.gov | 301-496-3976 |

*Transition Team

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**TRANSPORTATION AND PARKING INFORMATION**

Staff, visitors, and patients can travel to the main Bethesda campus by Metrorail, bus, NIH shuttles, and private vehicles. All individuals over age 15 must present an NIH employee ID or a valid government ID to enter the campus.

To enter the NIH campus by vehicle, employees must present their NIH badges. Visitors must present government identification and their vehicles must be inspected at one of three inspection facilities. Some parking lots (e.g., underground parking beneath buildings) require additional screening to park at that location. One multi-level parking facility is located outside the campus perimeter at the NIH Gateway Center for use by visitors who do not wish to drive onto the campus. Visitors should plan for the inspection process to take approximately 15 to 30 minutes, depending on the time of day.

The campus has 8,600 parking spaces for employees and contractors, serving an NIH campus staff population of 20,000. On average, approximately 6,700 NIH staff, volunteers, and patients take the metro each weekday to the Medical Center metro stop (Red line), located outside the campus on Route 355 – Rockville Pike.[1] Federal staff and volunteers are eligible for public transit subsidies. Non-patient visitors are strongly encouraged to use mass transit when visiting the Bethesda campus.

A total of 920 short-term metered parking, and long-term attendant-controlled parking spaces are available to visitors at a cost of $2 per hour for the first three hours or $12 per day. The Clinical Center has free, validated parking for patients and their guests, including valet parking for those with mobility limitations.

[1] These are pre-pandemic numbers.

NIH has an extensive, free shuttle system available to all staff, visitors, and patients. Three shuttle routes serve the NIH campus exclusively, while an additional three routes travel between campus and off-campus leased facilities, located throughout Montgomery County, Maryland.[2]

## LESSONS LEARNED FOR SUCCESS ON DAY 1

**Interviews**

Virtual or in-person meetings can be arranged at the request of the Director.

1. Introduction – NIH Director
2. Introduction – NIH Principal Deputy Director/First Assistant
3. Introduction – NIH Associate Deputy Director; NIH Chief of Staff (acting)
4. Introduction – NIH Deputy Directors (4)
5. Small Group of NIH Institute and Center Directors – Select Top Issues
6. Optional: Introduction – NIH Executive Committee
7. Optional: Introduction – All NIH Institute and Center Directors

The following questions are provided as suggestions for a new director:

- Please tell me about yourself and the work you do here at NIH. What brought you to NIH, and what keeps you here?
- What would you say are the major opportunities for scientific progress at NIH and the major challenges and/or barriers to progress?
- What do you see as the major science policy issues facing NIH right now?
- What factors are most important to your ability to do your work, such as having the flexibility to take on new scientific challenges? Do the current NIH structure, programs, and processes enable efficient and effective collaboration and adequate flexibility? What could be improved?
- What improvements should we look at to enhance the work culture at NIH?
- What are the top lessons learned from the SARS-CoV-2 pandemic?

**Demands on Administration:**

Space and Security: There will be an administrative demand to bring a new NIH director and leadership onboard.

- Providing directions to the NIH campus
- Clearing through security
- Completing security screening and badging process prior to arrival
- Providing access to NIH buildings
- Providing office space, potentially including provision of keys and office supplies
- Assigning parking permits

IT Support: There may be a surge in demand for IT support as existing staff change roles, and new staff come onboard. Will Welch, CIT IT Specialist, and IMOD IT Support Services Team Email are available to assist in this process.

- New staff will need access to network resources (share drives, printers, calendars, permissions)
- Training with new staff about existing equipment and/or new equipment procurement
- Access to third party applications and SharePoint sites will be provided

[2] The NIH is operating under a maximum telework directive and some shuttle services have been suspended or reduced pending recovery from COVID-19.

- There may also be a demand for after-hours support as staff setup home offices and get acclimated with remote access services

Records Management: All work-related email messages sent or received by Capstone Officials are potentially Federal records, and by default, will be designated as permanent records, which will eventually be accessioned to NARA. Capstone Officials are individuals identified as occupying the highest primary decision-making roles for NIH.

# APPENDIX: ISSUE PAPERS

## TOP ISSUE: *ALL OF US* RESEARCH PROGRAM

### KEY PROGRESS TO DATE

- As of mid-September, *All of Us* has more than 357,000 participants, including more than 271,000 who have completed the protocol's initial steps. More than 80 percent of these participants are from communities that have been historically underrepresented in biomedical research, and more than 50 percent are from racial and ethnic minority groups.
- Since making initial awards in July 2016, the program launched national enrollment in May 2018 and started beta testing the data platform in May 2020. More than 200 researchers have signed up to use the beta researcher platform in the first three months. This is the first, broadly accessible, fully cloud-based researcher platform, and pioneers a new data access model. This feat of opening up data access within two years of launching national enrollment is a remarkable achievement compared to the traditional cohorts where data access usually occurs many years after a study ends.
- In September 2020, the NIH Council of Councils approved the Nutrition for Precision Health, powered by the *All of Us* Research Program concept. This will be *All of Us'* first ancillary study and demonstrates how the NIH community may leverage this study. It is a broad, cross-cutting research study that will build on the backbone of *All of Us* and will make its data available to all *All of Us* researchers.

### KEY CHALLENGES TO DATE

- **Scale:** No other study has attempted to develop such a resource in terms of its size of one million or more; diversity including geography, racial/ethnic minorities, and individuals who have been underrepresented in biomedical research; and data types including electronic health records, survey, biospecimens, mHealth, and genomic sequencing. The current version of our data platform has limitations as it is in beta phase. We are still enrolling participants and therefore are still receiving data variables from participants. Survey completion rates vary across participants, and the collection and harmonization of electronic health record data from many providers, remain a work in progress.
- **COVID-19 Pandemic:** *All of Us* was affected by the pandemic and had to pause its in-person enrollment activities. These are still limited; however, the program is working on expanding digital participation activities and planning for the resumption of in-person activities. In response to COVID-19, *All of Us* launched 3 new studies: 1) a serology analysis of participant blood to see the prevalence of COVID-19 leading up to the outbreak, 2) a survey about how the pandemic has impacted participants, and 3) enhanced collection of electronic health records.
- **Genomics:** The program had to develop the infrastructure necessary to responsibly return genetic results to participants who wish to have them. The program worked closely with the FDA to obtain regulatory approval to permit the return of health-related genomics results. This has been an incredibly challenging, but important effort.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Josh Denny, M.D., M.S.** | CEO, *All of Us* Research Program | joshua.denny@nih.gov | Dr. Denny leads NIH's *All of Us* Research Program |
| ***All of Us* LCT** | n/a | n/a | *All of Us* formed this trans-NIH effort as a two-way dialogue with the ICs |

**External**

None identified

## TOP ISSUE: DIVERSITY, INCLUSION, EQUITY AND CULTURE

### ISSUE SUMMARY

- **Harassment** – Federal agencies are required to have a harassment policy and established procedures for employees to raise allegations of harassment. The Notification and Federal Employee Anti-discrimination and Retaliation (No FEAR) Act of 2002 requires federal agencies to provide training on rights and remedies available under employment discrimination and whistleblower protection laws. NIH commits approximately $242,000 annually to fund an on-line version of anti-harassment training which meets the requirements for No FEAR, as well as addresses the Prevention of Sexual Harassment. Agency-wide leadership support is needed to obtain compliance with the mandatory anti-harassment training. To aid in the process for obtaining full compliance, all EDI training course offerings contain content which meets the No FEAR Act requirements.
- **Workplace Diversity** - All federal agencies must report annually on their progress and plans toward establishing and maintaining effective equal employment opportunity programs. These efforts are compiled annually in NIH's Management Directive 715 (MD-715) Report and Plan that is filed with the U.S. Equal Employment Opportunity Commission. Under the MD-715 framework, EDI conducts analysis on workforce demographics and provides data-driven strategies to NIH and IC leaders that are designed to eliminate and/or mitigate institutional barriers to equal employment and support workforce diversity and inclusion.
- **Sex, Gender, Minorities (SGM)** - Section 404N of the 21st Century Cures Act (Public Law 114-255), signed into law on December 13, 2016, calls upon the director of the NIH to encourage efforts to improve research related to the health of SGM populations. SGM populations are an official health disparity population for NIH research. Sexual and gender minority rights in the workplace – three Supreme Court cases (Gerald Lynn Bostock v. Clayton County, Georgia; Altitude Express v. Melissa Zarda; and R.G. & G.R. Harris Funeral Homes v. Equal Employment Opportunity Commission) determined SGM employees cannot legally be fired because of their sexual orientation and/or gender identity.

### KEY PROGRESS TO DATE

**Harassment**

- NIH, in response to media and Congressional concerns, implemented the Anti-Harassment Prevention Program in late 2018, to include a survey of our workforce. NIH leadership designated the NIH Civil Program as the entity charged with receiving allegations of harassment and overseeing the appropriate inquiry. Since its implementation, the number of allegations of inappropriate conduct that the Civil Program reviews has increased significantly. As a result of this growth, and in order to meet the requirements for the NIH MD-715 report by ensuring the NIH has sufficient staff and resources to complete administrative inquiries on harassment claims in a timely fashion, the Civil Program created a business case to support an additional expansion to effectively manage the workload.
- NIH launched an on-line version of the anti-harassment training in 2019 which allows compliance tracking and disables the active directory accounts of those who do not comply with the training requirement until compliance is met.
- Further, since the first round of the NIH Climate Survey in 2019, created to evaluate NIH staff experience with harassment, we have been evaluating what went well, what we learned, and how the survey should continue in the long term. As a result, we developed a plan that will maintain momentum and build enhancements. Moving forward, the Climate

Survey will shift to the Office of Human Resources (OHR), where it will be housed within the Workforce Support and Development Division (WSDD), who has extensive experience with survey promotion, design, delivery, and analysis, as well as post-survey action planning. OHR is adding staff to support this effort. A multi-level data analysis tool, starting at the NIH wide level, and down to sub-organizations with 10 or more responses, will facilitate action planning.

- The Advisory Committee of the Director (ACD) Working Group (WG) on Changing the Culture to End Sexual Harassment convened in January 2019, and developed a report and recommendations, which were presented to the ACD in December 2019. Implementation of the report recommendations is ongoing, with leadership by WG co-chair Dr. Carrie Wolinetz, in coordination with NIH Office of Extramural Research. Implementation activities have included reporting and transparency-related measures. A progress update was delivered during the June 2020 meeting of the ACD.

**Workplace Diversity**

- Faculty Institutional Recruitment for Sustainable Transformation (FIRST) - The ultimate goal of FIRST, supported by the NIH Common Fund, is to employ a faculty cohort model to foster cultures of inclusive excellence at NIH-funded institutions with a sustained commitment to diversity and inclusion in biomedical research. Two FOAs will be issued in fall 2020, for the FIRST Cohort and a second for a Coordination and Evaluation Center.
- EDI has technical teams specifically designed to address the diversity and inclusion needs of each IC and provides training to educate the overall workforce on diversity and inclusion. In addition, EDI has three consultants who are assigned to work directly with ICs to increase the diversity of NIH applicant pools and pipelines for future employment, as well as assist in the retention and advancement of diverse talent spanning from onboarding through retirement.
- Diversity Programs Consortium (DPC) - The goal of the DPC is to develop approaches to engaging and mentoring students; enhance faculty development; and strengthen institutional research training infrastructure for underrepresented scientists. During the first phase (FY 2014 – FY 2019), the DPC consisted of three complementary initiatives.
- NIH Equity Committee (NEC) - SWD and OIR established the NIH Equity Committee (NEC) in 2017. The goal is to provide recommendations to the Scientific Directors of each IC's IRP in response to reports from them about demographics and steps to assure fairness.
- SWD Dashboard - The Dashboard displays demographic data for senior investigators and tenure-track investigators from the Intramural Research Program (IRP), the Association of American Medical Colleges (AAMC), and the National Science Foundation (NSF).

## KEY CHALLENGES TO DATE

**Harassment**

- Multiple surveys are administered across NIH each year. Survey fatigue and the ability to create a representative sample of the NIH population is always a challenge.

**Workplace Diversity**

- Recent guidance limiting topics that can be addressed in training to address racial and ethnic disparities.
- Data integrity issues with HHS BIIS data tables that are required for MD-715 reporting to EEOC. Need to utilize current OMB and EEOC standards for all demographic data used in compliance related reporting.

- Lack of available data for the NIH's Sexual and Gender Minority (SGM) community.

**SGM**

- **Data Collection.** Without a directive from the Office of Management and Budget (OMB), there is a lack of data collection on sexual orientation and gender identity in federally funded surveys and research studies, in administrative settings (such as grant and job applications), and in clinical settings (such as doctor's offices or clinical trials).
- **SGM harassment disparities at the NIH.** In the 2019 NIH Workplace Climate and Harassment Survey, results showed that employees who identify as a sexual and/or gender minorities were more likely to report experiences of gender harassment, unwanted sexual attention, and/or multiple forms of harassment in the workplace than their non-SGM counterparts.
- **Weakening of nondiscrimination protections at HHS.** Removal of requirements for HHS grant recipients to enforce nondiscrimination protections that prohibit discrimination on a number of bases including race, national origin, age, disability status, sex, sexual orientation, and gender identity.
- **Discrimination in healthcare.** On June 12, 2020, the final ruling of Section 1557 of the Affordable Care Act (ACA) returns the government's interpretation of sex discrimination according to the meaning of the word "sex" as male or female and as determined by biology and declines to recognize sexual orientation as a protected category under the ACA.
- **Sexual orientation and gender identity (SOGI) - related demographic data.** This data is not currently collected for NIH workforce through the Office of Human Resources, thus we are unable to assess if disparities exist in key elements of the employee life cycle (hiring, promotions, awards, separations, retention and within grade increases) for this population. This exemplifies a fundamental knowledge gap regarding the representation of sexual and gender minority (SGM) populations in the NIH workforce, and its impact on productivity. If disparities occur in any of these areas, the experience of an employee can be greatly affected.

**NEXT STEPS**

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**Workplace Diversity**

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SG

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lawrence A. Tabak, D.D.S., Ph.D.** | NIH Principal Deputy Director | Lawrence.Tabak@nih.gov | Chair, NIH Anti-Harassment Steering Committee |
| **Alfred C. Johnson, Ph.D.** | Deputy Director for Management | JohnsoA1@mail.nih.gov | Chair, NIH Anti-Harassment Steering Committee |
| **Marie A. Bernard, M.D.** | Acting Chief Officer for Scientific Workforce Diversity | mbernard@nia.nih.gov | Office leads NIH's effort to diversify the national scientific workforce and expand recruitment and retention |
| **Treava S. Hopkins-Laboy** | Acting Director, Office of Equity, Diversity and Inclusion | treava.hopkins-laboy@nih.gov | Cultivate a culture of inclusion where diverse talent is leveraged to advance health discovery |
| **Jessica Hawkins** | Civil Coordinator, Human Resources | hawkinj@od.nih.gov | Partners with stakeholders across the NIH to administer the NIH Anti-Harassment program and Workplace Violence Prevention program. |
| **Carrie D. Wolinetz, Ph.D.** | Acting Chief of Staff, Associate Director for Science Policy | carrie.wolinetz@nih.gov | Co-Chair ACD WG on Changing the Culture to End Sexual Harassment |

**External**

None identified

## TOP ISSUE: DATA SCIENCE AND MANAGEMENT: ARTIFICIAL INTELLIGENCE, MACHINE LEARNING, AND RELATED INNOVATIONS

### ISSUE SUMMARY

In July 2018, NIH hosted a workshop, "Harnessing Artificial Intelligence and Machine Learning to Advance Biomedical Research." The day brought to light several key challenges for broadly implementing AI in biomedical research safely and ethically. These key challenges around data, algorithms, transparency and bias, and the workforce were addressed by the Advisory Committee to the Director (ACD) Artificial Intelligence working group. The group, made up of experts in AI and machine learning, provided recommendations in December 2019 around how to address the challenges raised in the workshop. Almost immediately, through the leadership of the Common Fund, NIH assembled an internal group of IC Directors and leaders to start implementing a large subset of the recommendations. In May 2020, the IC leaders presented a concept to the Council of Councils for a new program, Artificial Intelligence for BiomedicaL Excellence (AIBLE) (note this program will launch under a different name). The concept was approved, and program development is underway. The FY 2021 President's Budget also included a $50 million initiative to employ AI to address chronic diseases, which will allow NIH to develop unbiased, ethical, and transparent datasets, algorithms, and models.

Artificial intelligence and machine learning are sub-categories in the larger and growing data science landscape at NIH. While AI/ML is of growing interest and importance, NIH is also actively building data science infrastructure, support, community, and workforce. The Office of Data Science Strategy leads and coordinates data science-related activities across NIH. The NIH Strategic Plan for Data Science, which was released in June 2018, serves ODSS as a roadmap for goals and activities. With an annual budget of $30 million, the ODSS initiates and builds its own programs, and augments data science activities ongoing at the ICs. These efforts are also being augmented and leveraged to use data to combat the ongoing COVID-19 pandemic. The NIH data ecosystem is being developed in tandem with data sharing policy development efforts (see data sharing policy).

### KEY PROGRESS TO DATE

The Office of Data Science Strategy is leading efforts to build a trans-NIH data ecosystem. Under the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative, agreements between NIH and commercial cloud providers support data storage – for example, NIH just moved 40 petabytes of sequence data to the two STRIDES commercial cloud providers. A trans-NIH team is implementing single sign-on to uniformly manage user identity and access to sensitive datasets, and another trans-NIH team is exploring use of generalist repositories for sharing data that are findable, accessible, interoperable, and reusable (FAIR). NIH, through support by the ODSS office, established a Common Data Elements (CDE) Repository and is promoting the use of Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) standard for exchange of health data across clinical systems.

To advance use of AI in biomedicine, and leverage the ongoing data ecosystem efforts, the NIH Common Fund plans to launch a new Artificial Intelligence program in fiscal year 2021. The overall goal of this program is to generate new biomedically relevant datasets amenable to machine learning analysis at scale. The program will support data, standards, and tools, that will be of lasting broad value to biomedical research.

## KEY CHALLENGES TO DATE

NIH has difficulty recruiting and retaining AI/ML and other data/computer science experts. Technical expertise in these fields does not require doctoral degrees, yet NIH's current pay scale cannot compensate these experts with bachelor's and master's degrees. ODSS seeks to address this issue through workforce programs like the Data and Technology Advancement Scholars and the Civic Digital Fellowship. NIH needs new federal hiring authorities to accommodate selection of non-PhD technical staff at competitive salaries. ODSS also supports code-a-thons, workshops, and other internal and extramural data science training, including opportunities for groups underrepresented in biomedical research to enhance their data skills. A workforce with appropriate skills will help NIH address technical challenges, for example, establishing interoperability across multiple NIH repositories and developing cloud-based algorithms for data discovery that protect patient identity.

Other challenges include the lack of broad cloud use by researchers and the need for support cloud-enabled infrastructure for use at less-resourced institutions. Additionally, the diversity of data standards across fields has limited the efficiency of data interoperability for biomedical research.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Susan Gregurick, Ph.D.** | Associate Director for Data Science | susan.gregurick@nih.gov | ODSS Director, NIH leader on Data Science and AI |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Staff directors/clerks** | House and Senate Labor HHS Appropriations | Contact through NIH Office of Legislative Policy and Analysis | The clerks have great interest in data science and AI/ML and are supportive of these activities at NIH |

## TOP ISSUE: MATERNAL MORBIDITY AND MORTALITY

### ISSUE SUMMARY

An estimated 700 women die each year in the U.S. from conditions related to or associated with pregnancy, and more than 50,000 women in the U.S. experience severe maternal morbidity. Maternal mortality is higher in the U.S. than in other industrialized nations and an estimated 60% of such deaths – that disproportionately occur in minority women – are considered preventable. Large-scale, multi-faceted and rigorous research is essential to save women's lives and improve maternal health. However, policy, regulatory, funding, and logistical challenges require attention. In the past several years NIH has moved to work across organizational lines and advance maternal health research. Additional resources will be required to promote inclusion of pregnant women in research, develop and test community-based interventions, and link large-scale health systems to make these data useful and available for research.

### KEY PROGRESS TO DATE

NIH supports a robust research infrastructure that enables scientists to conduct rigorous basic and clinical research studies that provide the evidence base for preventing maternal morbidity and mortality (MMM).

- Infrastructure: The NICHD's Maternal and Fetal Medicine Units (MFMU) Network conducts rigorous clinical trials in maternal, fetal, and obstetric medicine. MFMU is currently evaluating medical records of 24,000 women to discern possible impacts on pregnancy-related complications of health care changes implemented because of the SARS-CoV-2/COVID 19 pandemic. In mid-2021, NICHD is launching the Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub program that will provide pharmacology expertise, basic science research, and technology platforms for use by scientists conducting pharmacology research in pregnant women, lactating women, and children. NIMHD recently issued a collaborative funding opportunity focused on social determinants of health in addressing racial disparities in maternal morbidity and mortality. Within NICHD's Intramural program, scientists are studying how to prevent preeclampsia, a blood pressure disorder in pregnant women that can have serious effects for both mother and fetus. NHLBI has sponsored research on the long-term cardiovascular effects of preeclampsia and other threats to maternal health. Many of NIH's maternal health research studies include a higher number of women who are minorities, to better understand and address health disparities.
- Collaborations: The congressionally mandated Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) brought together clinical, research, advocacy, public health, regulatory, and pharmaceutical industry leaders to address the significant gap in research on safety, efficacy, and dosing of medications currently used to manage pregnancy-related and other conditions of pregnant and lactating women. The Task Force generated multiple, concrete implementation steps for public- and private-sector action on its 15 recommendations. As the first step in a new, NIH-wide initiative (Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone, or IMPROVE), a notice was published to encourage maternal mortality-related research applications. The Notice requests research proposals in areas that would meet one or more of 3 goals, including community partnerships to resolve health disparities and attain maternal health equity, expanding research on leading causes of MMM in the U.S., and developing understanding of underlying causes to identify preventable risk factors and develop interventions. Another notice requested proposals in women's health, with a particular emphasis on projects involving maternal (and infant) mortality and morbidity.

## KEY CHALLENGES TO DATE

- Inclusion in Research: Most women take at least one medication while pregnant, yet most of these therapies have not been tested on pregnant women. Achieving scientifically validated safe and effective interventions for pregnant women and lactating women is difficult because many researchers routinely exclude these women from clinical research, without adequately considering potential risks of untreated maternal disorders to both the mother or the fetus. Through the implementation of the PRGLAC recommendations, NIH plans to promote inclusion of pregnant women and prioritize maternal and obstetric pharmacology research.
- Community-specific interventions: A number of community programs have proved successful in improving maternal health at the community level. At a recent NIH-supported Community Engagement Forum, participants emphasized building the healthcare infrastructure so that many more women can receive quality healthcare near where they live; developing provider education on respectful care for all patients; providing education on treating women with disabilities and chronic conditions; improving care coordination among providers; and ensuring that best practices in maternal care are followed for all women.
- Health records systems: The lack of connectivity among health records systems in the U.S. and lack of linkages between maternal and child health records makes it more difficult for scientists to use real-world evidence to study maternal and newborn conditions. Recognizing the difficulty of the task and the need for collaborations, NIH is exploring partnerships with other agencies and organizations to address this problem and confront policy, regulatory, and interoperability issues. Ultimately, system improvements systems could allow researchers to better characterize the effects of interventions during pregnancy or lactation on the health of both a woman and her offspring.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Diana Bianchi, M.D. (co-chair)**<br>**Janine Clayton, M.D. (co-chair)**<br>**Tara Schwetz, Ph.D. (co-chair)** | Trans-NIH Task Force on Maternal Morbidity and Mortality | n/a | Co-chairs, Trans-NIH Task Force on Maternal Morbidity and Mortality |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Katie Schubert (CEO)** | Society for Women's Health Research | kschubert@shr.org | Key policy resource on MMM issues |
| **Rachel Tetlow (Director of Federal Affairs)** | American College of Obstetrics and Gynecology | rtetlow@acog.org | Key policy resource on MMM issues |
| **Rebecca Abbott (Director of Federal Affairs)** | Society for Maternal and Fetal Medicine | rabbott@smfm.org | Key policy resource on MMM issues |

## TOP ISSUE: RARE DISEASES

### ISSUE SUMMARY

A "rare disease" is defined, per the Orphan Drug Act, as a condition that affects fewer than 200,000 people in the United States (US). There are over 7,000 different rare diseases that collectively affect an estimated 30 million people in the US (or 1:10 people—on the order of Type 2 Diabetes). This is more than twice the number of people living with cancer, and more than the number of people living with HIV and Alzheimer's disease combined. Thus, rare diseases, taken as a whole, are not rare. Rare diseases are also hard to diagnose, and in many cases, it takes 5-15 years to obtain an accurate diagnosis (referred to as the "diagnostic odyssey."), and the true number of patients with rare diseases is likely higher than estimated. Additionally, most rare diseases are serious, resulting in substantial health care costs, disability, and early death, and they disproportionately affect children and young adults. Thus, rare diseases are a large public health concern; yet, fewer than approximately 500 rare diseases currently have an FDA-approved treatment. On the current trajectory of drug development and approval, it could take approximately 2 millennia to find treatments for the ~7000 diseases that do not have a therapy.

Most rare diseases are genetic (around 80%)—they are caused by changes to a person's DNA (mutations) usually present at birth. In recent years with substantial advances in genetic science, the underlying causes for many rare diseases are becoming better understood, and a large proportion of rare genetic diseases are now potentially treatable. There are three key advances that would greatly accelerate research, diagnosis, and treatment development for rare disease patients:

- Greater access to early genetic/genomic testing: most rare diseases can now be diagnosed readily; this would short-circuit the typical diagnostic delays and provide increased understanding of how many people are actually affected.
- Greater application of gene therapy or other "targeted" approaches: many rare diseases are potentially readily treatable with currently available technology and therapeutic approaches, but realization of these treatments is limited by capacity.
- Shifting to a strategy of studying, and developing treatments for, many rare diseases at time. Focusing on commonalities among multiple rare diseases and platforms to treat them provides an opportunity to explore potential treatments for more than one disease at a time and presents efficiencies in the use of research time and resources in getting therapies to patients.

### KEY PROGRESS TO DATE

The NIH-Wide Strategic Plan for FYs 2016-2020 includes a priority to "advance opportunities presented by rare diseases" and highlights how public funding enables researchers to pursue scientific questions, such as those posed by rare diseases, on the basis of opportunity, not just perceived market value.

The Office of Rare Diseases Research (ORDR), within NCATS, was established in 2002 by the Rare Disease Act and is focused on addressing many of the issues related to rare diseases. It manages the Rare Diseases Clinical Research Network (RDCRN), which advances medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment and data sharing. The Genetic and Rare Diseases Information Center (GARD) provides comprehensive information about rare and genetic diseases to patients, their families, health care providers, researchers and the public. It has sponsored the Rare Diseases are Not Rare! Challenges which sought innovative ways from the public to communicate with others and educate people about rare diseases. ORDR recently initiated the Platform Vector Gene Therapy (PaVe-GT) pilot project, which seeks to increase the efficiency of clinical trial startup by using the same gene delivery system and manufacturing methods for multiple rare

disease gene therapies. NCATS also houses the Therapeutics for Rare and Neglected Diseases Program, which supports preclinical development of therapeutic candidates intended to treat rare or neglected disorders, with the goal of enabling an Investigational New Drug (IND) application.

## KEY CHALLENGES TO DATE

The overarching framework for the challenges in the rare disease space is that rare diseases are under resourced relative to their health and societal impacts. The use and expansion of cancer-style research networks, collective disease approaches, gene banks, and registry studies could dramatically accelerate rare diseases therapeutics development in the near-term, for the thousands of rare diseases that currently considered potentially treatable. As stated in the three key issues above, many rare diseases' therapeutics and research needs could be readily addressed by focusing on the 3 major challenges of: 1) Rare diseases awareness and diagnosis; 2) Many-disease-at-time, many-therapies-at-a-time approaches; and 3) Expansion of the rare disease knowledge base to inform research priorities.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Anne Pariser, M.D.** | Director, Office of Rare Diseases Research, NCATS | Anne.Pariser@nih.gov | Leads NIH's efforts on rare diseases, in coordination with all NIH ICs |
| **Donald Lo, Ph.D.** | Director, Therapeutic Development Branch, NCATS | Donald.Lo@nih.gov | Leads NCATS' efforts on rare diseases preclinical drug development |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Rare Disease Legislative Advocates** | n/a | https://rareadvocates.org/rarecaucus/ | Growing the patient advocacy community and working with local, state, and federal policy makers |

## TOP ISSUE: SUSTAINING THE PROGRESS OF THE CANCER MOONSHOT℠

### ISSUE SUMMARY

The Cancer Moonshot℠, established in 2016, is a national effort to accelerate the pace of cancer research. To advise on the scientific opportunities that could be accelerated through this initiative, a Blue Ribbon Panel (BRP) of the National Cancer Advisory Board was convened. This panel was comprised of some of the nation's top cancer experts—cancer researchers, oncologists, patient advocates, and private-sector leaders—who in turn gathered input from other scientists, clinicians, advocates, industry professionals, and the public.

The BRP put forth 10 ambitious recommendations for achieving the Moonshot's goal:

a. Establish a framework for direct patient involvement
b. Create a translational science network devoted exclusively to immunotherapy
c. Develop ways to overcome cancer's resistance to therapy
d. Build a national cancer data ecosystem
e. Intensify research on major drivers of childhood cancers
f. Minimize cancer treatment's debilitating side effects
g. Expand use of proven cancer prevention and early detection strategies
h. Mine past patient data to predict future patient outcomes
i. Develop a 3-D cancer atlas
j. Develop new cancer technologies

Over the past 3 fiscal years (FY), NCI has work diligently to develop an implementation plan and launch research programs and networks to fulfill these recommendations. With funding authorized in the 21st Century Cures Act in 2016, NCI began funding new research to advance adult and pediatric immuno-oncology, study specific drivers of childhood cancers, generate human tumors atlases, increase screening for inherited cancers, and other initiatives.

The 21st Century Cures Act authorized a total of $1.8 billion to fund the Cancer Moonshot℠ over 7 years, from FY 2017 through FY 2023. The funding is authorized at varying annual amounts which peeked in FY 2019 and declined by more than 50% in FY 2020. To maximize the opportunity for NCI to achieve the Moonshot goals, Congress appropriated Moonshot resources to remain available until expended (also known as "no-year" funding). This greatly increases NCI flexibility to structure research initiatives and make Moonshot awards. For example, the no-year nature of Moonshot funding allows NCI to provide multiple years of grant funding to researchers at the time of the initial award. This approach enhances the ability of research scientists to plan and execute their research, while still allowing NCI to continue to monitor research progress. In subsequent years, this reduces the financial burden of non-competing Moonshot awards. It also ensures NCI can support new research initiatives in years when Moonshot funding declines (FY 2020-2023) although to a lesser extent than in the first 3 years of the Moonshot.

### KEY PROGRESS TO DATE

Over the past four fiscal years, NCI has awarded over 200 new projects in support of the Cancer Moonshot℠ goals. These include research across the cancer continuum from projects to increase our fundamental understanding of the drivers of childhood cancers to research that aims to increase genetic counseling and screening for individuals with inherited predispositions to develop cancer to efforts to engage cancer patients more directly in research. Building on recent advances in immunotherapy, the Cancer Moonshot℠ funds both an Adult Immuno-Oncology Network and a Pediatric Immunotherapy

Discovery and Development Network. While each network has objectives unique to their respective patient populations, both are developing new immune-based therapies and designing approaches to minimize treatment side effects. Other key initiatives include efforts to improve and implement smoking cessation programs for socioeconomically disadvantaged populations who struggle disproportionally with tobacco use, and efforts to improve the quality of life of cancer patients and survivors, particularly pediatric cancer survivors who deal with the long-term side effects of cancer treatments well into adulthood. Additionally, technology development is a critical component of accelerating progress against cancer and the Cancer Moonshot℠ funds technology development through traditional grant mechanisms and the SBIR/STTR program.

The Cancer Moonshot℠ also highlights the need for collaboration and partnerships. NCI is collaborating with the Department of Energy to use advanced computation capacity to accelerate cancer research through the Joint Design of Advanced Computing Solutions for Cancer (JDACS4C) Program. This collaboration uses technologies such as artificial intelligence to identify new treatments and evaluate them more effectively using predictive computational modeling; help researchers find new avenues to target the RAS oncogene, which drives more than 30 percent of all human cancers; and transform cancer surveillance through real-time analysis of patient data to assess the impact of new diagnostics and treatments. The Partnership for Accelerating Cancer Therapies (PACT) is a novel five-year public-private research collaboration between the NIH and 12 biopharmaceutical companies focused on identifying, developing, and validating biomarkers to advance immunotherapy.

## KEY CHALLENGES TO DATE

Funding for the Cancer Moonshot℠ peaked in FY 2019 and declined by more than half in FY 2020, resulting in fewer new Cancer Moonshot℠ initiatives beginning in FY 2020. Furthermore, the remaining authorized funds for FY 2021-2023 are similar to FY 2020 levels.

- Funding beyond FY 2023 is needed to ensure that research keeps pace with the significant progress made so far through the Cancer Moonshot℠
- Reducing cancer disparities that are experienced by certain population groups (racial/ethnic, rural/urban, etc.) is a theme that cuts across all of the Cancer Moonshot℠ recommendations

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Blue Ribbon Panel (BRP)/National Cancer Advisory Board (NCAB)** | Cancer Moonshot℠ BRP | n/a | Developed the Moonshot recommendations |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **American Association for Cancer Research** | n/a | n/a | AACR provides leadership on the current state of cancer research |

## TOP ISSUE: GENE-BASED CURES FOR SICKELE CELL DISEASE AND HIV – A COLLABORATION BETWEEN THE NIH AND THE BILL AND MELINDA GATES FOUNDATION

### ISSUE SUMMARY

In October 2019, the National Institutes of Health (NIH) Director Francis S. Collins, M.D., Ph.D. and the Bill & Melinda Gates Foundation (BMGF) President of Global Health, Trevor Mundel, M.D., Ph.D., announced a new collaboration to work toward the bold goal of developing safe, effective, and durable gene-based cures that could be implemented in low resource settings where SCD and HIV are major burdens on health. Approximately 95% of the 38 million people living with HIV globally are in the developing world, with 67% in sub-Saharan Africa, half of whom are untreated. Fifteen million babies will be born with SCD globally over the next 30 years, with about 75% of those births occurring in sub-Saharan Africa. An estimated 50-90% of infants born with SCD in low-income countries will die before their 5th birthday.

The NIH-BMGF Collaboration aims to align aggressive, high-reward research efforts to accelerate progress on shared gene-based strategies to cure SCD and HIV. Each organization is committing $100 million toward this goal. Furthermore, the NIH and BMGF are bringing other collective strengths to bear on this important endeavor, including:

- Extensive scientific and clinical expertise in both diseases
- Significant investments and infrastructure in HIV and SCD
- Rigorous merit-based review
- International engagement with scientists, governments, and non-governmental organizations
- Combined presence in Sub-Saharan Africa
- Industry engagement and expertise in planning commercial development pathway
- Ability to “spotlight” issues and convene influential stakeholders

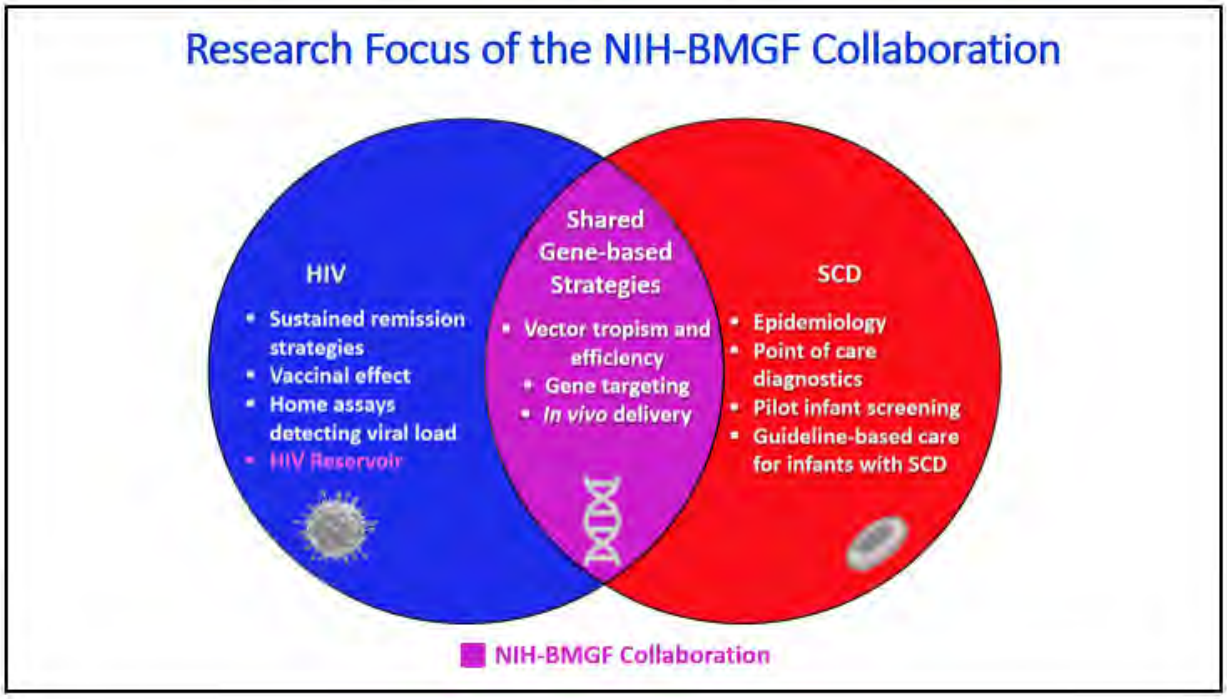
This effort builds on dramatic advances in *ex vivo* (outside the body) gene modification techniques over the past decade, which have yielded remarkable advances in treatments for both SCD and HIV. For instance, with respect to HIV, gene modification approaches have been demonstrated to create an HIV infection-resistant state. Patients underwent toxic conditioning regimens followed by bone marrow transplant with HLA-matched donor cells carrying the CCR5delta32 deletion and now appear to have cleared HIV from their bodies. In the SCD arena, at least five patients have been treated with CRISPR-Cas9 mediated gene editing for severe hemoglobinopathies. One of the patients had serious complications largely related to the conditioning regimen but now is reportedly free of vaso-occlusive crises and of the need for transfusion, an important proof of concept for the use of gene editing to treat this disease. Research continues on the use of *ex vivo* gene modification to treat SCD through programs such as the NHLBI Cure Sickle Cell Initiative, which is helping to develop important scientific stepping stones that will be key to the NIH-Gates Collaboration.

As promising as *ex vivo* gene modification approaches are to treat SCD and HIV, they are highly time and resource intensive and may be associated with significant clinical complications. They involve multiple complex manufacturing procedures, conditioning regimens, highly specialized procedures for blood stem cell collection, as well as intensive clinical interventions and monitoring. As a result, such approaches would only be feasible in high resource settings and could not be scaled up to help solve public health problems on a broad scale. A globally feasible gene-based approach must be designed and

developed with scalability, sustainability, and accessibility in mind at the start – and hence the importance of the NIH-BMGF Collaboration.

The NIH-BMGF Collaboration is focused on the development of new gene delivery systems that can be given directly to patients in a single treatment, targeting and genetically modifying the cells involved in the respective diseases. Such treatments that happen entirely within the body, known as *in vivo* treatments, would be a major step forward from current *ex vivo* treatments. For SCD, this means repairing or compensating for the mutations in hemoglobin that cause SCD in hematopoietic stem cells. For HIV, that would mean targeting the reservoir of proviral DNA that continues to lurk inside a small number of cells, even after many years of effective antiviral treatment.

The figure below depicts the research that will be supported under the NIH-BMGF collaboration specific to HIV and SCD, as well as those that benefit strategies to treat both conditions.




## KEY PROGRESS TO DATE

NIH and BMGF have collaborated on the development of a research blueprint that sets strategic scientific goals for the endeavor and guides future funding. The blueprint includes milestones for the targeting cells of interest, gene editing and expression, safety, target product profiles, public-private partnerships, and capacity building.

In May 2020, NIH and BMGF organized a pivotal scientific workshop on *Safe and Effective In Vivo Targeting and Gene Editing in Hematopoietic Stem Cells: Strategies for Accelerating Development* to understand more about the current state of the science and to foster conversations about key opportunities and challenges among leading scientists. Participants brought to the table diverse expertise in SCD, HIV, hematopoietic stem cells, gene therapy, gene editing, viral and non-viral vector development, animal models, and more. That event informs not only the future directions of the Collaboration but will be disseminated widely to the scientific community to inform the field at large.

## KEY CHALLENGES TO DATE

There are a number of scientific and practical challenges that need to be overcome before the goal of fully accessible, single-shot therapies will be realizable.

- Scientific and technical:
  - Many gene delivery systems are inefficient in their ability to transduce cells, and it will be key to find ways to efficiently deliver gene to the target cells, particularly for an approach that is intended to be delivered once.
  - Ensuring efficient, precise, and durable gene expression is vitally important. Transduced cells may not last, and gene editing in particular risks creating off-target and unwanted effects.
- Ethical:
  - Populations in low resources settings are particularly vulnerable, underscoring the need for attention to such matters as beneficence, justice, and respect for persons.
  - Sickle cell patients are disproportionately pediatric, and research with children raises special concerns for their welfare and voluntary participation.
- Limited resources and health care delivery capacity in resource-poor regions:
  - The aims of this program are bold and cannot be achieved without significant resources.
  - Healthcare and research facilities are extremely limited in many regions of Africa where these two diseases are endemic.
- Global access:
  - Once products are available on the market, they must be affordable. At present, gene therapies are extremely expensive and only accessible by individuals in resource-rich environments; event those with health insurance may not be covered for the full expenses associated with these treatments.
  - Developing a product that is financially accessible in low-resources regions is both critically important and very difficult.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Amy Patterson M.D.**<br><br>**Keith Hoots M.D.** | Chief Science Advisor<br><br>Director, Division of Blood Diseases and Resources | amy.patterson@nih.gov<br><br>keith.hoots@nih.gov | NHLBI assigned to lead strategic management of the Collaboration. |
| **Carl Dieffenbach, Ph.D.** | Director, Division of AIDS | carl.dieffenbach@nih.gov | Key partner in the collaboration and the lead on the HIV research component |
| **Jill Heemskerk, Ph.D.** | Deputy Director | jill.heemskerk@nih.gov | Key partner in the collaboration |

| | | | |
|---|---|---|---|
| **Elizabeth Wilder, Ph.D.** | Director, NIH Office of Strategic Coordination - Common Fund | elizabeeth.wilder@nih.gov | Key partner in the collaboration |
| **Jessica Tucker, Ph.D.** | Director, Biosafety, Biosecurity, and Emerging Biotechnology, Office of Science Policy | Jessica.tucker@nih.gov | NIH-BMGF Executive Committee - Provides guidance from the senior leadership of NIH and BMGF |

**External**

| Name | POC | Contact Information | Critical Role |
|---|---|---|---|
| **American Society for Gene and Cell Therapy** | **Betsy Foss-Campbell, M.A.,** Director of Policy and Advocacy | BFoss@asgct.org | Serves as the professional and scientific society for scientists working in the field of gene and cell therapy; they have expressed an interest in findings way to work with the Collaboration |
| **Cure Sickle Cell Initiative** | **Keith Hoots**, M.D., Director, Division of Blood Diseases and Resources<br><br>**Edward J. Benz**, M.D., Executive Director, Cure Sickle Cell and CEO Emeritus, Dana Farber Cancer Institute | keith.hoots@nih.gov | Effort to engage the SCD patient community and investigators as well as other sectors to develop gene-based therapeutics for sickle cell disease. Currently focused on *ex vivo* strategies. Several elements of this initiative will be informative for the NIH-Gates Collaboration, particularly the work in biomanufacturing and clinical strategies. |
| **HIV Cure Africa Acceleration Partnership** | **Mike McCune**, M.D., Ph.D., Head, HIV Frontiers, Global Health Innovative Technology Solutions, BMGF | Mike.McCune@gatesfoundation.org | Informs not only the development of HIV cures but also to maximize their uptake and implementation. |

## TOP ISSUE: COVID-19 RESEARCH

### ISSUE SUMMARY

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 and the disease it causes, COVID-19, has created a daunting public health challenge. As part of the U.S. government's response to the COVID-19 pandemic, NIH is conducting and supporting clinical research to diagnose, prevent, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). These efforts include clinical trials evaluating therapeutics and vaccine candidates against SARS-CoV-2, as well as studies of people who have recovered from infection to better understand how to prevent and treat this serious disease. Community engagement activities are critical to ensure the wide-spread implementation of public health strategies developed as part of the pandemic responses. NIH is establishing programs to target information to underrepresented racial and ethnic populations and individuals from low-income areas who are disproportionated affected by COVID-19.

### KEY PROGRESS TO DATE

The growing public health threat posed by SARS-CoV-2 underscored the need for rapid characterization of basic viral attributes to support an effective response. NIH-supported research has provided fundamental knowledge about the structure and stability of SARS-CoV-2 and how the virus causes disease. One such study elucidated a key feature of the virus structure called the spike protein which dots the viral surface and is used to bind human cells. It is also the is a target for many of the medical countermeasures currently being tested. This basic research was complemented by the launch of numerous observational studies in humans to better understand how the virus is transmitted, characteristics of disease, and the immune response to infection. One of these studies, the NIAID Human Epidemiology and Response to SARS-CoV-2 (HEROS) study, builds on an existing pediatric research network to examine the rate of infection and disease in children, and of transmission within households, with a focus on high-risk underrepresented populations. In addition, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NHLBI, and NIAID launched a study of the multi-system inflammatory syndrome seen in some children following SARS-CoV-2 infection. These collaborations are critical for developing public health interventions to minimize the impact of the current pandemic.

A key feature of the early response to this pandemic is the development of rapid, accurate, and easy-to-administer diagnostics to characterize and mitigate the spread of SARS-CoV-2, such as those supported by the trans-NIH Rapid Acceleration of Diagnostics (RADx) initiative. As of September 15, 2020, there are 16 projects currently funded in Phase 2 of this milestone-driven program. These are expected to provide 15 million tests per month by the end of September 2020, 21 million per month by the end of October 2020, 45 million tests per month by the end of November 2020, and 60 million tests per month by the end of December 2020.

NIH-supported advances in treatment strategies are already informing the way clinicians treat patients with COVID-19. For example, results from the NIAID Adaptive COVID-19 Treatment Trial (ACTT) demonstrated that remdesivir, an experimental broad-spectrum antiviral, accelerated the recovery of hospitalized patients. Building on such findings, NIH is coordinating the conduct of multiple clinical trials, including the trans-NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership trials to examine monoclonal antibodies and other experimental therapeutics for diverse populations with varying severity of disease. NIH is also advancing the development of

multiple promising vaccine candidates through early stage clinical testing. Several promising vaccine candidates, including the Moderna mRNA-1273 and AstraZeneca AZD1222 vaccine candidates, are already being tested in phase 3 clinical trials leveraging NIH clinical research networks.

## KEY CHALLENGES TO DATE

- Early in outbreak, availability of viral isolates; international virus sharing was slow and had the virus not spread to the U.S., research would have been delayed.
- To support the biomedical research response, researchers rely on a steady supply of research reagents and supplies for their studies. Supply chain bottlenecks of research and clinical trial supplies, including PPE, swabs and research reagents, have presented challenges in the research response to COVID-19.
- Relevant animal models provide valuable insight into the potential safety and effectiveness of candidate therapeutics and vaccines prior to clinical testing in humans. The availability of appropriate animal models, including non-human primates, presented a challenge in conducting the early studies.
- To support the final testing of promising vaccines and therapeutics to COVID-19, clinical trials rely on the participation of thousands of volunteer participants needed to test the safety and efficacy of medical countermeasures. For several studies, steady enrollment of key populations has presented a challenge toward rapidly completing the testing of critical vaccines or therapeutics prior to release to the public.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

**Relevant Stakeholders**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Anthony Fauci, M.D.** | Director, NIAID | afauci@niaid.nih.gov | COVID Vaccines and Therapeutics |
| **Bruce Tromberg, Ph.D.** | Director, NIBIB | bruce.tromberg@nih.gov | COVID Diagnostics |
| **Gary Gibbons, M.D.** | Director, NHLBI | gary.gibbons@nih.gov | CEAL Co-Chair; COVID Therapeutics |
| **Eliseo Pérez-Stable, M.D.** | Director, NIMHD | eliseo.perez-stable@nih.gov | CEAL Co-Chair; RADx-UP |
| **Ned Sharpless, M.D.** | Director, NCI | norman.sharpless@nih.gov | SeroNet |
| **Rick Woychik, Ph.D.** | Director, NIEHS | rick.woychik@nih.gov | RADx$^{SM}$ Executive Committee, RADx-rad |
| **Tara A. Schwetz, Ph.D.** | Associate Deputy Director, NIH | tara.schwetz@nih.gov | RADx$^{SM}$ Executive Committee, RADx-rad, RADx-UP |

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Cliff Lane, M.D.** | Director, Division of Clinical Research | clane@niaid.nih.gov | NIAID representative on ACTIV leadership team |
| **Hilary Marston, M.D., M.P.H.** | Medical Officer and Policy Advisor for Pandemic Preparedness | Hilary.marston@nih.gov | Coordinate research across NIAID, NIH, and other federal agencies during outbreaks |
| **Nicholas Bushar** | Section Chief, Policy, Planning, and Reporting | Nicholas.bushar@nih.gov | NIAID Preparedness SWAT Team POC - Coordinate research across NIAID during outbreaks |
| **John Mascola, M.D.** | Director, Vaccine Research Center | jmascola@mail.nih.gov | Director, OWS Vaccine Development Team |
| **Sarah Read, M.D.** | Deputy Director, Division of AIDS | readsa@niaid.nih.gov | Co-chair of the ACTIV Therapeutics Team |
| **Mary Marovich, M.D.**<br><br>**Carl Dieffenbach, Ph.D.**<br><br>**Emily Erbelding, M.D., M.P.H.** | n/a | Mary.marovich@nih.gov<br><br>cdieffenba@niaid.nih.gov<br><br>Emily.erbelding@niaid.nih.gov | COVID-19 Prevention Network - NIAID leads for this clinical network |
| **Alan Embry, Ph.D.** | Section Chief, Respiratory Diseases Branch | embrya@niaid.nih.gov | Lead for extramural COVID-19 coordination NIAID |

**External**
None identified

## TOP ISSUE: PANDEMIC PREPAREDNESS

### ISSUE SUMMARY

The continual emergence and re-emergence of infectious diseases, accelerated by globalization and rapidly evolving microbes, threatens the health of people worldwide. A critical component of preparedness is biomedical research to develop medical countermeasures that could be rapidly deployed in response to a naturally occurring or deliberately introduced infectious disease outbreak. NIH conducts and supports biomedical research that informs future approaches to responding to an emerging pandemic. One approach is the conduct of research focusing on specific pathogens that are likely to emerge. Some examples include Ebola, Lassa, and Nipah viruses. Another method involves prototype pathogen research, in which basic research on one microbe may inform the development of medical countermeasures for a closely related pathogen. Early, rapid advances in the understanding of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, were the result of prior research on related viruses, severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV). NIH is developing flexible platform-based technologies. The field of vaccinology is advancing from the historical requirement of growing a virus and either inactivating it or attenuating it for use as a vaccine, an approach that is cumbersome and often associated with delays in production. Now, various novel vaccine "platforms" that have been intensively studied employ recombinant nucleic acid technology that bypasses the need to grow the virus. These platforms can be rapidly adapted against a variety of pathogens.

### KEY PROGRESS TO DATE

When a large Ebola virus disease (EVD) outbreak began in the Democratic Republic of Congo (DRC) in 2018, NIH swiftly mobilized its flexible infrastructure and extensive experience establishing collaborative research partnerships to advance several promising agents for treating EVD. The Ebola outbreak was occurring in an area of armed conflict and tenuous security, hindering response efforts. Despite these challenges, a randomized, controlled clinical trial evaluating four investigational agents (ZMapp, remdesivir, REGN-EB3, and mAb114) was launched in the DRC. Preliminary data suggested the superiority of both mAb114 or REGN-EB3 in increasing survivorship, leading to a halt of the trial and the results being made public to help save lives and stem the latest outbreak. This experience demonstrated the efficacy of promising therapeutics to treat EVD and serves as a potential guide for conducting future clinical trials in outbreak settings.

In response to the emergence of SARS-CoV-2, NIAID researchers were able to rapidly leverage foundational research on virus characteristics and mobilize vaccine platforms developed during the 2002 SARS and 2012 MERS outbreaks to construct a vaccine candidate, called mRNA-1273, for testing on a compressed timeline. The first Phase 1 clinical trial of mRNA-1273 launched on March 16, 2020, to evaluate different doses for safety and the ability to generate an immune response as diagnosed cases began to escalate in the United States.

By pivoting research in its established clinical networks, NIH created the COVID-19 Prevention Trials Network (CoVPN) to facilitate the recruitment of volunteers to test multiple experimental COVID-19 vaccine candidates across the United States and globally. Through the coordinated efforts of NIH researchers and its partners, the prompt activation of clinical sites allowed the initiation of Phase 3 clinical trials for multiple vaccine candidates, including mRNA-1273, beginning in July 2020. These unprecedented efforts are providing promise for a safe and effective vaccine to combat the pandemic within an extraordinary timeframe.

To prepare for the continual challenge of emerging and re-emerging threats, NIH is expanding its infrastructure to facilitate pandemic preparedness. As part of this effort, the NIAID Vaccine Research Center and Division of Intramural Research are expanding capacity to study prototype pathogens and develop vaccine approaches for viral families that are at high risk for causing pandemics. Additionally, in 2020, NIH established the Centers for Research in Emerging Infectious Diseases (CREID) Network, a global network of multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people. Knowledge gained from this network will allow early warnings of emerging diseases wherever they occur and increase preparedness efforts for future outbreaks.

## KEY CHALLENGES TO DATE

To continue research efforts to fight the COVID-19 pandemic—and to be able to respond rapidly and effectively to other infectious disease threats yet to arise—NIH needs robust and consistent funding. In the case of COVID-19 research, such funding is vital for continued SARS-CoV-2 and related coronavirus research and rapid advanced development, clinical evaluation, and commercialization of new vaccine candidates, diagnostic tests, and therapeutics.

Relevant animal models provide valuable insight into the potential safety and effectiveness of candidate therapeutics and vaccines prior to clinical testing in humans. Challenge studies, which often cannot be conducted in humans, provide key evidence that a specific medical countermeasure will be a viable solution to halting a pandemic. The limited availability of non-human primates has created bottlenecks in medical countermeasures research and a coordinated effort across the government has been integral to prioritize their use and advance potential candidate countermeasures into clinical trials.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Hilary Marston, M.D., M.P.H.** | Medical Officer and Policy Advisor for Pandemic Preparedness | Hilary Marston Hilary.marston@nih.gov | Coordinate research across NIAID, NIH, and other federal agencies during outbreaks |

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **NIAID Preparedness SWAT Team** | Section Chief, Policy, Planning, and Reporting | Nicholas Bushar Nicholas.bushar@nih.gov | Coordinate research across NIAID during outbreaks |
| **Cliff Lane, M.D.** | Director, Division of Clinical Research | clane@niaid.nih.gov | Rapid deployment of clinical trials in endemic areas |

**External**
None identified

## TOP ISSUE: UNIVERSAL INFLUENZA VACCINE

### ISSUE SUMMARY

Each year in the United States, seasonal influenza sickens millions and causes thousands of hospitalizations and flu-related deaths. Most individuals who get the flu get better within two weeks. Some people, however, may develop serious complications, such as pneumonia. Pandemic influenza occurs when a new flu virus strain arises that can spread easily from person-to-person and the virus is one for which most people have no immunity.

A primary NIH priority is the development of a safe and effective universal influenza vaccine that would provide long-lasting protection against multiple strains of the virus, including strains with the potential to cause a pandemic. In 2018, NIAID, a component of the NIH, published the *Strategic Plan for the Development of a Universal Influenza Vaccine* to guide these efforts. NIH continues to implement components of the Strategic Plan as mandated in the White House issued Executive Order 13887 on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health. The executive order calls for the full implementation of NIAID's strategic plan and research agenda for development of broadly protective vaccine candidates that provide more effective and longer lasting immunity as part of a long-term strategy to reduce the risk of an influenza pandemic.

### KEY PROGRESS TO DATE

NIH scientists have advanced several promising universal influenza vaccine candidates into various stages of clinical testing. One vaccine candidate, called H1ssF_3928, leverages a strategy to target the "stem" region of the influenza hemagglutinin (HA) protein on the surface of the virus; whereas the head of HA changes significantly from season to season, the stem remains largely unchanged. This vaccine is currently being evaluated in a Phase 1 clinical trial in healthy volunteers that have received at least one licensed influenza vaccine since the start of 2014. Another promising vaccine candidate, which uses nanoparticle technology to expose the immune system to the HA stem derived from group 1 influenza viruses, was shown to be safe and to induce an immune response in a Phase 1 clinical trial. In addition, NIH is developing a "mosaic nanoparticle"–based vaccine candidate for human testing. This vaccine incorporates HAs from multiple influenza strains into nanoparticles, which may induce a broader immune response than current vaccines. In collaboration with industry partners, NIH scientists also are assessing a novel peptide-based candidate vaccine that is designed to prompt a different type of immune response than most vaccines. The experimental vaccine, called FLU-v, targets several other influenza proteins which tend to be conserved across influenza strains. A Phase 2 trial of Flu-v showed that volunteers who received the vaccine were less likely to develop mild to moderate influenza disease when compared to volunteers who received a placebo.

A critical part of the effort to develop a universal influenza vaccine are influenza research networks that provide research vaccine development capacity. In 2019, the Collaborative Influenza Vaccine Innovation Centers (CIVICS) were established to advance promising new influenza vaccine candidates that provide broader and more durable protection and to make improvements to seasonal influenza vaccines. The CIVICS support a coordinated multi-disciplinary effort of guided discovery, facilitated product development and managed progress through iterative testing in pre-clinical studies, clinical trials, and human challenge studies. NIH also continues to support the development of reagents, tools, and services that facilitate discovery and evaluation of universal vaccine candidates. Notably, research capacity and dedicated influenza strains were established to conduct human influenza challenge studies with the goal of enabling evaluation of promising experimental universal influenza vaccines.

## KEY CHALLENGES TO DATE

Antigenic shifts occur when major genetic changes allow an influenza virus to "spillover" from an animal population to infect humans, who lack existing immunity. Due to the long timeframe for influenza vaccine production, vaccines cannot be readily available if an antigenic shift occurs and a previously unidentified strain of pandemic influenza suddenly emerges. Currently, a novel vaccine is needed for each new strain of influenza with pandemic potential, which is an ineffective strategy for long-term preparedness against pandemic influenza. During the most recent influenza pandemic in 2009, a strain-specific vaccine was not available to the public until well after the peak of the pandemic. Continually chasing influenza viruses that jump from animals to humans comes at a substantial economic cost and leaves human health at risk. It is essential that we move beyond the current strain-specific influenza vaccine development strategy to address both seasonal and pandemic influenza.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Alan Embry, Ph.D.** | Section Chief, Respiratory Diseases Branch | embrya@niaid.nih.gov | Chairs the Influenza Working Group |
| **Matt Memoli, M.D., M.S.**<br><br>**Barney Graham, M.D., Ph.D.**<br><br>**Karin Bok, Ph.D.** | n/a | memolim@niaid.nih.gov<br><br>bgraham@mail.nih.gov<br><br>Karin.bok@nih.gov | NIAID Influenza Challenge Studies Working Group POCs - Responsible for designing influenza challenge studies |

**External**

None identified

## TOP ISSUE: INTELLECTUAL AND DEVELOPMENTAL DISABILITIES

### ISSUE SUMMARY

As many as seven percent of children are affected by intellectual and developmental disabilities (IDDs)—these encompass a wide range of conditions including Down, Fragile X and Rett syndromes, inborn errors of metabolism, autism spectrum disorders (ASDs), and many others. Individuals with IDDs often have cognitive limitations and other functional difficulties, and many IDDs are associated with increased risk of serious comorbid conditions, including cardiac problems, gastrointestinal disorders, Alzheimer's disease, and psychiatric disorders. Clinical studies from the past three decades have made it clear that individuals with IDDs benefit greatly from early detection and evidence-based interventions. Research with these populations is crucially important to improve the quality of life of individuals with IDDs and their families. However, policy, regulatory, funding, and logistical challenges require attention. Inclusion of individuals with IDDs in research has proven challenging, and the COVID-19 pandemic has disrupted both research and crucially needed services for the IDD community.

### KEY PROGRESS TO DATE

In creating the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) in 1962, Congress charged the Institute with encouraging investigations of human development throughout the lifespan, with an emphasis on understanding IDDs. The research infrastructure supported by NICHD's and NIH-wide programs provides resources for sustained research and enables rapid responses to emerging health threats, including COVID-19. The NIH has successfully established collaborative partnerships across institutes, federal agencies, researchers, clinicians, advocates, and families.

Infrastructure: NIH-supported infrastructure programs include the NICHD's long-established Intellectual and Developmental Disabilities Research Centers (IDDRCs), located at universities and children's hospitals across the U.S. The IDDRCs offer a variety of research services to scientists, including bioinformatics and biostatistics; genomic, proteomic, and metabolomics facilities; cellular neuroimaging and optogenetic services; neuroimaging; and animal and human behavioral testing. Specific research projects within the IDDRCs have included multimodal treatment studies in Fragile X syndrome, among others. Other examples of important NIH infrastructure programs include the Autism Centers of Excellence (ACE) and the Centers for Collaborative Research in Fragile X and *FMR-1* Associated conditions. NICHD's Pediatric Trials Network is currently developing resources to promote inclusion of children with Down syndrome in clinical research – an effort expected to lead to best practices relevant for other IDDs.

Collaboration: Although NICHD leads many IDD research efforts, close collaboration among NIH ICs and with other agencies and private partners is essential. The congressionally mandated INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) project is a multi-Institute initiative focused on Down syndrome (DS), and conditions (such as Alzheimer's disease/dementia, congenital heart disease, and diabetes) that affect both individuals with DS and the general population. Overall research goals are a) high-risk, high-reward basic science studies on trisomy 21 biospecimens and animal models; b) engagement of a large cohort of research participants with DS; and c) inclusion of individuals with DS in existing and future clinical trials. Recently, NIH published the 2020 *Notice of Special Interest for Research on Coronavirus Disease 2019 (COVID-19) in Individuals with Down Syndrome* (NOT-OD-20-129). The *DS Connect®* Down Syndrome Registry, sponsored by NICHD, is a unique online resource and registry to engage individuals with DS and their families as well as researchers and clinicians. Collaborative working groups ensure coordination of research efforts. For example, the Interagency Autism Coordinating Committee (IACC) brings together Federal and public

members and coordinates Federal efforts on issues related to autism spectrum disorder (ASD). Within NIH, working groups bring together institutes and centers to coordinate research programs and develop joint initiatives for ASD and Fragile X/ *FMR-1* research.

## KEY CHALLENGES TO DATE

The cognitive effects of IDDs present challenges for affected individuals' participation in research. Some individuals may need special procedures to be able to provide informed consent, and/or consent may be needed also from caretakers or parents. Some individuals with IDDs may find it difficult to consistently follow research protocols or may need additional assistance to provide information on the effects of treatment (for example, non-verbal individuals may need to use augmented communication tools). Directly or indirectly, individuals with IDDs are often excluded from the research that tests interventions they will use to manage co-morbid conditions. NIH has addressed this problem through education of the research community, by funding studies specific to individuals with IDDs, and by incentivizing researchers to add cohorts of IDD individuals, especially through the INCLUDE program.

The pandemic has disproportionately affected people with IDDs, with higher rates of severe complications and hospitalizations. Many children with IDDs receive in-person, school-based interventions, and interruption of these services has been disruptive to the children and in some cases to research studies. Additional research on the effects of remote learning on children with IDDs is especially urgent.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lisa Gilotty, Ph.D. (chair; other NIH ICs represented)** | NIH Autism Coordinating Committee | gilottyl@mail.nih.gov | Committee coordinates activities related to autism spectrum disorders across the NIH |
| **Diana Bianchi , M.D. (co-chair)**<br>**Gary Gibbons, M.D., (co-chair)** | NIH-wide Steering Committee for INCLUDE project | n/a | This committee coordinates activities related to the NIH-wide INCLUDE project |
| **Melissa Parisi, M.D., Ph.D.** | Down syndrome Consortium | parisima@mail.nih.gov | The Consortium is a public-private partnership to exchange information and promote the DS Connect® registry |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **John Tschida, M.P.P.** | CEO, Association of University Centers on Disabilities | jtschida@aucd.org | The Association addresses multiple IDD issues, interacts with larger disabilities community |

## TOP ISSUE: ADDICTION AND OVERDOSE CRISIS

### ISSUE SUMMARY

Scientific solutions are needed to stop the public health crisis of opioid misuse, addiction, and overdose. More than 67,300 people died from drug overdose in the United States in 2018, and deaths involving synthetic opioids, cocaine, and methamphetamine, and combinations of these drugs, have continued to increase sharply. In addition, over 10 million Americans misuse opioids, and more than 50 million Americans experience chronic pain, putting them at risk of opioid misuse and addiction. The COVID-19 pandemic is exacerbating these trends, highlighting the need for innovate and data-driven approaches to address the crisis.

### KEY PROGRESS TO DATE

The Helping to End Addiction Long-term℠ Initiative, launched in 2018, is a trans-agency plan spanning basic, translational, and clinical research on opioid misuse, addiction, and pain. Through the NIH HEAL Initiative, NIH has awarded over $1.5 billion in research representing more than 500 research projects.

- To develop new medications for opioid use disorder (OUD) and overdose, HEAL supports 63 targeted studies and a consortium to develop immunotherapies. Eight projects obtained Investigational New Drug applications.
- To evaluate integration of evidence-based interventions for treating OUD into practice, HEAL supports 110 research studies, including the HEALing Communities Study (HCS) which is testing a coordinated set of interventions within 67 communities across 4 states. The Justice Community Opioid Innovation Network (JCOIN) is testing strategies to expand effective substance use disorder treatment in justice settings.
- To determine the most effective therapies for specific pain conditions, 55 HEAL studies are testing non-addictive pain treatments to advance evidence and guidelines for treatment of pain.
- To accelerate development of non-addictive analgesics and reduce reliance on opioids, 90 HEAL preclinical studies will validate therapeutic targets for acute and chronic pain conditions, develop accurate research models to predict how drugs will affect patients, and advance innovative device-based treatments.
- To develop new or improved prevention and treatment strategies for opioid addiction, 125 HEAL projects, including 46 small business innovation awards, will test new approaches such as a collaborative care model for treating OUD and mental illness in primary care settings.
- To improve care for infants born with neonatal opioid withdrawal syndrome, the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT-NOW) program will determine how to safely reduce or eliminate opioid treatment among neonates with opioid withdrawal symptoms and understand the long-term outcomes of infants exposed to opioids in utero.

### KEY CHALLENGES TO DATE

- Deaths involving fentanyl and stimulants dramatically increased since 2016. There are no FDA-approved pharmacotherapies for stimulant use disorders or stimulant overdose, and opioid overdose reversal agents are not as effective against synthetic opioids or against opioids when used in combination with stimulants. NIH is supporting numerous studies across the therapeutics development pipeline to advance treatments for these conditions.
- COVID-19 presents challenges to people with substance use disorder (SUD) and in recovery. People with SUD are more susceptible to COVID-19 and its complications. Social distancing, in

addition to increasing stress that can contribute to substance misuse, has challenged access to SUD treatment and recovery supports. The pandemic has had a negative effect on research, including HEAL-funded programs, which were impacted by the closure of research universities, justice settings, and other study sites and supports.

- Most people who could benefit from medications for SUD do not get it, and access to medications is inequitable across subgroups of the population. Regulations around methadone and buprenorphine prescribing, including those limiting methadone prescribing to certified opioid treatment programs, and challenges to obtaining certification contribute to the underutilization of these medications.

**N** (b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Rebecca Baker, Ph.D.** | Director, HEAL Initiative, OD | rebecca.baker@nih.gov | Coordinates HEAL activities across ICs, manages HEAL budget, governance groups |
| **Walter Koroshetz, M.D. and Nora Volkow, M.D.** | Directors, NINDS and NIDA | koroshetzw@ninds.nih.gov nvolkow@nida.nih.gov | Directors of ICs where HEAL funds are appropriated |
| **NIH HEAL Initiative Executive Committee** | NIH IC Directors with equities in HEAL | Committee Members | Advise the NIH Director to make final decisions on HEAL |
| **Wilson Compton, M.D., M.P.E.** | NIDA Deputy Director | wcompton@nida.nih.gov | Chair Behavioral Health Coordinating Committee Opioids and Controlled Substances Subcommittee |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **ADM Brett Giroir, M.D.** | Assistant Secretary for Health | Brett.Giroir@hhs.gov | Serves as Senior Adviser to the Secretary for Opioid Policy |
| **Elinore McCance-Katz, M.D., Ph.D.** | Assistant Secretary for Mental Health and Substance Use | Elinore.Mccance-katz@samhsa.hhs.gov | Partner in HEALing Communities Study; regulates opioid treatment programs |
| **HEAL Multidisciplinary Working Group** | n/a | Working Group | Council members and experts in pain and addiction research |

## TOP ISSUE: HEALTH DISPARITIES RESEARCH IN THE BIOMEDICAL ENTERPRISE

### ISSUE SUMMARY

In the U.S., disparities in health outcomes have been persistent, and progress to eliminate them has been slow. Populations with health disparities are defined as racial/ethnic minorities, less privileged socio-economic status, underserved rural residents, and sexual and gender minorities, all of whom are subjected to discrimination, have experienced higher incidence or prevalence of disease, premature or excessive mortality, greater global burden of disease, and poorer health behaviors and clinical outcomes, often as a result of being socially disadvantaged and underserved in health care.

Health disparities are multifactorial and are influenced by health determinants at multiple levels, including behavioral, social, economic, environmental, biological and health care. Examples of health determinants include education, health insurance, community environment, discrimination, racism, biological vulnerability and health care access. In particular, social determinants of health, the conditions and environments where people are born, live, learn, work, play, worship, and age, are key contributors to health and health disparities.

Addressing health disparities requires a concerted effort from multi-sectoral partners to address the broad array of health determinants, including the social determinants of health, in order to reduce health disparities.

### KEY PROGRESS TO DATE

Minority health and health disparities are an evolving scientific field that coalesced in the past 20 years. Between 1980 to 2000, there was a dearth of data on the causes of poor health outcomes among racial and ethnic minorities, with many studies limited to comparisons among Black and White populations. The creation of the National Center on Minority Health and Health Disparities (NCMHD) at NIH and its elevation to an Institute, illuminated the important role of research to improve minority health and address health disparities. Key progress to date:

- Legislative milestones: Heckler Report (1985), Office of Research on Minority Health (1993), National Center on Minority Health and Health Disparities (2000), National Institute on Minority Health and Health Disparities (2010)
- Established clear definitions for minority health and health disparities and defined health disparity outcomes – Novel Approaches to Advance Minority Health and Health Disparities Research
- Developed the Minority Health and Health Disparities Research Framework that depicts health determinants that can impact health at multiple levels across the life course
- Designated U.S. populations with health disparities as: Racial and Ethnic minorities; Socioeconomically disadvantaged populations; Underserved rural populations: and Sexual and gender minorities.
- Prioritized building research capacity at institutions that support career development among racial and ethnic minority populations underrepresented in the biomedical science workforce
- Identified Community-engaged participatory research as an important scientific approach to understand and intervene amongst populations with health disparities
- Published New Perspectives to Advance Minority Health and Health Disparities Research, a NIH-wide collaboration with scientists from across the United States to identify research strategies to monitor and reduce health disparities

## KEY CHALLENGES TO DATE

- Low recruitment and retention of racial and ethnic minorities into clinical trials
- Limited evidence that applies a multifactorial approach to characterize the health status and research priorities of populations with health disparities
- Lack of standard methods and measurements to monitor and address minority health and health disparities in research
- Limited effective and targeted multi-level interventions that incorporate multiple levels of health determinants that contribute to reducing health disparities and promoting health equity

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eliseo Pérez-Stable, M.D.** | Director, NIMHD | Eliseo.perez-stable@nih.gov | Leads scientific research to improve minority health and reduce health disparities |

External

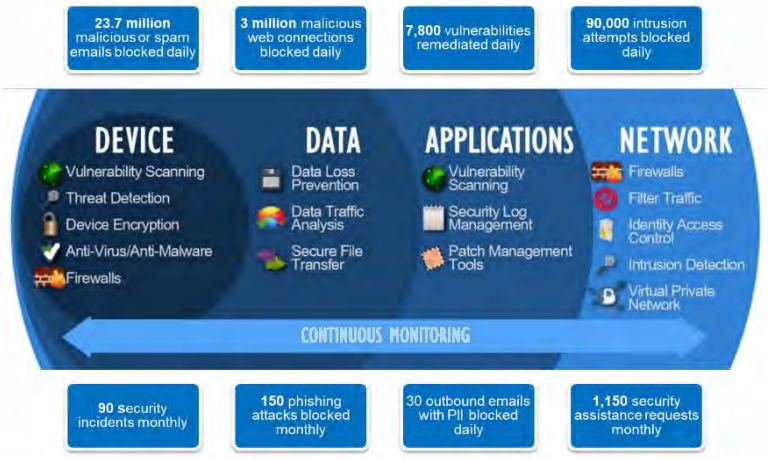
| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H.** | Deputy Assistant Secretary for Minority Health, OMH | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations |

## TOP ISSUE: CYBERSECURITY

## ISSUE SUMMARY

Protecting the NIH's information and systems is one of our most important technology challenges. Like other Federal agencies and large organizations, the NIH must respond to an increasing volume of cyber threats and security vulnerabilities. The NIH follows a risk-based approach to balance the needs for a collaborative and open research environment, while protecting NIH's key assets and focusing cybersecurity efforts on the areas of greatest potential risk. Additionally, the NIH provides near to real-time cybersecurity capabilities and risk management methodologies to protect sensitive data and information systems in support of the NIH's public health and research-driven mission.

The NIH's open research environment, global programming, and federated structure pose unique security challenges. The NIH's infrastructure consists of diverse platforms that operate in a federated, but functionally integrated environment. Three hundred cybersecurity staff across the Enterprise are responsible for implementing security controls within their local environments, consistent with NIH policy and standards. Due to the COVID-19 impact, the NIH has become an enhanced target for phishing, ransomware attacks, and multiple types of social engineering by actors who are trying to access our research, compromise our critical systems, and turn a profit. Even before the pandemic, the NIH was blocking 23 million malicious emails a day, a testament to the value of the information we store, access, and protect. The NIH has an infrastructure of tools in place to protect NIH devices, data, applications, and the network (see adjacent figure).




Additionally, NIH OCIO has initiated a holistic assessment of one of its largest cybersecurity tools – Splunk- which aggregates data from across the agency. The assessment is intended to identify areas of efficiency and enhancements to improve cybersecurity monitoring and reporting. The results will be used as roadmap for planning purposes.

## KEY PROGRESS TO DATE

- NIH leadership has recently established a new Capital Investment Cybersecurity Fund to allow up to $70 million in funding for each year in FY20-FY22 to support investments in cybersecurity improvements in 4 strategic areas: improving network re-architecture and security, tools rationalization, maturing cyber detection and response, and streamlining risk management and ATO processes. In addition, the fund also supports remediation efforts of recent audit findings.
- The NIH has implemented automatic protections and preventions from unauthorized access, theft or loss preventing 90,000 intrusion attempts and 37 million malicious emails daily.
- NIH remediated a material weakness for IT-related issues for the HHS financial statement audit.

## KEY CHALLENGES TO DATE

- In light of the NIH's role in coronavirus research, therapeutics, and vaccine initiatives, persistent cybersecurity threats exist, and the NIH continues to receive increased attention from malicious actors. The NIH has partnered with the Federal Bureau of Investigation's Cyber Task Force and Counterintelligence, the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA), and the National Security Agency to combat these threats and works closely with Department of Health and Human Services' Advance Cyber Defense unit and the Office of Inspector General's Criminal Crime Unit, for additional monitoring and threat intelligence support.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Andrea Norris, M.B.A.** | NIH Chief Information Officer (CIO) | andrea.norris@nih.gov | n/a |
| **Dennis Papula** | Acting OCIO Deputy Director | dennis.papula@nih.gov | n/a |
| **Amber Simco** | Acting CISO | amber.simco@nih.gov | n/a |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Janet Vogel** | HHS CISO | janet.vogel@hhs.gov | n/a |

## TOP ISSUE: IMPACT OF COVID-19 ON THE WORKFORCE, INTERNAL AND EXTERNAL

### ISSUE SUMMARY

The COVID-19 pandemic had unprecedented disruptive effects on the internal NIH workforce as well as the external biomedical research community. Early on, most laboratories and clinical research projects shifted to maintenance mode; recovery has been uneven. Researchers, especially those in earlier career stages, face an uncertain future. Extreme financial challenges have led institutions in the extramural community to scale back on hiring and promotions, raising concerns about the welfare of next generation researchers.

The NIH itself entered a maximum telework status on March 16th, 2020, in accordance with OMB guidance (M-20-13). While approximately 75% of the NIH workforce began teleworking, many remained onsite to support the NIH Clinical Center, conduct bench research, care for animals, and other critical functions that could not be handled remotely. The NIH Intramural Research Program began to limit presence in laboratories conducting non-missional-critical activities to serve only minimal maintenance functions on March 23rd.

The NIH began developing its Framework for Return to Physical Workspaces in April, in accordance with the *Guidelines for Opening Up America Again* and joint guidance from OMB and OPM (M-20-23). The Framework was approved by the NIH Coronavirus Response Team and distributed to staff on May 15th, after being cleared with the Department of Health and Human Services (HHS).

The Framework required each NIH Institute and Center (IC) to develop workforce plans and narratives for how they will return staff gradually and safely to NIH physical workspaces. The Framework established the following Groups that describe how we would focus our efforts to identify NIH staff that are allowed to return and in what order:

- Group 0: Staff who support mission-critical functions
- Group A: Work that cannot be completed remotely
- Group B: Work that is difficult to complete remotely
- Group C: Application Process for Voluntary Integration of Teleworkers
- Group D: Full return of staff

### KEY PROGRESS TO DATE

In close coordination with OMB, NIH allowed for a number of accommodations and flexibilities for the extramural community including allowances for continued salary support, extended deadlines for applications and reports, delayed audits, and extensions for NIH funded research and training grants. Some of these accommodations and flexibilities expired in late FY 2020. NIH is planning to issue a survey of NIH funded researchers and institutional leaders in October 2020 to learn more about how the pandemic has affected their workforce.

Within the NIH, staff that meet the Framework principles of Group 0 remained onsite throughout the pandemic. Staff in Group A began returning on June 22nd and Group B July 20th. As the NIH has facilities in seven counties in Maryland, Montana, North Carolina, Massachusetts, and Arizona, not every group began on the same day at every worksite. The NIH Response Team has reviewed the conditions at each location before approving staff to begin returning. The earliest that Group C is projected to begin is in November (if and where conditions allow).

## KEY CHALLENGES TO DATE

- Bringing back staff gradually and safely to NIH physical workspaces, prioritizing staff whose work can only be completed onsite
- Uncertainty about the course of the pandemic and the ability of external research institutions to restart bench and clinical research operations
- Concerns about effects on women who are disproportionately burdened with childcare responsibilities in the setting of widespread school closures
- Limitations in monitoring daily staffing levels in individual NIH buildings and facilities; coordinating daily staffing levels in multi-IC buildings
- Ensuring sufficient PPE and cleaning supplies for the NIH workforce

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Larry Tabak, D.D.S., Ph.D.** | Principal Deputy Director, NIH | t (b) (6) | NIH Coronavirus Response Team |
| **Alfred Johnson, Ph.D** | NIH Deputy Director for Management | johnsoA1@mail.nih.gov | NIH Coronavirus Response Team |
| **Michael Lauer, M.D.** | Deputy Director for Extramural Research | michael.lauer@nih.gov | NIH Coronavirus Response Team; oversees external workforce matters |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **J. Blair Duncan** | Chief Human Capital Officer and Deputy Assistant Secretary for Human Resources for HHS | (202) 260-2843 James.Duncan@hhs.gov | HHS HR POC for COVID-19 policy and guidance updates |
| **Bahar Niakan** | Deputy Chief Human Capital Officer and Director for Strategic Initiatives for HHS | (202) 578-3588 Bahar.Niakan@hhs.gov | HHS HR POC for COVID-19 policy and guidance updates |

## TOP ISSUE: DUAL USE RESEARCH OF CONCERN (DURC) AND GAIN-OF-FUNCTION (GOF) RESEARCH

### ISSUE SUMMARY

Life sciences research often can be characterized as "dual use" because the knowledge gleaned from research may be used for both benevolent or harmful purposes. However, Dual Use Research of Concern (DURC) is a small subset of research that is *reasonably anticipated* to provide information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agriculture, the environment, or other aspects of national security. Additionally, in recent years, certain studies with the potential to generate potential pandemic pathogens with enhanced pathogenicity and/or transmissibility (enhanced PPPs)—so-called gain-of-function (GOF) studies—have raised biosafety and biosecurity concerns, including potential dual use risks associated with the misuse of the information or products resulting from such research.

The USG issued two policies for the identification and oversight of DURC in 2012 and 2014. Moreover, in October 2014, the USG launched a deliberative process to re-evaluate the potential risks and benefits associated with such experiments. During this process, the USG paused federal funding for GOF studies anticipated to enhance the pathogenicity or transmissibility among mammals by respiratory droplets of influenza, MERS, or SARS viruses. The National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee that advises the USG on biosecurity and dual use issues, led the process and issued final recommendations to the USG in May 2016. In January 2017, OSTP issued *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (P3CO Policy Guidance) requiring federal departments and agencies conducting, supporting, or planning to conduct or support the creation, transfer, or use of enhanced PPPs to develop appropriate review mechanisms. In December 2017, HHS released its *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), which formalized a multidisciplinary Department-level review of individual, proposed research that is reasonably anticipated to create, transfer, or use enhanced PPPs to guide agency funding decisions and oversight. NIH simultaneously announced in a statement and notice to the research community the lifting of the funding pause instituted in 2014.

- **Policy and Legislative Issues** – A few concerns have been raised that the HHS P3CO review process and NIH funding decisions regarding enhanced PPP research lack adequate consideration of transparency. Concerns have also been raised that the scope of the DURC policies is too narrow to capture all possible DURC. The OSTP P3CO Policy Guidance also includes a commitment to consider approaches that would enable oversight of relevant research, regardless of the funding source. Modifications to the scope of DURC and/or P3CO policies would have significant effects on Federal research programs and grant administration and could unduly burden the research community.

### KEY PROGRESS TO DATE

- In accordance with the HHS P3CO Framework, NIH/NIAID has referred three extramural research proposals to the HHS P3CO review group after they were deemed to be scientifically meritorious and actively being considered for funding. The HHS P3CO review group has completed review of two proposals and, in both cases, determined that the research was acceptable for HHS funding. NIAID incorporated suggestions from the HHS review group into the awards to increase the potential benefits to the public while decreasing risks before allowing the projects to proceed.

- NIH released a statement in March 2019 reaffirming its commitment to transparency and HHS posted information about the reviews on the Science, Safety, Security website that included links to NIH Reporter.
- In January 2020, the NSABB convened in a public meeting to discuss balancing considerations regarding security and public transparency when sharing information about enhanced PPP research.
- The USG renewed the NSABB's charter in 2020, an indication of the continued value of the Board to the USG.

## KEY CHALLENGES TO DATE

- Enhanced PPP research remains sensitive and debate about necessity and risks/benefits persist.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie D. Wolinetz, Ph.D.** | Acting Chief of Staff and Associate Director for Science Policy (NIH/OD) | carrie.wolinetz@nih.gov | NIH lead for DURC and P3CO policy issues |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **David Christian Hassell, Ph.D.** | Senior Science Advisor, Assistant Secretary for Preparedness and Response (HHS/ASPR) | david.hassell@hhs.gov | Chairs the HHS P3CO Review Group |
| **Michael Schmoyer, Ph.D.** | Assistant Director for Health Security Threats (EOP/OSTP) | Michael.W.Schmoyer@ostp.eop.gov | Coordinates interagency biosecurity efforts |
| **Tom Inglesby, M.D.** | Director, Center for Health Security, John Hopkins University | tinglesby@jhu.edu | Long-term involvement in P3CO discussions |
| **Yoshihiro Kawaoka, Ph.D.** | Professor, University of Wisconsin-Madison | yoshihiro.kawaoka@wisc.edu | Influenza researcher |

## TOP ISSUE: RESEARCH ON HUMAN FETAL TISSUE

NIH conducts and funds basic, preclinical, and clinical research involving the analysis or use of human fetal tissue (HFT) for a wide range of diseases and conditions. Studying human fetal tissue allows researchers to understand the processes, abnormalities, and pathologies unique to early human development. In FY2019, NIH supported 200 grants and projects that involve research with HFT.

In 2019, HHS announced that it would convene an Ethics Advisory Board (EAB) (as authorized in the Public Health Service (PHS) Act) in FY2020 to advise, consult with, and make recommendations to the HHS Secretary regarding the ethics of research involving HFT from elective abortions proposed in grant applications and contract proposals that were recommended for funding. HHS also announced that no new research would be conducted within the NIH Intramural Research Program that required new acquisition of HFT from elective abortions. Section 492A of the PHS Act provides that if a project has been recommended for approval for purposes of peer review and IRB review, as applicable, the HHS Secretary may not withhold funding for a research project because of ethical considerations unless "the Secretary convenes an advisory board in accordance with [Section 492A] to study such considerations" and "(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or (ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the [board's] report…that the recommendation is arbitrary and capricious."

The PHS Act requires that the report of the EAB be submitted to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate less than 180 days after the original FRN soliciting names is published. The FY2020 EAB was established, met in July 2020, submitted its report, and was disbanded (as the statute required) in September 2020. HHS will need to establish a new EAB for FY2021 if HHS wishes to continue that review process. The FY2020 was also governed by the Federal Advisory Committee Act (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

### KEY PROGRESS TO DATE

To implement the HHS policy position, NIH issued guidance for potential applicants alerting them of the newly required information for applications using HFT (such as details on the tissue donation consent process) and the associated evaluation criteria . The FY2020 EAB met in July 2020, reviewed 14 research proposals, and recommended that the HHS Secretary withhold funds for 13 out of the 14 proposals for ethical reasons. A report outlining these recommendations was delivered to Congress, as required by statute, and is publicly available. Final funding decisions on the projects were pending as of September 17, 2020.

### KEY CHALLENGES TO DATE

- The statute establishing the EAB requires that a new Board is constituted for each review. This requirement has proven challenging in order to match NIH funding cycles and maintain FACA requirements.
- Different stakeholders have strongly held views on the use of HFT in research funded by NIH, which were reflected in the reactions to the EAB's report. Some religious organizations oppose the use of HFT and supported the EAB's report. Numerous scientific organizations support research with HFT and oppose the policy changes announced in 2019 and the EAB's report.

- Several senior members of Congress wrote to the Secretary in September 2020, asking that he halt efforts to withhold funding for HFT research, and cited correspondence between NIH and HHS senior leadership.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie Wolinetz, Ph.D.** | Associate Director for Science Policy | Carrie.Wolinetz@nih.gov | HFT policy lead |
| **Michael Lauer, M.D.** | Deputy Director for Extr amural Research | Michael.Lauer@nih.gov | HFT extramural research lead |
| **Tara Schwetz, Ph.D.** | Associate Deputy Director | Tara.Schwetz@nih.gov | NIH liaison to HHS |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eric Anthony** | Director of Policy, International Society for Stem Cell Research | eanthony@isscr.org | Key scientific organization |
| **David Prentice, Ph.D.** | Vice President, Charlotte Lozier Institute | DPrentice@lozierinstitute.org | Key pro-life advocacy organization; EAB member |
| **Kevin Wilson** | Director of Public Policy, American Society for Cell Biology | kwilson@ascb.org | Key scientific organization |

## OD: FACILITIES CONDITION AND FUNDING

### Issue Summary

NIH's Backlog of Maintenance and Repair (BMAR) is $2.4 billion, twice the sum of the other HHS Landholding Operating Divisions (CDC, FDA, and IHS), and growing at an alarming rate. The average Condition Index of NIH buildings is 69 of 100, among the lowest levels in the federal government. The BMAR presents major risks to basic, animal, and clinical research; occupational health and safety; environmental protection; operating costs due to emergencies (floods, fires, and utility outages); waste of prior taxpayer investments—the NIH Plant Replacement Value is $12.7 billion; and adverse impacts on recruiting, retention, and morale. Despite these well-documented issues understood by both the Executive and Legislative Branches, Buildings & Facilities (B&F) appropriations have remained flat. The Non-Expiring Expenses Fund (NEF) has been helpful, but it is unpredictable and does not represent a sustainable solution. In addition to B&F and NEF, General Provision Section 216 allows IC appropriations to be used for alteration, repair, or improvement of facilities; it would be helpful to increase this authority's total annual limit from $45M to $100M and to eliminate the per project limit of $3.5M per project. There are two potential long-term solutions: 1) a permanent increase in B&F to $400M (preferred); or 2) revision of the Section 216 Authority to allow the NIH Director to transfer up to 1% of all NIH appropriations into the B&F appropriation, a solution that all IC Directors concurred with during a May 30, 2019 presentation.

While the facilities issues are chronic, the NIH's most pressing priority is the Surgery, Radiology, and Laboratory Medicine (SRLM) project; NIH needs $492M to make an award in FY 2021, and will have $263M of NEF/B&F carryover from FY 2020, leaving a delta of $229M needed in FY 2021.

### KEY PROGRESS TO DATE

Appropriations for B&F were increased from the longstanding level of $129M to $200M in FY19, with FY 2020 appropriations also providing a one-time $225 million from a separate source, the HHS Nonrecurring Expenses Fund (NEF).

In August 2019, the NASEM released its Congressionally-mandated Consensus Report on the condition of NIH's Bethesda facilities. The 185-page report recommended near-term investments of $1.3 billion, which gained support from the Maryland Delegation. The report also included twelve recommendations, which are all either implemented or in the process of implementation. NIH had high hopes that this independent report would signal to both the Administration and Congress that major increases needed to be made. It is important to note that the NASEM report focuses exclusively on the Bethesda Campus, whereas NIH's facilities needs are broader, as they include Poolesville MD, NCI Frederick MD, Research Triangle Park NC, and Rocky Mountains Labs in Montana.

### KEY CHALLENGES TO DATE

- Congressional Support of B&F Appropriation. While NIH has convinced HHS/ASFR and OMB of the need to increase facilities investment levels, the most recent challenge regards a lack of Congressional support. Subsequent to the release of the NASEM report, the FY21 President's Budget included an increase in the B&F appropriation from $200M to $300M, but that increase was not incorporated into the House appropriations language, which maintains B&F at $200M and provides $225M of one-time funding for the SRLM project. As of the drafting of this issue paper, the Senate appropriations language is not available. It appears Congress prefers to selectively fund capital projects with one-time funding. Congressional reluctance does not seem

to be attributable to their understanding of the need for safe, reliable facilities to conduct science. Rather, the reluctance seems to come from pressures upon the appropriators to preserve extramural funding levels. As B&F primarily supports the Intramural Research Program in discrete locations in Maryland, Montana and North Carolina, Congress appears more interested in supporting the extramural community, given its more dispersed nature.

- Congressional Concerns Regarding Animal Research. While funding of the SRLM project is likely to occur, NIH's second priority project, the Center for Disease Research (CDR), is likely to be an even greater challenge. The CDR is predominantly an animal research facility, and key appropriators have the opinion that alternatives to animal research are viable. NIH has been attempting to educate Members that animal research is critical, and alternatives do not exist for all types of research; however, the opponents have successfully convinced some that animal research can be significantly decreased. The CDR is desperately needed, given the poor state of the legacy facilities, predominantly constructed in the 1950s. Our most viable strategy for funding the CDR (estimated between $600M and $700M) appears to be a combination of 1) breaking the project into severable phases; and 2) funding each phase with B&F (hopefully after having increased the base to $300M or $400M).

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| Alfred Johnson, Ph.D. | Deputy Director for Management | johnsoA1@mail.nih.gov | Also serves as Senior Real Property Official |
| Dan Wheeland | Director, Office of Research Facilities | wheeland@od.nih.gov | Also serves as Co-Chair, Facilities Working Group |
| Neil Shapiro | Associate Director for Budget, OD | neil.shapiro@nih.gov | Works closely with HHS/ASFR and OMB |
| Eric Green, Ph.D. | Director, NHGRI | egreen@nhgri.nih.gov | Co-Chair, Facilities Working Group |
| Adrienne Hallett | Director, Office of Legislative Policy and Analysis | Adrienne.hallett@nih.gov | Works closely with appropriators |

**External**

None identified

## OD: NUTRITION RESEARCH

### ISSUE SUMMARY

The goal of the 2020-2030 Strategic Plan for NIH Nutrition Research, the first NIH-wide plan for nutrition research, is to advance nutrition research and address diet-related diseases across the lifespan. The plan emphasizes cross-cutting, innovative opportunities across a wide range of areas, from basic science to experimental design to research training. Moving the Office of Nutrition Research (ONR) to NIH OD will elevate attention to and ensure a coordinated approach to nutrition research across NIH.
To fully realize the vision of the strategic plan, the new ONR/DPCPSI will need additional resources for new initiatives, workshops, and other activities. One way to maximize the impact of ONR is to launch time-limited goal-driven nutrition programs, based on the Common Fund model, designed to achieve high impact goals and catalyze discovery over a 10-year period.

Current ONR staff will be reassigned to ONR/DPCPSI, including the Director, detailed as the Acting Director, and Title 5 staff. ONR in NIDDK relied on NIDDK's Office of Science Program and Policy Analysis (OSPPA) and Office of Communications and Public Liaison (OCPL) to prepare responses to inquiries and conduct strategic planning and coordination efforts. DPCPSI's program offices have their own communications and planning and evaluation (P&E) staff. When ONR is moved to DPCPSI, the office will need to hire a Communications Specialist and a Health Science Policy Analyst to fulfill the roles currently performed by OCPL and OSPPA staff, requiring 1 or 2 additional FTEs (or 1 FTE and 1 contractor).

### KEY PROGRESS TO DATE

- NIH recently released the *2020-2030 Strategic Plan for NIH Nutrition Research,* which outlines initiatives that aim to address an urgent public health need by reducing diet-related diseases that are top causes of death, disability, and high health care costs.
- NIH held a workshop on January 11-12, 2021, to identify research gaps and opportunities in nutrition for precision health.
- The new NIH Common Fund Nutrition for Precision Health, powered by the *All of Us* Research Program, aims to use data collected from a large cohort as well as from smaller controlled studies to determine what individuals should eat to stay healthy. Plans for phase 1 of the program will include a study of 10,000 participants, the largest precision nutrition study to date. The diverse study population will allow insights into diet-related health disparities.

### KEY CHALLENGES TO DATE

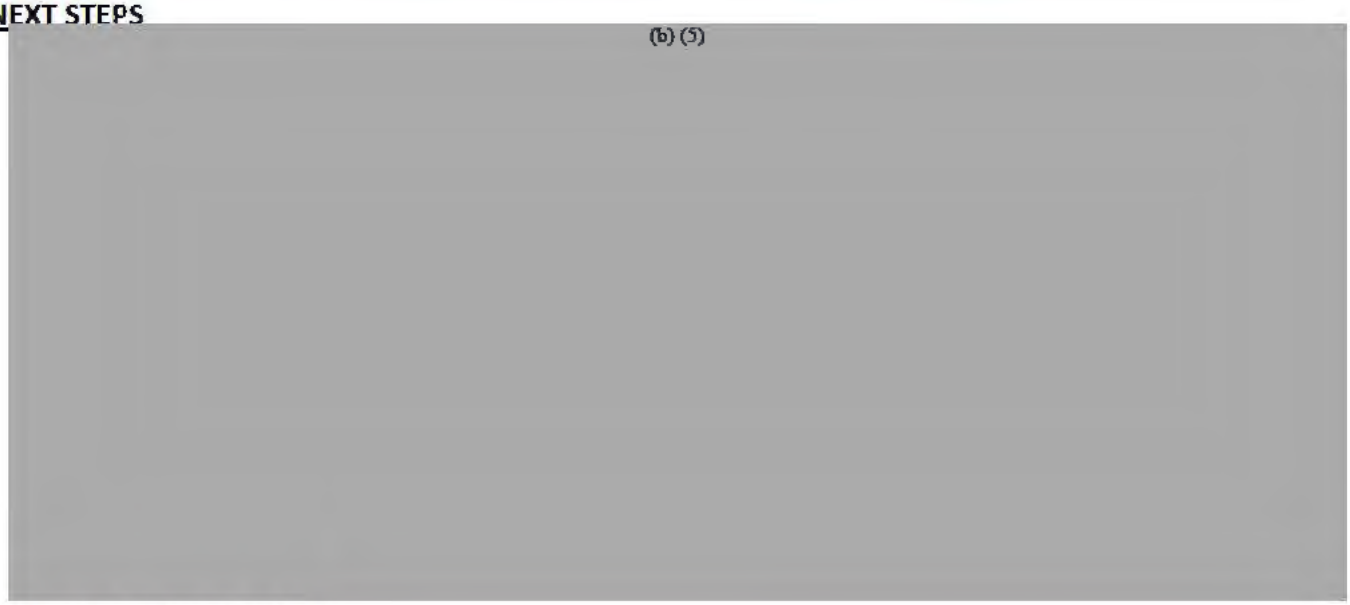
The Nutrition Research Strategic plans identifies 4 major challenges that the plan will address:

- **Spur Discovery and Innovation through Foundational Research—What do we eat and how does it affect us?** To ensure a strong foundation of basic and methodological research in nutrition science through integrated connections with other fields of study such as bioinformatics, neurobiology, and genomics.
- **Investigate the Role of Dietary Patterns and Behaviors for Optimal Health—What and when should we eat?** To illuminate and apply how specific dietary patterns influence health outcomes in different ways among individuals, subgroups, and communities.
- **Define the Role of Nutrition Across the Lifespan—How does what we eat promote health across our lifespan?** To lead to a better understanding of how nutritional needs and eating behaviors change over time, focusing on three time-windows that have been especially understudied: pregnancy, infancy and toddlerhood, and older adulthood.

- **Reduce the Burden of Disease in Clinical Settings—How can we improve the use of food as medicine?** To expand knowledge about the role of nutrition in disease and grow evidence toward development of medical nutrition therapies for improved health.

## NEXT STEPS

(b) (5)



## RELEVANT STAKEHOLDERS

**Internal**

| Name/Title | Contact Information | Critical Role |
|---|---|---|
| ***All of Us*, CSR, NCI, NHGRI, NHLBI, NIA, NIBIB, NICCH, NICHD, NIDA, NIDCR, NIDDK, NIEHS, NIMHD, OBSSR, ODP, ODS, ORWH, OSC** | Holly Nicastro, Ph.D<br>Christopher Lynch, Ph.D | Contributing NIH ICOs in the Nutrition for Precision Health, powered by the *All of Us* Research Program |
| **NIH Nutrition Research Coordinating Committee** | Christopher Lynch, Ph.D | Coordinates nutrition research activities across NIH and with other federal agencies. |

**External**

| Name/Title | Contact Information | Critical Role |
|---|---|---|
| **American Society for Nutrition** | Sarah Ohlhorst, M.S., R.D | Co-authored white paper. |
| **Federal Nutrition Research Advisory Group** | Dariush Mozaffarian, Dr.Ph., M.P.H, M.D | Co-authored white paper. |
| **Interagency Committee on Human Nutrition Research** | ADM Brett Giroir (HHS)<br>Scott Hutchins, Ph.D. (USDA) | Improves planning, coordination, and communication among federal agencies engaged in nutrition research. |
| **Joint Agency Nutrition Working Group (FDA and NIH)** | Susan Mayne, Ph.D. (FDA)<br>Christopher Lynch, Ph.D. (NIH) | Reports to the NIH-FDA Joint Leadership Council on dietary supplements and nutrition research on pregnant women and children, and chronic diseases |
| **Food is Medicine Working Group** | Rep. Jim McGovern (D-MA)<br>Rep. Lynn Jenkins (R-KS)<br>Rep. Chellie Pingree (D-ME<br>Rep. Roger Marshall (R-KS) | Bipartisan group in the House emphasizing the link between nutrition programs and health outcomes. |

## OD: USE AND AVAILABILITY OF NONHUMAN PRIMATES IN RESEARCH

### ISSUE SUMMARY

Nonhuman primates (NHPs) serve as critical animal models for many research areas, including infectious diseases, neuroscience, reproductive biology and regenerative medicine. Ensuring an adequate supply of NHPs to sustain NIH supported research has been an ongoing challenge, with periodic shortages or surpluses being experienced over the past several years. Research on COVID-19 pathogenesis, treatments, and preventions has exacerbated the demand for NHPs, particularly for rhesus macaques. A shortage of NHPs caused by the COVID-19 pandemic combined with export bans of NHPs from China and India may severely constrain U.S. biomedical research dependent on NHP models, particularly COVID-19 research.

NIH supports several primate facilities through grants and cooperative agreements to provide animals for biomedical research. At specific facilities, NIH supports not only the NHP colonies, but also access to facilities, expertise, and resources required by researchers in specific disease areas. Many NIH-wide initiatives (HIV/AIDS, Somatic Cell Genome Editing, and Brain Research through Advancing Innovative Neurotechnologies (BRAIN) depend on these NIH supported facilities.

In 2018, NIH conducted analyses on NIH's NHP demand and supply that demonstrated enhanced use of NHPs projected through 2022 and limitations on NHP availability. The Nonhuman Primate Evaluation and Analysis Part 1: Analysis of Future Demand and Supply report indicated a majority of NIH-funded investigators use NIH supported resources to perform their research, including the National Primate Research Centers (NPRCs)[3], and a shortfall in rhesus macaques and marmosets was predicted (even before the pandemic). A Trans-NIH NHP Resource Planning Working Group (NHPRP WG) was established in 2019 to enhance coordination and prioritization of extramural resource activities related to NHP use in research as requested in the Nonhuman Primate Evaluation and Analysis Part 2: Report of the Expert Panel Forum on Challenges in Assessing Nonhuman Primate Needs and Resources for Biomedical Research report.

The top priorities identified by the NHPRP WG were expansion of rhesus macaque colonies, enhancement of NHP reference genomes and annotation in parallel with a genotype-tissue expression program, and establishment of domestic cynomolgus macaque colonies. Since these reports were issued, demand for NHPs, particularly rhesus macaques, from NIH supported resources and access to biocontainment facilities has escalated as researchers seek to investigate COVID-19 pathology, treatments, and preventions using NHP models. The NPRCs and other NHP facilities require revitalization and expansion to provide for colony growth, develop new resources, and update center infrastructure. Besides NHP housing and quarantine space, the pandemic exposed a need for more specialized facilities and equipment at these centers to conduct aerosol exposure studies, have access to functional MRI instruments, or perform infectious disease studies requiring biological containment (e.g., Animal Biological Safety Level 3 and 4 [ABSL 3 and 4]).

*Recommendations*: Addressing the COVID-19 pandemic while sustaining other ongoing research will require expansion and continued support of critical NHP resources. Increased breeding at NIH supported NHP facilities is needed. This can only be accomplished with additional investment (roughly $85M over 5 years) for construction and renovation of NHP housing, specialized facilities, expansion and increased access to NHP models, expansion of veterinary medical support and expert staffing at NHP facilities, and the acquisition of instruments and research platforms.

[3]In partnership with the National Institutes of Health (NIH), other government organizations, private foundations, and private industry, NPRCs conduct and enable studies that make breakthrough discoveries of causes, preventions, treatments and cures possible.

## KEY PROGRESS TO DATE

NIH has begun implementing strategies to ensure urgently needed studies using NHP models to address the pandemic can proceed while limiting impact on other research areas requiring NHP models. NIH is addressing this increased demand by coordinating, prioritizing and streamlining research processes to maximize available NHP resources supported by the Office of Research Infrastructure Programs while prioritizing the most promising studies urgently required to save human lives or shorten the COVID-19 pandemic. This prioritization process has been announced through an NIH Guide Notice (NOT-OD-20-173). NIH has plans in place to maximize the use of animals assigned to COVID research by harmonizing studies across NHP sites to share controls across studies and reduce overall animal use.

## KEY CHALLENGES TO DATE

- Using funds from COVID-19 supplemental appropriations, NIH has invested in the infrastructure (e.g., expansion of NHP housing and ABSL 3 space, equipment purchases for ABSL 3 support space) of existing NPRCs and primate centers needed to increase rhesus macaque breeding capabilities. However, the benefits of this one-time increase in support will produce the first adult animals in 4-5 years as offspring must mature for use in NIH funded research projects.
- Campaigns organized by animal welfare organizations directed at NIH advocating reduced or no use of NHPs in research could impede or delay critical NIH research requiring NHP models, particularly COVID-19 research.
- There is public and Congressional interest regarding the use of NHPs in research, with some advocating for reduced use of NHPs and others for continued or expanded support of research that uses NHP models. This interest could affect congressional appropriations language.

N

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie D. Wolinetz, Ph.D.** | Acting Chief of Staff and Associate Director for Science Policy | carrie.wolinetz@nih.gov | Leads science policy for use of animals in research |
| **James Anderson, M.D., Ph.D.** | Director, DPCPSI | james.anderson2@nih.gov | Leads coordination of NHP resource strategy |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Matthew Bailey** | Executive Director, National Association for Biomedical Research | mbailey@nabr.org | Key scientific organization |
| **Nancy Haigwood, Ph.D.** | Center Director, Oregon National Primate Research Center | haigwoon@ohsu.edu | Director of a National Primate Center |
| **Steve Hyman, M.D.** | Director, Stanley Center for Psychiatric Research, Harvard University | shyman@fas.harvard.edu | NHP researcher |

# NCI: 15 BY 25 – RAISING THE NCI GRANTS PAYLINE TO THE 15TH PERCENTILE BY 2025

## ISSUE SUMMARY

An unprecedented enthusiasm has permeated the cancer research community. Over the past 6 years, there has been an explosion of new research ideas, as evidenced by a greater than 50% increase in grant applications to NCI, and the extraordinary number of new cancer drug approvals, which offer more options and hope to patients. This increase in grant applications is due in part to a dramatic increase in the number of investigators entering the cancer research field.

However, if the NCI budget is unable to meet the pace of this growing interest and enthusiasm, we will be confronted with a serious challenge. If discouraged researchers leave the field, we will squander the tremendous momentum and innovation alive in the research community today. In addition, we will lose an opportunity to increase the diversity of the NCI-funded cancer research workforce.

Investigator-initiated research supported through research project grants (RPGs), including R01 grants, is the source of some of the most innovative ideas in cancer research and leads to increased understanding of cancer biology and new cancer treatments. In recent years, the increase in grant applications has far outpaced the NCI budget and our ability to fund RPGs at an acceptable success rate. In FY 2018, the success rate for NCI grant applications was 10% lower, on average, than the rest of NIH.

In FY 2020, thanks to strong congressional support, NCI received a budget increase that allowed us to grow our investment in RPGs by increasing R01 paylines by 25% compared with the FY 2019 level. For the first time in 3 years, NCI was able to raise the R01 payline to the 10th percentile. Further budget increases will allow NCI to sustain this recent growth and to further boost the payline for R01 grants. NCI has set a goal to raise the R01 payline to the 15th percentile by FY 2025.

The 15 by 25 goal will only be possible with sustained annual increases to NCI's base appropriation. Along with increasing the R01 payline, additional increases to NCI's base appropriation will allow for added investments in training the next generation of diverse cancer researchers and supporting key infrastructure such as NCI-Designated Cancer Centers.

There can be no pause button for cancer research, as today's investments lay the foundation for tomorrow's breakthroughs. Raising the NCI R01 grant payline to the 15th percentile by 2025 will capitalize on today's scientific opportunities to prevent, detect, and treat cancer, while growing and diversifying the cancer research workforce.

## KEY PROGRESS TO DATE

With the FY 2020 budget increase, NCI was able to increase paylines by 25% over the previous year. For FY 2020, the R01 payline was the 10th percentile, up from the 8th percentile in FY 2019. NCI was also able to fund non-competing RPGs at 100% of their committed levels. This restored the budgets of grants that previously had been paid at only 97% in FY 2019. NCI also strengthened its commitment to grow and diversify the cancer research workforce by increasing the number of R01 awards to early-stage investigators over the past several years and using select pay to fund more investigators from underrepresented groups in FY 2020.

## KEY CHALLENGES TO DATE

While paylines are difficult to forecast, they are important indicators to the research community of support for and viability of the cancer research field. The large increase in the number of grant applications to NCI, the rising costs of conducting innovative research, and budget uncertainties are challenges to setting and maintaining NCI paylines.

- To achieve the 15 by 25 goal and fulfill its commitment to the research community, NCI will require sustained budget increases to allow for the resources required by the grants pool
- To increase the diversity of the cancer research workforce, NCI must to be able to fund more early-stage investigators and investigators from underrepresented groups who receive meritorious scores on their grant applications

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

None identified

**External**

None identified

## NCI: CHILDHOOD CANCER DATA INITIATIVE

### ISSUE SUMMARY

Each year, approximately 16,000 children and adolescents are diagnosed with cancer in the United States. While progress has been made in many forms of childhood cancer, there are still far too many children for whom we do not have high efficacy, low toxicity therapies.
In 2019, NCI launched the Childhood Cancer Data Initiative (CCDI) in alignment with the Presidentially proposed federal investment of $500 million over ten years to make progress against childhood cancers. In FY 2020, NCI received the first $50 million federal investment, with an additional $50 million proposed each year for the next 9 years.

The CCDI provides a blueprint for the bold vision of learning from every child with cancer while providing each of them state-of the-art clinical care and ultimately changing the course of cancer in all children. Through the CCDI, NCI will connect data repositories and registries, collect standardized, high-quality data on childhood and adolescent cancers, and promote efficient data sharing to accelerate research and discovery.

By building an integrated data infrastructure, NCI will connect multiple existing and new data repositories and offer software tools to analyze and share the data. The data repositories will include comprehensive and standardized patient information featuring some or all of the following: genomics, proteomics, imaging, pathology, side effect profiles, and outcomes reported by patients and caregivers. The CCDI aims to increase data use and sharing among the pediatric cancer research community to improve understanding of childhood cancers and advance research to develop new and better treatments. It will also serve as a model for what can be achieved in adult cancers through enhanced data sharing.

Overall, interconnecting data repositories will create a data ecosystem for childhood and adolescent cancers, ensuring data are more broadly accessible and interoperable. This will allow researchers to answer many questions that, to date, have been difficult or impossible to address, either because we have not collected the necessary information or because we lacked universal access to the data. Making data available in this powerful way will accelerate our ability to transform the childhood and adolescent cancer landscape with earlier diagnoses, less-toxic and more-effective treatments, and ultimately, better outcomes for these patients.

CCDI will not only be a foundational component of the NCI childhood cancer program, it will complement and inform other, ongoing pediatric cancer research. In sum, CCDI is a 10-year initiative still in its early days, and the pediatric cancer community expects much from it.

### KEY PROGRESS TO DATE

Since the initiative's launch in July of 2019, NCI has undertaken a range of research activities to lay the foundation for developing and supporting the CCDI.
CCDI activities currently underway include:

- Conducting a comprehensive review of existing childhood and adolescent cancer data, data repositories, and analytic tools that can be connected under the CCDI
- Developing the National Childhood Cancer Registry, as part of the CCDI data ecosystem, to enhance access to patient-linked childhood and adolescent cancer and survivorship data

- Building the technical infrastructure of the data ecosystem, which will connect various types of cancer and clinical care data and tools
- Expanding comprehensive data collection to include more institutions engaged in childhood and adolescent cancer and survivorship research
- Continuing to enhance data sharing to promote open access to data

In addition, NCI convened a working group of its Board of Scientific Advisors (BSA) to provide guidance regarding future priorities for CCDI. In June 2020, at a joint meeting of the BSA and the National Cancer Advisory Board, the working group presented its report, which includes 24 specific recommendations for implementing the CCDI that could lead to transformative discoveries in pediatric and adolescent cancer treatment and survivorship.

## KEY CHALLENGES TO DATE

There are many challenges inherent to standing up an initiative as bold as the CCDI. NCI is committed to providing the personnel and infrastructure needed for this initiative, and has the support of its advisory boards, the research community, and the childhood cancer advocacy community. However, a lack of dedicated financial support is a substantial challenge.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

None identified

**External**

None identified

## NCI: FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH

### ISSUE SUMMARY

The Frederick National Laboratory for Cancer Research (FNLCR) takes on urgent challenges to hasten the development and delivery of effective preventive, diagnostic, and therapeutic advances to people living with cancer and HIV/AIDS, along with those threatened by infectious diseases. The only Federally-Funded Research and Development Center solely dedicated to biomedical research, FNLCR is currently operated by Leidos Biomedical Research for NCI as a national resource. It also works on behalf of other NIH institutes and centers, particularly the NIAID.

FNLCR key research projects:

- The RAS Initiative, which is exploring approaches to attacking the longstanding, seemingly intractable problem of mutations in the *RAS* family of genes that are implicated in more than 30 percent of all human cancers.
- The National Cryo-Electron Microscopy Facility, a resource for the cancer research community, that produces three-dimensional images of individual molecules at near-atomic resolution and develops new tools and techniques for this leading edge of biomedical imaging.
- The Genomic Data Commons, a repository and portal for storing and sharing vast amounts of electronic data accrued from dozens of genomic studies of numerous cancer types.
- The Nanotechnology Characterization Laboratory, which, working in concert with the FDA and the National Institute of Standards and Technology, studies microscopic materials small enough to penetrate or bind to individual cells.
- The Vaccine Research Center (VRC) Pilot Plant, built and managed for the NIAID, is a production and warehouse facility operated under FDA's Current Good Manufacturing Practice (GMP) regulations.

Priority FNLCR COVID-19 research projects:

- Applying the expertise and resources of FNLCR's HPV Serology Laboratory to work on antibody testing for the novel coronavirus. The laboratory works in concert with the FDA, CDC, NIH, and other agencies to independently evaluate serology test kits submitted to FDA by outside companies.
- Using FNLCR's screening library to identify compounds that could potentially provide new therapies against the novel coronavirus.
- Conducting studies alongside and at the request of NCI, NIAID, and the NHRGI to identify genetic variants associated with a person's severity of infection.
- Supporting human clinical trials for investigational treatments, such as the antiviral drug remdesivir.

### KEY PROGRESS TO DATE

Much of FNLCR's work is foundational science: technologies, platforms, and services that government, academic, and industry scientists rely on. ar from simplistic, FNLCR conducts studies and provides research resources that make possible basic science discoveries, therapeutic development, technological advances, and clinical testing in areas where industry often does not invest. As cancer research becomes more data-intensive, FNLCR's work becomes ever-more crucial. Its discoveries and understandings of longstanding foes like cancer and emerging threats like COVID-19 are a testament to its strategic value.

### KEY CHALLENGES TO DATE

- Acquisition Authorities: Unlike the more than 40 other FFRDCs in the federal government, the acquisition authorities available to NCI and its national laboratory are more limited. This

constrains the ability of NCI's FFRDC to use flexible contract approaches to act with dispatch, just as other FFRDCs can. The most prominent acquisition authorities that NCI lacks are no-year appropriations and flexible contracting authority. The current contract is scheduled to be recompeted, with a new award made in 2023. The size of this acquisition and the complexity of the award requires significant collaboration with others at NIH and HHS.

- No-Year Funding for NCI: Although NCI does not receive no-year funds in its appropriation on a regular, ongoing basis, NCI recently experienced two powerful examples of how no-year funding allows the agency to deliver its cancer research mission more effectively. The first example emerged from the Cancer Moonshot (P.L. 114-255), where no-year funds allowed NCI to approach research questions in a more dynamic way than is possible with annual appropriations. The second occurred in the April 2020 emergency appropriation for COVID-19 response (P.L. 116-136), where NCI received no-year funds to lead a national program on serological testing, in collaboration with FDA, CDC and other HHS agencies.
- The IDIQ Challenge: The Indefinite Delivery / Indefinite Quantity (IDIQ) structure that NCI must use for FFRDC contracting is unnecessarily constraining. The cumbersome nature of IDIQ contracting impedes the ability to act with dispatch during an emergency, or whenever there is a need to adjust or shift focus in response to how the research is proceeding.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

None Identified

**External**

None Identified

## NEI: AUDACIOUS GOALS INITIATIVE

### ISSUE SUMMARY

The Audacious Goals Initiative (AGI) for Regenerative Medicine is an effort by the National Eye Institute (NEI) to push the boundaries of vision science and restore vision through regeneration of the retina, the light-sensitive tissue in the back of the eye. Many leading causes of blindness in the U.S., like age-related macular degeneration (AMD), DR, and glaucoma, result from degeneration of retinal neurons in the eye. Without new therapies, these diseases are projected to increase during the next decade. Though some animals can regenerate lost retinal neurons, humans cannot. Despite recent advances in understanding vision disorders, effective therapies for many conditions are still lacking. By facilitating and catalyzing cross-disciplinary research, AGI is tackling the most devastating and difficult-to-treat eye diseases.

### KEY PROGRESS AND CHALLENGES TO DATE

AGI began in 2012 with the Audacious Goals Challenge, a prize competition that challenged participants to imagine the greatest achievement for vision research during the next 10-15 years. The Challenge attracted more than 450 innovative proposals from around the world. NEI consolidated the proposals into six broad themes, which were further explored by leading scientists at the Audacious Goals Development Meeting. In 2013, NEI announced the Audacious Goal of *"Regenerating neurons and neural connections in the eye and the visual system."* The goal builds on the understanding that many leading causes of blindness result from degeneration of neurons in the eye.

To date, AGI launched three key research consortia, representing 16 projects, and invested $62 million:

- The AGI Functional Imaging Consortium is addressing the technical needs and opportunities for imaging cells of the visual system as they respond to light.
- The AGI Regenerative Factor Discovery Consortium is identifying factors that control cell regeneration in the visual system.
- The AGI Translation-Enabling Models Consortium is developing animal models that have fidelity to human eye disease, a crucial step toward testing regenerative therapies in clinical trials.

NEI is leveraging other trans-NIH activities in order to lead the field of regenerative medicine. Vision researchers actively participate in the Brain Research through Advancing Innovative Neurotechnologies, short for BRAIN Initiative and the NIH Regenerative Medicine Innovation Project (RMIP). The BRAIN Initiative is developing next-generation tools and technologies to catalogue cells of the brain and central nervous system and map its circuitry. The RMIP program is providing funding for three clinical trial-enabling studies and two clinical trials to test regenerative therapies for vision disorders.

An AGI workshop, "Pathways for Retinal Cell Replacement Therapies," highlights NEI's latest efforts to bridge the gap of translating preclinical advances to clinical testing by bringing together academia, industry, and regulators. NEI anticipates that clinical trials of new regenerative strategies for eye disease will begin in the next few years, as the work of AGI-funded consortia converges. AGI sponsored activities are informing plans to build capacity for human studies.

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Steven Becker, Ph.D.** | Associate Director | steven.becker@nih.gov | NEI Office of Regenerative Medicine, AGI Lead |
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| **Michael Chiang** | Incoming NEI Director | | |
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| **Michael Steinmetz, Ph.D.** | Extramural Director | steinmem@nei.nih.gov | AGI WG |
| **Tom Greenwell, Ph.D.** | Program Director | Thomas.Greenwell@nih.gov | AGI WG |
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### External – AGI Steering Committee Members

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Clive Svendsen, Ph.D.** | Director, Professor- Cedars Sinai | clive.svendsen@cshs.org | Member |
| **Leonard Levin, M.S., M.A.** | Director, Professor- Harvard University | leonard.levin@mcgill.ca | Member |
| **Michael Dyer, Ph.D.** | Professor Emeritus- Stanford University | Michael.Dyer@stjude.org | Member |
| **Rachel Wong, Ph.D.** | Professor- University of Washington | wongr2@uw.edu | Member |
| **Russ Van Gelder, M.D., Ph.D.** | Director, Professor- University of Washington | russvg@uw.edu | Member |

## NEI: CLINICAL APPLICATION OF STEM CELLS

### ISSUE SUMMARY

Stem cell therapy holds the promise to repair, regenerate, and treat diseases and conditions that have limited therapeutic options. Vision research has been at the forefront of stem cell progress, including efforts to regenerate retinal tissue damage due to macular degeneration, a perennial target in regenerative medicine. Recently, human cell-based model systems have complemented animal models and are more adequate in reflecting human tissue, but the proliferation of these models have exposed certain gaps in how they are generated and used. NEI is assessing ongoing stem cell issues necessary to conduct successful ocular human clinical trials.

### KEY PROGRESS AND CHALLENGES TO DATE

NEI has taken important steps to capitalize on the development of stem cell technology, particularly in age-related macular degeneration (AMD), the leading cause of vision loss in older Americans. Following the 3rd Annual Stem Cell Meeting co-sponsored by the NEI and NIH Center for Regenerative Medicine in 2013, researchers began to address the translational potential of developing stem cell–based therapeutics through the diverse resources at the NIH. A group of NEI researchers were exploring cell-based therapies for retinal degenerative diseases using replacement tissue derived from reprogramming stem cells called induced pluripotent stem cells (iPSCs) in AMD patients. After years of work, NEI researchers recently launched the first clinical trial in the United States using replacement tissues from patient-derived iPSCs to treat certain forms of AMD.

The legacy of NEI's broad range of foundational AMD research provide valuable insights on disease characteristics, progression, and standards of patient care. However, research findings are not always connected with each other, which limits the ability to fully comprehend the bigger picture of the disease. In response to this need, NEI created the AMD Integrative Biology Initiative in partnership with the New York Stem Cell Foundation (NYSCF), which provides a widely available resource for the research community to access patient-derived cell lines and their associated genomic and clinical datasets. Researchers can share data with the community and also access consenting patients' deidentified genomic and ocular imaging data, allowing researchers to compare genetic, molecular, and clinical characteristics The initiative includes an external committee of experts in AMD and supports efforts to correlate genetic risk factors to deficiencies in cellular function and the clinical symptoms they cause, allowing researchers to develop new targeted therapies for the disease.

In addition to AMD, NEI funds research to advance the application of stem cell technologies in other eye diseases and eye conditions. For example, as part of an ongoing NEI clinical trial to increase the proliferative abilities of cell regeneration in patients, surgeons were recently able to replace damaged corneas, the transparent outermost layer of the eye, from four patients who experienced chemical burns by using stem cells derived from their healthy eye. This procedure, a first of its kind to occur in the United States, showed successful results and is considered a big step for regenerative medicine.

Despite these successes, several challenges still impact this area of research, such as regulating the clinical use of cell-based therapies and standardizing GMPs and shared transparent protocols. While cell-based therapies have the potential to treat many conditions, where present conventional treatments are inadequate, their regulation and clinical use has come under close scrutiny. There are unregulated stem cell clinics offering unproven therapies to patients under the guise of a clinical trial, although in many cases, patients are required to pay to participate in these trials. They provide

unproven and risky treatments for patients with a variety of diseases, injuries, and congenital defects. In December 2016, NEI convened a group of experts with the FDA and NIH to discuss the state of the science, progress, challenges, and the pathways necessary to translate the science and technology of stem cells to clinical trials for therapy, including the issues of unregulated stem cell clinics and standardizing best practices. During that time, the 21st Century Cures Act signed into law included a provision to protect patients from fake stem cell clinics. Since then, FDA has acted against these clinics by releasing articles and frameworks on increased enforcement of regulations and oversight, establishing permanent injunctions against fake clinics on the marketing of unregulated products, and targeting specific dishonest companies through federal action. There are also challenges related to manufacturing cell-based products, including microbiological contamination, loss of cell function, cell transformation malignancies, and more. Establishing best practices and optimal criteria, like a gold standard on how to convert stem cells into human retinal tissue prior to transplantation into humans, is important to ensure traceability, consistency, effectiveness, safety, and long-term cell survival. As a result, NEI researchers have developed current GMP guidelines and procedures on iPSC-derived cell types for transplantation.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Steven Becker, Ph.D.** | Associate Director | steven.becker@nih.gov | NEI Office of Regenerative Medicine |
| **Charles Wright, Ph.D.** | Program Officer | charles.wright@nih.gov | Division of Extramural Science Programs |
| **Kapil Bharti, Ph.D.** | Senior Investigator | kapil.bharti@nih.gov | NEI Ocular and Stem Cell Translational Research Section |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Elizabeth Schwarzbach, Ph.D.** | NYSCF- Chief Business Officer | eschwarzbach@NYSCF.org | Oversees collaborations and partnerships, expert in drug discovery and development |

# NEI: DATA SCIENCE AND ARTIFICIAL INTELLIGENCE IN VISION RESEARCH

## ISSUE SUMMARY

In the interdisciplinary world of data science, artificial intelligence (AI) approaches are rapidly advancing the biomedical field by revolutionizing methods to interpret large-scale research information. NIH has a history of encouraging data sharing such as creating policies for data management and sharing, and establishing the NIH Strategic Plan for Data Science.

Vision research has been in the forefront of utilizing this new technology. Data science is an ever-evolving field and challenges remain in optimizing data management and data sharing while preserving privacy and data security safeguards and ethical protections. NEI is laying the foundation for expanding work in this area to support key areas, such as capitalizing on new imaging technologies to detect the progression of diseases and complications, identifying biomarkers and patterns to predict the effectiveness of therapies, and collaborating with physical and computational sciences to engineer new technologies.

## KEY PROGRESS AND CHALLENGES TO DATE

NEI is involved with various facets of data science. Recognizing the need for a framework that allows researchers to understand the datasets available for sharing and collaboration, the NEI Data Commons provides vision researchers a central source of NEI-supported biomedical digital objects to promote scientific discovery, knowledge, reusability, quality, rigor and reproducibility, and FAIR (findable, accessible, interoperable, and reusable) compliance. The NEI Data Commons is housed on the NIH Biomedical Research Informatics Computing System, which also holds information from several clinical trials to allow for secondary data analysis and linking data across studies. Data varies according to study parameters and participant-informed consent for data sharing and usage. There are a wide variety of data collected, including genomics, gene expression data, protein structures, clinical data, images, data analysis tools, Common Data Elements, and Data Dictionaries. One featured data set is from the National Ophthalmic Disease Genotyping and Phenotyping Network (eyeGENE®), which is a genomic medicine initiative and public private partnership that includes a DNA repository, registry, and research database created by NEI for researchers to utilize to combine clinical testing and genetic information on inherited eye diseases. The eyeGENE® dataset includes clinical, genetic, and image data for 6,400 consented participants with rare inherited eye conditions. All of this data is linked to the participants' DNA samples. Controlled-access is granted to researchers with approved research projects and user and data sharing agreements are required. Another example includes EYE Integration, a bioinformatics workflow for integration of publicly available eye-related RNA-sequence datasets that includes basic statistics, visualization and source code, and clustering and weighted gene correlation networks. NEI researchers employed AI-technology to classify 60,000 retinal images and calculate risk factors for age-related macular degeneration (AMD) based on valuable data collected from large NEI studies, progressing opportunities to prevent the leading cause of vision loss in older Americans.

NEI offers hands-on opportunities in this exciting new subject matter category. NEI participated in the Code it Forward Civic Digital Fellowship by hosting fellows to build hands-on experience with biomedical data-related challenges. This program is training the next generation of computer scientists from diverse backgrounds by offering them the opportunity to apply their data skill sets to biomedical problems. Additional training and workforce development are needed to progress the development of this field.

NEI provides funding for research that supports the application of AI and machine learning technologies to improve the prevention and detection of various eye diseases. For example, IDx-DR, an FDA-approved AI diagnostic system partly built on NEI-supported research, analyzes retinal images to screen and detect diabetic retinopathy (DR). Additional research is needed to successfully apply this technology in practice among community-based settings.

Barriers related to 'big data' continue to be an issue for NEI and the biomedical research community, such as data protection and patient privacy to safeguard confidentiality, data infrastructure including the standardization of data collection, and the application of data security on telemedicine.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Kerry Goetz, M.S.** | Health Policy Analyst for Data Science and Health Informatics | goetzke@nei.nih.gov | Subject matter expert |
| **Paek Lee, Ph.D.** | Program Officer | paek.lee@nih.gov | Extramural Research liaison |
| **James Gao, Ph.D.** | Program Analyst | james.gao@nih.gov | Extramural Research liaison |

**External**

None Identified

## NHGRI: DIVERSITY IN THE GENOMICS WORKFORCE

### ISSUE SUMMARY

Genomic medicine, the application of genomic information and technologies within clinical practice, will be a powerful tool for clinicians in managing patient care; however, success will depend on a robust genomics workforce from bench to bedside. Congress has recently demonstrated interest in this workforce via a provision for the U.S. Government Accountability Office (GAO) to conduct a nationwide analysis of the medical genetics workforce. In July 2020, the agency released a report compiling data on the size and geographical distribution of providers of clinical genetic services.

Although the clinical workforce size and distribution are important, the promise of genomics cannot be fully achieved without successfully attracting, developing, and retaining a *diverse* research workforce that includes people from groups underrepresented in the genomics enterprise. The genomics workforce does not currently reflect the diversity of the United States population, which risks the effective and equitable realization of benefits from genomic and precision medicine approaches. Moreover, research has documented that a diverse scientific workforce is crucial for increasing innovation, creativity, and problem solving.

NHGRI is committed to leading and accelerating efforts to increase the number of individuals from underrepresented backgrounds in the field in order to build a genomics workforce that serves today's challenges and meets the needs of the future. In October 2020, NHGRI published a new Strategic Vision for the field of genomics, following a two-year period of strategic planning. As part of the development process, the Institute established an internal Genomic Diversity Working Group, charged with gathering stakeholder feedback and developing a ten-year *Diversity in the Genomics Workforce Strategic Plan*. This document details progress and challenges, along with short- and long-term goals, objectives, and implementation strategies to develop appropriate programs to address this urgent issue and yield a substantial increase in the diversity of the genomics workforce in the next decade.

### KEY PROGRESS TO DATE

The Institute has a history in supporting training programs that focus on increasing the diversity of the next generation of genomic researchers.

- The NHGRI Diversity Action Plan (DAP) program was established in 2002 and has been helpful in increasing the pool of underrepresented scientists who are prepared to pursue genomics-related careers. Since its inception, the DAP program has included over 1,400 participants across 20 projects.
- NHGRI participates in several extramural programs to promote diversity in the research workforce. A listing of all funding opportunities can be found on NHGRI's Funding to Promote Diversity in the Genomics Workforce website.
- NHGRI has also established informal science and education programs to facilitate the genomics training of secondary school teachers, community college staff, and Tribal College faculty.

### KEY CHALLENGES TO DATE

Barriers to diversity in the biomedical workforce exist at various stages of career progression. In addition, there is a general lack of data on individuals with disabilities. As described in the DAP *s*ome of the major challenges associated with increasing the diversity of the biomedical workforce include:

- Limited awareness of opportunities
- Inadequate mentoring

- Institutional bias (including in the grant review process)
- Lack of support for research topics that are relevant to underrepresented communities
- Inequitable hiring and promotion practices

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Vence L. Bonham Jr, J.D.** | Senior Advisor to the Director on Genomics and Health Disparities Associate Investigator, Social and Behavioral Research Branch | bonhamv@nih.gov | Chair of the NHGRI Working Group on Diversity in Genomics Workforce |
| **Luis Cubano, Ph.D.** | Program Director | luis.cubano@nih.gov | NHGRI Training and Career Development Program Lead |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Dana Crawford, Ph.D.** | Professor, Case Western Reserve University | dana.crawford@case.edu | Chair of the American Society of Human Genetics Diversity & Inclusion Task Force |
| **Maximilian Muenke, MD, FACMG** | American College of Medical Genetics and Genomics (ACMG) | n/a | CEO of ACMG, leading efforts to increase the clinical genomic workforce diversity |

## NHGRI: GENOMIC PRIVACY PROTECTIONS

### ISSUE SUMMARY

Privacy is an issue at the forefront of societal dialogue in areas ranging from financial security to healthcare. While this conversation is occurring, vast quantities of genomic data, and its connections to health information, are needed to understand the genomic underpinnings of health and disease. Although collecting genomic information into large datasets enables our ability to advance science, it can also consolidate intimate biological information about individuals as well as large groups of people. The promise of genomic medicine requires that NIH, and the research community at large, remain vigilant regarding data security and confidentiality practices.

Federal regulations, such as the Genetic Information Nondiscrimination Act (GINA), the Health Information Portability and Accountability Act (HIPAA), and the Federal Policy for the Protection of Human Subjects (known as the "Common Rule"), set standards and expectations for protecting patients' and research participants' genomic and private health information. Therefore, privacy coverage often depends on specific scenarios. As more genomic information is being collected outside research and health care enterprises, there are more and more questions about the adequacy of protection of genomic information in these emerging contexts. There is growing interest in the regulation of direct-to-consumer genetic testing companies to ensure that they manage and protect the data that they accumulate on customers. In the law enforcement realm, it is important to consider whether it is appropriate to use genetic information available in various online databases to solve cold cases.

Research participants, and increasingly patients, volunteer to provide their personal health information and their unique genomic data to advance medical science. If NHGRI, NIH, and the broader genomics community are to maintain the public's trust and willingness to fuel genomic innovations through their research participation, it is incumbent upon us to keep genomic privacy concerns and the development of creative solutions to address them, among our highest priorities.

### KEY PROGRESS TO DATE

NHGRI is in a unique position to provide leadership in the genomic privacy space due to its diverse portfolio of quantitative and qualitative projects on the research questions related to genomic privacy.

- NHGRI has an ongoing interest in funding research to inform and enhance policies and develop new tools to promote the protection of research participants' genomic data. For example, the SAFEGENOMES study is a computational research project that analyzes privacy risks, in realistic attack models, to develop privacy methods that balance individual privacy and research utility. In addition, the Genetic Privacy and Identity in Community Settings (GetPreCiSe) project uses a multi-disciplinary approach to analyze legal and social notions of genetic privacy and identity, as well as engineer and evaluate new technologies.
- NHGRI is a leader within and beyond NIH on policy approaches to promote a balance between protecting research participant privacy interests and facilitating broad data sharing to support research advances. NHGRI's expectations build upon the NIH Genomic Data Sharing Policy's expectations and aim to both foster trust with research participants and expand the amount and quality of genomic data available to researchers.

### KEY CHALLENGES TO DATE

- Autonomy of Genomic Use Decisions: Since DNA is inherited from and shared with one's family members, there is an ethical question around, "Is one's genomic data ever entirely fully theirs to

give informed consent for sharing?" This issue was recently brought to renewed attention by the capture of the Golden State Killer, in which DNA from past crime scenes was a familial match to individuals who had publicly posted their genome data on an ancestry sharing platform.

- Identifiability: It is debated whether DNA data can ever really be 100% de-identified, as it is a code unique to an individual. Since 2008, several studies have been published investigating the ability to "re-identify" genomic data (e.g., Homer et. al., Schadt, et. al., Gymrek et. al., etc.). Under current regulations, genomic data absent other personally identifying information is considered de-identified. This debate is continually evolving, demonstrated by the 2018 revised Common Rule's call for reexamination of the definitions of "identifiable private information" and "identifiable biospecimen" within one year of implementation, and at least every four years thereafter.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Heidi Sofia, Ph.D.** | Program Director, Division of Genomic Medicine | sofiahj@mail.nih.gov | n/a |
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**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Laura Lyman Rodriguez, Ph.D.** | Interim Chief Program Support Officer and a Senior Advisor to the Executive Director at the Patient-Centered Outcomes Research Institute (PCORI) | https://www.pcori.org/people/laura-lyman-rodriguez-phd | n/a |
| **Bradley Malin, Ph.D.** | Vice Chair for Research and Professor of Biomedical Informatics at Vanderbilt University | bradley.malin@vumc.org | n/a |
| **Dixie Baker, Ph.D.** | Senior Partner with Martin, Blanck & Associates | dixie.baker@martin-blanck.com | n/a |

## NHLBI: RISKS OF VAPING: E-CIGARETTE/VAPING ASSOCIATED LUNG INJURY AND OTHER HEALTH OUTCOMES

### ISSUE SUMMARY

Electronic cigarettes (e-cigs) and other vaping products are the most commonly used form of nicotine among youth and young adults. Their easy availability, alluring advertisements, various e-liquid flavors, and the belief that they are safer than cigarettes have helped make them appealing. Early evidence suggests that vaping may be a gateway to conventional cigarettes, which are known to increase the risk of cancer, heart disease, and lung disease. The number of middle and high school students vaping nicotine and/or marijuana rose sharply from 2018-2019 (e.g., 1.4 million reported vaping in 2018 vs. 5 million in 2019). The long-term health effects of vaping on the lungs, heart, and other organs are largely unknown.

The acute risks from vaping became dramatically evident with an outbreak of e-cig/vaping-associated lung injury (EVALI) in March 2019. By the time the outbreak tapered in February 2020, CDC reported 2,807 hospitalized cases and 68 deaths. Many of these cases were associated with vaping a combination of tetrahydrocannabinol (THC), the psychoactive ingredient in marijuana, and vitamin E acetate, a "cutting agent" used to dilute THC while making it appear concentrated. Moreover, NHLBI-funded research shows that e-cig vapor containing vitamin E acetate causes acute lung damage in mice.

### KEY PROGRESS TO DATE

Even before the first reports of EVALI, NHLBI had begun to invest in research to better understand the health repercussions of vaping. For example, NHLBI-supported studies have found that:

- Just one vaping session—even without nicotine—can produce acute stiffening in the blood vessels of healthy nonsmokers.
- Regular vaping may prime the lungs for chronic disease by altering basic biological signals that control tissue maintenance and remodeling.
- Chronic e-cig exposure can adversely change the physiology of lung epithelial cells and compromise immune defenses again lung infection.

In October 2019, soon after the first EVALI cases were reported, NHLBI convened a workshop of researchers, clinicians, and representatives of FDA, CDC and NIH to identify the most urgent research questions related to EVALI.

In November 2019, NHLBI worked with other NIH Institutes/Centers to develop a notice of special interest (NOSI) inviting NIH-funded researchers to apply for additional funding to study vaping-related illness. As of September 2020, NIH has made 38 awards through this NOSI.

Also, in 2019, NHLBI launched two epidemiological studies to examine risk factors for cardiopulmonary disease, which are expected to help reveal long-term effects of vaping:

- The Lung Health Cohort will follow 4,000 healthy young adults (age 25-35); and
- The Risk Underlying Rural Areas Longitudinal (RURAL) Cohort will follow 4,000 young to middle-aged adults (age 25-64) in 10 rural counties in the Southeast.

### KEY CHALLENGES

Research on the health effects of vaping is complicated by:

- Lack of access to and, hence, testing of THC liquids used in vaping;

- Difficulty keeping pace with rapidly evolving e-cig products, vaping behaviors, and use patterns;
- Lack of data on vaping practices and behaviors, and how they affect disease risk;
- Difficulty testing commonly used devices/liquids and practices in animal models to mimic use patterns among vapers; and
- Lack of knowledge/standard measures for health outcomes from e-cig use, with over-reliance on health outcomes from conventional cigarette use

**NEXT STEPS**

(b) (5)

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**RELEVANT STAKEHOLDERS**

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **James Kiley, Ph.D.** | Director, Division of Lung Diseases, NHLBI | kileyj@nhlbi.nih.gov | Leads NIH research on chronic lung disease |
| **Heather Kimmel, Ph.D.** | Director, Population Assessment of Tobacco and Health (PATH) Study, NIDA | heather.kimmel@nih.gov | n/a |
| **Rachel Grana Mayne, Ph.D., M.P.H.** | Program Director, Tobacco Control Research Branch, NCI | rachel.mayne@nih.gov | n/a |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Nancy Brown** | CEO, American Heart Association | NBrown@heart.org | n/a |
| **Harold Wimmer, M.S.** | President and CEO, American Heart Association | Harold.Wimmer@lung.org | n/a |
| **Iilun Murphy, M.D.** | Deputy Director, Clinical and Regulatory Affairs, Office of Generic Drugs, CDER, FDA | Iilun.Murphy@fda.hhs.gov | n/a |

## NHLBI: RESEARCH TO ADDRESS CHRONIC DISEASE, WITH EMPHASIS ON UNDERSERVED POPULATIONS

### ISSUE SUMMARY

In the United States, chronic diseases are the main causes of poor health, disability, and death, and account for the majority of health-care expenditures. Chronic diseases and conditions, such as heart disease, hypertension, and chronic respiratory diseases are among the most common, costly ($3.5 trillion in annual heath care costs**),** and preventable of all health conditions, with heart disease being the leading cause of death in this country for both men and women. NIH-supported research has identified key modifiable risk factors that contribute to the chronic disease burden in the U.S. Yet, a high burden of chronic disease persists among racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities. Social determinants of health, including lack of access to quality affordable health care and low health literacy, contribute to these disparities in chronic disease.

The NIH is committed to supporting research to understand and ameliorate the causes and consequences of chronic diseases for all Americans, especially in minority and other underserved populations who are disproportionately affected.

### KEY PROGRESS TO DATE

Supporting Diverse Cohort Studies and Engaging Communities to Address Chronic Diseases. The NHLBI has a long history of investing in epidemiological studies to identify risk factors, understand mechanisms, and develop intervention strategies for chronic disease. The landmark multi-generational Framingham Heart Study has identified key cardiovascular risk factors and has evolved to explore more complex risk factors including genetics and epigenetics.

- The Jackson Heart Study is the Nation's largest study of CVD in African Americans.
- The Strong Heart Study is the largest, longest running study of heart disease in American Indians.
- The Multiethnic Study of Atherosclerosis study is looking at risk factors for CVD in more than 6000 adults from six diverse regions of the country.
- The Risk Underlying Rural Areas Longitudinal (RURAL) cohort study was established in 2019 to help address the high burden of chronic disease in America's heartland.
- The Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHeR) targets communities with a high burden of chronic heart and lung disease.

**Strategically Addressing Chronic Diseases.**

- Several objectives within the current NHLBI Strategic Vision are focused on investigating factors that account for differences in health among populations and working to optimize clinical and implementation research to improve health and reduce disease.
- To address high rates of COPD, at the request of Congress and with input from the broad COPD community, NHLBI has led development and implementation of the 2017 COPD National Action Plan – the blueprint for a multifaceted unified fight against COPD. Initial focus has been working with HRSA and others to address rural communities, where COPD rates are twice as high.
- NHLBI established a dedicated Center for Translation Research and Implementation Science to focus on working with communities to move evidence-based interventions into practice and address health disparities.

- The NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities, established in Sept. 2020, will address COVID-19 disparities by creating an inclusive network to conduct community-based research, to raise awareness about COVID-19 correct misinformation, and to promote inclusion of diverse racial and ethnic groups in clinical trials.

## KEY CHALLENGES TO DATE

- The need for a life-span approach to address health before chronic health problems develop.
- Limited effective multi-level interventions to reduce health disparities and chronic disease.
- Low recruitment and retention of racial and ethnic minorities into clinical studies.
- Lack of standard methods and measurements for evaluating interventions to improve minority health and reduce health disparities.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Gary H. Gibbons, M.D.** | Director, NHLBI | gary.gibbons@nih.gov | Leads the third largest NIH Institute and many trans-NIH efforts related to chronic diseases involving heart, lung, blood, and sleep disorders. |
| **Eliseo Pérez-Stable, M.D.** | Director, NIMHD | Eliseo.perez-stable@nih.gov | Leads scientific research to improve minority health and reduce health disparities |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H.** | Deputy Assistant Secretary for Minority Health, OMH | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations |
| **Jessica Seyfried, M.P.H., M.S.W.** | Director, National Minority Cardiovascular Health Alliance | Jessica@makewellknown.org | Stakeholder group focused on addressing CVH within minority populations |

## NHLBI: CARDIOVASCULAR DISEASE AND MATERNAL HEALTH

### ISSUE SUMMARY

Each year in the U.S., an estimated 700 women die from complications related to pregnancy and more than 50,000 experience severe morbidity. Most cases of maternal morbidity and mortality (MMM) are preventable and related to underlying heart, lung, blood, and sleep conditions. Cardiovascular disease (CVD) is the leading cause of pregnancy-related deaths, accounting for more than one-third of such deaths annually. Women from demographic groups with a disproportionate burden of CVD are also at higher risk for MMM. Rates of pregnancy-related death are 3-4 times higher in Black women, and 2.5 times higher in American Indian/Alaska Native women, compared to white women. The high rate of MMM in the U.S., higher than any other developed nation, may be a wake-up call signaling poor CVH among reproductive-age American women generally. NHLBI thus supports research toward preventing or managing cardiovascular risk factors and CVD across a woman's entire lifespan. This includes observational studies to understand risk factors for MMM, clinical trials to explore interventions, and implementation science to bring proven interventions into practice, especially in minority and rural populations.

### KEY PROGRESS TO DATE

- CVD risks after pregnancy: The nuMoM2b Heart Health Study. The study has enrolled a diverse cohort of women during their first pregnancy and aims to define the relationship between adverse pregnancy outcomes and later CVD.
- Sleep: The nuMoM2b Sleep Disordered Breathing (SDB) study found that nearly 10% of women develop SDB by mid-pregnancy. Women with SDB have a higher risk of incident maternal CVD, as well as gestational diabetes. An ongoing phase 3 clinical trial is now investigating whether treating SDB with continuous positive airway pressure (CPAP) can reduce the risk of these cardiovascular conditions.
- Overweight/obesity: The LIFE-Moms study, which compared usual standard prenatal care to lifestyle interventions that started during pregnancy and found that these interventions helped women avoid post-partum weight gain**.**
- Hypertension: The Chronic Hypertension and Pregnancy (CHAP) Trial is evaluating treatment of pregnant women with mild high blood pressure toward the target recommended for all reproductive-age adults.
- Pre-eclampsia: The PREP trial is comparing a cholesterol-lowering drug (pravastatin) to placebo in pregnant women at high risk for recurrent preeclampsia.
- Blood clotting: Women face a higher risk of life-threatening blood clots (thrombosis) during pregnancy and within the first several weeks after delivery. A program launched in 2017 aims to improve understanding and treatment of thrombosis in reproductive-age women.

### KEY CHALLENGES TO DATE

- Complex cultural and social trends play a role in rising rates of MMM. For example, higher numbers of women are giving birth later in life, entering pregnancy with one or more chronic medical conditions, and are having more C-sections than in the past.
- Disparities in MMM have been tied to social determinants of health (SDoH), including lack of access to high quality care, as well as structural and interpersonal racism/bias toward women of color.
- There are vastly more cases of severe maternal morbidity than mortality, but there is a lack of precise, standard measures and tools to collect morbidity data.

- Pregnant women are often not included in clinical trials, particularly those involving medications; there is a lack of data and consensus regarding how to perform such trials safely.
- Health outcomes and risk factors for mothers age 18 and under are not well studied.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Gary H. Gibbons, M.D.** | Director, NHLBI | gary.gibbons@nih.gov | Leads NIH efforts related to chronic heart, lung, blood, and sleep disorders. |
| **Diana Bianchi, M.D.** | Director, NICHD | diana.bianchi@nih.gov | Leads institute focused on healthy child development and healthy pregnancies. |
| **Diana Bianchi, M.D.**<br>**Janine Clayton, M.D.**<br>**Tara Schwetz, Ph.D.** | Director, NICHD<br>Director, ORWH<br>Assoc. Dep. Director, NIH | diana.bianchi@nih.gov<br>janine.clatyon@nih.gov<br>tara.schwetz@nin.gov | Co-chairs, Trans-NIH Task Force on Maternal Morbidity and Mortality |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Dorothy Fink, M.D.** | Deputy Assistant Sec for Women's Health, Director, Office on Women's Health, HHS | dorothy.fink@hhs.gov | Leads HHS Maternal Health Working Group |

## NIA: ALZHEIMER'S DISEASE AND RELATED DEMENTIAS

### ISSUE SUMMARY

Alzheimer's disease (AD) is a progressive, and at present, irreversible brain disease that slowly destroys memory and thinking skills, and eventually even the ability to carry out the simplest tasks of daily living. Several other dementias, including frontotemporal dementia, Lewy body dementia, and vascular cognitive impairment/dementia, are considered Alzheimer's disease-related dementias (ADRD) and share some biological and clinical features of AD. The physical, emotional, and financial toll that AD/ADRD exacts on family, caregivers, and friends is significant. Although drugs for the symptomatic improvement of AD have been approved by FDA, no interventions to prevent the disease or reverse the disease process have been validated in clinical testing, despite decades of investment in clinical trials.

In January 2011, President Barack Obama signed the National Alzheimer's Project Act (NAPA; P.L. 111–375), which called for an aggressive and coordinated national plan to attack AD/ADRD and improve care and services for affected individuals and their families. NAPA also called for the development of an Advisory Council on Alzheimer's Research, Care, and Services; this Council first met in September 2011, and it includes researchers, clinicians, state-based representatives, advocates, people with AD/ADRD and caregivers. It also includes multiple non-voting Federal representatives. The Council advises the HHS Secretary and makes recommendations for the annual update of a National Plan to Address Alzheimer's Disease. This National Plan outlines five goals and is updated each year; the first of these goals is the most relevant to the NIH: "Preventing and effectively treating Alzheimer's by 2025." Other goals focus on AD/ADRD supports, services, public awareness, and evaluation.

### KEY PROGRESS TO DATE

Since FY 2012, funding levels for AD/ADRD research have been on the rise. NIH redirected funds from other programs by $50 million in FY 2012 and $40 million in FY 2013 to support promising AD/ADRD research. Since that time, NIA has received extensive additional congressional appropriations. Overall, NIH spending on AD/ADRD research increased nearly 4.5-fold from FY 2015 ($631 million) to FY 2020 (an estimated $2.818 billion). NIH, led by the NIA, and with substantial scientific collaboration with NINDS, has reported its progress each year as part of the National Plan updates. A series of detailed Research Implementation Milestones drives programmatic investments that have contributed to the overarching National Plan effort.

Progress is also reported to policymakers as part of the Alzheimer's Disease and Related Dementias Bypass Budget (ADBB). In 2014, the President signed the FY 2015 Appropriations Act, which for the first time required NIH to produce "an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the NIH pursuant to the National Alzheimer's Plan" to be submitted to the President (to send to Congress) on an annual basis. NIH – led by the NIA but in collaboration with NINDS and reflecting contributions of multiple other NIH ICs – has since released six such ADBBs, based on the Implementation Milestones noted above, as well as the expertise of NIH program staff in research planning and implementation. Each ADBB includes both an estimate for new and total funds needed for AD/ADRD research, as well as a detailed progress report of the NIH's scientific accomplishments.

### KEY CHALLENGES TO DATE

Funding has been generous in this disease area, and the scientific progress has been substantial. However, the field is complex, and no singular "cure" or treatments are yet available. The 2025 goal

outlined in the National Alzheimer's Project Act is growing closer and it is not clear how this goal, and the Congressional mandate to produce an ADBB through 2025, will be handled by Congress when that deadline has passed.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Helen Lamont, Ph.D.** | Policy Analyst, HHS Office of the Assistant Secretary for Planning and Evaluation | Helen.Lamont@hhs.gov | Designated Federal Official for the Advisory Committee on Alzheimer's Research, Care and Services for the Secretary, HHS |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **House/Senate LHHS Appropriations Subcommittees** | n/a | n/a | Has a deep interest in progress in AD/ADRD research |
| **Senate Special Committee on Aging** | n/a | n/a | Has a deep interest in progress in AD/ADRD research |
| **Maria Carrillo, Ph.D.** | Chief Science Officer, Alzheimer's Association | mcarrillo@alz.org | Key leader in a prominent non-governmental organization |
| **George Vradenburg, J.D.** | Chairman and Co-founder, UsAgainstAlzheimer's | vradenburg@aol.com | Key leader in a prominent non-governmental organization |

## NIA: GEROSCIENCE

### ISSUE SUMMARY

Aging is the major risk factor for chronic diseases and frailty in people over the age of 55. The biology of aging examines the molecular features underlying regulation of lifespan and that cause frailty with advancing age. Geroscience is a separate field of study that specifically aims to understand what about the biology of aging makes it the major risk factor for chronic disease and frailty in older adults. It brings together three areas of medicine: the biology of *aging;* the biology of *disease;* and the physiology of functional decline (*frailty*). Researchers in the field hypothesize that slowing the rate of aging will have a beneficial impact on the health of older adults by delaying the onset or reducing the severity of most chronic diseases and frailty, i.e., improving health at older ages.

As indicated above, geroscience uses health as an outcome, rather than lifespan. Population data suggest that life expectancies of the human population have been increasing over the last century but gains in overall health have been harder to achieve despite significant gains fighting individual diseases. Research on the biology of aging continues to be the foundation of geroscience, based on the key observation that increased lifespan in laboratory animals is paired with increased vigor at older ages. This pairing is taken as a "slower rate of aging." Because findings from basic biology have shown that the molecular mechanisms of aging are conserved, the potential to translate these findings to humans has drawn attention of the biotechnology sector to develop therapeutics for geroscience (anti-aging therapies). Achieving the goal of geroscience – to improve overall health as we live longer – seems increasingly likely. Furthermore, geroscience has begun to play a significant role in response to the COVID-19 pandemic, because of the apparent linkage between frailty and comorbidities and severity of infections and outcomes, including the impact of older age. In the day-to-day practice of medicine, and in responses to emergency situations, geroscience is becoming a key field that spans basic research to clinically useful interventions and is generating intensive engagement from biotechnology.

### KEY PROGRESS TO DATE

NIH GeroScience Interest Group (GSIG): By developing a collaborative framework that includes several NIH Institutes with an interest in the biological mechanisms that drive the appearance of multiple chronic diseases of older adults, the GeroScience Interest Group (GSIG) aims to accelerate and coordinate efforts to promote further discoveries on the common risks and mechanisms behind such diseases. By pooling resources and expertise, the GSIG identifies major cross-cutting areas of research and proposes coordinated approaches to identify hurdles and envision solutions. To assist scientists interested in solving the health problems of our burgeoning population of older adults, the GSIG encourages the development of new tools, models and paradigms that address the basic biological underpinnings of multiple diseases within the context of aging. NIH has made several awards in response to the most recent GSIG request for applications, in some cases via co-funding with other NIH Institutes.

Geroscience Summits: Since the fall of 2013, the NIH has held three large research summits focused on geroscience – to expand the interest in this area of research and to foster collaborations. The most recent of these meetings, *Targeting Chronic Diseases Through Geroscience*, was held in fall 2019 and provided a forum for novel interactions between disease-focused professional societies and foundations, and the community of researchers and practitioners of geroscience. The aim of the Summit was to draw the attention of researchers and professional societies focused on specific age-related diseases to the emerging field of geroscience and its potential role in combating those diseases.

The Summit also included a forum to introduce the rapidly expanding interest from biotechnology in finding anti-aging therapeutics.

## KEY CHALLENGES TO DATE

As noted above, the GSIG was formed to accelerate research efforts around geroscience – to this end, it has been a productive internal collaboration and interest in research on geroscience is increasing. Some stakeholders in the field (including some attendees at the most recent NIH geroscience summit) believe, however, that further government-led policy actions are warranted in geroscience, to align its importance at the federal level with that of some highly prevalent medical conditions, e.g., Alzheimer's disease. As one example, the American Federation for Aging Research cites on their website:
[t]he current approach to biomedical research is to study and treat diseases separately. Geroscience transforms the "one disease at a time model", most recently illustrated by the Cancer Moonshot and congressional funding for Alzheimer's Disease. Counterintuitively, this approach has played a role in the current increase in multimorbidity and decrease in health among the elderly. Research on aging biology is not as robustly developed as research on specific diseases. In addition to more funding, a detailed plan akin to the National Alzheimer's Project Act (NAPA) needs to be developed for Geroscience. This will require consultation with multiple constituents.
As part of the Executive Branch, NIA has been careful not to take a position on these advocacy efforts; however, if legislation at any point mandated a federal-level effort in geroscience, NIA would comply with the mandate.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

None Identified

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Sue Peschin, M.H.S.** | President and CEO, Alliance for Aging Research | speschin@agingresearch.org | Has encouraged discussions between NIA and pharmaceutical companies around the topic of geroscience. |
| **Stephanie Lederman, Ed.M.** | Executive Director, American Federation for Aging Research | stephanie@afar.org | AFAR advocates for national-level planning/policy for geroscience. |

## NIAID: ANTIMICROBIAL RESISTANCE

### ISSUE SUMMARY

Antibiotics save countless lives, but bacteria can mutate to resist antibiotics' intended effects. According to the CDC, 2.8 million people in the United States become infected with antibiotic resistant bacteria or fungi each year, and 35,000 people die as a result. With the emergence of antibiotic resistance in bacteria, the choices for treating many bacterial infections are becoming increasingly limited, expensive, and, in some cases, nonexistent. Combating antibiotic resistance is an NIH research priority, and NIAID plays a lead role in the Government's research efforts. The NIAID research portfolio encompasses studies ranging from basic to clinical research in an aggressive program to better understand antimicrobial resistance (AMR) mechanisms and develop new and effective treatment strategies. These efforts include research to develop novel therapies and treatment regimens that are less likely than typical antibiotics to result in resistance, as well as strategies to preserve the effectiveness of existing antibiotics.

### KEY PROGRESS TO DATE

Through solicited funding opportunities, NIAID continues to spur innovative research focused on better understanding the nature of microbial communities, how antibiotics affect them, and how they can be harnessed to prevent disease.

- A recent study completed in mice characterized the molecule CD47 as a "brake" in the immune response by preventing the overactivation of immune cells called macrophages. Researchers showed that several different infections lead to the upregulation of CD47, which slows the resulting immune response to clear the pathogen. By blocking the signaling activity of this molecule, the mice were able to clear the infection quicker. Results from this study provide a potential target for new immunotherapies to combat a wide range of infections.
- An additional mouse study provided valuable insight into the mechanism by which "good" bacteria found in probiotic digestive supplements thwart the growth of *Staphylococcus aureus*, a bacterium that can cause severe antibiotic-resistant infections. As a next step, NIAID researchers plan to test whether a simple oral probiotic regimen can lead to a reduction in methicillin-resistant S*taphylococcus aureus* (MRSA) infection rates in hospitals.

NIAID recently renewed the Antibacterial Resistance Leadership Group (ARLG), an innovative global consortium that leads a comprehensive clinical research network focused on developing better countermeasures against antibiotic-resistant bacteria. ARLG also supports the discovery of improved diagnostic tests to identify antibiotic-resistant microbes and promotes studies to optimize the use of existing antibiotics. A recent ARLG clinical study showed that a rapid antibiotic susceptibility testing method enabled markedly faster adjustments in antibiotic therapy for bloodstream infections with Gram-negative bacteria such as *E. coli* when compared to conventional testing. Such tests could help physicians provide timely, effective therapy, while supporting antibiotic stewardship to mitigate the development of AMR.

Household contacts of individuals infected with multidrug resistant tuberculosis (MDR-TB) are at high risk for also becoming infected, therefore prevention strategies are critical to safeguard their health. NIAID recently launched a large clinical trial to assess whether the new tuberculosis drug delamanid is safe and effective in preventing active MDR-TB disease in children, adolescents, and adults who are exposed to an adult household member with MDR-TB. Results from this study may have a significant impact on reducing the global burden of MDR-TB.

## KEY CHALLENGES TO DATE

The available arsenal of antibiotics is increasingly inadequate to meet the needs of patients with often-deadly, debilitating, and costly antibiotic-resistant infections. Few pharmaceutical companies are developing new antibiotics because such efforts are costly with uncertain economic reward. NIAID conducts and supports basic research that informs the development of new antibiotics to enter into the pre-clinical pipeline for testing.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Dennis Dixon, Ph.D.**<br><br>**Jane Knisely, Ph.D.** | n/a | dmdixon@niaid.nih.gov<br><br>kniselyj@niaid.nih.gov | Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (CARB) Coordinates AMR activities across the federal government |
| **Dennis Dixon, Ph.D.**<br><br>**Jane Knisely, Ph.D.** | n/a | dmdixon@niaid.nih.gov<br><br>kniselyj@niaid.nih.gov | HHS Combating Antibiotic-Resistant Bacteria (CARB) National Database of Resistant Pathogens Implementation Working Group |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **CARB-X (Combating Antibiotic Resistant Bacteria)** | n/a | https://carb-x.org/ | Funder |

## NIAID: FOOD ALLERGY DIAGNOSIS, TREATMENT, AND PREVENTION

### ISSUE SUMMARY

According to recent population studies, food allergy affects approximately 11% of adults and 8% of children in the United States, and many people are allergic to more than one food. Food allergy results from an abnormal immune response to a component of a food. Symptoms can range from mild to severe, and in rare cases, can be life-threatening. Furthermore, avoiding food allergens can be challenging, and accidental exposures are difficult to circumvent. As the lead institute at the NIH responsible for food allergy research, NIAID conducts and supports a comprehensive portfolio of research which spans from foundational science to clinical studies for the diagnosis, prevention, and treatment of food allergies. Active engagement with the scientific community to promote interest and participation in NIAID food allergy research opportunities, both solicited and unsolicited, has led to a marked expansion in research capacity in this area.

### KEY PROGRESS TO DATE

NIAID has made substantial investments to establish research networks that focus on all aspects of food allergy, including clinical trials to test new treatment strategies.

The Consortium for Food Allergy Research (CoFAR) aims to characterize the underlying mechanisms in the development of food allergy, identify the genetic components associated with food allergy, and develop immune intervention strategies for treatment. CoFAR is currently evaluating various forms of immunotherapy for peanut and multiple food allergies.

The Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Immunotherapy in Food Allergic Children and Adults, or OUtMATCH study, was recently launched. This large Phase 3 clinical trial is testing whether the drug omalizumab (Xolair), either alone or with multi-allergen oral immunotherapy, can increase a person's ability to tolerate multiple foods to which they are allergic.

NIAID is investing in research to reduce the risk of developing food allergy and to treat those who are already affected. Results from a pivotal clinical trial led by the Immune Tolerance Network (ITN) called the Learning Early About Peanut Allergy (LEAP) study suggested that early exposure of peanut-containing foods in children can prevent the development of peanut allergy and resulted in changes in clinical practice, as outlined in the *Addendum Guidelines for the Prevention of Peanut Allergy in the United States.* The ITN is conducting a long-term follow-up study on the participants of the LEAP trial to establish the lasting effects of early consumption on the development of food allergy.

The pursuit of accurate diagnostics to identify specific foods that individuals are allergic to is a critical need to ensure patient health. In particular, sesame allergies often lead to severe reactions in children, but are difficult to identify using standard allergy tests. Using data from antibody tests in children combined with oral food challenges, NIAID scientists developed a mathematical model to predict the probability that a child with food allergy is also allergic to sesame. Further studies to validate the model will be pursued before it can eventually be applied to clinical practice, which will allow doctors to better guide treatment for children with multiple food allergies.

Another active area of diagnostic development is in atopic dermatitis and food allergy. These two conditions are highly associated, and the development of more accurate diagnostic tools could significantly affect treatment and prevention strategies. Atopic dermatitis is an immune disorder that

causes red, itchy skin and is associated with higher risk for the development of food allergies. Unfortunately, some food allergy tests are less accurate in individuals with atopic dermatitis. A new study to evaluate threshold levels of IgE, an allergic antibody, in blood samples of people with atopic dermatitis that could indicate an allergy to milk or peanut was recently initiated and holds promise for diagnosis in this population.

## KEY CHALLENGES TO DATE

Accurate diagnosis of specific food allergies and development of novel treatments are vital to the reduction in the public health burden associated with accidental exposure to allergens and clinical management of patients. A steady stream of funding for food allergy research is necessary to ensure the rapid advancement of fundamental knowledge and public health interventions, such as prevention and therapeutic strategies, to dampen the increasing incidence of food allergy in the United States.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Alkis Togias, M.D.** | Branch Chief, Allergy, Asthma, and Airway Biology Branch | Alkis.togias@niaid.nih.gov | Provides key oversight of all NIAID extramural research focused on food allergy |
| **Lisa Wheatley, M.D., M.P.H.** | Section Chief, Food Allergy, Atopic Dermatitis, and Allergic Mechanisms Section | Lisa.wheatley@nih.gov | Provides key oversight of all NIAID extramural research focused on food allergy |
| **Dean Metcalfe, M.D.** | Senior Investigator, Laboratory of Allergic Diseases | dmetcalfe@niaid.nih.gov | Oversees a portfolio of research focused on allergic mechanisms |

**External**

None identified

## NIAID: SEXUALLY TRANSMITTED INFECTIONS

### ISSUE SUMMARY

Sexually transmitted infections (STIs) are a global public health challenge, with one million new cases of gonorrhea, syphilis, chlamydia, and trichomoniasis diagnosed each day worldwide. Left untreated, STIs can result in serious health complications and often increase the risk of HIV transmission and acquisition. Moreover, increasing antimicrobial resistance (AMR) will make STIs more difficult to treat as existing drugs become less effective. NIAID supports a wide range of research focused on STIs, from basic research on the growth, pathogenesis, structure, and evolution of pathogens responsible for sexually transmitted infections to clinical research to test novel medical countermeasures to combat these infections. Given the surge in global STI rates, NIAID is refocusing its research programs dedicated to the development of innovative diagnostics, safe and effective vaccines, and new and improved therapeutics.

### KEY PROGRESS TO DATE

To advance research towards the generation of safe and effective vaccines, NIAID established a collaborative network of multidisciplinary researchers focused on the development of vaccine candidates for syphilis, gonorrhea, and chlamydia. By the end of this program, each of the awardees in this network is expected to have identified at least one vaccine candidate to enter into the pipeline for ultimate testing in clinical trials.

To shorten the pathway to the identification of safe and effective countermeasures against STIs, NIAID is placing a priority on testing drugs and vaccines that have already been approved by the FDA for other indications. Clinical trials in high-risk populations are critical to confirm the effectiveness of new interventions. There have been alarming increases in gonorrhea and syphilis in bisexual men and men who have sex with men, two key groups also at risk for human immunodeficiency virus (HIV). NIAID has initiated a Phase 4 clinical trial to evaluate the safety and impact of oral doxycycline, an antibiotic already approved by the FDA for other indications, compared with standard of care when taken as soon as possible after sexual contact without a condom. This study will examine the incidence of STIs in the participants and will determine the rate of doxycycline resistance in both STIs and commensal bacteria. Results from this clinical trial have implications for potential STI preventative measures in high-risk individuals. Additionally, this fall, NIAID is launching a Phase 2 trial of the licensed meningococcal Group B vaccine, Bexsero, to explore efficacy against gonorrhea in disproportionately vulnerable men and women.

The rapid emergence of drug-resistant *Neisseria gonorrhoeae* has made new research and development efforts a high priority. Uncomplicated gonorrhea, which does not result in bacteremia and spread to the joints and tissues, has become very common and requires new treatments to manage the spread of disease. NIAID recently completed a Phase 2 clinical trial to investigate a new drug candidate called zoliflodacin, or AZD0914. This drug was found to be safe and effective in treating uncomplicated gonorrhea and is now undergoing further testing in a large, multicenter Phase 3 clinical trial sponsored by the Global Antibiotic Research and Development Partnership.

### KEY CHALLENGES TO DATE

The incidence of STIs is rapidly increasing, making them a global health concern. A renewed focus of biomedical research programs to combat this increase through the development of medical countermeasures is required to promote innovative approaches to outpace the emergence of AMR in

these infections. Collaborations between government agencies, academia, private sector, and community healthcare providers are vital to the successful implementation of resulting interventions. As such, NIAID participated in the development of the *HHS National Strategic Plan on STIs*, which involved 20 federal agencies and offices with input from the public.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carolyn Deal, Ph.D.** | Chief, STI and Enteric Diseases Branch/DMID/NIAID | cdeal@niaid.nih.gov | NIAID representative, STI Federal Steering Committee |
| **Emily Erbelding, M.D., M.P.H.** | Division Director, DMID, NIAID | Emily.erbelding@nih.gov | STI SME<br>NIAID representative, STI Federal Steering Committee |

**External**

None identified

## NIBIB: INNOVATION FUNNEL FOR TECHNOLOGY DEVELOPMENT

### ISSUE SUMMARY

NIBIB received $500 million from the H.R. 266 Paycheck Protection Program and Health Care Enhancement Act to develop new tests for SARS-CoV-2. With these funds, NIBIB quickly stood up the Rapid Acceleration of Diagnostics (RADx[SM]) Tech Innovation Funnel, a phased funding program that has successfully developed and deployed new diagnostic tests to help contain the COVID-19 global pandemic. The highly specialized mechanism was built on a process that has been evolving since 2007 through the NIBIB Point of Care Research Network (POCTRN). This innovative funding structure has succeeded in accelerating the typical five to six-year technology development and commercialization timeline to under six months. By drawing on the enormous innovation in the bioengineering research community, RADx[SM] Tech has been able to translate ideas into novel diagnostics with unprecedented speed. Because of the demonstrated power of this approach to rapidly convert biomedical innovation into benefit for patients, NIBIB is proposing to expand this framework. The Innovation Funnel is poised to translate discoveries from across NIH into health solutions that can be deployed to meet urgent clinical needs (see Rapid Scaling Up of COVID-19 Diagnostic Testing in the U.S.).

### KEY PROGRESS TO DATE

The RADx℠ Fast-Track Program for COVID-19 Test Development and Distribution has demonstrated the success of the Innovation Funnel approach. RADx[SM] Tech and its companion program RADx[SM] Advanced Technology Platforms (ATP) leveraged the infrastructure, expertise, and experience of an established POCTRN that NIBIB has funded since 2007. In just four months, the RADx[SM] Innovation Funnel reviewed more than 700 applications, vetted more than 150 projects during a one-week deep dive (Phase 0), de-risked more than 45 projects in Phase 1, and is supporting 22 projects in Phase 2 for clinical study, scale-up, and manufacturing (see Dashboard for details). Over $470 million has been invested in these 22 projects, which are estimated to increase testing capacity by more than 2.5 million tests per day by December 2020.

The structure of the Innovation Funnel includes initial rigorous vetting and a milestone driven approach that allow many ideas to fail early to find the best solutions in which to invest. The structure specifically includes:

- Rolling submission, review, and selection
    - Teams of reviews with technical, clinical, commercialization, and regulatory expertise
- Milestone-driven, staged management and oversight
    - Phase 0, multiple expert reviewers provide a detailed assessment of the technology
    - Phase 1, technologies are rigorously tested and validated over a month-long process to ensure that these new tests meet or exceed their predicted performance
    - Phase 2, rapid scale-up and commercialization with substantial financial assistance and oversight.

### KEY CHALLENGES TO DATE

A key challenge in technology development has been the siloed approach where innovators, regulators, clinicians, and marketers operate in a lengthy, iterative process, and many good ideas fall into a valley of death because of a lack of support in key areas. With a streamlined structure, Innovation Funnel will offer the research community a more efficient pipeline and provide the business, technical, clinical, and regulatory support system that can identify promising technologies and propel these ideas into viable,

commercialized products. This strategy eliminates the barriers innovators typically face and compresses a five-year development timeline to as little as six months.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Bruce Tromberg, Ph.D.** | Director, NIBIB | Bruce.tromberg@nih.gov | Lead oversight and funding decisions |
| **Jill Heemskerk Ph.D.** | Deputy Director, NIBIB | Jill.heemskerk@nih.gov | Oversight and funding decisions |
| **Todd Merchak** | Program Director, NIBIB | Todd.merchak@nih.gov | Co-lead program management |
| **Tiffani Lash, Ph.D.** | Program Director, NIBIB | Tiffani.lash@nih.gov | Co-lead program management |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jeff Shuren, M.D., J.D.** | Director, CDRH, FDA | jeff.shuren@fda.hhs.gov | FDA regulatory requirements |
| **Gary Disbrow, Ph.D.** | BARDA | gary.disbrow@hhs.gov | BARDA supply and manufacturing capacity |
| **Steven Schacter, M.D.** | n/a | sschacht@bidmc.harvard.edu | POCTRN/CIMIT coordinating center |
| **Andrea Belz, Ph.D.** | Division Director, Division of Industrial Innovation & Partnerships | abelz@nsf.gov | NSF Liaison |
| **Harriett Kung, Ph.D.** | Asso. Director for Basic Energy Sciences, Office of Science, DOE | harriet.kung@science.doe.gov | DOE Liaison |
| **Maj. Gen. Lee Payne, M.D., M.B.A.** | COVID-19 Task Force Diagnostics and Testing Lead, DOD COVID-19 Task Force (CVTF) | lee.e.payne.mil@mail.mil | DOD liaison/supply, capacity, distribution |

## NICHD: GYNECOLOGIC AND ANDROLOGIC HEALTH

### ISSUE SUMMARY

NICHD supports extramural and intramural research in gynecologic conditions, male and female infertility, contraception, and male reproductive disorders (andrology). Gynecologic conditions and diseases affect millions of women of all ages in the United States and around the world. Uterine fibroids, pelvic floor disorders, endometriosis, vulvodynia, and polycystic ovary syndrome (PCOS) lead to pain and infertility for millions of American women. Male reproductive system disorders are typically less common but can also lead to significant problems, including infertility. Recent estimates indicate that fibroids affect nearly 70 percent of women by age 50, with prevalence increasing to more than 80 percent for African American women. Endometriosis and PCOS are each present in approximately 10-15 percent of reproductive-aged women, although the prevalence of both are likely underestimated due to difficulty in diagnosing the conditions. Pelvic floor disorders, which occur when the muscles or connective tissues of the pelvic area weaken or are injured, affect from 25 to 60 percent of adult women and can cause urinary incontinence, fecal incontinence, and pelvic organ prolapse. Nearly 9 percent of men in the U.S. experience infertility, and ensuring effective contraception is another vital area of andrologic health research, with the potential to affect millions of reproductive-aged men.

Because gynecologic conditions collectively affect such a large portion of the population, Congress has expressed substantial and increasing interest particularly in gynecologic diseases, including endometriosis, PCOS, and fibroids. Notably, a Report to Congress was submitted in Spring 2020 on Endometriosis Research, and Senator Harris introduced a bill on fibroids research and education in August 2020. NIH is advancing research in gynecologic and andrologic health by investing in research infrastructure, including multi-site clinical trials and national research networks. However, scientific and other barriers remain, and additional research is needed to improve diagnosis and treatment for these conditions.

### KEY PROGRESS TO DATE

NICHD supports infrastructure investments, small business innovation opportunities, and investigator-initiated grants to advance gynecologic and andrologic research. Examples of specific advances include:

- Endometriosis – Led by NICHD, NIH has substantially increased research spending on endometriosis over the last three years. Scientists have emphasized diagnostic research because current diagnostic methods for endometriosis are invasive, sometimes delaying accurate diagnoses for years. NIH-funded researchers recently determined that levels of specific microRNAs (miRNAs) in the blood could collectively be a biomarker to diagnose endometriosis. If developed further, this approach could potentially lead to less invasive and more rapid diagnosis, sparing years of patient discomfort, disease progression, and healthcare costs.
- Fibroids – Uterine fibroids are the most common cause for hysterectomies in the United States. Scientists are developing a technique to shrink fibroids as a less-invasive alternative to surgical removal. This method, tested successfully in mice, delivers nanoparticles with a tumor-killing drug directly to the fibroid.
- PCOS – After analyzing the genes of nearly 900 women who had irregular menstrual periods, researchers identified two PCOS subtypes, each associated with distinct groups of gene variants. These findings could provide important information on the possible causes of PCOS and for developing more effective ways to treat the condition.
- Pelvic floor disorders – Pelvic floor disorders are most commonly treated surgically. There are different approaches to conducting these operations, and NIH has supported the challenging research to help determine which surgical approaches lead to better outcomes. For example,

researchers compared the 2-year surgical outcomes of two different surgical approaches in women with advanced pelvic organ prolapse and stress urinary incontinence. The study results showed equal overall surgical success (58 percent) at 2 years for women undergoing each type of procedure.

- Male infertility and contraception – NICHD intramural researchers found that supplements marketed to treat male infertility – zinc and folic acid – did not improve pregnancy rates. In another area of andrologic health, scientists have recently developed and tested new contraceptive pills for men. Study participants indicated that they would be willing to use the method, potentially providing a new alternative to prevent unintended pregnancy.

## KEY CHALLENGES TO DATE

- Health disparities – Minority women are disproportionately affected by many gynecologic conditions. African American women are up to three times more likely to suffer from fibroids than white women. As research advances, it is vital to include underrepresented minorities in research to ensure development of accurate diagnostic methods and effective treatments for all populations.
- Collaborative research approaches – Smaller fields of research may struggle to make breakthroughs without significant, focused support. Growing these research areas often requires a collaborative approach. NICHD aims to accelerate endometriosis research through investing in new Centers to Advance Research in Endometriosis (CARE). These multidisciplinary programs will incorporate basic, translational, and/or clinical studies in a collaborative entity to accelerate research advances to prevent and treat endometriosis.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Diana Bianchi, M.D.** | Director, NICHD | Diana.bianchi@nih.gov | Director of NICHD, which leads reproductive health research at the NIH |
| **Lisa Begg, DrPH, R.N.** | Office of Research on Women's Health, NIH | BeggL@od.nih.gov | ORWH serves to coordinate women's health research across the NIH. |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Kathryn Schubert, M.P.P.** | President & CEO, Society for Women's Health Research | Kathryn@swhr.org | Key policy resource for women's health research |

## NICHD: PRETERM BIRTH AND THE HEALTH OF THE NEWBORN

### ISSUE SUMMARY

Despite a wealth of medical resources, 10 percent of newborns in the United States are born preterm – a rate higher than in many other industrialized countries. Over the past five years the preterm birth rate has increased, and preterm rates have remained consistently higher for non-Hispanic Blacks, Hispanics, and Native Americans. Both preterm and full-term newborns can be vulnerable to the effects of serious conditions, including lung problems, congenital abnormalities, and infections. NIH advances research by providing sustained infrastructure for research involving pregnant women and newborns and launching a collaborative effort to better understand the placenta's role in health and disease. However, policy, regulatory, funding, and logistical challenges require attention. Additional efforts are needed to promote inclusion of pregnant women and neonates in research. Collaborative initiatives are urgently required to link data collected through large-scale health systems to make these data useful and available for research.

### KEY PROGRESS TO DATE

NICHD supports a robust research infrastructure that enables scientists to conduct rigorous clinical studies in preterm birth and newborn health. Many of these research studies on preterm birth and newborn health include a higher number of women and newborns who are minorities, to better understand and address health disparities. Examples of specific programs include:

- Problems with the placenta can lead to preterm birth, fetal growth restriction, and other conditions that affect lifelong health, such as predisposition to CVD. Through the **Human Placenta Project (HPP)**, NICHD is developing new tools to study in real time how the placenta develops and functions throughout pregnancy. That knowledge may one day help treat, and even prevent, preterm birth, and other common pregnancy complications. For example, one promising technology developed under the HPP uses non-invasive imaging to more accurately monitor contractions for signs of preterm labor.
- The NICHD's **Maternal and Fetal Medicine Units (MFMU) Network** conducts rigorous clinical trials in maternal, fetal, and obstetric medicine. Evidence generated by this network has contributed to 25% of professional guidelines for obstetric practice. MFMU is currently conducting the Gestational Research Assessments for coVID (GRAVID) study, evaluating medical records of 24,500 women to discern possible impacts of health care changes implemented because of the COVID 19 pandemic, including preterm birth and newborn outcomes.
- Within NICHD's **Intramural** program, scientists are studying how to prevent preeclampsia, a blood pressure disorder in pregnant women that can have serious effects for both mother and fetus and is often linked to preterm birth.
- NICHD's **Neonatal Research Network (NRN)** is a collaborative network of neonatal intensive care units across the United States. Focused on newborns, particularly preterm and low birth weight infants, NRN supports multicenter clinical trials to provide answers more rapidly than individual centers could if they were acting alone. For example, in one recent NRN study, researchers demonstrated that corticosteroid treatment reduced both the risk of lung diseases and the overall cost of healthcare for late preterm infants.
- Soon after babies are born, they routinely receive a simple heel stick, where a small amount of blood is drawn. With these few drops of blood, laboratory tests can identify babies that appear healthy, but may have a serious disorder. NICHD's **Newborn Screening** research program is responsible for many of these tests that save lives and prevent disability.

## KEY CHALLENGES TO DATE

- Inclusion in Research: Research on preterm birth and newborn health requires the participation of pregnant women, new mothers, and neonates. Federal regulations, guidance, and rules for research participation are aimed at protecting the woman, fetus, and/or child. However, many researchers routinely exclude pregnant women and newborns from clinical research, denying them the benefits of scientific evidence. Over the past several years, experts and groups, such as the HHS Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), have strongly urged increased efforts to include pregnant women and newborns in the clinical research agenda. Regulatory changes – including a consistent standard for parental consent for a fetus or a newborn – could facilitate inclusion. NIH will promote inclusion of pregnant women across research studies and will emphasize pediatric and obstetric pharmacology research. For example, within the NIH's research programs under the Best Pharmaceuticals for Children Act (BPCA), scientists have prioritized pharmacology research for newborns because their bodies metabolize pharmaceuticals differently, compared with older children and adults.
- Health records systems: The lack of linkages between maternal and child health records and the lack of connectivity among health records systems in the U.S. make it more difficult for scientists to use real-world evidence to study maternal and newborn conditions. Recognizing the difficulty of the task and the need for collaborations, NIH is exploring partnerships with other agencies and organizations to address this problem and confront policy, regulatory, and interoperability issues.

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Diana Bianchi, M.D.** | Director, NICHD | Diana.bianchi@nih.gov | Director of NICHD |
| **David Weinberg, Ph.D.** | Director, Human Placenta Project (HPP), NICHD | David.weinberg@nih.gov | Director of the HPP research effort |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Rachel Tetlow** | Director of Federal Affairs, American College of Obstetrics and Gynecology (ACOG) | rtetlow@acog.org | Key policy resource on issues related to pregnancy and newborn health |
| **Rebecca Abbott** | Director of Federal Affairs, Society for Maternal and Fetal Medicine | rabbott@smfm.org | Key policy resource on issues related to pregnancy and newborn health |

## NICHD: PEDIATRIC AND OBSTETRIC THERAPEUTICS RESEARCH

### ISSUE SUMMARY

About three-fifths of medicines on the market are not approved for pediatric use, although physicians frequently prescribe these drugs "off label" for children. Because of physiological differences between children and adults, using an adult medicine for a child can be ineffective at best and dangerous at worst. Historically, there have been highly publicized cases of drugs prescribed for pregnant women that ended with tragic results, such as thalidomide. These cases resulted in measures, codified in part in federal regulations, that have often resulted in the exclusion of pregnant women from clinical studies. As a result, pregnant and lactating women, as well as all parents of children, face difficult choices – either going without treatment or undergoing a treatment that has not been tested for their use. Additional efforts are needed to overcome regulatory, policy, and funding challenges. These challenges include lowering barriers to inclusion of pregnant women, lactating women, and children in clinical research; developing improved methods to manage the complexity of testing therapeutics in different populations; and addressing the difficulties of forming public-private collaborations to advance research.

### KEY PROGRESS TO DATE

The Best Pharmaceuticals for Children Act (BPCA) was passed in 2002, and reauthorized in 2007, 2012, and 2017, to encourage both government and industry to conduct additional research in support of safe and effective pharmaceutical treatments for children. Under the NIH portion of the BPCA, NICHD leads a process to identify off-patent drugs in need of further study, consult with stakeholders to prioritize needs in pediatric therapeutics, and sponsor clinical studies to inform FDA labeling for pediatric indications. This year, the BPCA-supported Pediatric Trials Network (PTN) quickly began collecting data on COVID-19 drugs that clinicians at approximately 40 PTN sites are using to treat infants, children, and adolescents. To further expand pharmacology research in both pediatrics and obstetrics, the NICHD's new Maternal and Pediatric Precision in Therapeutics (MPRINT) program will provide pharmacology expertise, basic science research, and technology platforms for pharmacology research in pregnant women, lactating women, and children.

Through the federal Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), NICHD brought together clinical, research, advocacy, public health, regulatory, and pharmaceutical industry leaders to address the significant gap in research on safety, efficacy, and dosing of medications currently used by pregnant and lactating women. Building on its 2018 report that summarized challenges in this area and provided 15 recommendations, in 2020 the Task Force generated multiple, concrete implementation steps to guide public- and private-sector efforts. Major areas for action include developing a systematic plan to collect data on therapeutics' safety, pharmacokinetics, pharmacodynamics, and pharmacogenomics during pregnancy and lactation and establishing a prioritization process (similar to that of BPCA) for studies in pregnancy and lactation. Other implementation steps focus on Task Force recommendations to address ethical considerations and industry concerns about liability, and to encourage participation in obstetric therapeutics research. NICHD's Maternal and Fetal Medicine Units (MFMU) Network conducts rigorous clinical research in maternal, fetal, and obstetric medicine across the country. For example, MFMU is currently conducting a clinical trial evaluating whether tranexamic acid, a drug used to prevent hemorrhage in trauma and high-risk surgery patients, can prevent obstetric hemorrhage after cesarean delivery.

## KEY CHALLENGES TO DATE

- Inclusion in Research: Achieving scientifically validated safe and effective interventions for pregnant women and lactating women is difficult because many researchers routinely exclude these women from clinical research, without adequately considering potential risks of untreated maternal disorders to both the mother and the fetus. Despite considerable progress since the early years of BPCA, many researchers are still reluctant to include children in clinical studies or conduct pediatric-specific analyses to inform use of therapies in children. Through the implementation of the PRGLAC recommendations and the BPCA process, NIH plans to promote inclusion of pregnant women and children in clinical studies and prioritize pediatric and obstetric pharmacology research.
- Complexity: Developmental processes from infancy through adolescence present significant challenges to clinical research in therapeutics, resulting in different safety and efficacy profiles for therapeutics. Similarly, because dynamic physiologic changes occur throughout pregnancy and lactation that affect drug levels and action in the body, data from studies of non-pregnant adults cannot be extrapolated to pregnant women.
- Collaborations: Public-private collaborations in pediatric and obstetric pharmacology have been challenged by limited incentives for industry to study therapies in children, particularly therapies that are off-patent; liability concerns about studies involving pregnant women and children; and the time and detailed effort needed to develop and execute partnerships. NIH has executed several successful partnerships and these efforts may pave the way for future initiatives.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Diana Bianchi, M.D.** | Director, NICHD | Diana.Bianchi@nih.gov | Director of NICHD |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Katie Schubert, M.P.P.** | CEO, Society for Women's Health Research | kschubert@shr.org | Key policy resource on obstetric pharmacology issues |
| **Rachel Tetlow** | Director of Federal Affairs, American College of Obstetrics and Gynecology | rtetlow@acog.org | Key policy resource on obstetric pharmacology issues |
| **James Baumberger, M.P.P.** | Senior Director, American Academy of Pediatrics | jbaumberger@aap.org | Key policy resource on pediatric pharmacology issues |

## NIDA: EMERGING STIMULANT USE DISORDER CRISIS

### ISSUE SUMMARY

More than 67,300 people died from drug overdose in the U.S. in 2018. Over 25,000 of these deaths involved the stimulant drugs methamphetamine or cocaine, figures that have risen sharply over the last decade. Illicit fentanyl was involved in 29% of methamphetamine related-deaths and 59% of cocaine-related deaths, leading some to refer to this emerging public health crisis as the "fourth wave of the opioid epidemic." According to provisional CDC data, stimulant-related overdoses are on a trajectory to increase further in 2019. Unlike for opioid use disorder, there are no FDA-approved treatments for stimulant use disorders, and the combination of opioid and stimulant use can make opioid overdoses more difficult to reverse. While NIDA is supporting research to develop new medications, progress is hampered by a relative lack of industry interest in substance use disorder product development and barriers to the implementation of effective behavioral interventions.

### KEY PROGRESS TO DATE

NIDA supports research to evaluate the safety and efficacy of pharmacotherapies and devices to treat stimulant use disorders across the medical product development pipeline, including synthesis and preclinical evaluation of potential therapeutics, clinical trial design and execution, and preparing regulatory submissions. Through these investments, NIDA is currently supporting approximately 30 studies on potential new medications for stimulant use disorders. These include a promising trial examining IXT-m200, a monoclonal antibody designed to sequester methamphetamine in the blood so that it does not reach the brain. Another study funded through NIDA's Clinical Trials Network is examining a combination of naltrexone, which is FDA approved for opioid and alcohol use disorders, and bupropion, an antidepressant, for methamphetamine use disorder. Results of that study are expected to be published soon.

### KEY CHALLENGES TO DATE

- There are no FDA-approved pharmacotherapies for stimulant use disorders or stimulant overdose, and opioid overdose reversal agents are not as effective against synthetic opioids or against opioids when used in combination with stimulants. A 2015 Institute of Medicine (IOM) workshop report noted that despite the growing need, industry is disinvesting in the development of treatments for brain disorders, particularly psychiatric conditions. Medical product development incentives, such as priority review vouchers, exclusivity extension, and tax credits, which have been used successfully to stimulate industry investment in other neglected disease areas, could be powerful incentives for the development of new treatments for stimulant use disorder.
- Additional FDA guidance on stimulant drug use disorder treatment development is needed, particularly around acceptable endpoints for clinical trials in addition to abstinence.
- Contingency management is a behavioral treatment in which behavioral change targets (such as drug abstinence) are set and carefully monitored, and rewards are issued for compliance. Contingency management is the most effective behavioral treatment for stimulant addiction, and studies demonstrating its efficacy have used incentives ranging between $200-2000 over the course of treatment. Yet, HHS policy limits the monetary value of patient incentives offered by treatment programs receiving federal funds to $75/patient/year. Several advocacy groups have urged legislative and regulatory action to waive or increase the limit when provided as part of therapy.

## NEXT STEPS

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## RELEVANT STAKEHOLDERS

**Internal**

None identified

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Alan Slobodin** | Minority Chief Investigative Counsel, House E&C Committee | Alan.Slobodin@mail.house.gov | Interest in working with NIDA to explore opportunities to advance the treatment of stimulant use disorders |
| **Sean Couglin** | President and CEO, National Association of Behavioral Health Care | nabh@nabh.org | Staff lead for Friends of NIDA, coalition |
| **H. Westley Clark, M.D., J.D., M.P.H.** | Dean's Executive Professor of Public Health Psychiatrist and Addiction Medicine Specialist, Santa Clara University | hclark@scu.edu | Former NIDA Council Member, Addiction Psychiatrist, and Leadership of Motivational Incentives Group advocating for increase in allowable value of monetary incentives provided for stimulant use disorder therapy |

## NIDA: INTERSECTION OF COVID-19 AND SUBSTANCE USE DISORDER

### ISSUE SUMMARY

The COVID-19 pandemic presents significant challenges to people with substance use disorder (SUD) and in recovery. People with SUD are more susceptible to COVID-19 and its complications. Social distancing, in addition to increasing stress that can contribute to substance misuse, has challenged access to SUD treatment and recovery supports. The pandemic has had a negative effect on research, including research supported under the NIH HEAL Initiative, which has been impacted by the closure of research universities, justice settings, and other study sites. NIDA is supporting numerous research projects to elucidate the impact of COVID-19 on people with SUD.

### KEY PROGRESS TO DATE

- NIDA awarded 80 supplements to existing grants for research at the intersection of COVID and SUD. These projects address a range of topics including basic research on SARS-COV-2 infection, the effect of COVID on people who use drugs, the effect of COVID on child and adolescent development, and the impact of COVID-related policy changes on access to SUD treatment. NIDA is also funding research through its intramural research program examining the impact of social distancing on recovery, relapse, and medication adherence among people with SUD and participating in trans-NIH COVID initiatives aimed at accelerating the developing and implementation of COVID testing technologies.
- NIDA Director Dr. Nora Volkow coauthored a study in the journal *Molecular Psychiatry* that used EHR data to demonstrate that patients with a recent SUD diagnosis were at significantly increased risk for COVID-19, an effect that was strongest for people with opioid and tobacco use disorders. COVID patients with SUD had significantly worse outcomes than those without SUD, and African Americans with COVID and SUD had worse outcomes than their white counterparts.
- NIDA has contracted with Faces and Voices of Recovery and the Addiction Policy Forum to gather information through focus groups and individual interviews on the lived experiences of people in recovery from SUD during the pandemic and to hear their perspectives on a potential vaccine for COVID-19. This information may be used to inform research with these populations and develop effective public health messaging related to COVID and vaccine uptake.
- Although COVID has presented challenges to access to treatment and recovery support services for people with SUD, it has also opened opportunities. For example, people with OUD can now begin treatment with buprenorphine without an initial in-person doctor visit; patients taking methadone who are stable may obtain up to 28 days of take-home doses, a change from daily supervised dosing with tightly controlled take-home options; and there has been an expansion of telehealth services, facilitating access to SUD treatment. NIDA is supporting research to understand the impact of COVID-related policy changes on treatment access.

### KEY CHALLENGES TO DATE

- Significant increases in many kinds of drug use have been recorded since the start of the pandemic. A NIDA-supported survey of over 1,000 people with SUD conducted by the Addiction Policy Forum found that 20% of the respondents reported that their own or a family member's substance use had increased since the start of the pandemic. An analysis of a nationwide sample of 500,000 urine drug test results conducted by Millennium Health showed steep increases in cocaine, heroin, methamphetamine, and non-prescribed fentanyl use since mid-March. Comprehensive national data are not yet available on overdoses, but data from some

states suggest increases in overdose deaths and drug-related emergency room admissions in the first half of 2020 compared to last year.

- NIDA research programs were impacted by the closure of research universities as well as other COVID-related disruptions. Clinical research trials were put on hold as IRBs halted operations, EDs could no longer accommodate research protocols, justice settings did not allow for researchers to enter their facilities, and schools were closed. NIDA's Monitoring the Future survey, which collects data from 8, 10th, and 12th graders, has been put on hold due to school closures. Within NIDA's Clinical Trials Network, trials were delayed as a result of the COVID pandemic by local restrictions limiting research staff to essential personnel, and increased patient care responsibilities of some investigators.

**NEXT STEPS**

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## RELEVANT STAKEHOLDERS

**Internal**

None identified

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jessica Hulsey** | Founder and CEO, Addiction Policy Forum | Jess3@addictionpolicy.org | Advocacy organization for people touched by addiction. Engaged in collecting information on impact of COVID on people with SUD |
| **Timothy Shea, J.D.** | Acting Administrator, Drug Enforcement Agency (DEA) | n/a | DEA has role in policy relaxation related to access to methadone & buprenorphine for OUD treatment under COVID |
| **Elinore McCance-Katz, M.D., Ph.D.** | Assistant Secretary for Mental Health | Elinore.mccance-katz@samhsa.hhs.gov | SAMHSA has role in policy relaxation related to access to methadone & buprenorphine for OUD treatment under COVID |

## NIDA: EFFECT OF SOCIOECONOMIC STATUS AND RACIAL INEQUITY DETERMINANTS OF HEALTH ON SUBSTANCE USE OUTCOMES

### ISSUE SUMMARY

Risk of developing a substance use disorder (SUD) is dependent on many interacting biological and environmental factors, social determinants of health, low socioeconomic status (SES) in particular, are strong drivers of health disparities. While these disparities are continually exacerbated by low SES over the life course, they may be seeded very early in a child's development. Low SES is associated with profound impacts on the cognitive and social development of children, as well as on the development of the brain. The impacts of drug use and addiction, including difficulties in accessing care, continue to disproportionately affect racial/ethnic minority communities and also drive health disparities.

### KEY PROGRESS TO DATE

- NIDA's Adolescent Brain Cognitive Development (ABCD) Study, which is tracking the biological and behavioral development of nearly 12,000 children through adolescence into young adulthood, has begun to characterize interactions between SES and environment: recent findings demonstrate that children from low income families may be more vulnerable to adverse cognitive outcomes conferred by environments with high risk of lead exposure.
- Current NIDA research is tailoring a prevention intervention to a low-income and racial/ethnic minority population. Planning projects are also underway for the HBCD Study, which will complement the ABCD Study, with a cohort of children followed from birth through the first ten years of life and will help describe the impact of early life adversity on developmental outcomes.
- In June of 2020, NIDA established an initiative to address and promote equity, diversity, and inclusion in the NIDA workplace and the extramural workforce, and to identify related research gaps/opportunities. Feedback from extensive listening sessions, an internal survey, and two requests for information will be used to develop an Action Plan with short- and long-term goals to address the challenge at NIDA and more broadly in addiction science.

### KEY CHALLENGES TO DATE

The intersecting impacts of low SES and racial inequity confer especially high risk of SUD and associated negative outcomes. Challenges that are being addressed by NIDA's equity initiative include:

- Workplace: a small poll of NIH staff indicates that 42% of respondents had witnessed racism, discrimination, or harassment at NIH.
- Workforce: While African Americans constitute 13.4% of the U.S. population, less than 5% of NIDA funded PIs are African American. Disparities such as this are indicative of the need to develop effective strategies for the engagement, progression, retention, and promotion of scientists from underrepresented racial/ethnic groups within the science pipeline.
- Research: The impacts of drug use and difficulties in accessing care continue to disproportionately affect racial/ethnic minority communities. Furthermore, NIDA has been met with some criticism for its emphasis on the harms associated with drug use and the disease model of addiction, which some scientists argue contributes to stereotypes about people who misuse drugs and adversely affects minority communities.

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Lawrence A. Tabak, D.D.S., Ph.D.** | Deputy Director, NIH | lawrence.tabak@nih.gov | NIH working group focused on addressing equity, diversity, and inclusion across NIH. |
| **Nora Volkow, M.D.** | Director, NIDA | nvolkow@nida.nih.gov | n/a |

## NIDCD: RESEARCH DRIVES CHANGES TO MAKE HEARING HEALTH CARE MORE ACCESSIBLE AND AFFORDABLE

### ISSUE SUMMARY

Approximately 15% of U.S. adults report some degree of hearing loss. Untreated hearing loss may lead to isolation, and it has also been associated with serious conditions such as depression, anxiety, low self-esteem, dementia, reduced mobility, and falls. Hearing aids and other assistive devices can significantly improve the quality of life for many people, but the majority of individuals who could benefit do not use them.

### KEY PROGRESS TO DATE

As the lead federal agency supporting research and initiatives to prevent, detect, and treat hearing loss, the NIDCD has made research on improving access to and affordability of hearing health care a priority over the past decade. In 2009, the NIDCD started a coordinated effort to tackle accessible and affordable hearing health care by forming a working group. The working group created a blueprint for research priorities to enhance the affordability and accessibility of hearing health care for adults with mild-to-moderate hearing loss. This launched a focused effort by the institute that has, to date, inspired a dozen funding opportunities leading to the NIDCD's support of 40 research projects on the topic.
In 2016, the National Academies of Sciences, Engineering, and Medicine (NASEM) published a consensus report, Hearing Health Care for Adults: Priorities for Improving Access and Affordability (www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and). The NIDCD co-sponsored this effort with other federal agencies and the Hearing Loss Association of America. The independent expert panel that conducted the study made recommendations for hearing health care reform, prioritizing the needs of adults with hearing loss. The panelists encouraged agencies, organizations, and professionals to improve access and affordability of services, develop innovative technologies, and better inform consumers about their choices for managing hearing loss.

### KEY CHALLENGES TO DATE

Only one in four adults who could benefit from hearing aids has ever used these devices. Roadblocks cited include cost, stigma, perception that they are not effective, and limited access to hearing health care.

### NEXT STEPS

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### RELEVANT STAKEHOLDERS

None identified

## NIDCR: TEMPOROMANDIBULAR JOINT DISORDER (TMJD)

### ISSUE SUMMARY

Five to twelve percent of the U.S. population is estimated to be affected by temporomandibular joint disorders (TMJDs), a diverse group of conditions that cause jaw joint and muscle dysfunction and pain. Because of the complexity of the causes, diagnoses, and treatments of these disorders, TMJDs continue to confound medical and dental health care providers and researchers. Therefore, in 2017 the United States Senate requested NIH provide recommendations to Congress on the state of TMJD science and education, the safety and efficacy of current clinical treatments of TMJD, and the burden and costs associated with TMJD.

### KEY PROGRESS TO DATE

In 2018, partially in response to the request from Congress, NIDCR and the NIH OD commissioned a study by the National Academies of Sciences, Engineering, and Medicine (NASEM) to address the current state of knowledge about TMJD research, TMJD provider education and training, safety and efficacy of treatments, and TMJD-associated burden and costs. In March of 2020, NASEM released their report, *Temporomandibular Disorders: Priorities for Research and Care*. The report makes it clear that although current and past research has resulted in advances in our knowledge of TMJDs, significant gaps remain in our understanding of their underlying biological mechanisms. The report includes eleven recommendations, four of which align with NIH's mission and are focused on building and sustaining a multidisciplinary TMJD research community:

- Create and sustain a national TMJD collaborative research consortium
- Strengthen basic TMJD research and translational efforts
- Strengthen population-based research on the public health burden of TMJD
- Bolster clinical research efforts to build the evidence base for patient-centered care and public health interventions for TMJD

NIDCR continues to invest in a broad array of basic, translational, and clinical TMJD research with the goal of improving the health and daily lives of people living with TMJDs. For example, NIDCR-funded investigators are using data science and machine learning to improve early diagnosis of temporomandibular joint osteoarthritis, a TMJD characterized by breakdown of the protective cartilage of the jaw joint that can lead to pain and/or dysfunction in jaw movement. In May 2020, NIDCR announced a future research initiative to study the expression of genes and proteins in thousands of individual cells simultaneously to better understand the molecular mechanisms underpinning TMJD pain. NIDCR is also collaborating with other NIH ICOs to solicit research on the transition from acute to chronic pain and to advance TMJD research and therapies through the Helping to End Addiction Long-term℠ Initiative.

### KEY CHALLENGES TO DATE

- Using NASEM recommendations as a guide, identify specific prioritized TMJD research and training opportunities within the mission of NIDCR and NIH.
- Collaborate with other NIH ICOs to advance multidisciplinary TMJD research and training to increase understanding of TMJDs and chronic overlapping pain conditions.

### NEXT STEPS

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## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Denise Stredrick, Ph.D.** | TMJD Multi-Council Working Group POC | stredrid@mail.nih.gov | Using NASEM Report to prioritize roadmap to address TMJD research opportunities |
| **NIH HEAL Initiative[SM]** | n/n | HEALquestion@od.nih.gov | Funding Pain research, including TMJD |
| **NIH Pain Consortium** | n/a | contact form: https://www.painconsortium.nih.gov/PAIN_Contact_us | Enhancing pain research; promoting collaborations |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **The TMJ Association** | Terrie Cowley, president | info@tmj.org | Advocacy group; advocated for NASEM TMJD Report |
| **Tammy Baldwin, J.D.** | Senator | e-mail form: https://www.baldwin.senate.gov/feedback | Requested TMJD report |
| **Food and Drug Administration** | n/a | danica.marinac-dabic@fda.hhs.gov | Medical device regulation; report TMJD device problems |
| **TMJ Roundtable** | n/a | http://www.tmj.org/Page/450/48 | Patient-led roundtable to advise on TMJD studies |

## NIDDK: SPECIAL STATUTORY FUNDING PROGRAM FOR TYPE 1 DIABETES RESEARCH

### ISSUE SUMMARY

Codified in Section 330B of the Public Health Service Act, the Special Statutory Funding Program for Type 1 Diabetes Research (Program) began in FY 1998. It is a special appropriation (currently $150 million/year) supporting research on prevention, treatment, and cure of type 1 diabetes (T1D) and its complications. The Program is administered by the NIDDK on behalf of the DHHS Secretary and in collaboration with other NIH components and the CDC. The Program has been reauthorized 15 times by the Congress (most recently through December 11, 2020) and has supported significant progress in multiple areas of type 1 diabetes research. The major legislative/budget issues facing the Program are uncertainty of future funding and the effects of the recent trend toward very short-term extensions.

### KEY PROGRESS TO DATE

The Program has provided the foundation for significant scientific progress in T1D research, supporting ambitious, unique, long-term research projects that may not be possible otherwise. Examples of Program-funded progress include:

- **The Environmental Determinants of Diabetes in the Young (TEDDY)**: TEDDY is a long-term, ambitious study following over 6,000 newborns to identify environmental triggers of T1D. Research suggests that environmental factors are contributing to rising rates of T1D, so knowledge from TEDDY could revolutionize the ability to prevent the disease. To complete TEDDY as planned, the children must be followed until 2025, when the youngest will turn 15 years old.
- **Type 1 Diabetes TrialNet**: TrialNet is a large, international network studying T1D prevention and early treatment. TrialNet demonstrated that an immune-modulating therapy delayed onset of the disease in high-risk individuals for at least 2 years. Follow-up studies are required to determine the durability and long-term effects of this treatment. TrialNet has two other ongoing prevention trials, as well as several planned trials; these trials require screening large numbers of people (15,000 annually) to identify those with autoimmune risk factors. It has the only infrastructure worldwide for screening such large numbers of people for T1D prevention trials, and thus is a unique and important resource.
- **Artificial Pancreas (AP)**: Program-supported research has resulted in significant advances in AP technology, which automatically links real-time glucose sensing and insulin delivery. This technology could reduce the burden of managing T1D and reduce people's risk for long-term complications. For example, in December 2019, the FDA approved the first algorithm authorized as an interoperable, automated glycemic controller for use as part of an AP system. Future research opportunities include supporting clinical trials toward FDA approval of improved devices, research to improve AP components, and research to ensure that all people with T1D can use and benefit from new devices.
- **Cell Replacement**: With Program support, significant progress has been made to better understand how beta cells are lost in type 1 diabetes, to inform strategies to protect or replace them in people with the disease. For example, using cutting-edge technologies, a Program-supported consortium provided an unprecedented single-cell visualization of the pancreas that revealed differences between and within individuals with type 1 diabetes, changing the fundamental understanding of this disease. Future research could build on these findings to develop new strategies to prevent or treat type 1 diabetes.

## KEY CHALLENGES TO DATE

- Without a Program extension beyond the current end-date of December 11, 2020, many Program-supported research efforts (such as those listed in the Key Progress section above) would be scaled back or curtailed. This would jeopardize past investment of Program funds, prevent pursuit of promising new opportunities, and stall research progress.
- In the past, the Program has often received multi-year reauthorizations, allowing for the inception of ambitious, long-term clinical trials and research networks. Although the Program continues to receive bipartisan support, recent Program extensions have been for short time periods, sometimes only months or weeks. This trend hampers long-term planning and promotes uncertainty about the Program's future.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **William T. Cefalu, M.D.** | Director, Division of Diabetes, Endocrinology, and Metabolic Diseases | william.cefalu@nih.gov | Oversees Program T1D portfolio, chairs Diabetes Mellitus Interagency Coordinating Committee |
| **Heather Rieff, Ph.D.** | Director, Office of Scientific Program and Policy Analysis | Heather.Rieff@nih.gov | T1D policy contact |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **JDRF** | President and CEO | Aaron J. Kowalski, Ph.D. | Advocacy group supporting Program and T1D research |
| **The Endocrine Society** | President | Gary D. Hammer, M.D., Ph.D. | Advocacy group supporting Program and T1D research |
| **American Diabetes Association** | CEO | Tracey D. Brown | Advocacy group supporting Program and T1D research |
| **Sen. Susan Collins Sen. Jeanne Shaheen** | Senators | N/A | Major Program Supporters; Co-chairs, Senate Diabetes Caucus |
| **Rep. Diana DeGette Rep. Tom Reed** | Representatives | N/A | Major Program Supporters; Chairs of Congressional Diabetes Caucus |

## NIDDK, NIAID: VIRAL HEPATITIS

### ISSUE SUMMARY

Research on viral hepatitis infection (e.g., with hepatitis B virus [HBV], hepatitis C virus [HCV]), sponsored by the NIDDK, NIAID, and others at NIH, has improved the lives of people with viral hepatitis and its outcomes (e.g., cirrhosis and liver cancer). Further research is needed to eliminate these causes of liver disease in the U.S. Issues with policy/legislative implications include:

- NIH staff coordinate and plan future directions in viral hepatitis research through such activities as the: 1) Trans-NIH Committee on Viral Hepatitis, 2) NIH Hepatitis B Cure Strategic Plan, and 3) HHS Viral Hepatitis Action Plan. These efforts have often been responsive to stakeholder input from scientists, advocacy groups, and congressional interest.
- Stakeholder interest exists in raising the profile of viral hepatitis research at NIH (e.g., House and Senate bills to include "liver" in the name of the NIDDK elevate NIDDK's Liver Disease Research Branch to a Division and issue more hepatitis B FOAs from NIAID).

### KEY PROGRESS TO DATE

The NIDDK and NIAID support the majority of NIH-funded viral hepatitis research, which has provided the foundation for developing effective ways to manage viral hepatitis, such as the following:

- NIH research led to the identification of early, partially effective hepatitis C treatments; later, techniques developed led to identification of highly effective, direct-acting antiviral drugs now used to treat the disease and cure a majority of patients. These antiviral regimens have cured millions of people worldwide and may allow for elimination of hepatitis C in the U.S.
- Early NIH research on hepatitis B therapy led to identification of antiviral agents that suppress the virus and control disease in the majority of patients with long-term treatment. NIDDK's Hepatitis B Research Network highlighted disparate impacts on foreign-born individuals, showed that careful management of chronic disease leads to long-term survival and low rates of cirrhosis, liver cancer, and end-stage liver disease, and showed the need for improved treatments to cure more people.
- NIAID intramural research identified mechanisms of HBV-associated acute liver failure. NIAID research also helped advance the development of new therapeutic agents against HCV, such as SB 9200, a RIG-I agonist of the interferon pathway, effective against both HBV and HCV.
- NIAID led, and NIDDK participated, in the Trans-NIH Strategic Plan for a Hepatitis B Cure.
- NIAID issued FOAs to advance diagnosis of HCV infection, design new HCV vaccines, and support research on curing hepatitis B in those co-infected with HIV.

### KEY CHALLENGES TO DATE

Research challenges remain in improving treatments and vaccines available for viral hepatitis:

- Hepatitis C prevention and elimination is hindered by lack of a vaccine. NIAID's Phase I/II trial to evaluate safety, immunogenicity, and efficacy of an HCV vaccine to prevent acute and chronic infections in high-risk people transiently reduced viremia but did not prevent chronic infection. NIAID also supports studies on antibodies to HCV and new treatment approaches to hepatitis B.
- Stakeholders have called for increased NIH resources to be allocated for viral hepatitis research. NIH has taken steps, such as issuing FOAs, to encourage more viral hepatitis research applications.

### NEXT STEPS

(b) (5)

[redacted]

(b) (5)

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jay H. Hoofnagle, M.D.** | Director, Liver Disease Research Branch | jay.hoofnagle@nih.gov | Oversees extramural viral hepatitis research portfolio and chairs Trans-NIH Committee on Viral Hepatitis |
| **T. Jake Liang, M.D.** | Chief, Liver Diseases Branch | jake.liang@nih.gov | Oversees intramural viral hepatitis research portfolio |
| **Megan Singh, Ph.D.** | Health Science Policy Analyst | meganm@niddk.nih.gov | Digestive diseases and nutrition policy contact |
| **Juliane Caviston, Ph.D.** | Health Science Policy Analyst | juliane.caviston@nih.gov | Hepatitis planning and policy contact |
| **Johanna Schneider, Ph.D.** | Chief, Policy, Planning and Evaluation Branch | schneiderjs@niaid.nih.gov | Hepatitis planning and policy contact |
| **Rajen Koshy, Ph.D.** | Program Officer, Division of Microbiology and Infectious Diseases | rkoshy@niaid.nih.gov | Viral hepatitis research and funding |
| **Beverly Alston, M.D.** | Medical Officer, Chief, Complications and Co-Infections Research Branch, Therapeutics Research Program | BALSTON@niaid.nih.gov | HIV and Viral hepatitis coinfection research and funding |
| **Carl Dieffenbach, Ph.D.** | Director, Division of AIDS | CDieffenba@niaid.nih.gov | Co-author, HHS National Viral Hepatitis Action Plan, 2021-5 |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **HHS Viral Hepatitis Implementation Group** | Office of the Assistant Secretary for Health, HHS | Carol S. Jimenez, Carol.Jimenez@hhs.gov | NIH and other Federal agencies participate; develops the HHS National Viral Hepatitis Action Plan |
| **Sen. Bill Cassidy** | Senator | N/A | Interest in viral hepatitis (e.g., JAMA viewpoint, HBV vaccination efforts) |
| **Hepatitis B Foundation** | President | Timothy M. Block, Ph.D. | Advocacy group; developed research roadmap |
| **Coalition for Global Hepatitis Elimination** | Director | John Ward, M.D. | Advocacy group supporting work on hepatitis B and C elimination |
| **Global Liver Institute** | President and CEO | Donna R. Cryer, J.D. | Advocacy group promoting global liver health |

## NIEHS: NATIONAL TOXICOLOGY PROGRAM—CURRENT ISSUES IN REGULATORY SCIENCE

### ISSUE SUMMARY

The National Toxicology Program (NTP) is an interagency program within the Public Health Service of the U.S. HHS. NTP's activities are executed through a partnership of the National Institute for Occupational Safety and Health of the CDC, the FDA, and the NIEHS, where the program is located administratively. It offers a unique venue for the testing, research, and analysis of agents of public health concern and provides scientific data, interpretation, and guidance in the appropriate uses of those data to health regulatory agencies, policy makers, other health-related research groups and the public. NTP also works to develop and apply new and improved methods and approaches that advance toxicology and better assess health effects from environmental exposures. The American people and government agencies rely on NTP to provide a strong scientific basis for making credible decisions that will protect public health. In the past 42 years, NTP has studied and shared information on the health effects of more than 2,800 substances, including dietary supplements, industrial chemicals, consumer products, and complex mixtures.

***The Report on Carcinogens.*** The Report on Carcinogens is a congressionally mandated, scientific, and public health document that identifies substances that pose a cancer hazard for people in the United States. It is intended to help the public make informed decisions about their health. The report is prepared for the HHS Secretary by NTP using an established process with multiple opportunities for public input. The report identifies many different types of environmental factors including industrial chemicals, infectious agents such as viruses, physical agents such as X-rays, and mixtures of chemicals, in two categories: known to be a human carcinogen and reasonably anticipated to be a human carcinogen. The 14th report, which has 248 listings, is the current edition. Under consideration for possible listing in the 15th report, which is in preparation, are the chemical antimony trioxide, six haloacetic acids found as water disinfection by-products, and the bacterium *Helicobacter pylori*. Information about the Report on Carcinogens is available at http://ntp.niehs.nih.gov/go/roc14.

***A Strategic Roadmap for Establishing Less Animal-Dependent Approaches***. An efficient, predictive, and economical system for assessing the effects of chemical substances on human health was envisioned in the seminal National Research Council report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*, which called for a new approach to toxicity testing that would rely less on animals and focus on human, cell-based, *in vitro* methods to evaluate the effects of chemicals on biological processes. The Division of the National Toxicology Program at NIEHS is a key partner in the interagency Tox21 program, which has developed high-throughput, cell-based approaches to characterizing the biological activity of chemicals and drugs. NIEHS and NTP also play a leadership role through the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The congressionally mandated, 16-member ICCVAM is charged with facilitating the development, validation, and regulatory acceptance of test methods that will replace, reduce, or refine the use of animals. To realize the full potential for improving human health offered by advances in science and technology, in January 2018 ICCVAM published *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States* as a resource to guide and expedite the development and utilization of new approach methodologies that would provide information more relevant to human health than existing animal-based methods. The strategic roadmap provides a conceptual framework to

support the development, evaluation, and use of new methods, and facilitate communication and collaboration within and between government agencies, stakeholders, and international partners.

## RELEVANT STAKEHOLDERS

**Internal**
None Identified

**External**
None Identified

## NIGMS: DIVERSITY IN THE BIOMEDICAL WORKFORCE

### ISSUE SUMMARY

A diverse and equitable biomedical research enterprise contributes to excellence in research training environments, strengthens the U.S. innovation base, and supports key sectors of the economy such as the provision of healthcare for U.S. citizens. Promoting diversity and inclusion within the biomedical scientific workforce is critical to the success of the NIH mission and is consistent with the mandates of the 21st Century Cures Act.

While the United States has made strides at increasing the number of Ph.D. degrees in the biomedical sciences awarded to individuals from historically underrepresented racial and ethnic groups, individuals from these groups remain underrepresented in the overall biomedical sciences research workforce, as described in the Notice of NIH's Interest in Diversity (NOT-OD-20-031). The severity of this underrepresentation increases throughout the different career training stages. For example, an increase in diversity in the ranks of faculty from basic science departments remains elusive (Gibbs, et al., *eLife,* 2016; Valantine, Lund & Gammie, *CBE-Life Sciences Education*, 2016). While efforts from NIH and NIGMS have contributed to the development of highly trained biomedical scientists who have the necessary knowledge and skills to productively pursue laboratory research, there remains a need to develop additional strategies to promote transitions to *independent faculty positions* at research-intensive institutions.

### KEY PROGRESS TO DATE

NIGMS maintains a strong commitment to strategies that enable and incentivize the scientific community to develop cultures that are inclusive, safe, and supportive of all community members. In 2018, NIGMS published a request for information (RFI) to obtain input from key community stakeholders, including postdoctoral scientists, biomedical faculty, scientific societies and advocacy organizations, and academic institutions, as well as from interested members of the public, on strategies to enhance postdoctoral career transitions that promote faculty diversity at research-intensive institutions.

Following the analysis of results stemming from this RFI, NIGMS is further enhancing its diversity-building efforts to ensure the involvement of multiple institution types throughout the country (e.g., T32 institutional training awards), participation of individuals from a wide variety of backgrounds (e.g., different racial/ethnic backgrounds, low socio-economic and/or rural backgrounds, or first-generation college students), and support of multiple stages of the career development pathway, including as early as K - 12 (e.g., the Science Education Partnership Awards, also known as SEPA).

### KEY CHALLENGES TO DATE

In FY 2019, NIGMS has directed its efforts at addressing the critical issue of faculty underrepresentation by facilitating career transitions to heighten the diversity and representation of academic faculty positions at institutions throughout the country. The recently launched Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program, for instance, focuses on enhancing diversity by facilitating the timely transition of promising postdoctoral researchers from diverse backgrounds from their mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions at research-intensive institutions. The program has two components: an institutionally focused research education cooperative agreement (UE5) and an individual postdoctoral career transition award (K99/R00). The UE5 cooperative agreements allow scientific professional societies to support educational activities that further develop the professional skills of MOSAIC

K99/R00 grantees, thus providing them with the appropriate mentoring and professional networks to allow them to successfully transition into independent academic research careers at research-intensive institutions.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jon Lorsch, Ph.D.** | Director, NIGMS | Jon.Lorsch@nih.gov | Institute Director |
| **Alison Gammie, Ph.D.** | Director, Division of Training, Workforce Development, and Diversity | Alison.Gammie@nih.gov | Director of NIGMS Division that administers biomedical workforce development training grants. |
| **Kenneth Gibbs, Ph.D.** | Program Director, Division of Training and Workforce, Diversity | Kenneth.gibbs@nih.gov | Manages the MOSAIC program. |
| **Michael Sesma, Ph.D.** | Branch Chief, Division of Training, Workforce Development, and Diversity | Msesma@mail.nih.gov | Oversees Postdoctoral programs for Research Training, Postdoctoral Fellowship, and Career Development Programs |

**External**

None identified

## NIGMS: LABORATORY SAFETY

### ISSUE SUMMARY

The NIGMS is committed to supporting the safety of the nation's biomedical research and training environments. The Institute has thus initiated efforts to promote the development and maintenance of robust cultures of safety at U.S. academic institutions in which biomedical research is conducted. While such efforts have been focused on building a culture of laboratory safety, many of the strategies for improving laboratory safety are also applicable to other forms of safety, including the prevention of harassment, intimidation, and discrimination. Laboratory safety takes on profound importance when one considers the number of recent examples of tragic accidents, the lessons learned from these recent events, and steps that institutions can take to improve their safety cultures.

### KEY PROGRESS TO DATE

All new FOAs for training programs supported by the NIGMS contain the expectation that the programs will promote "inclusive, safe and supportive scientific and training environments." In this context, the word "safe" refers to several aspects of safety, including: a) an environment free from harassment and intimidation, in which every individual participating in research is treated in a respectful and supportive manner, optimized for productive learning and research, b) the safety of institutional campuses so that individuals can focus on their studies and research, and c) the safety within both laboratory and clinical spaces.

Applicants and reviewers to the above-described FOAs are now asked to address how a program will promote a safe research training environment. In the required institutional letter of support for training grant applications, for instance, senior institutional leaders such as provosts or deans must provide information about how the institution ensures that the research and clinical facilities as well as the laboratory and clinical practices promote the safety of trainees. Similarly, the peer review panels that evaluate the applications are asked to assess the adequacy of these policies, procedures, and plans. Lab safety is also a topic that can be covered during the teaching of Responsible Conduct of Research (RCR). The application reviewers evaluate the RCR training plans and how RCR training is incorporated into each program's curriculum.

To help programs meet these new expectations, NIGMS has been providing administrative supplements to currently funded training grants to develop new curricular offerings and other activities aimed at enhancing safety training. In 2020, the Institute issued another announcement for lab safety training supplements, along with a companion announcement for supplements to promote safe and inclusive research training environments. We are encouraged by the number of supplement applications and look forward to following the outcomes of these new initiatives. In addition, NIGMS stood up a section of its website dedicated to Laboratory Safety Training and Guidelines to serve as a resource for the community.

### KEY CHALLENGES TO DATE

- Weak laboratory safety cultures have been repeatedly identified as significant contributors to accidents (U.S. Chemical Safety and Hazard Investigation Board, 2011; Hill, 2012; Safety Culture Task Force of the ACS Committee on Chemical Safety, 2012; National Research Council, 2014; Staehle *et al.*, 2016; University of California Center for Laboratory Safety, 2016a,b).
- Refocusing an academic institution on safety—or any other priority—must cascade from the top (Van Noorden, 2011; Gibson *et al.*, 2014).

- There is a need to articulate a clear and consistent message about safety; thus, institutional and organizational leaders should consider how to incentivize and reward good practices (National Research Council, 2014).

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jon Lorsch, Ph.D.** | Director, NIGMS | jon.lorsch@nih.gov | Institute Director |
| **Alison Gammie, Ph.D.** | Director, NIGMS Division of Training, Workforce Development, and Diversity | alison.gammie@nih.gov | Division Director |

**External**

None identified

## NIGMS: REGIONAL AND NATIONAL RESOURCES

### ISSUE SUMMARY

NIGMS is committed to supporting the development, maintenance, and accessibility of high-quality technologies and research resources, including laboratory and computational tools and technologies as well as reagent, biological, and data resources for the biomedical research community. These research resources enable access to state-of-the-art technologies, methods, and associated expertise essential to the advancement of biomedical research but, due to factors such as complexity or cost, may remain out of reach to individual laboratories. Moreover, regional (e.g., multi-state) or national resources can achieve economies of scale by serving substantial numbers of users more efficiently and economically than would be achieved by grants made to individual institutions, each with its own administrative, equipment, staffing, and related maintenance needs and costs.

NIGMS supports the provision of shared resources on both the national and regional levels. As an example of multi-state research resource provision, for instance, NIGMS supports resources in certain states that have received traditionally lower levels of NIH funding. These states are supported through NIGMS' Institutional Development Award (IDeA) program, which fosters the development, coordination and sharing of research resources and expertise to expand research opportunities and increase the number of competitive investigators in IDeA states. NIGMS also supports the commercialization of innovative technologies and methodologies developed in IDeA states through Regional Technology Transfer Accelerator Hubs. These hubs act as regional consortia to provide and build both infrastructure and entrepreneurial culture at IDeA institutions within each of the four IDeA regions (Central, Northeastern, Southwestern, and Western United States).

### KEY PROGRESS TO DATE

In light of the current COVID-19 pandemic, NIGMS has recently launched the IDeA State COVID-19 Data Registry. The registry will represent a secure clinical data portal that offers controlled access to clinicians providing care to patients and researchers studying the spread of SARS-CoV-2 and/or the pathology of COVID-19 for public health intervention measures. Similarly, the Institute also administers the IDeA National Proteomics Center and Northeast Bioinformatics Consortium as resources for scientific investigators.

In addition to the above, NIGMS has supported the full spectrum of development of unique technical capabilities and scientific research tools, from demonstration of proof-of-concept to prototyping, scaling, dissemination, and expansion. One area in which NIGMS has invested heavily is synchrotron technology, which enables determining the structure of biological molecules by x-ray crystallography. NIGMS currently supports mature synchrotron resources, providing state-of-the-art instrumentation, along with user support and training, made accessible to all biomedical researchers whose projects are vetted through a peer review process. NIGMS supports beamlines at five synchrotrons across the country, most of which are at National Labs; through a limited competition, NIGMS Mature Synchrotron Resources for Structural Biology (P30) award, NIGMS is ensuring that these beamlines remain up-to-date and provide the best possible service to the research community.

Within the field of imaging and structural biology, NIGMS and the NEI are leading NIH's Common Fund program on Transformative Cryo-Electron Microscopy (CryoEM), which enables structures to be determined for molecules that cannot be crystallized. The initiative has established three national service centers to provide researchers from across the country access to state-of-the-art equipment,

technical support, and cross-training for the production and analysis of high resolution CryoEM data. The initiative also supports four research education program grants that address the instructional needs for new users of CryoEM methods through the development of online and computer-based instructional materials in CryoEM technology.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jon Lorsch, Ph.D.** | Director, NIGMS | jon.lorsch@nih.gov | Institute Director |
| **Ming Lei, Ph.D.** | Division Director | leim@mail.nih.gov | Director, Division of Research Capacity Building, NIGMS |

**External**

None identified

## NIMH: AUTISM SPECTRUM DISORDER

### ISSUE SUMMARY

An estimated 1 in 54 eight-year old children in the United States have autism spectrum disorder (ASD), which is characterized by persistent deficits in social communication and social interaction across multiple contexts, and restricted, repetitive patterns of behavior, interests, or activities. Autism is known as a "spectrum" disorder because there is wide variation in the type and severity of symptoms people experience. ASD occurs in all ethnic, racial, and economic groups. Symptoms must be present in the early developmental period, can cause significant functional impairments, and can also be accompanied by language and/or intellectual disabilities.

As part of NIMH's role in shaping priorities in ASD research, the NIMH Director chairs the Interagency Autism Coordinating Committee (IACC), a federal advisory committee charged with coordinating federal activities concerning ASD and providing advice to the Secretary of Health and Human Services (HHS) on issues related to ASD. In June 2020, the IACC released the 2019 Summary of Advances In Autism Spectrum Disorder Research, which provides summaries of 20 studies that represent the top scientific advances in ASD research in 2019, as selected by the IACC. In August, the IACC released the IACC Strategic Plan 2018-2019 Update, which provides summaries of committee and federal activities in 2018 and 2019 that have contributed to progress toward Strategic Plan goals.

The identification of new biomarkers is an increasingly essential element of predictive, preventive, and personalized medicine for ASD and is a high priority area for NIMH. NIMH is a partner supporting the Autism Biomarkers Consortium for Clinical Trials (ABC-CT) cooperative agreement, which was established in 2015 to address the need for biomarkers of ASD. The ABC-CT award was renewed in 2020 to continue testing and refining clinical measures of social impairment in ASD in order to better evaluate potential behavioral and drug therapies for ASD. For example, one ABC-CT funded multi-site study is evaluating preschool- and school-aged children with and without ASD to test the utility of specified biomarkers for future use as stratification measures in clinical trials.

Even though ASD can be diagnosed as early as two years of age, most children are not diagnosed until after their fourth birthday. Screening children in primary care settings could help identify those at high risk for ASD, enabling early intervention and better long-term outcomes. As such, NIMH is supporting efforts to identify ASD at the earliest age possible. For example, NIMH funds the ASD Prevention, Early Detection, Engagement, and Services Research (ASD PEDS) Network, which comprises five separate but coordinated studies to test strategies for universal screening and early treatment. NIMH-funded research has identified risk markers within the first 12 months of age. Yet, a critical gap exists in translating these methods into practical, efficient, and inexpensive screening tools that could be implemented in the general population and within pediatric primary care settings. NIMH is supporting research to develop and validate new screening methods for ASD that can be used in the first year of life.

### KEY CHALLENGES TO DATE

- Because ASD is a heterogeneous disorder, there is a need for objective biomarkers to identify personalized interventions for individuals with ASD.
- Earlier interventions in ASD are associated with better long-term outcomes, but most children with ASD are not diagnosed until after their fourth birthday.

## KEY PROGRESS TO DATE

- In May 2019, an Electroencephalogram (EEG) biomarker known as "N170" became the first biomarker for a neurodevelopmental disorder or psychiatric condition accepted into FDA's Center for Drug Evaluation and Research Biomarker Qualification Program. This was one of the candidate biomarkers evaluated through the ABC-CT program.
- In FY 2019 NIMH awarded more than $4 million to support seven research projects aimed at developing and validating screening tools to detect signs of ASD in the first year of life.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Interagency Autism Coordinating Committee** | n/a | IACCPublicInquiries@mail.nih.gov | Coordinates ASD-related activities across the U.S. Department of Health and Human Services |
| **Lisa Gilotty, Ph.D.** | Chair, NIH Autism Coordinating Committee | gilottyl@mail.nih.gov | Oversees ASD-related research across NIH |
| Ann Wagner, Ph.D. | National Autism Coordinator | awagner@mail.nih.gov | Ensures the implementation of national ASD research, services, and support activities across federal agencies |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Autism Science Foundation** | n/a | contactus@autismsciencefoundation.org | Provides funding and other assistance to scientists and organizations conducting, facilitating, publicizing and disseminating autism research |
| **Autism Society** | n/a | info@autism-society.org | Provides advocacy, education, information and referral, support, and community at national, state and local levels |
| **Autism Speaks** | n/a | help@autismspeaks.org | Promotes solutions, across the spectrum and throughout the life span, for the needs of individuals with autism and their families |

## NIMH: PSYCHOSIS AND SCHIZOPHRENIA

### ISSUE SUMMARY

Schizophrenia is a serious mental illness and one of the top 15 leading causes of disability worldwide. It is characterized by alterations to a person's thoughts, feelings, and behaviors, which can include a loss of contact with reality known as psychosis. Individuals with schizophrenia often experience a delay between diagnosis and the start of treatment, typically ranging from one to three years. Delaying the start of treatment is often associated with poorer response and significantly worse long-term outcomes. Early detection of symptoms and intervention before psychosis develops, could attenuate, postpone, or even prevent the transition to psychosis, and improve individuals' clinical and functional outcomes. In addition to supporting earlier interventions, NIMH also continues to support basic research focused on understanding the underlying genetic and neurobiological causes of this illness.

The NIMH-supported Recovery After an Initial Schizophrenia Episode (RAISE) project demonstrated that early intervention improves clinical outcomes among youth with first episode psychosis (FEP), including members of racial and ethnic minority groups, and that Coordinated Specialty Care (CSC) is a feasible and cost-effective approach to early intervention for these individuals. Building on the findings of RAISE, and in support of continuing to expand CSC programs across the United States, NIMH established the Early Psychosis Intervention Network (EPINET), which now includes 98 CSC programs in 16 states. EPINET aims to create an early psychosis "learning healthcare system," in which data that are routinely collected drive continuous improvement in patient care and scientific discovery. By studying large, nationally representative data sets, EPINET may provide crucial insights into how best to tailor early psychosis care and provide information to guide improvements in diagnosis and intervention.

Although research has developed clinical and biological measures that can identify individuals who are at increased risk for developing psychosis, these findings have not yet translated into targeted interventions. This critical need for additional research is why the Foundation for NIH (FNIH) has launched a new Accelerating Medicines Partnership (AMP), in coordination with NIMH, focused on identifying and validating the most promising biological targets for therapeutics for people who are at risk of developing schizophrenia (SCZ). AMP SCZ is a public-private partnership that aims to develop measures that further define early stages of risk and predict the likelihood of progression to psychosis and other outcomes. Such tools will enable clinical trials to test new pharmacologic interventions that may prevent the onset of psychosis. AMP SCZ brings together NIMH, FDA, and multiple private partners, including patient advocacy groups, non-profit research organizations, and pharmaceutical industry representatives with the shared goal of discovering better ways of identifying and treating those at clinical high risk for psychosis.

### KEY CHALLENGES TO DATE

- Individuals with schizophrenia often experience long delays between their FEP and the start of treatment.
- Research has enabled identification of people at high risk for developing psychosis, but there are not yet effective targeted interventions for this high-risk population.

### KEY PROGRESS TO DATE

- **Start treatment for individuals with schizophrenia as early as possible.** CSC is now the standard of care for early psychosis, with over 285 CSC programs across the country. NIMH also recently funded eight EPINET regional scientific hubs and one national data coordinating center

that will make CSC practice tools available to all CSC community programs, standardize, collect, and aggregate data across community clinics, and use computational methods to study CSC fidelity, quality, and treatment effectiveness.

- **Develop targeted interventions for individuals at clinical high risk for psychosis.** In September 2020 NIMH announced the launch of the Accelerating Medicines Partnership – Schizophrenia (AMP SCZ). Three large NIMH grants will support this work via an unprecedented 42-site international research network and a state-of-the art centralized data center.

(b) (5)

## RELEVANT STAKEHOLDERS

### Internal

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Susan Azrin, Ph.D.** | Chief of the Early Psychosis Prediction and Prevention Unit (EP3) in the Division of Services and Intervention Research | azrinst@mail.nih.gov | Oversees a portfolio of grants including RAISE, EPINET, and other FEP projects |
| **Sarah Morris, Ph.D.** | Chief of the Psychotic Disorders Research Program in the NIMH Division of Translational Research | sarah.morris@nih.gov | Manages a portfolio of grants on the origins, onset, course, and outcome of schizophrenia spectrum disorders and other psychotic psychopathology |

### External

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Schizophrenia and Related Disorders Alliance of America** | n/a | info@sardaa.org | Provides support programs, education, collaboration, and advocacy for people living with schizophrenia-related brain disorders |
| **National Alliance on Mental Illness** | n/a | https://www.nami.org | Provides advocacy, education, support and public awareness to benefit individuals and families living with mental illness. |
| **OneMind** | n/a | https://onemind.org/ | Brings together scientists, clinicians, patient advocacy groups, industry leaders, health care providers, and policy makers to identify and solve important problems in brain health. |

## NIMH: SUICIDE PREVENTION

### ISSUE SUMMARY

Suicide is the tenth leading cause of death in the United States, with over 48,000 people dying by suicide in 2018. Additionally, the national suicide rate has been rising for two decades across all age groups, genders, races, and ethnicities. Suicide prevention research remains an urgent priority for NIMH. NIMH supports research aimed at understanding the complex mechanisms underlying suicide risk to develop the transformative prevention and treatment interventions of tomorrow. NIMH's portfolio includes projects aimed at identifying those most at risk for suicide, understanding the causes of suicide risk, developing suicide prevention interventions, and testing the effectiveness of these interventions and services in real-world settings. As the government lead in the National Action Alliance for Suicide Prevention's Prioritized Research Agenda for Suicide Prevention, NIMH has further helped to shape priorities in suicide prevention research.

Suicidal behavior is complex, and there is no single cause. Access to affordable and effective evidence-based care is inadequate and inequitably distributed, representing a significant challenge to implementing suicide prevention measures. However, people most at risk tend to share specific characteristics, and suicide is often preventable. Because most suicide decedents in the U.S. have accessed healthcare services in the 12 months preceding their death, healthcare systems can play a vital role. NIMH research has focused on emergency departments (EDs) as a critical focal point, demonstrating that brief screening tools can improve providers' ability to identify individuals at risk for suicidal behavior and refer them to treatment NIMH supports research examining suicide preventive practices in healthcare systems. For example, NIMH is supporting three grants under the NIH-wide Firearm Injury and Mortality Prevention Research funding opportunity. These studies will address topics of importance – such as safe storage of firearms – to advance the science of suicide prevention. NIMH is also supporting a grant to assess the effectiveness of clinician-administered interventions including Safety Planning, an approach that reduces access to lethal means, identifies coping strategies to decrease risk of suicidal behavior, and provides resources that could help in crisis.

Further, NIMH and extramural scientists' collaboration on a mathematical modeling exercise demonstrates that mail-, phone-, and psychotherapy-based interventions could all be cost-effective if administered to patients identified as at-risk during emergency room visits. NIMH is also supporting ED efforts to identify and implement telehealth-supplied suicide prevention practices. Partnerships such as these are essential for the uptake of evidence-based suicide prevention practices that save lives.

Combining data from 2001 through 2015, researchers examined suicides among children ages 12 and younger and found that Black children were more likely to die by suicide than their white peers. In response to this pattern, the Congressional Black Caucus (CBC) Emergency Taskforce on Black Youth Suicide and Mental Health released a report, "Ring the Alarm: The Crisis of Black Youth Suicide in America," which included recommendations to identify risk and protective factors among Black youth; research mental health motivation, utilization, and engagement among Black youth; and, address practical, systemic, and cultural barriers for this at-risk group. On April 21, 2020, the NIMH Office for Disparities Research and Workforce Diversity and the Office of Behavioral Health Equity at the Substance Abuse and Mental Health Services Administration (SAMHSA) co-hosted a virtual panel to discuss the CBC Taskforce report and formulate strategies. NIMH is also preparing to convene a series of roundtable discussions and workshops on risk and risk trajectories for preteen suicide. NIMH will

continue to support research focused on developing preventive, treatment, and services interventions, as well as identifying strategies to expand access for Black youth and other vulnerable populations.

## KEY CHALLENGES TO DATE

- The annual rate of death by suicide has risen by over 30 percent over the last 20 years.
- The majority of those who die by suicide have accessed the healthcare system within the year before their death – yet for many, their risk for suicide goes undetected.
- The rising rate of suicide deaths and attempts has been especially pronounced among vulnerable populations including Black and American Indian/Alaska Native youth.

## KEY PROGRESS TO DATE

- NIH steadily increased its support for suicide research: NIH spent approximately $52 million on suicide research in FY 2016 and $117 million in FY 2019.
- Building on NIMH research on the antidepressant properties of the drug ketamine, in 2018 researchers demonstrated that a single low dose of ketamine rapidly alleviated suicidal ideation among depressed, highly suicidal patients. NIMH recently funded studies to examine the safety, dosing, and durability of a number of rapid acting interventions to reduce suicide risk.
- NIMH is encouraging research to identify telehealth-supplied suicide prevention practices.
- In June 2020 NIMH issued Notice of Special Interest (NOSI) (NOT-MH-20-055) to encourage research focused on reducing suicide specifically among Black children and adolescents.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Jane Pearson, Ph.D.** | Special Advisor to the NIMH Director on Suicide Research | jpearson@mail.nih.gov | Advises the NIMH Director on topics related to suicide and suicide prevention |
| **Stephen O'Connor, Ph.D.** | Chief of the NIMH Suicide Prevention Research Program | stephen.o'connor2@nih.gov | Manages a grant portfolio on youth and adult-related suicide risk detection and interventions |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **National Action Alliance for Suicide Prevention** | n/a | info@theActionAlliance.org | Works with national partners to implement efforts aimed at reducing the annual suicide rate by 20 percent by 2025 |

## NIMHD: CHRONIC HEALTH CARE OUTCOMES POST DISASTER

### ISSUE SUMMARY

Natural and human-made disasters are common occurrences across the U.S. and its territories and vary by factors such as geographic location and seasonal weather changes. Natural disasters include extreme weather-related events such as hurricanes, wildfires, floods, tornadoes, volcanic eruptions, earthquakes, and snowstorms. Human-made disasters include oil and chemical spills and contamination, nuclear testing and contamination, and water contamination.

The aftermath of disasters can result in adverse health outcomes, including onset or worsening of chronic conditions, especially for individuals experiencing health disparities. Chronic conditions, including heart disease, diabetes, cancer, stroke, Alzheimer's disease, chronic lung disease, and chronic kidney disease, are the leading causes of death and disability in the U.S. and are costly to the health care system. Racial and ethnic minorities, and other populations with health disparities, experience a disproportionate burden of morbidity and mortality due to chronic conditions. For example, loss of medical infrastructure following disasters may trigger a prolonged level of increased need for medical services and health care professionals. Disaster-related psychosocial stressors can contribute to post-traumatic distress, or other mental health issues, or further exacerbate existing chronic medical or psychiatric illnesses. These stressors can also lead to an increase in risk factors for subsequent chronic disease morbidity and mortality, such as poor nutrition, physical inactivity, smoking, alcohol and substance use, and lack of adherence to health maintenance or disease self-management behaviors.

Research on disasters often focuses on disaster preparation, the effect of environmental risk factors, or changes in mental health and substance use following disasters. The long-term effects of disasters on chronic health care outcomes is an understudied research area. NIMHD is increasing its focus on research to better understand disaster-related chronic health care outcomes that could lead to more effective implementation of clinical care guidelines and health care delivery strategies prior to, during and after disasters, and potentially prevent an increase in health care disparities in the most vulnerable communities.

### KEY PROGRESS TO DATE

NIMHD is committed to enhancing understanding of, and addressing, chronic diseases in populations that experience health disparities and chronic health care outcomes post-disaster. Progress to date includes the release of FOAs to support research focused on:

- Long-term Effects of Disasters on Health Care Systems Serving Health Disparity Populations, which will support investigative and collaborative research to understand the long-term effects of natural and/or human-made disasters on health care systems serving populations with health disparities in the U.S. and its territories. Research will focus on strategies to ensure access to services and continuity of care, enhance prevention and treatment of acute exacerbations of chronic diseases, for example, mitigation strategies to ensure storage, availability and delivery of medications, and protection of EHRs and health care system functionality.
- Clinical and Epidemiological Research on Chronic Disease in the Caribbean, supports U.S.-Caribbean collaborative research to develop or extend cohort or surveillance studies on chronic disease in the Caribbean region. Chronic disease prevalence and mortality are increasing in the Caribbean region, an area prone to hurricanes. This initiative will support research that can assist in discerning consistent patterns of disease risk and prevalence within the Caribbean region and/or to make comparisons with individuals of Caribbean-origin in the U.S.

- Time Sensitive Research on Health Risks and Resilience after Hurricanes Irma and Maria in Puerto Rico and the U.S. Virgin Islands, supports time-sensitive research on risk and resilience factors related to short- and long-term health outcomes following Hurricanes Irma and Maria in Puerto Rico and the US Virgin Islands. A total of 12 awards were made in collaboration with the National Cancer Institute, National Institute on Mental Health, and the National Institute on Drug Abuse.

## KEY CHALLENGES TO DATE

- Impact of disasters on populations with health disparities is understudied
- Disaster response and recovery activities focus on short-term assessment of the infrastructure and functionality of health care facilities
- Lack of understanding of the long-term effects of disasters on health care systems and health outcomes for people with chronic diseases

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eliseo J. Pérez-Stable, M.D.** | NIMHD Director | eliseo.perez-stable@nih.gov | Leads scientific research to improve minority health and reduce health disparities |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H.** | Director, HHS Office of Minority Health | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities |

## NIMHD: COMMUNITY-ENGAGED INTERVENTIONS TO PROMOTE HEALTHY LIFESTYLES AND MANAGE CHRONIC DISEASE

### Issue Summary

Community-engaged interventions hold much promise for improving health and reducing health disparities, with positive results on health behaviors, self-efficacy, disease management, social support, and clinical outcomes. Such interventions promote a collaborative approach that engages both community and research partners in the translational research process. Engagement of the community in research to understand and address minority health and health disparities is critical to identifying important health issues in the community. It also contributes to building community capacity, designing and implementing interventions, soliciting the community's participation in research studies, and disseminating evidence-based research findings and health information to educate the community and inform policy and practice.

The community engagement research process involves community members, persons affected or impacted, researchers, public health and policy professionals, and other key stakeholders, in the community's health as full participants in each phase of the research. These include conception, design, implementation, analysis, interpretation, communication, and dissemination of the results.

Community-engaged approaches provide many benefits, including the creation of bridges between the community, scientists, and policy professionals, to facilitate the bidirectional transfer of knowledge and skills, improved community research literacy, and creation of appropriate and effective interventions. It supports the intensive partnership and coalition-building that is needed to develop meaningful, successful research, to improve minority health and address health disparities in socially disadvantaged populations and communities.

### KEY PROGRESS TO DATE

- Established the Community-Based Participatory Research Program in 2005, to support collaborative interventions that involve scientific researchers and community members to address diseases and conditions disproportionately affecting populations with health disparities.
- Inclusion of community-engagement as a required component of key NIMHD programs:
    - NIMHD Specialized Centers of Excellence on Minority Health and Health Disparities, which fund transdisciplinary, multi-level research and provide research opportunities for post-doctoral fellows, junior faculty, and other ESIs to engage in research on minority health and health disparities.
    - The Research Centers in Minority Institutions (RCMI) Specialized Centers, which develop and strengthen the research infrastructure necessary to conduct state-of-the-art biomedical research and foster the next generation of researchers from underrepresented populations.
- Collaborated with the National Heart, Lung, and Blood Institute (NHLBI) to support the Community Engaged Alliance (CEAL) Against COVID-19 Disparities, which promotes diversity and inclusion in COVID-19 prevention, vaccine, and therapeutic trials, and conducts urgent community-engaged research and outreach focused on COVID-19 awareness and education.
- Recent FOAs related to community-engaged interventions:
    - Community Interventions to Address the Consequences of the COVID-19 Pandemic among Health Disparity and Vulnerable Populations (PAR-20-237) will support research to test the impacts of mitigation strategies to prevent COVID-19 transmission, and interventions that

address the pandemic's adverse psychosocial, behavioral, and socioeconomic consequences among populations with health disparities and other vulnerable groups.
  - Research Centers in Minority Institutions Specialized Centers (RFA-MD-17-003)
  - NIMHD Specialized Centers of Excellence on Minority Health and Health Disparities (RFA-MD-17-005)
  - Advancing Health Disparities Interventions through Community-Based Participatory Research Program (RFA-MD-15-010)

## KEY CHALLENGES TO DATE

- Convincing the scientific research community that community-engaged interventions can be effective in improving health outcomes and reducing health disparities.
- Identification and use of a standard or consistent definition for community-engaged interventions. The term has variations from community-based participatory research, community-based research, to community-engaged research.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Eliseo J. Pérez-Stable, M.D.** | NIMHD Director | eliseo.perez-stable@nih.gov | Leads scientific research to improve minority health and reduce health disparities |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **RADM Felicia Collins, M.D., M.P.H.** | Director, HHS Office of Minority Health | Felicia.Collins@hhs.gov | Leads efforts to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. |

## NINDS: BRAIN RESEARCH THROUGH ADVANCING INNOVATIVE NEUROTECHNOLOGIES (BRAIN) INITIATIVE

### ISSUE SUMMARY

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is an ambitious program to develop and apply new technologies to answer fundamental questions about the brain and, ultimately, to understand and treat brain diseases. The early successes of the Initiative set the path for implementing larger scale, transformative projects.

Launched in 2014, The BRAIN Initiative leverages a timely convergence of public health needs and scientific opportunity. The need: dysfunction of brain circuits underlies neurological, psychiatric, and substance use disorders that impose an immense public health burden, yet the complexity and inaccessibility of the brain have limited research tools that would answer fundamental questions about brain function in health and disease. The opportunity: science and engineering advances now offer the potential to address these limitations, enabling researchers to monitor the activity of thousands of brain cells in real time, precisely modulate brain circuits, and map the intricate connections among nerve cells.

At the Initiative's inception, an independent group of scientists consulted with the scientific community and wrote BRAIN 2025: A Scientific Vision, which provided an overarching vision and plan for this multi-faceted program. Staff from 10 NIH Institutes and Centers manage the trans-NIH Initiative through fully integrated teams. Congress has targeted support to the Initiative through both the 21st Century Cures Act and regularly appropriated funds specified for the BRAIN Initiative to NINDS and NIMH. In 2020, NIH received $500M for BRAIN, which corresponds with the recommended estimate in the BRAIN 2025 report.

### KEY PROGRESS TO DATE

In 2019, a new external scientific BRAIN Initiative Working Group 2.0, reported to the ACD, after extensive evaluation and consultation with the scientific community, that the scientific goals of the Initiative were still compelling and the Initiative is advancing on all major priorities of the plan.

From its inception, the Initiative focused on the normal brain, largely in laboratory animals, with the expectation that this will in due course provide tools and knowledge to combat human brain diseases. The extent to which the Initiative is already opening new avenues for progress against human disease is encouraging. Among these are methods to identify brain cell types affected by specific diseases and target drugs to them; self-adjusting deep brain stimulation (DBS) therapies; brain computer interfaces that decode speech directly from brain activity; and approaches to partially restoring vision. Beyond medical science, private sector investments inspired by the BRAIN Initiative in artificial intelligence, "neuromorphic" computer hardware, and human computer interfaces are also already underway.

### KEY CHALLENGES TO DATE

In addition to pushing the frontiers of science and engineering, challenges include:

- Diverse perspectives strengthen science. The Initiative successfully attracted scientists and engineers from many disciplines but attracting women and underrepresented minorities remains challenging and is a major focus moving forward. Further, while the American scientific enterprise historically has benefited from the participation of scientists and trainees from around the world, in recent years such collaborations have become increasingly disincentivized, leading to a contraction of the talent pool required to propel our multi-disciplinary studies.

- Data archiving, dissemination, and analysis present challenges because of the immense quantity and diversity of data types. The Initiative is developing data standards, analysis tools, archives, and theoretical frameworks, and has implemented a stringent data sharing policy.
- Increasing and concerning legislative emphasis on reducing research conducted with non-human primate (NHP) animal models: The ability to develop tools and technologies to conduct scientifically rigorous, ethical, efficient, and cost-effective research in NHP models is a critical bridge for understanding the human brain and translating basic discoveries into cures.
- Increased restrictions on conducting research with ethically sourced HFT has hampered scientific efforts. Fully understanding the development of neural circuitry in humans, as outlined in the BRAIN strategic plan, will require the study of HFT, as will understanding tragic disorders of abnormal brain development.
- Research at the frontiers of neuroscience raises many potential ethical issues requiring thoughtful consideration for anticipating and navigating the challenges arising from new brain technologies. The Initiative's Neuroethics Working Group provides leadership in this domain.

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **John Ngai, Ph.D.** | Director, NIH BRAIN Initiative | john.ngai@nih.gov | Directs BRAIN Initiative activities across NIH |
| **Walter Koroshetz, M.D.** | Director, NINDS | koroshetzw@ninds.nih.gov | Co-chair of BRAIN IC Directors group and BRAIN MCWG |
| **Josh Gordon, M.D., Ph.D.** | Director, NIMH | joshua.gordon@nih.gov | Co-chair of BRAIN IC Directors group and BRAIN MCWG |
| **Christine Grady, M.S.N., Ph.D.** | Chief, Department of Bioethics, NIH Clinical Center | CGrady@cc.nih.gov | Co-chair, BRAIN Neuroethics Working Group |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Brain Initiative Alliance** | n/a | https://www.braininitiative.org/ | Coordinates BRAIN activities across agencies. |

## NINDS: MYALGIC ENCEPHALOMYELITIS/CHRONIC FATIGUE SYNDROME (ME/CFS)

### ISSUE SUMMARY

ME/CFS is defined by persistent fatigue lasting more than six months, post-exertional malaise, unrefreshing sleep, and either cognitive dysfunction or orthostatic intolerance. ME/CFS onset is often triggered by a bacterial or viral infection; but its ultimate cause is unknown, its pathophysiology is poorly understood, and there are no approved diagnostic tests. ME/CFS is estimated to affect between 836,000 and 2.5 million people in the US, with at least one-quarter being bed or housebound at some point. Many people with ME/CFS believe their disease and accompanying symptoms have been often ignored or discredited by the medical community, and that NIH funding for ME/CFS is too low given estimates of the number of affected people, many undiagnosed. NIH announced plans to strengthen and expand ME/CFS research and has subsequently taken several important steps in that direction.

ME/CFS has recently gained increased attention in the media because chronic fatigue that is strikingly similar to that seen in ME/CFS has been highlighted as one of the long-term symptoms of COVID-19 that can linger for months following clearance of the virus. So-called long-haulers (individuals with chronic post-COVID-19 symptoms) and ME/CFS advocates have speculated that COVID-19 will increase the numbers of individuals suffering from ME/CFS. They are advocating for increased research to follow people with chronic symptoms post-COVID-19 to determine if some will also be diagnosed with ME/CFS.

### KEY PROGRESS TO DATE

**Ongoing Research:** In 2017 NIH established ME/CFSnet, with three ME/CFS Collaborative Research Centers and a Data Management and Coordinating Center (DMCC). ME/CFSnet aims to develop and identify new diagnostics, novel biomarkers, and ways to stratify patients into subgroups based on clinical presentation. ME/CFSnet research suggests that immune dysregulation and differences in immune cell metabolism play important roles in ME/CFS. The Centers are conducting interim data analysis and finishing participant recruitment for clinical studies, and the DMCC has developed tools for ME/CFS researchers to deposit, search for, and use data, biospecimens, and published studies. In April 2020, NIH posted two ME/CFS research funding opportunities, which increased ME/CFS applications for the current grant cycle. Since October 2016, NINDS Clinical Director Dr. Avi Nath has led a comprehensive multisystem study to evaluate individuals with post-infectious ME/CFS to identify clinical and biological markers and disease mechanisms. The team also reported initial findings from in-depth focus groups to understand the perspectives of people with ME/CFS who have post-exertional malaise.

**Collaboration and Coordination**: Due to the complexity of ME/CFS, NIH has adopted an interdisciplinary approach involving 23 NIH Institutes, Centers, and Offices and coordinated through the Trans-NIH ME/CFS Working Group, which meets regularly to discuss the best approaches to foster ME/CFS research. The Interagency ME/CFS Working Group, led by NIH and CDC, first met in August 2020. Participants included multiple government agencies and ME/CFS patient advocacy organizations interested in research and care issues. The group will meet regularly to share updates, discuss research issues, and foster communication and collaboration across agencies and with ME/CFS stakeholders.

**Other Efforts to Facilitate Research:** NINDS and the CDC have worked with clinicians, researchers, people with ME/CFS, and caregivers to develop and release the first set of Common Data Elements for ME/CFS. These data standards will enable researchers to systematically collect data and will facilitate study start-up and data aggregation and sharing across studies. In September 2019, the National Advisory Neurological Disorders and Stroke Council (NANDSC) Working Group for ME/CFS Research

made recommendations for advancing ME/CFS research, including on research opportunities and ways to attract and train new researchers, and enhance collaboration, coordination, and communication.

## KEY CHALLENGES TO DATE

- ME/CFS is a poorly understood disease with no known cause, no approved diagnostic tests or treatments, and variable symptom presentation across patients and within patients over time. It has a high disease burden, with at least a quarter of ME/CFS patients bedbound or housebound.
- The ME/CFS advocacy community is well-informed, very active on social media, and regularly contacts NIH, CDC, and HHS to strenuously advocate for more research. In March 2020, ME/CFS protesters interrupted the House Appropriations Hearing during Dr. Collins' opening statements and demanded that the NIH take urgent action to address the ME/CFS crisis.
- The pool of academic investigators studying ME/CFS is small, and it is difficult to draw scientific conclusions from published research because of small sample sizes, use of different classifications of ME/CFS, and lack of standardized clinical outcome measures. In April 2019, NIH held a ME/CFS research conference and a workshop specifically for young investigators in the ME/CFS field.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Walter Koroshetz, M.D.**<br>**Vicky Whittemore, Ph.D.**<br>**Joe Breen, Ph.D.** | Trans-NIH ME/CFS Working Group | walter.koroshetz@nih.gov<br>vicky.whittemore@nih.gov<br>Jbreen@niaid.nih.gov | Coordinates ME/CFS research activities across NIH |
| **Walter Koroshetz, M.D.**<br>**Inger Damon, M.D., Ph.D.** | Interagency ME/CFS Working Group | walter.koroshetz@nih.gov<br>lad7@cdc.gov | Coordinates and communicates ME/CFS efforts across agencies and advocacy organizations |
| **Avindra Nath, M.D.** | Clinical Director, NINDS | natha@ninds.nih.gov | Principal Investigator of the Intramural ME/CFS study |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Linda Tannenbaum** | Open Medicine Foundation; CEO | ltannenbaum@omf.ngo | Nonprofit group; raises funds for, supports ME/CFS research |
| **Sadie Whitaker, Ph.D.** | Solve M.E.; CSO | swhittaker@solvecfs.org | Nonprofit group; engages ME/CFS community in research, advocacy, and patient support |
| **Jaime Seltzer, M.S.** | MEAction; Director, Scientific and Medical Outreach) | jaime@meaction.net | Nonprofit group; supports ME/CFS awareness/education, advocacy, and patient support |

## NINDS: ULTRA-RARE GENE THERAPY (URGENT) NETWORK

### ISSUE SUMMARY

NINDS is establishing the Ultra-Rare Gene Therapy (URGenT) network to support the development of state-of-the-art gene-based therapies for ultra-rare diseases, which affect as few or fewer than one in fifty thousand people. Altogether, around 7,000 known rare and ultra-rare diseases affect 30 million people in the US. Many are life-threatening, and few have FDA-approved treatments. About 45% of rare diseases, including ultra-rare diseases, are neurological disorders, and 90% of rare childhood disorders have major neurological effects. Most rare diseases have a genetic origin, and for ultra-rare diseases, the causal mutations are unique to very small numbers of people, sometimes to a single patient. Although ultra-rare diseases cumulatively represent a large medical need, the small number of people with each condition makes research difficult and limits incentives for commercial investment.

Given the lack of available treatments and the devastating and often rapid progression that occurs with many rare diseases, patients, families, and advocacy organizations are eager to see progress. The success of gene-based treatments for some rare diseases, including spinal muscular atrophy and muscular dystrophy, has motivated efforts for even the rarest of diseases. In recent years, a number of N of 1 studies of custom-designed treatments for a single patient have gained public attention. Such efforts present tough challenges for safety and efficacy research, regulatory approval, and business processes built around larger numbers of patients, as well as implications for equitable access, as few families have the resources necessary to advocate for, launch, and support N of 1 therapy development.

The URGenT network is a late stage preclinical therapy development program that aims to speed the delivery of therapies to patients with ultra-rare diseases; standardize and harmonize best practices; and encourage innovation in clinical trials. It will address specific challenges of gene targeting technologies, with a focus on de-risking these modalities for industry adoption and coordinating their entry into clinical trials. The network will advance the science and pipeline for gene-based therapies, train a diverse translational workforce, and create meaningful partnerships with the pharmaceutical and biotechnology industries. The URGenT network will be supported through the NINDS Division of Translational Research (DTR), which has significant experience leading milestone-driven programs for developing small molecule drugs, biologics (including gene-targeted therapies), and devices from preclinical development to first-in-human testing.

### KEY PROGRESS TO DATE

Since receiving concept approval from the National Advisory Neurological Disorders and Stroke Council in February 2020, NINDS has developed a detailed design for the URGenT network and initiated efforts to establish contract resources for conducting studies to prepare for IND applications to the FDA, for manufacturing, and for making subject matter experts available to grantees and program staff. FOAs for the program are in development.

### KEY CHALLENGES TO DATE

- Identifying and Prioritizing Eligible Diseases: Resources will not be available for every disease, and progress may be more likely for some diseases than others, depending on how much is known about a disease and other factors. NINDS will need to establish clear criteria for identifying and prioritizing candidate diseases for entry into the URGenT network and ethical considerations also will be critical. It is anticipated that URGent will need to accommodate continued treatment over time for some disorders. Potential criteria will include whether:

- the disease or mutation is potentially treatable with a gene-based approach,
- treatment is likely to have a favorable risk to benefit ratio, and
- measurable and sustainable patient outcomes have been established.

- Communicating and Setting Expectations for Patients and Families: Patients and families affected by severe ultra-rare diseases are understandably desperate for new and effective treatments. The URGenT network will need to be transparent about its processes for selecting and continuing projects.
- Streamlining the Development of Tailored Therapeutics: Means to standardize and share data, resources, and best practices across diseases will help to make therapy development for ultra-rare diseases more efficient and accessible. Significant effort will be required to develop and implement the therapy development process, including designing and screening therapeutic candidates, conducting preclinical and clinical safety testing, preparing IND materials for the FDA, and manufacturing clinical grade therapeutic agents.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Chris Boshoff, Ph.D.** | Program Director, NINDS DTR | chris.boshoff@nih.gov | Staff lead for URGenT |
| **Ann-Marie Broome, M.B.A., Ph.D.** | Program Director, NINDS DTR | ann-marie.broome@nih.gov | Staff lead for URGenT |
| **Nina Schor, M.D., Ph.D.** | Deputy Director, NINDS | nina.schor@nih.gov | Lead for URGent |
| **Jill Morris, Ph.D.** | Program Director, NINDS DON | jill.morris@nih.gov | Staff lead for URGent |
| **Amir Tamiz, Ph.D.** | Director, NINDS DTR | amir.tamiz@nih.gov | Program oversight and coordination with other NINDS activities |

## NLM: GROW RESEARCH DATA SERVICES IN A SUSTAINABLE WAY

### ISSUE SUMMARY

It is anticipated that by 2025 the amount of biomedical and related data available to researchers will exceed 175 zettabytes. This exponential growth in biomedical data is a result of a transition from treating data as a by-product of research to recognizing data as an asset in itself, a valuable output of research. Leveraging the value of the public's investment in data creation requires advanced efforts in data collection and management, accompanied by policies and practices that promote data sharing and reuse. NLM collects, preserves, and provides access to biomedical research data that is used by millions of people and computers every day. These critical, advanced data services support biomedical research, clinical care, and public health. As biomedical research becomes more data-intensive and NIH establishes broader expectations for the management and sharing of data resulting from NIH-supported research, demands on NLM services will grow at rates that outpace growth in research budgets. New approaches to support data services, including long-term roadmaps outlining research needs, technological advances, and resource requirements are needed to effectively manage and keep pace with the anticipated growth in data.

### KEY PROGRESS TO DATE

- NIH issued a Strategic Plan for Data Science in June 2018 that provides a roadmap for modernizing the NIH-funded biomedical data science ecosystem. NLM plays key roles in implementing the strategy through leadership of and participation in trans-NIH working groups.
- NLM supported a study by the NASEM to develop and disseminate modeling approaches to estimate the cost of long-term preservation and storage of biomedical data.
- NLM is building reusable, scalable tools needed to keep pace with the growth of research data, including criteria for data repositories; metadata models to promote discovery; and standards for data collection, representation, and communication.
- NLM modernized its data services and resources to improve efficiencies and boost effectiveness by consolidating data onto a smaller number of independent platforms and transitioning some data services to cloud-based services.

### KEY CHALLENGES TO DATE

- Reconciling budget constraints and efforts to sustain important data services, such as the ClinicalTrials.gov registry and results database, and the fast-growing Sequence Read Archive (SRA) of genomic sequence information. NIH provided needed funding to support the modernization of ClinicalTrials.gov and transition the SRA to cloud-based services.
- Building support for trans-NIH common principles to inform decisions about data services and associated funding decisions. Metrics are needed to support repository evaluation. NLM is participating in newly established trans-NIH groups to develop such principles.
- Gaining alignment around strategies to promote data discoverability (including assignment of persistent identifiers to data sets); develop efficient approaches to data acquisition and curation; and adopt data standards to promote interoperability.
- Facilitating partnerships among NIH, other federal agencies, and private partners in industry and academia to ensure that NIH applies state-of-the art data management and storage technologies and avoids duplication of effort. NLM is engaged in several interagency working groups to identify good practices and develop common approaches to common challenges.

**NEXT STEPS**

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Susan Gregurick, Ph.D.** | Director, Office of Data Science Strategy | Susan.gregurick@nih.gov | Key leader and coordinator of data science across NIH |
| **Jon Lorsch, Ph.D.** | Chair, NIH Scientific Data Council | jon.lorsch@nih.gov | Council oversees data science across NIH |

**External**

None identified

## NLM: REORGANIZATION AND PERSONNEL

### ISSUE SUMMARY

NLM is implementing a multi-phase reorganization to support objectives of its Strategic Plan, 2017-2027, and improve operational efficiencies. The plan advances NLM's congressionally mandated mission and creates a future in which data and information transform and accelerate biomedical discovery and improve health and health care. By increasing efficiencies in the delivery of NLM's heavily used health data and information services, the reorganization enables NLM to expand its intramural and extramural research and training programs in health-related data science – areas of growing importance in the health and biomedical research communities — and improve the management of its intramural research program by integrating its strong program in computational biology with a newly focused program in computational health. The reorganization provides NLM with the opportunity to launch senior-level recruitments for directors of NLM's Lister Hill National Center for Biomedical Communications (LHNCBC) and National Center for Biotechnology Information (NCBI), in addition to a Scientific Director to set scientific priorities for NLM's broad intramural research program.

### KEY PROGRESS TO DATE

NLM implemented Phase 1 of its reorganization in January 2019 resulting in the elimination of the Division of Specialized Information Services, Audiovisual Program Development Branch, and Office of High-Performance Computing. The changes allowed NLM to reassign more than 70 Federal employees to higher priority NLM activities and sunset more than 30 NLM information products and services. As part of this process, NLM improved access to important toxicological and environmental health information by embedding it onto more established NLM platforms where it can be integrated with related information. NLM also consolidated its outreach and training programs and established new organizational structures within the OD to better coordinate its growing efforts in data science, data standards, open science, and strategic planning.

NLM has completed plans for Phase 2 of its reorganization to position NLM to better coordinate management and growth of its intramural research program, which has units in both LHNCBC and NCBI. The reorganization will orient LHNCBC towards a focus on clinical data and restructure its staff into three branches dedicated to: research (Computational Health Research Branch), technology development (Applied Clinical Informatics Branch), and computational support (Scientific Computing Branch). By consolidating research activities and principal investigators from across LHNCBC into the Computational Health Research Branch, the reorganization will position NLM to implement the recommendation of its 2018 BRP Review to unify the management of intramural research currently housed in LHNCBC and NCBI under a single Scientific Director.

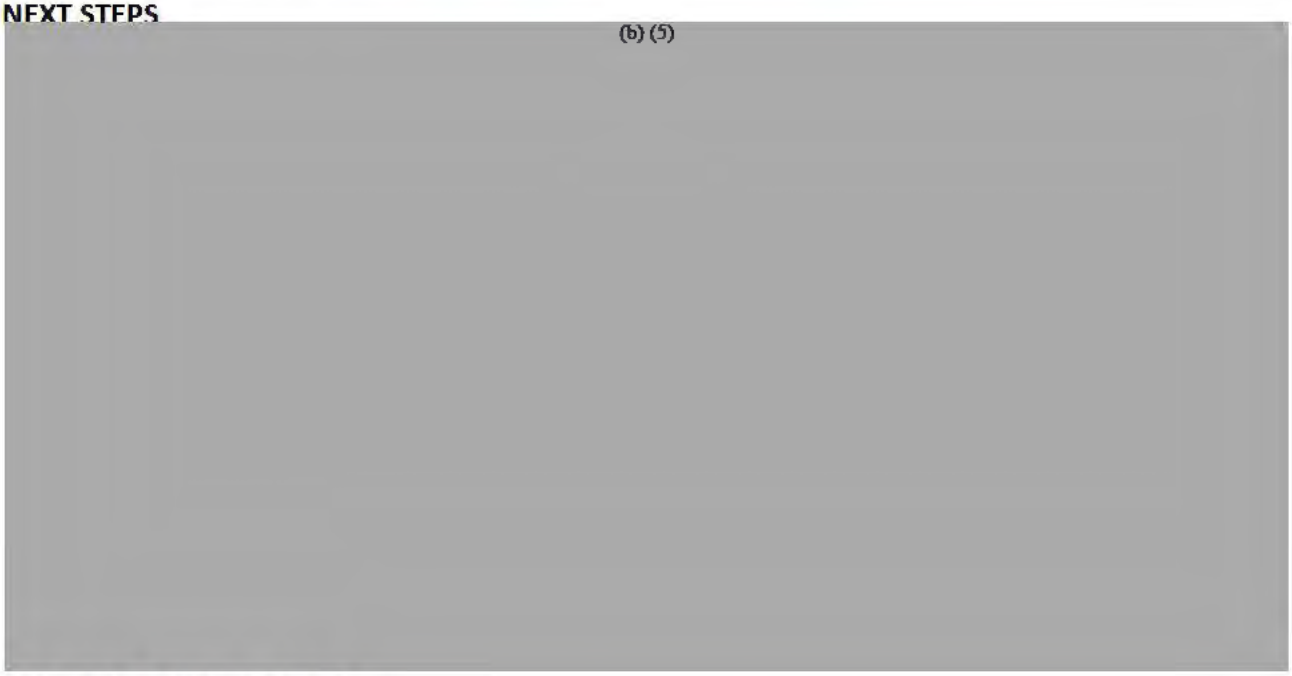
### KEY CHALLENGES TO DATE

- Transitioning to an integrated intramural research program will demand significant changes in culture and practices for managing budgets, personnel, and programs. NLM has made significant progress through a joint seminar series, recruitment of new investigators, establishment of a single Board of Scientific Counselors, and appointment of an acting Scientific Director.
- Implementing the planned reorganization will require the recruitment of a new Scientific Director and new directors of LHNCBC and NCBI. All three positions are currently filled on an acting basis, which allows NLM to move swiftly to launch recruitments in 2021. Ideal recruits will be scholars and innovators with advanced skills in biomedical data science. Significant

market demand for these skills will make attracting such individuals to federal service a considerable challenge.

**NEXT STEPS**

(b) (5)



## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Alfred Johnson, Ph.D.** | Deputy Director for Management, NIH | Johnsoa1@mail.nih.gov | Approval of Concept Plan |
| **Julie Broussard Berko, M.P.A.** | Director, Office of Human Resources, NIH | berkojb@mail.nih.gov | Recruitment of LHNCBC and NCBI Directors |
| **Michael Gottesman, M.D.** | Deputy Director for Intramural Research | mgottesman@nih.gov | Recruitment of Scientific Director |

**External**

None identified

## CC: PATIENT SAFETY

### ISSUE SUMMARY

In the last few years, the NIH Clinical Center has enhanced its focus on patient safety through the implementation of a number of novel programs.

### KEY PROGRESS TO DATE

The Clinical Center has implemented a daily Patient Safety Huddle. All NIH staff are welcome to attend, with CC senior leadership always in attendance to address any issues that arise. The meeting has greatly enhanced communication between areas and has resulted in a much faster rate of confronting systemic issues that are mentioned at huddle. Even now, during the COVID-19 epidemic, the CC continues to hold a daily patient safety huddle with no more than 10 people physically present at any given time. Patient safety continues to be a top priority at the Clinical Center, even with the decreased patient numbers in the last months due to COVID-19.

Another crucial new initiative is the Clinical Center Hand Hygiene program, which aims to improve compliance with hand hygiene standards across the hospital. All employees have been trained how to follow hand hygiene standards throughout the building, while a subset of employees have been trained to observe employee behavior and report compliance weekly. Compliance is reported at the daily Patient Safety Huddle, with a standard report comprised of hundreds of observations. Since the implementation of the program, hand hygiene compliance has increased to an average of over 90%. The Clinical Center continues to promote hand hygiene widely, and even includes specific training (with a video) at New Employee Orientation.

Specific to the COVID-19 outbreak, the Clinical Center also manages a robust testing apparatus for both symptomatic patients and asymptomatic employees. Run as a collaboration between the Nursing Department, Occupational Medical Services, and the Department of Laboratory Medicine (DLM), this program provides rapid testing options for anyone entering the Clinical Center. The asymptomatic testing program has had a particularly broad reach, as it is available to all NIH employees. Since the beginning of the program, CC has run over 24,000 tests for asymptomatic employees to ensure patient safety by working to eliminate the possibility of hospital acquired COVID infections.

### KEY CHALLENGES TO DATE

In order to provide the best possible patient care experience, the Clinical Center must continue to develop its facilities. Sandwiched in between the original part of the building (completed in 1953) and the newest addition (completed in 2005), the second major building program of the Building 10 complex resulted in the structure referred to as the ACRF. Built in 1983, the ACRF houses the outpatient clinics as well as the DLM offices and clinical laboratory work areas. The westward extension of this construction still houses part of the Department of Transfusion Medicine (DTM), the operating rooms and the offices of the Department of Perioperative Medicine (DPM), and the imaging suites and offices of the Department of Radiology and Imaging Sciences. The cardiac catheterization laboratory of the NHLBI is also housed in this complex.

While this building provided much needed outpatient space, the ACRF was not constructed to be as durable as the Magnuson portion of Building 10. The construction does not facilitate inspection and preventive maintenance of water pipes, mechanical-heating, ventilation, and air conditioning (HVAC) systems, and electrical systems. When one of these systems fails, repair is equally difficult. The

difficulty and expense of maintaining and repairing the systems in the ACRF have grown significantly. The fact that this construction houses the service providers in the disciplines of radiology, laboratory medicine, transfusion medicine, and surgery that are so integral to clinical care and research makes replacement of a portion of the ACRF construction an imperative. The Clinical Center is working to make this replacement construction take place in the near future.

## NEXT STEPS


## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| James Gilman, M.D. | Clinical Center CEO | james.gilman@nih.gov | CC CEO |
| **Institute Clinical Directors** | Clinical Director | NIH IRP Clinical Directors | Support and direct CC research program |

**External**

None identified

## FIC: GENERAL DATA PROTECTION REGULATION (GDPR)

### ISSUE SUMMARY

The GDPR took effect on May 25, 2018, superseding the European Union (EU) Data Protection Directive. As a result, many longstanding research collaborations that included full and appropriate consent from participants are now stalled. Since enactment of GDPR, NIH has concluded only one data sharing agreement with a European partner. As a regulation of the EU, the GDPR applies directly to data controllers and data processors in the 28 member states of the EU and in the three additional countries (Iceland, Liechtenstein, and Norway) that together, make up the European Economic Area (EEA). Unlike the Directive, the GDPR applies to the processing of personal data by a controller or processor not established in the EEA, i.e., that lacks a physical presence in the EEA, when the processing is related to (a) offering goods or services to data subjects in the EEA; or (b) the monitoring of behavior of data subjects who are in the EEA. This means that the GDPR applies directly to much of the U.S. based use and processing of personal data that have been collected in the EEA for clinical and other research purposes. Challenges that have emerged affect U.S. based researchers, institutions, research funders, such as the NIH, and industry sponsors of research, including private pharmaceutical, biotechnology and medical device companies, as they seek to use personal data collected at research sites based in the EEA and transferred to the U.S. The GDPR privacy standards generally exceed those under the Health Insurance Portability and Accountability Act (HIPAA) and "Common Rule" and have prevented, delayed or complicated current and planned NIH-cooperative projects with institutions in the EEA. Due to uncertainties in the scope and interpretation of the GDPR requirements, the Department of State is advising U.S. government agencies not to sign or agree to contractual language that implies that the U.S. government complies with or will comply with the GDPR.

### EXAMPLES OF KEY PROGRESS TO DATE

NIH was able to conclude a formal data use agreement under GDPR. The project represents a long-standing partnership with the Finnish National Institute of Health and Welfare (THL) to identify susceptibility genes for Type 2 diabetes and associated traits. Following 18 months of negotiation, the general counsel of THL determined that data transfers could resume under GDPR's derogation to the prohibition on international data transfers for transfers that are *necessary for important reasons of public interest*. (Article 49). NIH hopes this agreement proves a precedent for future collaborative projects. However, to make this precedent a working practice, the scientific community require additional guidance from the European Data Protection Board on transferring personal data for research purposes under the permissible legal basis of public interest.

Also, in coordination with the Department of State, NIH was instrumental in persuading the European Data Protection Board to issue new guidance that provides legal assurance that COVID-19 international data transfers for research purposes are permissible under the public interest exception. Although welcome, the guidance is limited to "initial transfers" and restricts the duration of data storage.

### KEY CHALLENGES TO DATE

NIH and many U.S. public institutions cannot comply with GDPR-required contractual clauses, including those specifying indemnification, ownership, auditing of data systems by a foreign entity and submitting to the jurisdiction of foreign courts. Affected projects range from genomic studies on type 2 diabetes and cancer, to access to epidemiological research databases, to multi-site clinical trials and biobanking.

We especially are concerned with the prospect that patients who provide biospecimens and informed consent in hopes of speeding research may find that aspiration hindered due to undue caution or uncertainties surrounding this regulation.

Different countries, and individual institutions within the same country, are interpreting the GDPR requirements for research in different ways. For example, NIH has encountered divergent approaches across the EU regarding whether pseudonymized data may be considered anonymized data and thus outside the regulatory scope of GDPR.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Carrie Wolinetz, Ph.D.** | NIH Associate Director for Science Policy | carrie.wolinetz@nih.gov | Designated Contact |
| **Robert Eiss, M.A.** | Senior Adviser, FIC | eissr@mail.nih.gov | Designated Contact |
| **Chris Hammond, J.D.** | Senior Attorney, OGC | christopher.hammond2@nih.gov | Lead Counsel |

**External**

None identified

## FIC: NIH ENGAGEMENT IN GLOBAL HEALTH

### ISSUE SUMMARY

The NIH plays a critical role in global health research. Every NIH IC has some level of global health engagement, in recognition of the fact that scientific advances depend on harnessing the best and brightest minds, wherever they may be. In addition, discoveries made abroad can often be utilized for the benefit of the U.S. populations. Finally, many important research questions can only be answered in global settings and require robust international research partnerships. It is critical that NIH leadership in global health research continue so that cutting-edge science can continue to inform the prevention, diagnosis and treatment of diseases that span the globe and affect our own population. This will require collaboration and coordination across the NIH, which is in part, conducted through a trans-NIH Global Health Working Group (GHWG) that includes high-level representatives from every Institute, Center and Office at NIH.

The FIC maintains interagency collaborations and partnership programs with key countries. FIC also assesses how certain policies and new research laws impact international collaborations across the NIH. For example, the expected exit of the United States from the WHO will impact technical interactions and long-standing partnerships by NIH IC and is a topic of attention and discussion. NIH's close connections with U.S. Embassies in key countries, working through HHS/Office of Global Affairs and the Department of State, are instrumental in assuring that issues inherent in global research are appropriately addressed through interaction with appropriate government offices.

For over 50 years, FIC has invested in strengthening research capacity across a wide range of diseases and cross-cutting scientific areas. The current COVID-19 pandemic illustrates the importance of having international networks of scientists who can collaborate on common questions, share insights and work together to prevent the spread of emerging infections. Continued commitment to ensuring this global research workforce is an essential part of NIH's international leadership.

### KEY PROGRESS TO DATE

Current and former FIC grantees and trainees have provided scientific leadership across the world, including with respect to COVID-19, leading research and response in many countries and international organizations. For example, when Cambodia identified its first patient with COVID-19 in late January, former Fogarty Scholar Dr. Jessica Manning was able to quickly sequence the genome of a virus sample and post it on Nextstrain, the global collaboration database. Her lab was the first from a developing country to contribute to this global knowledge base and was among the first 20 to be shared on the site, which now includes thousands of COVID 19 genomes. The collective effort provides insights for diagnostics and vaccine development and helps track the transmission, mutation and spread of the novel coronavirus.

Former FIC-supported trainees are now working with mentors and current trainees from FIC's HIV and Global Infectious Disease Research Training Programs to conduct COVID-19 research. Led by a senior investigator at SUNY Buffalo, this team (including scientists from the University of Zimbabwe and the University of the West Indies) has adapted HIV projects to focus on genomics, proteomics and meta-omics to identify biomarkers that can predict which COVID-19 patients might progress to more severe disease. They are also investigating a new approach to point-of-care antibody testing for use in low-resource countries and in collaboration with the University of Maryland's Institute of Human Virology

project, exploring the possibility of activating the immune system with oral polio vaccine to protect against COVID-19.

## KEY CHALLENGES TO DATE

To continue research capacity-building efforts to fight emerging infections like COVID-19 and to be able to respond rapidly and effectively to other infectious disease threats yet to arise, NIH and FIC need robust and consistent funding. As seen in the West Africa Ebola outbreak in 2014-16, many countries have inadequate research capacity to develop medical countermeasures for emerging global health threats. Additional funding is vital to expand the global health research workforce that serves on the frontlines of fighting disease and improving health worldwide.

NIH has longstanding technical interactions and collaborations with the WHO. The pending exit from the WHO and its affiliated organizations and regional offices will require close coordination among the Operational Divisions of HHS to assure that engagements are terminated in line with HHS guidance and sequences to retain key programmatic interactions, e.g. for infectious diseases and pandemic response, are continued until the exit is completed.

## NEXT STEPS

(b) (5)

[redacted]

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Flora Katz, Ph.D.** | Director, Division of International Training and Research, FIC | katzf@mail.nih.gov | Oversees FIC extramural portfolio |
| **Christine Sizemore, Ph.D.** | Director, Division of International Relations, FIC | christine.sizemore@nih.gov | Trans NIH int'l agency coordination; management of int'l agreements; NIH contact for foreign embassies and ministries of health |

**External**

None identified

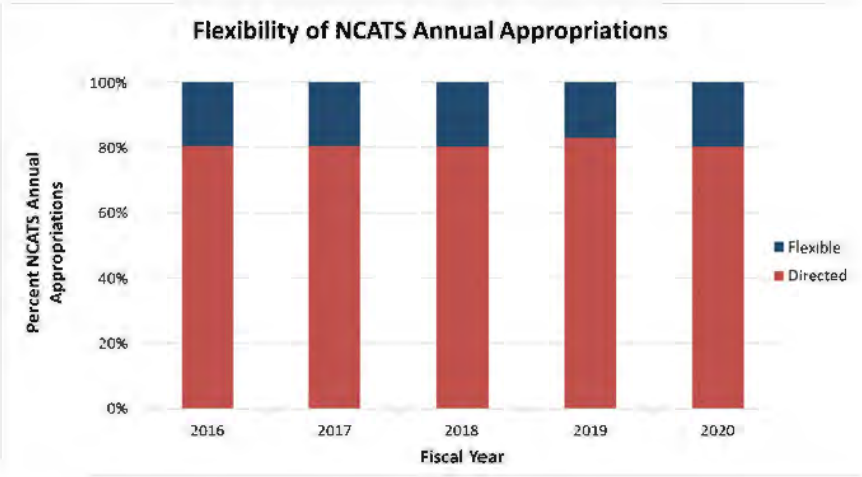
## NCATS: INCREASING BUDGETARY FLEXIBILITY TO MEET TRANSLATIONAL SCIENCE NEEDS

### ISSUE SUMMARY

NCATS has limited budgetary flexibility to allocate its resources to projects, programs, and individuals holding the greatest potential for catalyzing translational innovation. NCATS is committed to getting more treatments to more patients more quickly by developing new technologies and operational models to accelerate translation; demonstrating their usefulness in specific applications; and disseminating the approaches, data, and methodologies to the scientific community. Currently, the annual budgetary appropriation to NCATS contains directives and restrictions that provide limited flexibility for the Center to address priority translational science needs and opportunities. Allowing NCATS greater flexibility in allocating its financial resources would ensure that its funds are being used to support the highest-quality research on translational science that ultimately could lead to advances in human health.

### KEY PROGRESS TO DATE

NCATS's first appropriation in FY 2012 directed approximately 90 percent of the budget to a few select programs, leaving NCATS with flexibility over roughly 10 percent of its own budget. The flexibility has risen slightly since then, as the FY 2020 appropriation provided NCATS with flexibility over approximately 20 percent of its overall budget. The stacked bar chart below displays the percentage of NCATS annual appropriations that were either directed to particular programs or were considered flexible.




Additionally, one of the Center's directed appropriations contains a restriction, per authorization language, on the use of a valuable award mechanism that enables NCATS to form novel partnerships to accelerate the development of high-need cures. The NCATS Cures Acceleration Network (CAN) was established to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials. To achieve these objectives, CAN provides NCATS with new flexibilities in funding authorities. Under CAN, NCATS may make flexible research awards using the special funding mechanism called Other Transactions Authority (OTA). Using OTA, NCATS can make research awards that are not the typical NIH grant, contract, or cooperative agreement. Instead, the Center can more nimbly add or subtract specific expertise, tools, technologies, and approaches to achieve scientific goals. This flexible research authority also lowers certain regulatory and policy barriers, making it possible to attract nontraditional partners and form novel arrangements to bring innovative ideas and new technologies to solving the biggest challenges in translational science.

NCATS's CAN authorization language currently caps the percentage of CAN funds that can be awarded using OTA. Specifically, it states "awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated ... for such fiscal year." CAN was originally authorized to NIH (prior to NCATS's establishment) for $500 million in FY 2010, which would have made up to $100 million available for OTA awards under this cap. No actual dollars were appropriated to CAN until December 2011 when $10 million was allocated. CAN appropriations increased to $25.835 million for FY 2016 in concert with the FY 2016 increase to the overall NIH budget, enabling NCATS to use approximately $5 million under OTA to begin the innovative Biomedical Data Translator Program. In FY 2020, CAN appropriations increased to $60 million, allowing for up to $12 million to be used for OTA awards for the second phase of the Translator Program, but leaving no ability to use OTA awards for other highly innovative CAN programs that would greatly benefit from OTA flexibilities.

## KEY CHALLENGES TO DATE

The key challenges are the NCATS annual appropriation and authorization, which both contain directives and restrictions that provide limited flexibility for the Center to fix roadblocks in translational research. NCATS has an obligation to ensure that its significant public investment most effectively contributes to improving the health of patients and the public. Therefore, the Center needs greater flexibility over its fiscal resources to more effectively address significant challenges and opportunities in translational science that currently hinder the development and dissemination of medical interventions. The ability to adjust its funding levels accordingly would enable NCATS to ensure the highest achievable performance of its current programs. This change also would enable the Center to address other pressing translational science needs and opportunities. In addition, the ability to apply OTA toward the entire CAN appropriation would enable NCATS to achieve the ambitious goals originally set for CAN. This unique authority allows NCATS the flexibility to alter the course of the science projects in real time to meet the overarching program goals or to immediately pursue unexpected developments (e.g., COVID-19). The U.S. House of Representatives E&C Committee recognized that CAN funds could be more effectively used to develop high-need cures if all of the appropriated dollars were granted use of OTA. Removal of the 20 percent cap on use of OTA was included in an early version of the 21st Century Cures Act, but it was not included in the final bill that passed. Efforts were recently under way to develop a Cures 2.0 bill in the House, but that process may be delayed.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

None identified

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Congressional Appropriation and Authorizing Committees** | n/a | n/a | Sets NCATS appropriation amount, which includes funding directives, and authorizing language, which restricts OTA funding |

## NCATS: STRENGTHENING AND STREAMLINING THE NATION'S CAPACITY TO CONDUCT CLINICAL TRIALS

### ISSUE SUMMARY

The mission of NCATS is to advance the science of translation, which is the process of turning observations into interventions to improve health. NCATS collaborates with researchers, the public and other stakeholder groups to design new approaches and technologies that ultimately will deliver more treatments to more people more quickly. Through numerous different programs and efforts, NCATS works to address roadblocks in the translational science process that slow the development, demonstration, and dissemination of treatments. Although NCATS fosters innovation in clinical and translational research, legislative restrictions have prevented the Center from being able to work on addressing translational roadblocks as they relate to the efficiency and effectiveness of phase III clinical trials.

### KEY PROGRESS TO DATE

Since the promulgation of the Common Rule in 1974, the research landscape has undergone significant changes. The volume of clinical research and the number of multisite studies has increased. In addition, there has been an advancement in new systems and technologies such as using archived biospecimens and data, genomics, bioimaging, real world data, and informatics to conduct or to further contextualize research. These changes raise questions about whether the traditional ways clinical trials have been conducted are always the most effective approaches. This means that NIH, and NCATS in particular, can explore novel ways to approach and design clinical trials, as well as our ability to leverage clinical trials, particularly Phase III trials, to evaluate whether there is efficacy in new approaches.

### KEY CHALLENGES TO DATE

Authorization language in Section 479 (b) of the Public Health Service Act allows NCATS to develop and provide infrastructure and resources for all phases of clinical trials research. However, it restricts the Center's support (i.e. funding) of clinical trials research beyond Phase II (trials designed to test drugs for efficacy and side effects in a limited number of patients). The restriction allows NCATS to support a phase III clinical trial for a rare disease or condition, but only after ensuring that no other entity is planning to conduct the same clinical trial. To do this, NCATS must announce its intent to support such a phase III clinical trial for a period of 120 days. No other Institute/Center at NIH has a similar restriction regarding support of clinical trials and all Institutes and Centers that have research programs support and/or conduct Phase III clinical trials.

- **Ethical risk**: Because clinical trials and their design may evolve over time after implementation, NCATS has discovered an unintended consequence of this statute. An NCATS-supported pediatric rare disease trial (STeroids to REduce Systemic Inflammation After Infant Heart Surgery (STRESS)) had to be paused when it evolved from a Phase II into a Phase III clinical trial after funding started. Even though the condition was determined to be rare and the phase III clinical trial could be supported by NCATS, enrollment of new infants into the trial had to be halted while NCATS sought comments for 120 days "from public or private organizations with credible, timely plans to conduct Phase III clinical trials of a similar nature." No comments were received during this period, but this pause resulted in a four-month delay of full support and additional recruitment for a critical trial designed to determine whether commonly used high-dose steroids benefit or harm infants undergoing heart surgery. Halting a trial should only be done for trial-related concerns such as safety of the participants.

- **Missed scientific opportunities**: This restriction prevents NCATS from fully engaging in complex biomedical issues and public health crises, including the Center's ability to apply its resources, particularly the Clinical and Translational Science Awards (CTSA) and New Therapeutic Uses programs, and expertise to such areas as the opioid epidemic and the COVID-19 pandemic. Unfortunately, because of this statute, NCATS must inform potential applicants that the Center cannot accept applications designed to accelerate and improve the very expensive, slow Phase III clinical trials process or to use Phase III trials to address other translational science roadblocks. In addition, NCATS is limited in its ability to collaborate with other NIH Institutes and Centers in supporting a specific application because it includes a phase III clinical trial. One example: Because it involved a Phase III clinical trial, NCATS could not fund an application on novel strategies for treating opioid addiction in a rural health setting, which is a significant public health concern. This was a missed opportunity to address a significant translational roadblock in an urgent public health context: adaptation of pain treatment strategies into a rural health setting. Congress has previously urged NCATS, through its CTSA Program, to support rural health research.
- **Inability to achieve mission**: The current legislation results in a direct impact on NCATS's ability to fully achieve its mission of improving and speeding the translational process into effective therapies. At its core, NCATS's mission is to partner with external organizations, including industry, to solve translational science problems. This mission is not intended to replace or compete with industry in drug development, rather the role is to enable research to be completed more efficiently, effectively, and ideally more rapidly.

## NEXT STEPS

(b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **IC Directors** | NIH Institutes and Centers | IC Directors | Often support phase III clinical trials on which NCATS cannot collaborate. |

**External**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Applicants** | n/a | n/a | Often propose phase III clinical trial research that NCATS cannot support. |

## NCATS: ADDRESSING ROADBLOCKS TO REPURPOSING EXISTING THERAPEUTICS

### ISSUE SUMMARY

Developing a brand-new therapeutic takes time, money, and effort, and many fail due to bottlenecks in the therapeutic development process. More knowledge is needed about why. Delays and barriers mean that *translation* of a promising molecule into an approved drug often takes one to two decades, if successful at all. Compounding this, there are over 7,000 rare diseases lacking a therapeutic. One strategy to reduce this time frame, decrease costs, and improve success rates is drug repurposing, which involves evaluating whether existing drugs or already studied compounds can be evaluated for a different purpose than originally thought and can shorten the time to clinical evaluation in patients. Many therapies approved for other uses already have been tested in humans, so detailed information is available on their pharmacology, formulation, and potential toxicity. Because repurposing builds upon previous research and development efforts, new candidate therapies can often be readied for clinical trials more quickly, speeding their review by the FDA and, if approved, their integration into health care.

NCATS is actively working on the repurposing process. Early-stage programs include an extensive pharmaceutical compound library to screen for potential treatments for a wide variety of diseases or conditions with established disease models. Late-stage repurposing efforts include addressing other roadblocks such as regulatory approvals, access to shelved compounds, and supporting research to enable early stage clinical testing of potential therapeutics.

### KEY PROGRESS TO DATE

NCATS has several efforts underway to address therapeutics roadblocks using different drug repurposing approaches. NCATS utilizes screening technologies on its NCATS Pharmaceutical Collection, a library of nearly 3000 drugs approved for clinical use, and partners with external organizations to enable studies to get ready for regulatory approval through its Therapeutics Development Branch (TDB). Through this, NCATS has facilitated some 30 Investigational New Drug (IND) applications to and clearances by the FDA, six of which were repurposed drugs or combinations of approved drugs. More recently, NCATS developed or updated programs in response to the COVID-19 pandemic, including an OpenData Portal designed to further reduce the drug development timeline by openly and quickly sharing COVID-19-related drug repurposing data and experiments for all approved drugs. In addition, NCATS issued several funding opportunities to the extramural research community to stimulate research on potential therapeutics that are strong candidates for repurposing, including adapting those to rapidly respond to the COVID-19 pandemic. NCATS developed template agreements for repurposing programs which are designed to significantly streamline the legal and administrative process for partnering across multiple organizations. NCATS partnered with the FDA and held a workshop titled *Repurposing Off-Patent Drugs: Research & Regulatory Challenges* in December 2019. The workshop was designed to identify and further understand the policy, regulatory, and research challenges to speeding translation of potential treatments, particularly for existing off label drugs. In addition, NCATS and FDA collaborated and rolled out CURE ID, which is an internet-based repository that enables the clinical community to report novel uses of existing drugs for difficult-to-treat infectious diseases.

### KEY CHALLENGES TO DATE

- **Bringing together diverse stakeholders with complex policy drivers**: Repurposing includes complicated policy issues such as reimbursement, prescribing behavior particularly for off label drugs, and how to incentivize the development of treatments, particularly for rare and neglected diseases. NCATS is working with others to first understand the complex policy issues,

who are the key stakeholders, and how best to engage. This can be particularly challenging because some of the policy needs are not within the NCATS mission to resolve; engagement across government agencies will be critical to successfully address some of these roadblocks.

- **Accessing and prioritizing assets**: There are numerous potential compounds that could be repurposed. In addition to considering how to incentivize needed partners (e.g., researchers, industry, and funders) to come together to conduct the needed research, two additional issues present a significant challenge. First is accessing assets, particularly if still under patent protection or shelved and not publicly available. Second is prioritizing which candidates that are available are ready for testing and how best to utilize limited funds for those candidates since the number of candidates far outweighs the resources.
- **Issues amplified in repurposing off patent drugs**: The concept of drug repurposing or drug repositioning for drugs with remaining patent life and regulatory exclusivity is not new. The attractiveness of drug repurposing for these drugs, when there is a sizable additional market, is clear – the path for FDA approval and return-on-investment (ROI) is faster, cheaper, and more likely to succeed than starting with a new chemical entity. Ninety percent of the pharmacopeia has no patent life or regulatory exclusivity remaining. For these drugs, there is no incentive to invest in research and development, particularly because of off label, generic substitutions with other product(s). A successful business model for repurposing off patent drugs is needed.

**NE** (b) (5)

## RELEVANT STAKEHOLDERS

**Internal**

| Name | Title | Contact Information | Critical Role |
|---|---|---|---|
| **Christine Colvis, Ph.D.** | Director, Drug Development Partnership Programs | christine.colvis@nih.gov | Oversees NTU and other extramural activities related to repurposing drugs |
| **Matt Hall, Ph.D.** | Acting Chief, Early Therapeutics Branch | hallma@mail.nih.gov | Directs the OpenData Portal, Repurposing drug screening |
| **Don Lo, Ph.D.** | Chief, Therapeutic Development Branch | donald.lo@nih.gov | Leads the TDB efforts on enabling studies to get ready for regulatory approval |
| **Bobbie Ann Mount, Ph.D.** | Program Officer, New Therapeutic Uses | bobbieann.mount@nih.gov | Program Officer, extramural research initiatives on New Therapeutic Uses (NTU) for existing drugs |

**External**

None Identified

# APPENDIX: PERFORMANCE MEASURES TO BE INCLUDED IN NIH'S FY 2022 CONGRESSIONAL JUSTIFICATION

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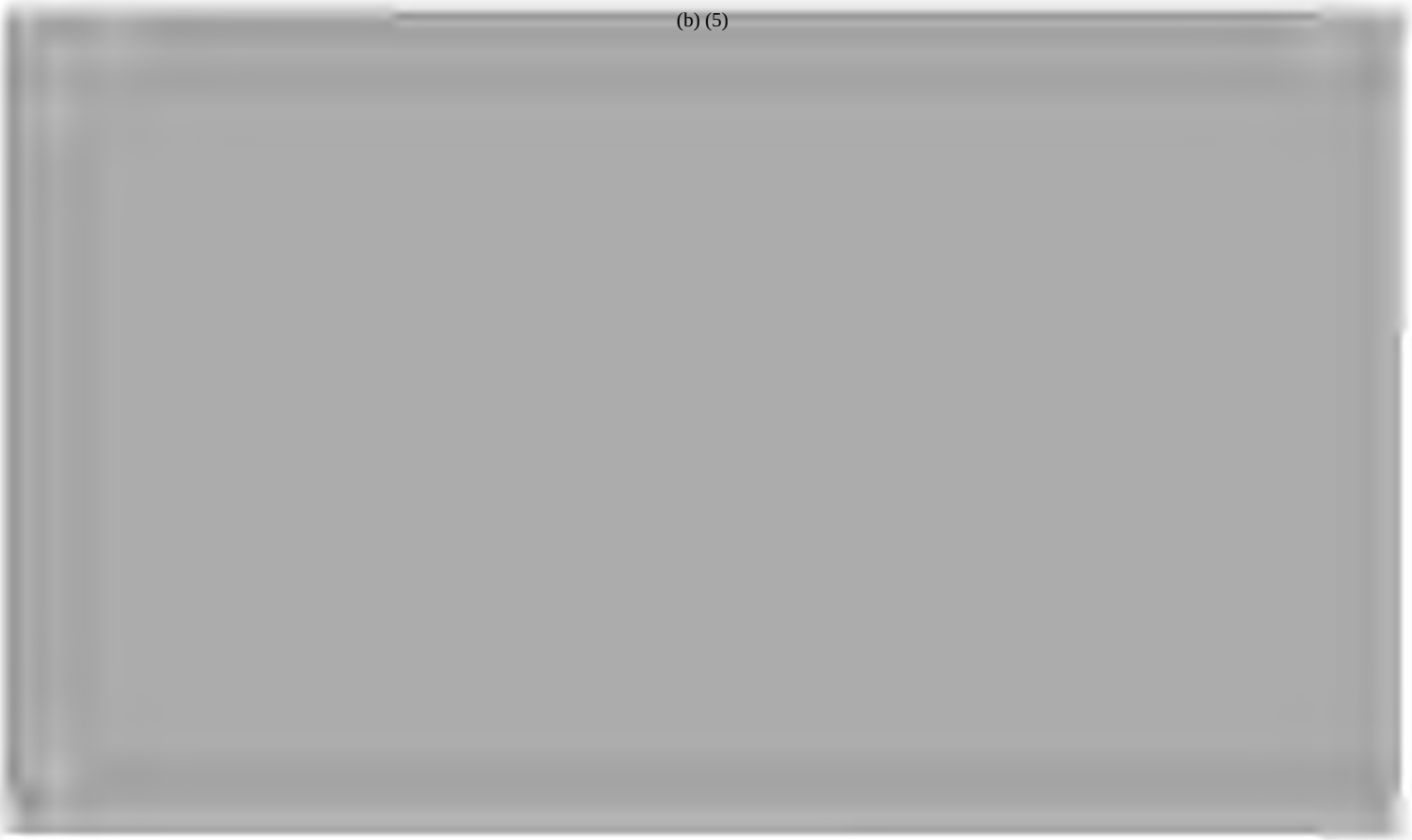


# APPENDIX: ABBREVIATIONS

| Abbreviation | Meaning |
|---|---|
| 3D | Three dimensional |
| AAMC | Association of American Medical Colleges |
| ABC-CT | Autism Biomarkers Consortium for Clinical Trials |
| ABCD | Adolescent Brain Cognitive Development |
| ACBCYW | Advisory Committee on Breast Cancer in Young Women |
| ACBTSA | Advisory Committee on Blood and Tissue Safety and Availability |
| ACC | Autism Coordinating Committee |
| ACD | Advisory Committee to the NIH Director |
| ACE | Autism Centers of Excellence |
| ACF | Administration for Children and Families |
| ACOT | Advisory Committee for Organ Transplantation |
| ACRF | Ambulatory Care Research Facility |
| ACTIV | Accelerating COVID-19 Therapeutic Interventions and Vaccines |
| ACTT | Adaptive COVID-19 Treatment Trial |
| AD | Alzheimer's Disease |
| ADC | Administrative Data Council |
| ADCC | Autoimmune Diseases Coordinating Committee |
| ADRD | Alzheimer's Disease Related Dementias |
| AGI | Audacious Goals Initiative |
| AHRQ | Agency for Healthcare Research and Quality |
| AI | Artificial Intelligence |
| AI/AN | American Indian/Alaska Native |
| AIDS | Acquired Immune Deficiency Syndrome |
| AMD | Age-Related Macular Degeneration |
| amFAR | American Foundation for AIDS Research |
| AMP | Accelerating Medicines Partnership |
| AMP-AD | Accelerating Medicines Partnership - Alzheimer's Disease |
| AMP AIM | Accelerating Medicines Partnership Autoimmune and Immune-mediated Diseases |
| AMP RA/SLE | Accelerating Medicines Partnership in Rheumatoid Arthritis and Systemic Lupus Erythematosus |
| AMP-T2D | Accelerating Medicines Partnership- Type 2 Diabetes |
| AMR | Antimicrobial Resistance |
| ANPRM | Advance Notice of Proposed Rulemaking |
| APG | Agency Priority Goals |
| ARILO | Agency Research Integrity Liaison Officer |
| ARLG | Antibacterial Resistance Leadership Group |
| ARRA | American Recovery and Reinvestment Act |

| Abbreviation | Meaning |
|---|---|
| ART | Antiretroviral Therapy |
| ASD | Autism Spectrum Disorder |
| ASD PEDS | Autism Spectrum Disorder Prevention, Early Detection, Engagement, and Service Research |
| ASBMB | American Society for Biochemistry and Molecular Biology |
| ASCB | American Society for Cell Biology |
| ASFR | Assistant Secretary for Financial Resources |
| ASL | Assistant Secretary for Legislation |
| ASPE | Assistant Secretary for Planning and Evaluation |
| ASPR | Assistant Secretary for Preparedness and Response |
| ASQ | Ask Suicide-Screening Questions |
| AUD | Alcohol Use Disorder |
| B&F | Buildings and Facilities |
| BACPAC | Back Pain Consortium |
| BARDA | Biomedical Advanced Research and Development Authority |
| BMAR | Backlog of Maintenance and Repair |
| BOTSEC | Blood, Organ, and Tissue Safety Executive Committee |
| BPCA | Best Pharmaceuticals for Children Act Working Group |
| BRAIN | Brain Research through Advancing Innovative Neurotechnologies |
| BRDPI | Biomedical Research and Development Price Index |
| BRP | Blue Ribbon Panel |
| BSA | Board of Scientific Advisors |
| CABS | Community Advisory Board for Security |
| CAN | Cures Acceleration Network |
| CAP | Cross-Agency Priority |
| CARB | Combating Antibiotic-Resistant Bacteria |
| CARB-X | Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator |
| CARE | Centers to Advance Research in Endometriosis |
| CARES | Coronavirus Aid, Relief, and Economic Security |
| CBPR | Community-Based Participatory Research |
| CC | Clinical Center |
| CCDI | Childhood Cancer Data Initiative |
| CCGB | Clinical Center Governing Board |
| CCIA | CTSA Clinical Innovation Award |
| CCo | Commissioned Corps |
| CCRHB | Clinical Center Research Hospital Board |
| CDC | Centers for Disease Control and Prevention |
| CDE | Common Data Elements |
| CDM | Continuous Diagnostics and Mitigation |

| Abbreviation | Meaning |
|---|---|
| CDMRP | Congressionally Directed Medical Research Program |
| CEAL | The NIH Community Engagement Alliance Against COVID-19 Disparities |
| CEO | Chief Executive Officer |
| CHAP | Chronic Hypertension and Pregnancy Trial |
| CI | Counterintelligence |
| CIO | Chief Information Officer |
| CISA | Cybersecurity and Infrastructure Security Agency |
| CISO | Chief Information Security Officer |
| CIT | Center for Information Technology |
| CIVICS | Collaborative Influenza Vaccine Innovation Centers |
| CMS | Centers for Medicare and Medicaid Services |
| CNRM | Center for Neuroscience and Regenerative Medicine |
| COC | NIH Council of Councils |
| CoFAR | Consortium for Food Allergy Research |
| CONNECTS | Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies |
| COOP | Continuity of Operations Plan |
| COPD | Chronic Obstructive Pulmonary Disease |
| COSWD | Chief Officer for Scientific Workforce Diversity |
| COVID-19 | Coronavirus Disease 2019 |
| CoVPN | Coronavirus Prevention Network |
| CPAP | Continuous Positive Airway Pressure |
| CR | Continuing Resolution |
| CRADA | Cooperative Research and Development Agreement |
| CRC | Clinical Research Center |
| CRCB | Center for Research Capacity Building |
| CROMS | Clinical Research Operations & Management System |
| CryoEM | Cryo-Electron Microscopy |
| CryoET | Cryo-Electron Tomography |
| CSAC | Central Services Advisory Committee |
| CSC | Coordinated Specialty Care |
| CSO | Chief Security Officer |
| CSO/ADCR | Chief Scientific Officer/Associate Director for Clinical Research |
| CSR | Center for Scientific Review |
| CT | Connecticut |
| CTRIS | Center for Translation Research and Implementation Science |
| CTSA | Clinical and Translational Science Awards |
| CUPAC | Clinical Utilization Plan for Anthrax Medical Countermeasure Use in a Mass Casualty Event |
| CVD | Cardiovascular Disease |

| Abbreviation | Meaning |
|---|---|
| CVH | Cardiovascular Health |
| DABP | Division of AIDS, Behavior and Population Services |
| DARPA | Defense Advanced Research Projects Agency |
| dbGaP | Database of Genotypes and Phenotypes |
| DBIB | Division of Basic and Integrative Biological Sciences |
| DBS | Deep Brain Stimulation |
| DC | District of Columbia |
| DCI | Division of Clinical Innovation |
| DCSO | Deputy Chief Security Officer |
| DDM | Deputy Director for Management |
| DEA | Drug Enforcement Administration |
| DEA | Division of Extramural Activities |
| DECIPHeR | The Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk Program |
| DEI | Diversity, Equity, and Inclusion |
| DEM | Division of Emergency Management |
| DEPD | NIH Principal Deputy Director |
| DER | Division of Extramural Research |
| DFRS | Division of Fire and Rescue Services |
| DHS | Department of Homeland Security |
| DIEPS | Division of International Epidemiology and Population Studies |
| DIMA | Division of Data Integration, Modeling, and Analytics |
| DIVRO | Diversity in Vision Research and Ophthalmology Program |
| DLM | Department of Laboratory Medicine |
| DLP | Data Loss Prevention |
| DMCC | Data Management and Coordinating Center |
| DMD | Division of Medications Development |
| DMICC | Diabetes Mellitus Interagency Coordinating Committee |
| DMS | Division of Management Services |
| DNA | Deoxyribonucleic Acid |
| DNDA | Division of Neuroscience, Development and Aging |
| DOC | Dental, Oral, and Craniofacial |
| DOCTR-C | Dental, Oral, and Craniofacial Tissue Regenerative Consortium |
| DOD | Department of Defense |
| DOE | Department of Energy |
| DOJ | Department of Justice |
| DPC | Diversity Programs Consortium |
| DPCE | Division of Policy, Communication and Education |
| DPCPSI | Division of Program Coordination, Planning, and Strategic Initiatives |

| Abbreviation | Meaning |
|---|---|
| DPI | Division of Pre-Clinical Innovation |
| DPM | Department of Perioperative Medicine |
| DPP | Diabetes Prevention Program |
| DPPS | Division of Physiological and Pathological Sciences |
| DR | Diabetic Retinopathy |
| DRCB | Division of Research Capacity Building |
| DRR | Division of Receipt and Referral |
| DS | Down's Syndrome |
| DSI-Africa | Harnessing Data Science for Health Discovery and Innovation in Africa Program |
| DSLD | Dietary Supplement Label Database |
| DTCS | Division of Translational and Clinical Sciences |
| DTM | Department of Transfusion Medicine |
| DURC | Dual Use Research of Concern |
| DWG | Diversity Working Group |
| E&C | Energy and Commerce Committee |
| EAWG | Extramural Activities Working Group |
| ECC | Emergency Communications Center |
| ECHO | Environmental Influences on Child Health Outcomes |
| E-cigs | Electronic Cigarettes |
| ED | Emergency Department |
| EDIfy-MH | Ending Disparities in Mental Health |
| EDI | Office of Equity, Diversity, and Inclusion |
| EEA | European Economic Area |
| EEG | Electroencephalogram |
| EEO | Equal Employment Opportunity |
| EHR | Electronic Health Record |
| EIDs | Emerging Infectious Diseases |
| ELSI | Ethical, Legal, and Social Implications |
| eMERGE | Electronic Medical Records and Genomics Network |
| EMR | Electronic Medical Records |
| ENQUIRE | Evaluating Panel Quality in Review |
| ENRICH | Early Intervention to Promote Cardiovascular Health of Mothers and Children Initiative |
| EOC | Emergency Operations Center |
| EOP | Emergency Operations Plan |
| EP3 | Early Psychosis Prediction and Prevention |
| EPA | Environmental Protection Agency |
| EPINET | Early Psychosis Intervention Network |
| EPPIC-Net | Early Phase Pain Investigation Clinical Network |
| ESI | Early Stage Investigator |

| Abbreviation | Meaning |
|---|---|
| ESRD | End-Stage Renal Disease |
| EU | European Union |
| EVALI | E-cig/vaping-associated Lung Injury |
| EVD | Ebola Virus Disease |
| FACA | Federal Advisory Committee Act |
| FAIR | Findability, Accessibility, Interoperability, and Reuse |
| FASD | Fetal Alcohol Spectrum Disorders |
| FBI | Federal Bureau of Investigation |
| FDA | Food and Drug Administration |
| FEDIAWG | Interagency Workgroup on Child Abuse and Neglect |
| FEP | First Episode Psychosis |
| FEVS | Federal Employee Viewpoint Survey |
| FFRDC | Federally Funded Research and Development Center |
| FIC | Fogarty International Center |
| FIRST | Faculty Institutional Recruitment for Sustainable Transformation |
| FISMA | Federal Information Security Management Act |
| FITBIR | Federal Interagency Traumatic Brain Injury Research |
| FMFIA | Federal Manager's Financial Integrity Act |
| FNIH | Foundation for the National Institutes of Health |
| FNLCR | Frederick National Laboratory for Cancer Research |
| FNLM | Friends of the National Library of Medicine |
| FOA | Funding Opportunity Announcement |
| FOIA | Freedom of Information Act |
| FTE | Full-Time Equivalent |
| FWG | Facilities Working Group |
| FWGoDS | Federal Working Group on Dietary Supplements |
| FY | Fiscal Year |
| GAO | Government Accountability Office |
| GARD | Genetic and Rare Diseases Information Center |
| GDPR | General Data Protection Regulation |
| GHWG | Global Health Working Group |
| GMP | Good Manufacturing Practices |
| GOF | Gain of Function |
| GP | Physicians and dentists covered by the General Schedule (GS) classification system and GS base pay ranges who receive title 38 market pay instead of locality pay (formerly GS) |
| GPRA | Government Performance and Results Act |
| GR | Physicians and dentists covered by the General Schedule classification system and GS base pay range who receive title 38 market pay instead of locality pay (formerly GM) |
| GS | General Schedule |

| Abbreviation | Meaning |
|---|---|
| GSA | General Service Administration |
| GSIG | GeroScience Interest Group |
| H.R. | House of Representatives |
| HAZMAT | Hazardous Materials |
| HCAP | Healthy Cognitive Aging Project |
| HCS | HEALing Communities Study |
| HCV | Hepatitis C |
| HD | Health Disparities |
| HEAL | Helping to End Addiction Long-term Initiative |
| HEALthy BCD | HEALthy Brain and Child Development |
| HELP | Health, Education, Labor and Pensions |
| HEROS | Human Epidemiology and Response to SARS-CoV-2 |
| HFT | Human Fetal Tissue |
| HGP | Human Genome Project |
| HHS | Department of Health and Human Services |
| HICPAC | HHS Healthcare Infection Control Practices Advisory Committee |
| HIPPA | Health Insurance Portability and Accountability Act |
| HIV / AIDS | Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome |
| HOPE | Hemodialysis Opioid Prescription Effort |
| HPC | High Performance Computing |
| HPP | Human Placenta Project |
| HPV | Human Papillomavirus |
| HPV+ | Human Papillomavirus Positive |
| HRS | Health and Retirement Study |
| HRSA | Health Resources and Services Administration |
| IACC | Interagency Autism Coordinating Committee |
| IBC | Institutional Biosafety Committee |
| IBCERCC | Interagency Breast Cancer and Environmental Research Coordinating Committee |
| IBD | Inflammatory Bowel Disease |
| IC | Institute or Center |
| ICARE | Interagency Collaborative to Advance Research in Epilepsy |
| ICD | Institute or Center Director |
| ICO(s) | NIH Institute (s), Center (s), or OD Office (s) |
| IC(s) | NIH Institutes, Centers, and Offices |
| ICS | Incident Command System |
| IDD | Intellectual and Developmental Disabilities |
| IDDRC | Intellectual and Developmental Disabilities Research Centers |
| IdEA | Institutional Development Award |
| IG | Inspector General |

| Abbreviation | Meaning |
|---|---|
| IGVF | Impact of Genomic Variation on Function Consortium |
| IHS | Indian Health Service |
| IMOD | Immediate Office of the Director |
| IMPROVE | Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone |
| INCLUDE | Investigation of Co-occurring conditions across the Lifespan to Understand Down Syndrome |
| IND | Investigational New Drug |
| IOM | Institute of Medicine |
| IPA | Intergovernmental Personnel Act |
| IPRCC | Interagency Pain Research Coordinating Committee |
| iPSCs | Induced Pluripotent Stem Cells |
| IQ | Inclusion Quotient |
| IRB | Institutional Review Board |
| IRP | Intramural Research Programs |
| IT | Information Technology |
| ITBAC | Information Technology Budget Advisory Committee |
| ITF | Interagency Task Force on Military and Veterans Mental Health |
| ITP | Interventions Testing Program |
| JAK | Janus Kinase |
| JCOIN | Justice Community Opioid Innovation Network |
| KICC | Kidney Interagency Coordinating Committee |
| LAP | Language Access Plan |
| LEAP | Learning Early About Peanut Allergy |
| LEP | Limited English Proficient |
| LFWG | Lupus Federal Working Group |
| LGBT | Lesbian, Gay, Bisexual, and Transgender |
| LHHS | Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations Subcommittees |
| LHNCBC | Lister Hill National Center for Biomedical Communications |
| M&M | Morbidity and Mortality |
| MAbs | Monoclonal Antibodies |
| MACP | Master, American College of Physicians |
| MAPP | The Multidisciplinary Approach to the Study of Chronic Pelvic Pain |
| MBWG | Management and Budget Working Group |
| MD | Doctor of Medicine |
| MDCC | Muscular Dystrophy Coordinating Committee |
| MDR-TB | Multidrug Resistant Tuberculosis |
| ME/CFS | Myalgic Encephalomyelitis/Chronic Fatigue Syndrome |
| MEF | Mission Essential Function |

| Abbreviation | Meaning |
|---|---|
| **MERIT** | Method to Extend Research in Time (MERIT) Award |
| **MF** | Management Fund |
| **MFMU** | Maternal-Fetal Medicine Units |
| **MH** | Minority Health |
| **mHealth** | Mobile Health: Technology and Outcomes in LMICs program |
| **miRNAs** | Micro RNAs |
| **MIS-C** | Multisystem Inflammatory Syndrome in Children |
| **ML** | Machine Learning |
| **MMM** | Maternal Morbidity and Mortality |
| **MOSAIC** | Maximizing Opportunities for Scientific and Academic Independent Careers |
| **MPRINT** | Maternal and Pediatric Precision in Therapeutics |
| **MRI** | Magnetic Resonance Imaging |
| **MRSA** | Methicillin-resistant *Staphylococcus aureus* |
| **MS** | Master of Science |
| **MS** | Mississippi |
| **n/a** | Not Applicable/Not Available |
| **N3C** | National COVID Cohort Collaborative |
| **NANDSC** | National Advisory Neurological Disorders and Stroke Council |
| **NAPA** | National Alzheimer's Project Act |
| **NAS** | National Academy of Sciences |
| **NASA** | National Aeronautics and Space Administration |
| **NASEM** | National Academies of Sciences, Engineering, and Medicine |
| **NBIB** | National Institute of Biomedical Imaging and Bioengineering |
| **NBS** | NIH Business System |
| **NCAB** | National Cancer Advisory Board |
| **NCATS** | National Center for Advancing Translational Sciences |
| **NCBI** | National Center for Biotechnology Information |
| **NCC** | NIH Compensation Committee |
| **NCCIH** | National Center for Complementary and Integrative Health |
| **NCCOR** | National Collaborative on Childhood Obesity Research |
| **NCCP** | NIH Clinical Compensation Panel |
| **NCI** | National Cancer Institute |
| **NCITF** | National Insider Threat Task Force |
| **NCMHD** | National Center on Minority Health and Health Disparities |
| **NCMRR** | National Center for Medical Rehabilitation Research |
| **NCR** | National Capital Region |
| **NCRR** | National Center for Research Resources |
| **NCTR** | National Center for Toxicological Research |
| **NCVHS** | National Committee on Vital and Health Statistics |

| Abbreviation | Meaning |
|---|---|
| NDAR | National Database for Autism Research |
| NDIRS | NIH Distinguished Investigators Review Subcommittee |
| NEC | NIH Equity Committee |
| NEF | HHS Nonrecurring Expenses Fund |
| NEI | National Eye Institute |
| NEMS | NIH Emergency Management System |
| NHGRI | National Human Genome Research Institute |
| NHLBI | National Heart, Lung, and Blood Institute |
| NHP | Non-Human Primates |
| NIA | National Institute of Aging |
| NIAAA | National Institute on Alcohol Abuse and Alcoholism |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIAMS | National Institute of Arthritis and Musculoskeletal and Skin Diseases |
| NICHD | *Eunice Kennedy Shriver* National Institute of Child Health and Human Development |
| NIDA | National Institute on Drug Abuse |
| NIDCD | National Institute of Deafness and other Communication Disorders |
| NIDCR | National Institute of Dental and Craniofacial Research |
| NIDDK | National Institute of Diabetes and Digestive and Kidney Diseases |
| NIEHS | National Institute of Environmental Health Sciences |
| NIGMS | National Institute of General Medical Sciences |
| NIH | National Institutes of Health |
| NIHAC | National Institutes of Health Animal Center |
| NIMH | National Institute of Mental Health |
| NIMHD | National Institute on Minority Health and Health Disparities |
| NIMS | National Incident Management System |
| NINDS | National Institute of Neurological Disorders and Stroke |
| NINR | National Institute of Nursing Research |
| NIOSH | National Institute for Occupational Safety and Health |
| NJ | New Jersey |
| NLM | National Library of Medicine |
| NM | New Mexico |
| NMRN | National Research Mentoring Network |
| NNLM | Network of the National Library of Medicine |
| NOSI | Notice of Special Interest |
| NPDB | National Practitioner Data Bank |
| NPRM | Notices of Proposed Rulemaking |
| NRAP | National Research Action Plan |
| NRCC | Nutrition Research Coordinating Committee |
| NRN | Neonatal Research Network |

| Abbreviation | Meaning |
|---|---|
| NSABB | National Science Advisory Board for Biosecurity |
| NSF | National Science Foundation |
| NSTC | National Science and Technology Council |
| NSTC-CoS | Committee on Science |
| NTP | National Toxicology Program |
| NYSCF | New York Stem Cell Foundation |
| OA | Osteoarthritis |
| OAI | Osteoarthritis Initiative |
| OAR | Office of AIDS Research |
| OARC | Office of Autism Research Coordination |
| OB | Office of Budget |
| OBSSR | Office of Behavioral and Social Sciences Research |
| OCIO | Office of the Chief Information Officer |
| OCPL | Office of Communications and Public Liaison |
| OD | Office of the Director |
| OD CSAC | Office of the Director Central Services Advisory Committee |
| ODEO | Office of the Director Executive Office |
| ODP | Office of Disease Prevention |
| ODWD | Office for Disparities Research and Workforce Diversity |
| OEPCR | Office of End-of-Life and Palliative Care Research |
| OER | Office of Extramural Research |
| OFACP | Office of Federal Advisory Committee Policy |
| OGC | NIH Branch of the HHS Office of the General Counsel's Public Health Division |
| OHR | Office of Human Resources |
| OHRP | Office of Human Research Protections |
| OIA | Outstanding Investigator Award |
| OIG | HHS Office of the Inspector General |
| OIR | Office of Intramural Research |
| OIRA | Office of Information and Regulatory Affairs |
| OLPA | Office of Legislative and Policy Analysis |
| OM | Office of Management |
| OMA | Office of Management Assessment |
| OMB | Office of Management and Budget |
| OMP | Office of Minority Programs |
| ONIH | Optimize NIH |
| ONR | The Office of Nutrition Research |
| OOCCR | Office of the Ombudsman/Center for Cooperative Resolution |
| OPA | Office of Portfolio Analysis |
| OPDIV | Operating Division |

| Abbreviation | Meaning |
|---|---|
| OPM | Office of Personnel Management |
| OPP | Office of Pain Policy |
| ORDR | Office of Rare Diseases Research |
| ORF | Office of Research Facilities |
| ORIP | Office of Research Infrastructure Programs |
| ORS | Office of Research Services |
| ORSAC | Office of Research Services Advisory Committee |
| ORSC | Office of Research Support and Compliance |
| ORWH | Office of Research on Women's Health |
| OS/DHHS | Office of the Secretary DHHS |
| OSC | Office of Strategic Coordination |
| OSCS | Office of Scientific Computing Services |
| OSHA | Occupational Safety and Health Administration |
| OSOP | Office of the Senior Official for Privacy |
| OSP | Office of Science Policy |
| OSPMO | Office of Strategic Planning and Management Operations |
| OSTP | Office of Science and Technology Policy |
| OTA | Other Transactions Authority |
| OTC | Over-the-Counter |
| OTIPI | Office of Translational Initiatives and Program Innovations |
| OTT | Office of Technology Transfer |
| OUD | Opioid Use Disorder |
| OUtMATCH | Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Immunotherapy in Food Allergic Children and Adults |
| P30 | A Center Core Grant to support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. |
| P50 | A Specialized Center Grant to support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or research and development effort. |
| PaVe-GT | Platform Vector Gene Therapy |
| Pb | Lead |
| PB | President's Budget |
| PCHEMCE | Public Health and Emergency Medical Countermeasures Medical Countermeasures Enterprise |
| PCOS | Polycystic Ovary Syndrome |
| PCORI | Patient Centered Outcomes Research Institute |
| PCRC | Palliative care research cooperative |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PET | Positron Emission Tomography Department |

| Abbreviation | Meaning |
|---|---|
| **PhD** | Doctor of Philosophy |
| **PHEMCE** | Public Health Emergency Medical Countermeasures Enterprise |
| **PHS** | Public Health Service |
| **PIO** | Public Information Officer |
| **PIV** | Personal Identity Verification |
| **PMI** | Precision Medicine Initiative |
| **PMI CP** | Precision Medicine Initiative Cohort Program |
| **PMI-O** | Precision Medicine Initiative in Oncology |
| **POC** | Point of Contact |
| **POC** | Point of Care |
| **POCTRN** | Point of Care Technologies Research Network |
| **PPA** | Programs, Projects, and Activities |
| **PPP** | Public-Private Partnership |
| **PPP** | Pathogens with Pandemic Potential |
| **PRCC** | Prevention Research Coordinating Committee |
| **PrecISE** | Precision Interventions for Severe and Exacerbation Prone Asthma |
| **PREP** | Randomized Control Trial of Pravastatin to Prevent Preeclampsia in High-risk Women |
| **PreVAIL kids** | Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence |
| **PRGLAC** | HHS Task Force on Research Specific to Pregnant Women and Lactating Women |
| **PTN** | Pediatric Trials Network |
| **PTSD** | Post-Traumatic Stress Disorder |
| **R01** | Research Project Grant for investigator-initiated research |
| **R21** | Research Project Grant for exploratory/developmental research |
| **RA** | Rheumatoid Arthritis |
| **RAC** | Recombinant DNA Advisory Committee |
| **RADx$^{SM}$** | Rapid Acceleration of Diagnostics |
| **RADx-ATP** | Rapid Acceleration of Diagnostics Advanced Technology Platform |
| **RADx-rad** | Rapid Acceleration of Diagnostics Radical |
| **RADx$^{SM}$ Tech** | Rapid Acceleration of Diagnostics Fast-Track Program for COVID-19 Test Development and Distribution |
| **RADx-UP** | Rapid Acceleration of Diagnostics Underserved Populations |
| **RAISE** | Recovery After an Initial Schizophrenia Episode |
| **RAISE-ETP** | Recovery After an Initial Schizophrenia Episode - Early Treatment Program |
| **RAISE-IES** | Recovery After an Initial Schizophrenia Episode - Implementation and Evaluation Study |
| **RCMI** | Research Centers in Minority Institutions |
| **RCR** | Responsible Conduct of Research |
| **RDCRN** | Rare Diseases Clinical Research Network |
| **RDoC** | Research Domain Criteria |
| **RePORT** | Research Portfolio Online Reporting Tools |

| Abbreviation | Meaning |
|---|---|
| RFA | Request for Application |
| RFI | Request for Information |
| RHHS | Relmagine HHS |
| RM | Risk Management |
| RMIP | Regenerative Medicine Innovation Project |
| RML | Rocky Mountain Laboratories |
| RMS | Research Management and Support |
| RN | Registered Nurse |
| RPG | Research Project Grant |
| RTP | Research Triangle Park |
| RURAL | Risk Underlying Rural Areas Longitudinal Cohort |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SARS-CoV-2 | Severe Acute Respiratory Syndrome Coronavirus 2 |
| SBIR | Small Business Innovation Research |
| SBRS | Senior Biomedical Research Service |
| SC | Steering Committee |
| SCD | Sickle Cell Disease |
| SCZ | Schizophrenia |
| SDB | Sleep Disorders Breathing Study |
| SDC | Scientific Data Council |
| SDoH | Social Determinant of Health |
| SEER | Surveillance, Epidemiology, and End Results |
| SEPA | Science Education Partnership Awards |
| SeroNet | Serological Sciences Network |
| SES | Senior Executive Service |
| SES | Socioeconomic Status |
| SGM | Sexual and Gender Minority |
| SGM RCC | Trans-NIH LGBT Research Coordinating Committee |
| SGMRO | Sexual & Gender Minority Research Office |
| SGMY | Sexual Gender and Minority youth |
| SIREN | Strategies to Innovate Emergency Care Clinical Trials Network |
| SL | Senior Level |
| SL/ST | Senior Level/Scientific or Professional |
| SMG | Senior Management Group |
| SMI | Serious Mental Illness |
| SOGI | Sexual Orientation and Gender Identity |
| SRA | Sequence Read Archive |
| SREA | Scientific Review and Evaluation Activities |
| SRP | Superfund Research Program |

| Abbreviation | Meaning |
|---|---|
| SSA | Social Services Administration |
| SSF | Service Supply Fund |
| ST | Scientific (executive management position) |
| STAC | Secretary's Tribal Advisory Committee |
| STEM | Science, Technology, Engineering and Mathematics |
| STI | Sexually Transmitted Infection |
| STRIDES | Science and Technology Research Infrastructure for Discover, Experimentation, and Sustainability |
| STTR | Small Business Technology Transfer |
| SUD | Substance Use Disorder |
| SWD | Scientific Workforce Diversity |
| T1D | Type 1 Diabetes |
| T-42 | Title 42 |
| T42 CRS | Title 42 Clinical Research Support |
| TAMB | Translational Addiction Medicine Branch |
| TasP | Treatment as Prevention |
| TB | Tuberculosis |
| TBI | Traumatic Brain Injury |
| TCAC | NIH Tribal Consultation Advisory Committee |
| TDB | Therapeutics Development Branch, NCATS |
| THC | Tetrahydrocannabinol |
| THRO | Tribal Health Research Office |
| THL | Finnish National Institute of Health and Welfare |
| TIN | Trial Innovation Network |
| TMC1 | Transmembrane channel-like 1 |
| TMJA | Temporomandibular Joint Association |
| TMJ | Temporomandibular Joint |
| TMJDs | Temporomandibular Joint Disorders |
| TN | Tennessee |
| TOPMed | Trans-Omics for Precision Medicine Program |
| Tox21 | Toxicology Testing in the 21st Century |
| TRI | Translational Research Initiative |
| TWD | Division of Training, Workforce Development, and Diversity |
| TX | Texas |
| U.S. | United States |
| URG | Underrepresented Group |
| URGenT | Ultra-Rare Gene Therapy Network |
| USG | United States Government |
| VA | Veterans Affairs |

| Abbreviation | Meaning |
|---|---|
| VOIP | Voice Over Internet Protocol |
| VPN | Virtual Private Network |
| VRC | Vaccine Research Center |
| WA | Washington |
| WG | Working Group |
| WHO | World Health Organization |
| WSDD | Workforce Support and Development |
| WTP | Worker Training Program |

# WORKFORCE SNAPSHOT METHODOLOGY

*Data sources:*
- nVision HR-29 FTE Staff by Pay Plan Report
- nVision HR-76 Personnel Actions- All Accession Report
- nVision HR-79 Personnel Actions- All Separations Report

*Data currency:*
- October 1, 2020 (first day of FY2021)
- All analyses are calculated as of October 1, 2020.
- Retirement eligibility is calculated as of October 1, 2020 based on employees' retirement eligibility date in nVision. Employees with no retirement eligibility date are excluded from analysis.
- Onboard data is headcount as of October 1st for each fiscal year.
- Average time past retirement is the average number of years employees stayed at NIH after they became retirement eligible before retiring. Retirement data from FY16-FY20 is used for calculations.

*Additional notes:*
- For Gender analysis, "Other" is excluded from analysis.
  - "Other" has extremely limited count. Less than 5 at the NIH level.
  - "Other" appeared in FY21 data only.
- For Pay Plan analysis, "ZZ" and "EF" pay plans are excluded from analysis due to limited count.
  - Only 1 ZZ pay plan employee in FY20 and FY21.
  - Only 2 EF pay plan employee in FY17.
  - ZZ pay plan = Non-applicable Code is for use only with pay basis WC (without compensation) when other pay plan codes are not applicable.
  - EF pay plan = Consultant (5 U S C 3109) Use when the individual is appointed under 5 U S C 3109 as consultant Do not use when the appointment as a consultant is solely for service as an advisory committee member.

U.S. Department of Health and Human Services

National Institutes of Health

ARB

November 2020

# NATIONAL INSTITUTES OF HEALTH

# AGENCY REVIEW TEAM BOOK

NOVEMBER 2020

# Contents

# NIH AGENCY REVIEW TEAM TRANSITION BOOK

## DIVISION CONTACT

RADM Erica Schwartz, Deputy Surgeon General, (b) (6).

## IN-PERSON BRIEFING SCHEDULE

### BRIEFING SCHEDULE

Virtual or in-person meetings can be arranged at the request of the Agency Review Team.

1. Introduction – NIH Director
2. Introduction – NIH Principal Deputy Director/First Assistant
3. Introduction – NIH Associate Deputy Director; NIH Chief of Staff (acting)
4. Introduction – NIH Deputy Directors (4)
5. Small Group of NIH Institute and Center Directors – Select Top Issues
6. Optional: Introduction – NIH Executive Committee
7. Optional: Introduction – All NIH Institute and Center Directors

### INTERVIEW GUIDE

The following questions are provided as suggestions for the Agency Review Team Staff:

1. Please tell me about yourself and the work you do here at NIH. What brought you to NIH, and what keeps you here?
2. What would you say are the major opportunities for scientific progress at NIH and the major challenges and/or barriers to progress?
3. What do you see as the major science policy issues facing NIH right now?
4. What factors are most important to your ability to do your work, such as having the flexibility to take on new scientific challenges? Do the current NIH structure, programs, and processes enable efficient and effective collaboration and adequate flexibility? What could be improved?
5. What improvements should we look at to enhance the work culture at NIH?
6. What are the top lessons learned from the SARS-CoV-2 pandemic?

For additional information on items of interest to NIH, please refer to the Top Issues Section.

## ORGANIZATIONAL OVERVIEW

### MISSION AND PRIORITIES

The National Institutes of Health (NIH) is the steward of medical and behavioral research for the Nation. The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The agency's goals in pursuit of this mission are to:

- Foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to significantly advance the Nation's capacity to protect and improve health;
- Develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
- Expand the knowledge base in medical and associated sciences to enhance the Nation's economic well-being and ensure a continued high return on public investment in research; and
- Exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

# NATIONAL INSTITUTES OF HEALTH ORGANIZATIONAL CHART

## OFFICE OF THE DIRECTOR

**Director**
Francis S. Collins, MD, PhD

**Principal Deputy Director**
Lawrence Tabak, DDS, PhD

**Deputy Director for Management**
Alfred C. Johnson, PhD

**Deputy Director for Extramural Research**
Michael S. Lauer, MD

**Deputy Director for Intramural Research**
Michael M. Gottesman MD

**Deputy Director for Program Coordination, Planning, and Strategic Initiatives**
James M. Anderson, MD, PhD

**Chief of Staff**
Carrie D. Wolinetz, PhD (Acting)

**Associate Deputy Director**
Tara A. Schwetz, PhD

**National Cancer Institute**
Norman E. Sharpless MD

**National Eye Institute**
Michael F. Chiang MD

**National Heart, Lung, and Blood Institute**
Gary H. Gibbons MD

**National Human Genome Research Institute**
Eric D. Green MD PhD

**National Institute on Aging**
Richard J. Hodes MD

**National Institute on Alcohol Abuse and Alcoholism**
George F. Koob PhD

**National Institute of Allergy and Infectious Diseases**
Anthony S. Fauci MD

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**
Robert Carter MD (Acting*)

**National Institute of Biomedical Imaging and Bioengineering**
Bruce J. Tromberg, PhD

**Eunice Kennedy Shriver National Institute of Child Health and Human Development**
Diana W. Bianchi, MD

**National Institute on Deafness and Other Communication Disorders**
Debara L. Tucci, MD, MS MBA

**National Institute of Dental and Craniofacial Research**
Rena D'Souza DDS, MS PhD

**National Institute of Diabetes and Digestive and Kidney Diseases**
Griffin P. Rodgers, MD, MACP

**National Institute on Drug Abuse**
Nora D. Volkow, MD

**National Institute of Environmental Health Sciences**
Rick Woychik PhD

**National Institute of General Medical Sciences**
Jon R. Lorsch, PhD

**National Institute of Mental Health**
Joshua A. Gordon MD PhD

**National Institute on Minority Health and Health Disparities**
Eliseo J. Pérez-Stable, MD

**Center for Information Technology**
Andrea T. Norris MBA

**Center for Scientific Review**
Noni H. Byrnes, PhD

**National Library of Medicine**
Patricia Flatley Brennan RN PhD

**John E. Fogarty International Center for Advanced Study in the Health Sciences**
Roger I. Glass MD PhD

**National Center for Advancing Translational Sciences**
Christopher P. Austin, MD

**National Center for Complementary and Integrative Health**
Helene Langevin MD

**National Institute of Neurological Disorders and Stroke**
Walter Koroshetz MD

**National Institute of Nursing Research**
Shannon N. Zenk PhD MPH, RN, FAAN

**Clinical Center**
James Gilman, MD

*Lindsay A. Criswell MD MPH DSc. has been selected as the next NIAMS Director and will start in January 2021

**Color-Coding for Personnel Categories**

- Senior Executive Position
- Key Subject Matter Expert
- Schedule C Position
- Vacant Position
- Individual in Position (acting)

NIH is comprised of 27 different components, termed Institutes and Centers (ICs), with 24 Institutes and the Office of the Director having their own individual appropriation. Each IC is led by a director, and develops its own specific research agenda, often focusing on particular diseases/conditions, and maintains its own budget.

## TOP ISSUES FOR NEW LEADERSHIP

(b) (5)

[redacted]

### KEY CHALLENGES TO DATE

- (b) (5)
  - [redacted]
  - [redacted]
  - [redacted]

### NEXT STEPS

- (b) (5)
  - [redacted]
  - [redacted]

(b) (5)

[redacted]

(b) (5)

[redacted]

### KEY CHALLENGES TO DATE

- (b) (5)

(b) (5)

**NEXT STEPS**

(b) (5)

**TOP ISSUE:** (b) (5)

(b) (5)

**KEY CHALLENGES TO DATE**

(b) (5)

**NEXT STEPS**

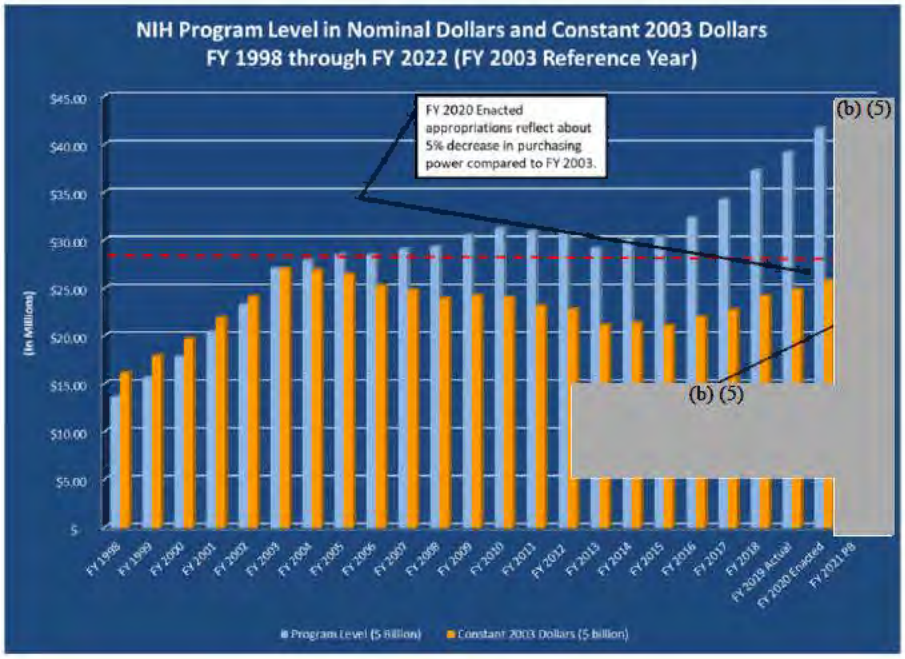
(b) (5)

(b) (5)

## BUDGET OVERVIEW

### MAJOR BUDGET CHANGES FY 2016-FY 2021

Due to strong Congressional support, the NIH budget rose from $32.3 billion in fiscal year (FY) 2016 to $41.7 billion in FY 2020. Based on the rate of biomedical research inflation, NIH's purchasing power in FY 2015 was 22 percent below its peak in FY 2003; however, recent increases helped address declining purchasing power due to erosion by inflation and have made up all but 5 percent of that loss in real dollars.




### CORONAVIRUS SUPPLEMENTAL APPROPRIATIONS

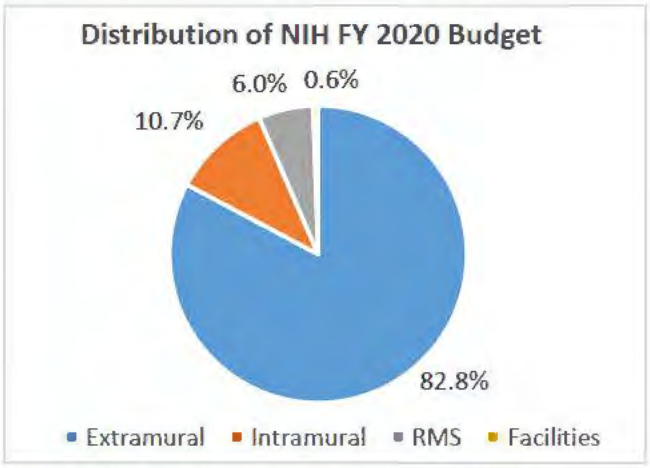
NIH received a total of $3.587 billion from three FY 2020 supplemental appropriations enacted in response to the COVID-19 pandemic, including $836 million in P.L. 116-123, $945 million in P.L. 116-136, and $1.806 billion in P.L. 116-139 (by transfer from the Public Health and Social Services Emergency Fund). The funds were provided to seven ICs—the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHL8I), the National Center for Advancing Translational Sciences (NCATS), the National Institute of Environmental Sciences (NIEHS), and the National Library of Medicine (NLM)—and the Office of the Director (OD). The largest portion of the funds are for diagnostics, including over $1 billion for RADx[SM], implemented by NIBI8 and OD. The other major categories are vaccines, therapeutics, basic research, and facilities. As of September 30, 2020, NIH has obligated (entered a binding agreement that will results in disbursements/outlays) a total of $1.535 billion and disbursed $254 million. In addition, under Operation Warp Speed (OWS), NIH is implementing a number of major clinical trials on behalf of the Biomedical Advanced Research and Development Authority (BARDA). This includes vaccine and therapeutic trials under the ACTIV public-private partnership. As of September 30, 2020, NIH has obligated about $1.573 billion for OWS.

## FUNDING SOURCES

NIH receives the bulk of its funding from the Labor, Health and Human Services, and Education, and Related Agencies annual appropriations act, including both discretionary budget authority and Program Evaluation financing for the National Institute of General Medical Sciences (NIGMS). It receives a small amount ($81 million) from the Interior, Environment, and Related Agencies appropriations act for the NIEHS Superfund Research program. It also receives mandatory budget authority ($150 million) for the Type 1 Diabetes Special Statutory Program account [the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)].

## EXPENDITURES

NIH expenditures fall into the following major categories:




- **Extramural research**. NIH typically makes grants for a multi-year period and awards funding one year at a time, allowing for oversight. A large portion of the research budget is committed to noncompeting renewals, with a smaller portion for new competing awards.
- **Intramural research**. Conducted by NIH employees in NIH labs and the Clinical Center. Expenses include personnel costs (23%) and contract and other non-personnel costs (77%).
- **Research management and support (RMS)**. RMS covers administrative, budgetary, logistical, and scientific support activities. Expenses include personnel costs (35%), contract and other non-personnel costs (65%).
- **Facilities**. Facilities spending funds construction projects and repairs, improvements, and renovations at NIH-owned facilities on the main Bethesda campus and at other sites across the country.

## CONGRESSIONAL RELATIONS AND ISSUES

### DIVISION RELEVANT COMMITTEE

| United States Senate | United States House of Representatives |
|---|---|
| Health, Education, Labor, and Pensions (HELP) Committee:<br>Chair *Lamar Alexander (R-TN);<br>Ranking Member Patty Murray (D-WA).<br>Principal majority staff Grace Graham, Andy Vogt, and Melissa Pfaff.<br>Principal minority staff Nick Bath and Garrett Devenney. | Energy and Commerce Committee:<br>Chair Frank Pallone (D-NJ);<br>Ranking Member *Greg Walden (R-OR)<br>Principal majority staff Tiffany Guarascio.<br>Principal minority staff Ryan Long. |
| Appropriations Committee:<br>Chair *Richard Shelby (R-AL);<br>Ranking Member Patrick Leahy (D-VT).<br>Principal majority staff Shannon Hines.<br>Principal minority staff Charles Kiefer. | Appropriations Committee:<br>Chair*Nita Lowey (D-NY);<br>Ranking Member Kay Granger (R-TX).<br>Principal majority staff Shalanda Young.<br>Principal minority staff Anne Marie Chotvacs. |
| Small Business Committee:<br>Chair Marco Rubio (R-FL);<br>Ranking Member Ben Cardin (D-MD).<br>Principal majority staff Samantha Soco.<br>Principal minority staff Kevin Wheeler. | Small Business Committee:<br>Chair Nydia Velázquez (D-NY);<br>Ranking Member Steve Chabot (R-OH).<br>Principal majority staff Megan Sunn.<br>Principal minority staff Joe Hartz. |

*Retiring

**OTHER MEMBERS WITH SPECIAL INTEREST OR SUBJECT MATTER EXPERTISE**

Disease-specific caucuses (Diabetes, Alzheimer's Disease, etc.); Science-oriented caucuses (Life Sciences Coalition); and subject matter expertise caucuses (Doctors Caucus). Congressional Member and Staff Organizations can be identified online.

**CONFIRMATION HEARING PREP**

Historically, confirmation has been non-controversial with the HELP Committee having sole jurisdiction.

**REQUIRED AUTHORIZATION/APPROPRIATIONS REPORTS AND UPDATES TO CONGRESS**

Most reporting requirements are contained in the NIH Triennial Report, due to Congress in fall 2020, and in the annual Congressional Budget Justification.

**KEY PENDING LEGISLATION**

Most legislation is disease specific, which is a significant concern to NIH and which our authorizing committees try to broaden. (b) (5)

**IMPLICATIONS OF CONTINUING RESOLUTION**

Not significant.

**IMPLICATIONS OF CHANGES IN NEW CONGRESS**

(b) (5)

## ADMINISTRATIVE INFORMATION

**SECURITY PROCEDURES**

(b) (7)(E)

**COMPUTER ACCESS, TECHNOLOGY USAGE, & TELEPHONE INSTRUCTIONS**

(b) (7)(E), (b) (6)

**FACILITY MAP**

(b) (7)(E) .