Office of the Director

CONGRESSIONAL JUSTIFICATION
FY 2022

Department of Health and Human Services
National Institutes of Health

National Institutes of Health
Office of the Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

Director's Overview

NIH Director Francis Collins, M.D., Ph.D.

The Office of the Director (OD) serves as the central office of the NIH. It provides leadership in planning, management, and coordination across the agency's Institutes and Centers (ICs).

Answering the call: Addressing public health needs with great urgency

With its central role at NIH, the OD has the unique ability to confront emerging, challenging scientific questions, to advance innovative science from bench to bedside, and to promote health nationwide. NIH research has proven its value to the United States and the world over the years by rising to meet the challenges of polio, AIDS, and many other formidable health challenges. Now, we face what may be the greatest public health crisis of our generation: COVID-19. Enabled by the strong support of Congress and other partners in the public and private sectors, NIH has mounted a vigorous research response against COVID-19 since the beginning of the pandemic. The OD coordinates NIH efforts to combat and prevent the devastating consequences of COVID-19, including the Rapid Acceleration of Diagnostics (RADx[SM]) initiative and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership. The scientific efforts behind the NIH's response to the COVID-19 pandemic are outlined in the NIH-Wide Strategic Plan for COVID-19 Research, developed by the OD, in partnership with the ICs.

While the Nation focuses on the coronavirus pandemic, the public health crisis of opioid misuse and addiction in America continues. More than 47,000 Americans died of opioid overdose in 2017, and more than 2 million Americans live with addiction to opioids.[1] The OD runs the Helping to End Addiction Long-term[SM] Initiative, or NIH HEAL Initiative, to provide scientific solutions to the opioid crisis and offer new hope for individuals, families, and communities affected by this devastating crisis.

Closing the gap in health disparities

As COVID-19 illustrates, there is a need to close serious gaps in health across the country. The OD provides guidance and resources to advance programs aimed at increasing diversity in the scientific workforce and scientific initiatives to study and prevent health disparities. While all of NIH shares the goal of eliminating health disparities, there are specific OD offices dedicated to addressing disparities of race, ethnicity, age, gender, or other populations. For example, the Sexual and Gender Minority Research Office (SGMRO) and the Tribal Health Research Office (THRO) coordinate research across NIH, include the respective communities in the development of research initiatives, and leverage resources to support research involving these populations. The OD also houses the *All of Us* Research Program, an effort to improve healthcare through

[1] heal.nih.gov/about/research-plan#references

research, which aims to include participants from groups that have previously been underrepresented in public health research to reflect the diversity of the United States. NIH has long recognized that the most critical assets in the biomedical research enterprise are the scientists who comprise its workforce. The advancement of researchers with diverse backgrounds and experiences increases creativity and performance in science and it is a key component of innovation and achievement in the workforce. The OD manages, prioritizes, and allocates funds for training and professional development opportunities for researchers from underrepresented backgrounds. The Office of the Chief Officer for Scientific Workforce Diversity (SWD) leads NIH's effort to diversify the national scientific workforce through expanded recruitment and retention. The Office of Equity, Diversity, and Inclusion (EDI) fosters an inclusive culture at NIH, increases representation, provides analyses of representation across NIH, and manages the agency's civil rights program.

Capitalizing on foundational investments and beyond

By supporting initiatives and programs across the NIH, the OD fosters innovative research and scientific and health resources to protect and improve health. The OD provides scientific and operational guidance to the ICs in setting trans-NIH policy and procedures, developing and maintaining shared resources, coordinating initiatives, programs, and activities, and anticipating new directions for the biomedical research enterprise. Within OD, the Office of Extramural Research (OER) provides the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio. The Office of Intramural Research (OIR) oversees policies that govern intramural research, as well as training conducted within the NIH Intramural Research Program. To achieve its mission, NIH must support a wide range of fundamental scientific research areas that provide the building blocks for future diagnostics, treatments, and cures across the entire spectrum of diseases and conditions. The Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the OD guides the NIH in identifying, reporting, and funding trans-NIH research in emerging scientific areas.

NIH seeks to continually optimize operations across a diverse array of business, administrative, and scientific functions as well as improve the physical and technological infrastructures supporting enterprise-wide operations. The OD continues NIH's stewardship of both public funds and the public trust by overseeing the operational processes of the NIH, such as budget and financial management, technology and property management, procurement services, ethics, and human capital management. Several OD offices and initiatives are working to build data science and computational resources, including in artificial intelligence and machine learning, and to effectively utilize these tools to advance discoveries in health. The Office of Data Science Strategy (ODSS) is charged with coordinating a broad range of data science activities that align with NIH's priorities and strategic plans.

The OD manages, prioritizes, and allocates funds for administrative services including budget and financial management, human resources, information technology, procurement services, property management, intramural and extramural support, ethics, and administration of equal employment and diversity management practices. The OD recently led an NIH-wide effort, Optimize NIH, to increase efficiency across the agency, which included updates to travel, hiring,

property management, and other processes and the launch of data dashboards to support decision-making across NIH. Much of this effort was led by Office of Management (OM) which advises, provides leadership, and oversees NIH administration and management, including (but not limited to) areas of budget, human resources, facilities, support services, security operations, and logistics.

Overall Budget Policy: The FY 2022 President's Budget request for the OD is $2,394.9 million, an increase of $111.0 million or 4.9 percent compared to the FY 2021 Enacted level.[2] Increases are distributed across programmatic and operational areas, as described below. This level includes an increase for the National Primate Research Centers and Caribbean Primate Research Center, the All of Us Research Program, and research related to the prevention of firearms injury and mortality. This funding will support the continuation of the COVID-19 pandemic response as well as other research, policy, and operational initiatives in support of the NIH mission to advance scientific discovery and improve health.

[2] The FY 2021 level is adjusted for the transfer of the ECHO and INCLUDE programs from the Office of the Director to the National Institute of Child Health and Human Development for comparability with the FY 2022 request.

National Institutes of Health
Office of the Director

Mission of the Office of the Director

The NIH Office of the Director (OD) serves as the central office of NIH and provides leadership in planning, managing, and coordinating across the agency's Institutes and Centers (ICs). The OD guides the agency's direction and develops plans to ensure a successful future. The OD provides scientific and operational guidance to the ICs by setting trans-NIH policy and procedures; developing and maintaining shared resources; coordinating initiatives, programs, and activities; and anticipating new directions for the biomedical research enterprise.

As NIH Director, Dr. Francis Collins plays a vital role in shaping the agency's overarching agenda and outlook. Dr. Collins provides leadership and guidance to the 27 ICs, especially in the many scientific and operational efforts that span the agency. The Director is responsible for seeking input from and collaborating with a wide range of stakeholders, including the scientific community, the public, other federal agencies, and Congress. With this critical perspective, the Director identifies and informs enterprise-wide priorities that advance the NIH mission.

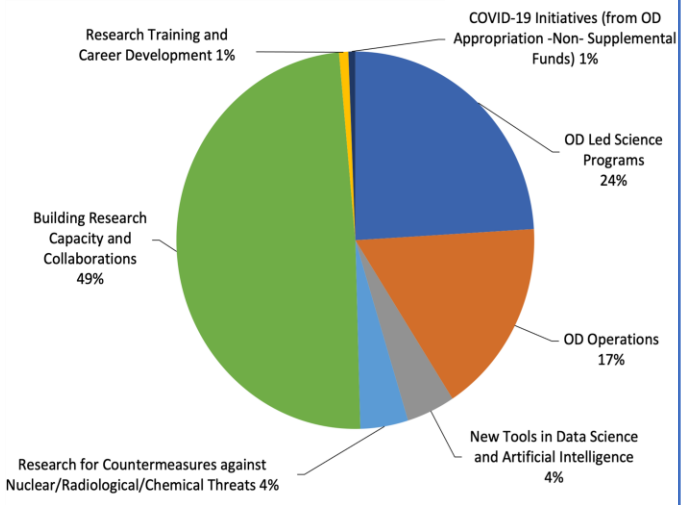
Highlights from the Office of the Director

- The OD led the rapid response to the COVID-19 pandemic by setting the path for public-private partnerships and trans-NIH efforts, and quickly adapting operations to advance the most promising solutions to the pandemic while ensuring safety.
- To advance the NIH mission, the *NIH-Wide Strategic Plan* outlines a vision for the future of biomedical research, scientific exploration, and solutions to new challenges for human health. In 2020, the OD worked with stakeholders and leaders from across the NIH to update the *Strategic Plan* and set priorities for the agency's future.

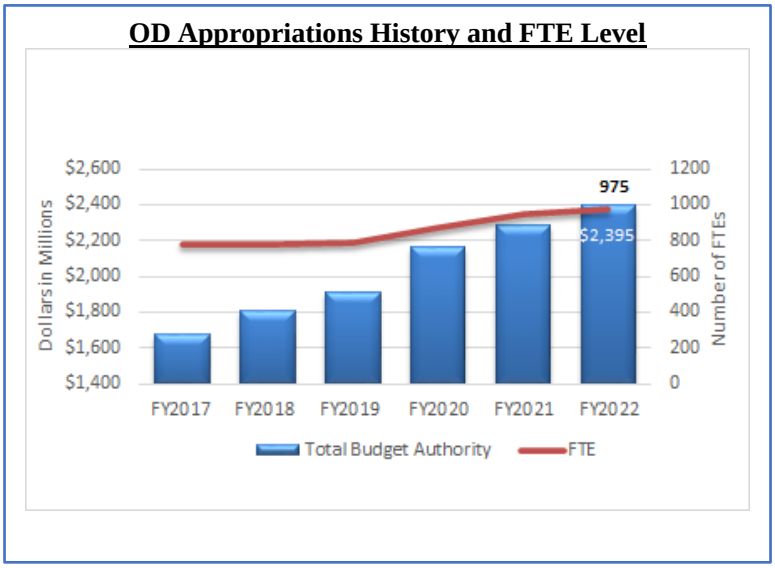
FY 2020 Facts and Figures

- 875 Full Time Equivalent Employees
- $960.4 million OD Funded Research Awards (excluding Common Fund)
  - *$10.8 million Pre-Term, LBW, Health of Newborn*
  - *$5.0 million Maternal Mortality & Morbidity*
- $1.030 billion COVID-19 Supplemental Funding

FY 2022 Funding by Focus Area



Recent Accomplishments



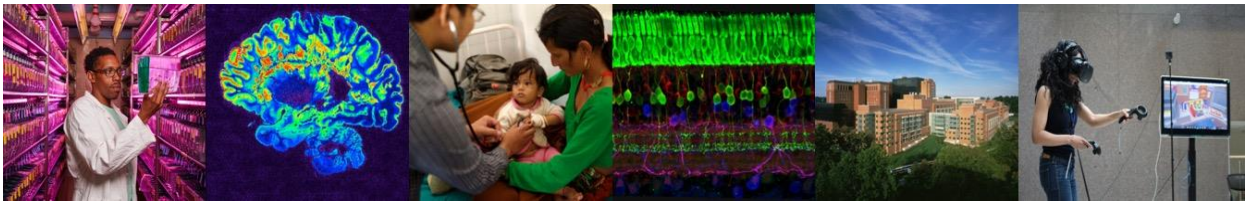
- **ACTIV and RADx:** The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and Rapid Acceleration of Diagnostics (RADx[SM]) initiatives, led by the OD, were launched early in the COVID-19 pandemic to support promising research aimed at stopping the spread of SARS-CoV-2 and treating the life-threatening disease.
- **Optimize NIH:** The OD led an NIH-wide effort to increase efficiency across the agency, which included updates to travel, hiring, property management, and other processes and the launch of data dashboards to support decision-making across NIH.

Current Activities

- **Enhancing Rigor and Reproducibility:** The OD has gathered partners from across the biomedical enterprise, including the Advisory Committee to the Director (ACD) Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research, to align goals, policies, and initiatives to support the highest quality science across all stages of biomedical research.
- **Addressing Health Inequities:** As COVID-19 illustrates, there is a need to close serious gaps in health across the country. The OD provides guidance and resources to advance programs aimed at increasing diversity in the scientific workforce and scientific initiatives to study and prevent health disparities.
- **Ending HIV:** The OD supports the nation-wide effort to end the HIV epidemic through trans-NIH research and public resources coordinated by the Office of AIDS Research.

Future Initiatives

- **Building Data Science and Computational Infrastructure:** Several OD offices and initiatives are working to build data science and computational resources, including in artificial intelligence and machine learning, and to effectively utilize these tools to advance discoveries in health.
- **Nutrition for Precision Health:** A trans-NIH initiative led by the OD will provide the evidence for individualized dietary/nutrition recommendations and advance research with new technologies and algorithms, and large cohorts of *All of Us* Research Program participants.
- **Maternal Morbidity and Mortality:** The OD leads the trans-NIH Maternal Morbidity Mortality Task Force to coordinate and grow research to address the concerning increase in pregnancy-related death and morbidities in the United States through the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative.



Major Changes in the Fiscal Year 2022 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2022 budget request for OD, which is $111.0 million above the comparably adjusted FY 2021 Enacted level for a total of $2,394.9 million.

National Primate Research Centers and Caribbean Primate Research Center (+$30.0 million; total $140.0 million): The FY 2022 budget requests funding to support the expansion of the non-human primate research infrastructure, including construction to increase capacity. The COVID-19 pandemic has highlighted the need for this expansion to ensure numbers sufficient for both pandemic research and existing NIH research.

All of Us Research Program (+$41.0 million; total $541.0 million): The FY 2022 President's Budget request for the *All of Us* Research Program will be used to continue enrollment and retention activities to advance individualized healthcare by building one of the largest, most diverse health databases in the world The request includes $150.0 million of funding authorized in the 21st Century Cures Act to support the *All of Us* program, a $41.0 million increase from the FY 2021 authorized and enacted level.

Firearms Research (+$12.5 million; total $25.0 million): The FY 2022 President's Budget request will enable NIH to increase its research efforts on firearm injury and mortality prevention.

Office of the Chief Information Officer for Scientific Workforce Diversity (+$16.0 million; total $22.2 million): The FY 2022 budget request provides funding to enhance NIH's effort to diversify the national scientific workforce and expand recruitment and retention.

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Budget Mechanism - Total[1,2,3]

(Dollars in Thousands)

MECHANISM	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		Change FY 2022	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects		$530,553		$558,844		$564,706		$5,862
Research Centers		225,968		252,636		297,290		$44,654
Other Research		822,416		840,870		890,948		$50,078
Total Research Grants		$1,578,937		$1,652,349		$1,752,944		$100,595
Training		$19,339		$22,936		$24,017		$1,081
R & D Contracts		77,341		95,806		106,371		$10,565
Intramural Research		18,990		12,832		12,960		$129
Res. Management & Support		413,865		443,800		462,423		$18,623
Construction		55,043		56,144		36,144		-$20,000
Total Other Than Research Grants		$584,579		$631,518		$641,915		$10,397
Subtotal, Labor/HHS Budget Authority		$2,163,516		$2,283,867		$2,394,859		$110,992
Total, OD		$2,163,516		$2,283,867		$2,394,859		$110,992

[1]Includes $157.0 million in FY 2020, $109.0 million in FY 2021, and $150.0 million in FY 2022 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

[2]FY 2020 and FY 2021 have been comparably adjusted for the proposed transfer of ECHO and INCLUDE from OD to NICHD in FY 2022.

[3]Reflects $5.0 million transfer to HHS Office of the Inspector General in all years.

OFFICE OF THE DIRECTOR

[(INCLUDING TRANSFER OF FUNDS)]

For carrying out the responsibilities of the Office of the Director, NIH, [$2,411,110,000]$*2,237,259,000: Provided,* That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: *Provided further,* That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: *Provided further,* That [$180,000,000 shall be for the Environmental Influences on Child Health Outcomes study: *Provided further,* That $635,939,000]*$645,939,000* shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: *Provided further,* That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: *Provided further,* That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act: *Provided further,* That [$50,000,000] *up to $30,000,000* shall be used to carry out section 404I of the PHS Act (42 U.S.C. [283K), relating to biomedical and behavioral research facilities] *283k) with respect to the National Primate Research Centers and Caribbean Primate Research Center*: *Provided further,* That $5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further,* That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior [approval of] *notification to* the Committees on Appropriations of the House

of Representatives and the Senate: *Provided further,* That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years [2021 and] 2022 *and 2023* no later than 30 days after the date of enactment of this Act*: Provided further, That amounts available under this heading are also available to establish, operate, and support the Research Policy Board authorized by section 2034(f) of the 21st Century Cures Act*.

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, $12,600,000 is appropriated to the Common Fund [from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code,] for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act*, of which $3,000,000 shall be derived from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code*. (Department of Health and Human Services Appropriations Act, 2021.)

[(INCLUDING TRANSFER OF FUNDS)]

[For an additional amount for "Office of the Director", $1,250,000,000, to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally: *Provided,* That of the amount appropriated under this heading in this Act,

$1,150,000,000 shall be provided for research and clinical trials related to long-term studies of COVID-19: *Provided further,* That of the amount appropriated under this heading in this Act, no less than $100,000,000 shall be for the Rapid Acceleration of Diagnostics: *Provided further,*

That funds appropriated under this heading in this Act may be transferred to the accounts of Institutes and Centers of the National Institutes of Health (NIH): *Provided further*, That this transfer authority is in addition to any other transfer authority available to the NIH: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.] (Coronavirus Response and Relief Supplemental Appropriations Act, 2021.)

NIH INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, [$404,000,000]*$496,000,000*, to remain available until expended: *Provided*, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further*, That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: *Provided further*, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. (Department of Health and Human Services Appropriations Act, 2021.)

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes

(Dollars in Thousands)

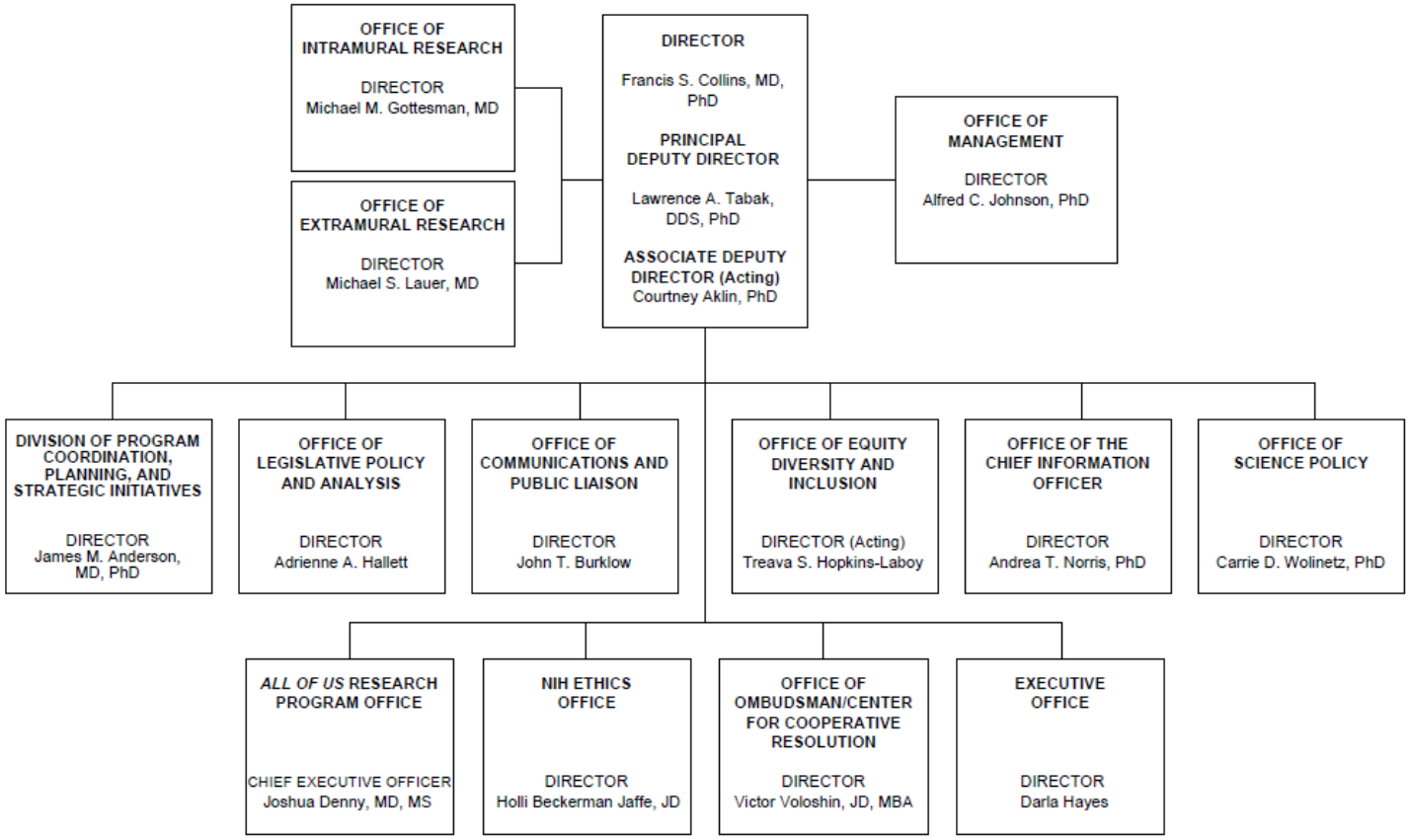
FY 2021 Enacted	$2,283,867
FY 2022 President's Budget	$2,394,859
Net change	$110,992

CHANGES	FY2021 Enacted		FY 2022 President's Budget		Change from FY 2021 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2021 pay increase & benefits		$4,207		$4,425		$13
b. January FY 2022 pay increase & benefits		$4,207		$4,425		$205
c. Paid days adjustment		$4,207		$4,425		$0
d. Differences attributable to change in FTE		$4,207		$4,425		$0
e. Payment for centrally furnished services		$0		$0		$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$8,624		$8,535		$155
Subtotal						$373
2. Research Management and Support:						
a. Annualization of January 2021 pay increase & benefits		$146,609		$154,495		$397
b. January FY 2022 pay increase & benefits		$146,609		$154,495		$4,052
c. Paid days adjustment		$146,609		$154,495		$0
d. Differences attributable to change in FTE		$146,609		$154,495		$3,585
e. Payment for centrally furnished services		$2,710		$2,846		$136
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$294,481		$305,082		$5,328
Subtotal						$13,498
Subtotal, Built-in						$13,871

CHANGES	FY2021 Enacted		FY 2022 President's Budget		Change from FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	324	$329,239	348	$350,821	24	$21,581
b. Competing	205	$221,266	183	$205,447	-22	-$15,819
c. SBIR/STTR	12	$8,338	12	$8,438	0	$100
Subtotal, RPGs	541	$558,844	543	$564,706	2	$5,862
2. Research Centers	104	$252,636	135	$297,290	31	$44,654
3. Other Research	405	$840,870	409	$890,948	4	$50,078
4. Research Training	573	$22,936	488	$24,017	-85	$1,081
5. Research and development contracts	8	$95,806	6	$106,371	-2	$10,565
Subtotal, Extramural		$1,771,091		$1,883,332		$112,241
	FTEs		FTEs		FTEs	
6. Intramural Research	0	$12,832	0	$12,960	0	-$244
7. Research Management and Support	952	$443,800	975	$462,423	23	$5,124
8. Construction	0	$56,144	0	$36,144	0	-$20,000
9. Buildings and Facilities	0	$0	0	$0	0	$0
Subtotal, Program	952	$2,283,867	975	$2,394,859	23	$97,121
Total changes						$110,992

NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure



NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY2021
OD Led Science Programs	**527,633**	**523,750**	**577,250**	**53,500**
All of Us Research Program	351,000	391,000	391,000	0
All of Us Research Program - Cures	149,000	109,000	150,000	41,000
Regenerative Medicine - Cures	8,000	0	0	0
BRAIN Initiative	10,000	10,000	10,000	0
Foundation for the National Institutes of Health	1,250	1,250	1,250	0
Firearm Injury and Mortality Prevention Research	8,383	12,500	25,000	12,500
New Tools in Data Science and Artificial Intelligence	**30,000**	**105,000**	**105,000**	**0**
Office of Data Science Strategy	30,000	55,000	55,000	0
Artificial Intelligence to Address Chronic Disease	0	50,000	50,000	0
Building Research Capacity and Collaborations	**1,129,395**	**1,158,339**	**1,175,479**	**17,140**
Common Fund	639,111	648,539	658,539	10,000
Division of Program Coordination, Planning and Strategic Initiatives	490,284	509,800	516,940	7,140
Research Training and Career Development	**19,669**	**19,926**	**20,062**	**136**
Intramural Loan Repayment and Scholarship	8,255	8,513	8,649	136
NIH Director's Challenge Fund	1,413	1,413	1,413	0
Director's Discretionary Fund	10,000	10,000	10,000	0
Research for Countermeasures against Nuclear/Radiological/Chemical Threats	**100,042**	**102,042**	**103,675**	**1,633**
OD Operations	**356,777**	**374,810**	**413,393**	**38,583**
Office of the Chief Officer for Scientfiic Workforce Diversity (non-add)	*(2,224)*	*(6,190)*	*(22,190)*	*(16,000)*
Reception and Representation Fund (non-add)	*(10)*	*(10)*	*(10)*	*(0)*
National Primate Research Center and Caribbean Primate Center (non-add)	*(0)*	*(0)*	*(30,000)*	*(30,000)*
Biomedical & Behavioral Research Facilities (non-add)	*(50,000)*	*(50,000)*	*(0)*	*(-50,000)*
Total	**$2,163,516**	**$2,283,867**	**$2,394,859**	**$110,992**

[1]FY 2020 and FY 2021 have been comparably adjusted for the proposed transfer of ECHO and INCLUDE from OD to NICHD in FY 2022.

Justification of Budget Request

Office of the Director

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as Amended.

Budget Authority (BA):

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
BA	$2,163,516,000	$2,283,867,000	$2,394,859,000	$110,992,000
FTE	875	952	975	23

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Program Descriptions

Scientific Programs of the Office of the Director: Coordination, Strategic Direction, and Investments

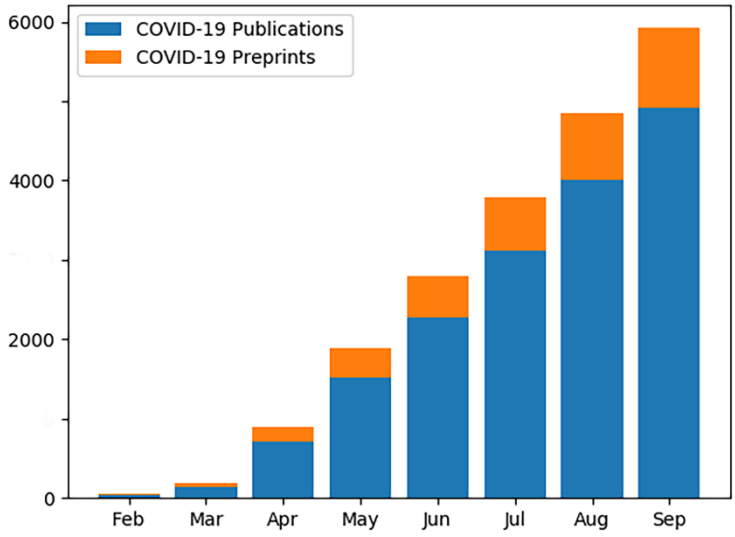
The OD coordinates and contributes to scientific research activities across the NIH that are housed in both the OD and the ICs. To provide a strategic direction for key programs, the OD guides investment and planning for scientific activities in pursuit of a greater understanding of and support for public health.

Supporting Scientific Solutions to the COVID-19 Pandemic

In early 2020, the COVID-19 pandemic quickly became the most pressing public health emergency in the United States. To answer this call, the NIH immediately began building research capacity to understand the spread of the SARS-CoV-2 virus and to develop diagnostics, therapeutics, and vaccines. By leveraging previous investments in tools and techniques used to study similar viruses and existing partnerships both within and outside the NIH, the agency developed scientific programs to innovate solutions to the pandemic. The scientific efforts behind the NIH's response to the COVID-19 pandemic are outlined in the NIH-Wide Strategic Plan for COVID-19 Research,[3] developed by the OD, in partnership with the ICs.

ACTIV, which is led in part by the NIH Director, brings together government agencies, nonprofit organizations, biopharmaceutical companies, and academia to leverage expertise and collaborations to prioritize and speed development of the most promising treatments and

[3] www.nih.gov/sites/default/files/research-training/initiatives/covid-19-strategic-plan/coronavirus-strategic-plan-20200713.pdf



Cumulative number of peer-reviewed publications and preprints on COVID-19/SARS-CoV-2 authored by NIH-funded investigators between February and September 2020. Publications and preprints were extracted from the *iSearch* COVID-19 Portfolio Tool. NIH-funded articles were identified using an algorithm developed by the Office of Portfolio Analysis to link article authors with researchers who had an active NIH award at the time the article was published.

vaccines. Coordinated by the Foundation for the NIH (FNIH), ACTIV focuses on four areas of opportunity: identify preclinical research for COVID-19 treatments, accelerate clinical testing for promising treatments, improve clinical trial capacity and effectiveness, and speed the evaluation of candidate vaccines. ACTIV has evaluated hundreds of available therapeutic agents with potential application for COVID-19, prioritized the most promising candidates, designed and harmonized master protocols for clinical trials, and selected numerous NIH-supported networks to launch clinical trials to test prioritized therapeutic candidates. ACTIV clinical trials to evaluate the safety and efficacy of various therapeutics are now underway.[4]

Similarly, the RADx^{SM} initiative was developed in April 2020 with support from the Paycheck Protection Program and Health Care Enhancement Act to innovate the development, commercialization, and implementation of COVID-19 testing technologies. Across four RADx^{SM} initiatives, the NIH has identified existing, potential, and novel technologies which could be quickly redirected, developed, and potentially advanced to commercialization. Strategies for implementing COVID-19 testing in underserved and underrepresented populations across the country have also been identified. In addition, an infrastructure for management of the various data types collected across the initiative has been established. By the fall of 2020, the RADx^{SM} initiative already had supported a wide range of scientific projects and dramatically increased COVID-19 testing availability across the country. Additional funding for RADx^{SM} was provided in the Coronavirus Response and Relief Supplemental Appropriations (CRRSA) Act.

In collaboration with other federal agencies, including offices across the Department of Health and Human Services (HHS) and the White House, NIH participates in the trans-governmental effort as part of the broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (countermeasures) while adhering to safety and efficacy standards. It coordinates centralized clinical evaluation of candidate countermeasures and jumpstarts the manufacturing process of the most promising candidates. ACTIV also advised on the protocol designs and endpoints to ensure a harmonized approach across multiple vaccine efficacy trials. The OD continues to work with contributing federal partners to deliver safe and effective doses of COVID-19 vaccines.

[4] www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials

With $30 million provided by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the NIH Common Fund supports research to prevent, prepare for, and respond to coronavirus, domestically and internationally. Funds provided in FY 2020 supported emergency competitive revisions to existing Common Fund awards. FY 2021 funds will support new coronavirus projects within the NIH Director's Transformative Research and Early Independence Awards. These awards, part of the High-Risk, High-Reward program, will bring new, innovative perspectives to coronavirus research. Any relevant area of coronavirus research is welcome, including behavioral and social science research, research on health disparities, novel therapeutics, and other related topics.

With $1.15 billion from the CRRSA Act, NIH has launched a new initiative to identify the causes and ultimately the means of prevention and treatment of individuals who have been sickened by COVID-19, and who experience continuing symptoms long past the point when they have recovered from the initial stages of illness. Often referred to as "Long COVID," these symptoms, which can include fatigue, shortness of breath, "brain fog," sleep disorders, fevers, gastrointestinal symptoms, anxiety, and depression, can persist for months and can range from mild to incapacitating. In some cases, new symptoms arise well after the time of infection or evolve over time. These and other long-term effects of COVID-19 are collectively referred to by the broad research term post-acute sequelae of SARS-CoV-2 infection (PASC). The PASC Initiative aims to understand how people recover from COVID-19 and why some people do not fully recover after the viral infection seems to have cleared. Research will include people who have SARS-CoV-2 infection and PASC, as well as comparison groups who may not have been infected. The research cohort will include both children and adults, and will emphasize diversity, to ensure that the findings apply to the communities who have been most affected by COVID-19.

Finally, the OD provided funds for several trans-NIH COVID-19 initiatives to answer some of the most pressing aspects of the pandemic. Initiatives include research into the effect of COVID-19 on pregnant and lactating women and studies into the development and prevention of Multisystem Inflammatory Syndrome in Children (MIS-C). To evaluate the effects of COVID-19 mitigation strategies on reducing disease transmission, the NIH-wide COVID-19 Social Behavioral and Economic Health (SBE) Initiative focuses on the social and economic impacts of these mitigation efforts, the downstream health and healthcare access effects, and the efficacy of digital and community-based interventions to reduce these impacts. The SBE Initiative, representing 21 Institutes, Centers, and Offices (ICOs), has funded 52 urgent competitive and administrative supplements and three R01 awards and released 2 funding opportunity announcements (FOAs) to address these research questions. The SBE Initiative will release two additional FOAs in FY 2021. In addition, the Office of Behavioral and Social Sciences Research (OBSSR) has made available to researchers two repositories of existing COVID-19 survey items on the NIH Public Health Emergency and Disaster Research Response[5] and the PhenX Toolkit[6] platforms to encourage comparison and collaboration across studies.

[5] dr2.nlm.nih.gov/
[6] www.phenxtoolkit.org/index.php

Building on Discovery: Ongoing Scientific Programs from the Office of the Director
The CDC estimates 700 women die each year of pregnancy-related deaths, 60 percent of which are preventable, and over 50,000 experience severe pregnancy-related morbidity.[7] To address this alarming trend, the OD leads the Maternal Morbidity and Mortality Task Force, a trans-NIH collaboration with the Office of Research on Women's Health (ORWH) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The Task Force is coordinating the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative. IMPROVE uses an integrated understanding of biological, behavioral, sociocultural and structural factors and engages the community in the development of solutions to maternal morbidity and mortality (MMM). This year, the OD and participating ICs released three funding opportunities to support research on the basic science and health disparities of MMM.[8,9,10]

The NIH Helping to End Addiction Long-term[SM] (HEAL) Initiative, launched in 2018, is a trans-agency program spanning basic, translational, and clinical research on opioid misuse, addiction, and pain. By the end of FY 2020, HEAL funded over $1.5 billion in research, representing more than 500 research projects across the United States. These projects aim to identify new therapeutic targets for both pain and opioid use disorder, reduce the risk of opioids through nonpharmacological strategies for pain management, and improve opioid addiction treatment in a variety of settings. To accelerate development of non-addictive analgesics and reduce reliance on opioids, the HEAL Initiative[SM] supports nearly 90 preclinical studies to 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 provide additional options for novel treatments for all aspects of the opioid addiction, HEAL supports more than 60 studies focused on progression to chronic use, withdrawal symptoms, craving, relapse, and overdose. To date, eight of these projects obtained Investigational New Drug applications from the FDA. HEAL Initiative[SM] research is also studying the best ways to assess and treat opioid exposure and dependence among infants. New programs initiated in FY 2020 include research to improve the treatment and management of co-occurring addiction and suicide risk, as well as research on stigma in the context of chronic pain management and opioid use or opioid use disorder. To encourage biomedical workforce diversity in the pain and addiction research space, HEAL initiated a research diversity supplement program to stimulate increased involvement from underrepresented groups.

The Regenerative Medicine Innovation Project (RMIP) was established in response to the 21st Century Cures Act to support clinical research on adult stem cells to advance the research field while encouraging scientific rigor.[11] Regenerative medicine is an emerging, promising area of research with the potential to repair or replace damaged cells, tissues, and organs with stem cells and other technologies. NIH works closely with the FDA to support the Regenerative Medicine Innovation Catalyst which provides funding for the characterization of stem cells and stem cell-derived products prior to research participant treatment.

[7] www.cdc.gov/vitalsigns/maternal-deaths/
[8] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-104.html
[9] grants.nih.gov/grants/guide/notice-files/NOT-GM-20-017.html
[10] grants.nih.gov/grants/guide/rfa-files/RFA-MD-20-008.html
[11] www.nih.gov/rmi

The *All of Us* Research Program aims to advance individualized healthcare by building one of the largest, most diverse health databases in the world. To do this, the *All of Us* Research Program intends to collect health information from one million or more participants. Researchers will use the data to learn how our biology, lifestyle, and environment affect health. As of February 2021, more than 371,000 participants had consented to join the program and more than 281,000 participants had completed all steps in the initial protocol. Starting in FY 2021 and 2022, *All of Us* plans to analyze whole genome sequences from its large and diverse participant cohort, responsibly return results to participants, and make available to researchers one of the largest collections of genomics data in the world. In FY 2022, participants will be able to choose from an expanded list of genetic information to receive including new information on hereditary disease risk and pharmacogenetics from their genomes. In 2020, *All of Us* launched the beta version of its data platform, the Researcher Workbench, allowing approved researchers to begin using the program's initial dataset and tools to make discoveries.

Over the previous decades, scientists have made many discoveries into the functions and diseases of the brain and nervous system. With the broad, interdisciplinary nature of neuroscience research, the NIH OD collaborates with 10 ICs to coordinate the BRAIN Initiative®. Shaped by an Advisory Committee to the NIH Director (ACD) Working Group and with support from the 21st Century Cures Act, the BRAIN Initiative® aims to build tools and foundational information on the brain and its functions in health and disease. In 2020, the BRAIN Initiative® announced investigator accomplishments in machine learning and large dataset use, released new funding opportunities for postdoctoral trainees, and held several workshops including one on sex differences in brain disorders. In FY 2022, the BRAIN Initiative® will continue to focus on the objectives outlined in the BRAIN 2025: Scientific Vision Report.[12]

As a public charity, the FNIH supports the mission of the NIH by fostering collaborations between NIH ICOs, federal departments and agencies, companies, and non-profit organizations to find new approaches to overcome roadblocks in research. For example, the Accelerating Medicines Partnership (AMP) is a public-private partnership managed by the FNIH to jointly identify and validate promising biological targets for therapeutics. This partnership has accelerated research in five disease areas: Type 2 diabetes, Alzheimer's disease, Rheumatoid Arthritis/Lupus, Parkinson's disease, and most recently, Schizophrenia. NIH and AMP partners are sharing expertise and resources and making AMP data and analyses publicly accessible to the broad biomedical community.

[12] braininitiative.nih.gov/strategic-planning/brain-2025-report

Several NIH ICOs support violence prevention research and studies on understanding violence perpetration and those affected by violence. OBSSR is working with those ICOs to identify research accomplishments, gaps, and priorities, and develop a framework for future research on victimhood and aggression. In FY 2020, Congress appropriated funds to address firearm violence prevention research. OBSSR and OER led a trans-NIH initiative focused on Firearm Injury and Mortality Prevention Research[13,14] that funded nine studies to improve understanding of the determinants of firearm injury, identify those at risk, evaluate innovative interventions to prevent firearm injury and mortality, and examine potential new approaches to prevent firearm injury and mortality.

Budget Policy: The FY 2022 President's Budget estimate for this program area is $577.3 million, an increase of $53.5 million or 10.2 percent compared to the FY 2021 Enacted level. The increase includes $41.0 million for the *All of Us* Research Program and $12.5 million for research into firearm injury and mortality. The OD will utilize the overall funds requested to pursue promising scientific opportunities across a range of areas from HIV research to the promise of regenerative medicine. In addition, the OD will continue to lead landmark scientific efforts such as the *All of Us* Research Program and HEAL Initiative. The OD will coordinate trans-NIH efforts, such as IMPROVE and the BRAIN Initiative, which capitalize upon the collective expertise of NIH Institutes and Centers.

Using *All of Us* to Understand the COVID-19 Pandemic

The *All of Us* Research Program has risen to the challenge of addressing the COVID-19 pandemic. *All of Us* is testing blood samples from more than 24,000 participants for the presence of SARS-CoV-2 antibodies, indicating prior infection. Specifically, *All of Us* is testing samples collected in March 2020 and will work backward to look for SARS-CoV-2 infections in regions across the country to provide a national estimate of prevalence and timing. Additionally, *All of Us* is collecting relevant information from the electronic health records of more than 237,000 participants, some of whom have been diagnosed with COVID-19 or sought healthcare for related symptoms to help researchers look for patterns and learn more about COVID-19 symptoms and the effects of different medicines and treatment. Another effort focuses on understanding the mental and physical impacts of the COVID-19 pandemic on participants and includes questions on symptoms, stress, social distancing, and economic impacts. As data become available from all of these efforts, researchers will look for new leads that may bring greater precision to the understanding of risks and outcomes of COVID-19, including for those communities that have been hit the hardest.

Building Research Capacity and Collaborations Across the Biomedical Enterprise

Within the OD, the OBSSR coordinates and enhances the impact of behavioral and social sciences research (BSSR) across NIH. At the request of the NIH Director and OBSSR, the NIH Council of Councils charged a Working Group on trans-NIH Research Opportunities in the Basic Behavioral and Social Sciences to work with researchers from across the country to explore the landscape of basic BSSR and develop a report on the current status of the science and potential future directions. This year, the trans-NIH BSSR Coordinating Committee developed a Working Group on Structural Racism and Health Effects, which brings together experts from nearly all NIH ICs and many OD Offices to identify areas for further research and to inform OD leadership

[13] grants.nih.gov/grants/guide/pa-files/PAR-20-143.html
[14] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-089.html

on research related to structural racism and health more efficiently.

The Sexual & Gender Minority Research Office (SGMRO) continues to coordinate and encourage sexual and gender minority (SGM) research across NIH. The NIH FY 2021-2025 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities builds on the foundation of the previous NIH SGM Strategic Plan, presenting scientific themes, operational goals, and objectives that aim to enhance the agency's SGM-related research and data collection efforts, while also supporting a diverse scientific workforce devoted to improving our understanding of the health of SGM communities.

The Office of AIDS Research (OAR) brings together ICOs from across NIH to accelerate research on prevention and treatment of HIV/AIDS and represents the largest public investment in HIV/AIDS research worldwide. To offer access to the latest HIV/AIDS clinical treatment and prevention guidelines OAR integrated AIDSinfo and infoSIDA websites into its portfolio as the new HIVinfo website.[15,16] The NIH Strategic Plan for HIV and HIV-Related Research was updated for FY 2021-2025 to coordinate goals and share the agency's priorities with stakeholders.[17] With the onset of the coronavirus pandemic, OAR supported studies on the impact of COVID-19 on individuals with HIV/AIDS and published interim guidance for individuals with HIV/AIDS and clinicians.[18] The OAR HIV and COVID-19 Taskforce was convened to provide recommendations to OAR on programmatic, scientific, and operational focus areas and action plans at the intersection of HIV and COVID-19. In addition, OAR with NIH and external partners is leveraging existing clinical trial networks, such as the HIV Vaccine Trials Network and HIV Prevention Trials Network, to coordinate and accelerate clinical testing of COVID-19 vaccines.

To identify research gaps in complex areas of public health and prevention, the Office of Disease Prevention (ODP) brings together NIH ICOs and other federal partners as co-sponsors of the Pathways to Prevention (P2P) workshop program.[19] P2P workshops aim to analyze and interpret the evidence in a particular scientific area, provide key research recommendations to further build the evidence base, and develop a federal action plan for increased collaboration and future research to advance the field. In FY 2021, the P2P workshop program focused on the impact of physical activity interventions for people at risk of using, or currently using, wheeled mobility devices as a result of disability, injury, or illness. The Tobacco Regulatory Science Program (TRSP),[20] a component of the ODP, coordinates the trans-NIH collaborative effort with the FDA's Center for Tobacco Products to conduct research supporting FDA's regulatory activities over tobacco products. Projects include the Population Assessment of Tobacco and Health Study,[21] a longitudinal investigation of tobacco product use. Recent findings by TRSP-funded researchers include insights on the toxicity of commercially available e-liquids in electronic cigarettes[22] and the association between e-cigarette use and myocardial infarction.[23]

[15] www.oar.nih.gov/about/directors-corner/aidsinfo-and-infosida-transitioning-to-oar
[16] HIVinfo.nih.gov
[17] www.oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf
[18] clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv-interim-guidance/interim-guidance-covid-19-and-persons-hiv
[19] prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention
[20] prevention.nih.gov/tobacco-regulatory-research
[21] www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health
[22] pubmed.ncbi.nlm.nih.gov/29584716/
[23] pubmed.ncbi.nlm.nih.gov/30166079/

The Office of Dietary Supplements (ODS) evaluates scientific information, stimulates research on dietary supplements, disseminates findings, and works to educate the public on safe and effective use of supplements. ODS with the National Center for Complementary and Integrative Health (NCCIH) and the National Institute on Aging (NIA) supports the Consortium for Advancing Research on Botanical and Other Natural Products (CARBON) Program[24] which promotes collaborative research on botanical dietary supplements, their safety and effectiveness. The CARBON Program was recompeted in 2020, and awards were made for three botanical research centers focused on enhancing methods and resources for research into the health effects of botanical dietary supplements, a technology center, and a center to establish an open data exchange to facilitate the accessibility of the chemical structures of natural products. A new CARBON initiative for pilot projects to increase the impact of the program will provide opportunities for additional researchers to collaborate with the research centers and leverage early phase research to extend the understanding of natural product dietary supplements.

The NIH Common Fund, managed by the Office of Strategic Coordination (OSC), is also capitalizing on previous research investments and partnerships to support innovative, high impact programs expected to enhance research across the NIH mission. A trans-NIH initiative on Nutrition for Precision Health exemplifies this type of program. In collaboration with the *All of Us* Research Program, the Common Fund is leveraging pan-omics technologies and the participant infrastructure of *All of Us* combined with innovations in artificial intelligence (AI) and machine learning (ML) to jumpstart precision nutrition research. The initiative aims to establish algorithms that predict individual responses to different dietary regimens; a second phase of the program will validate these algorithms. Ultimately, this will improve health and reduce chronic disease through a bold application of predictive algorithms to inform dietary recommendations. In FY 2021, the OD Division of Program Coordination, Planning, and Strategic Initiatives established an Office of Nutrition Research to better support and coordinate nutrition research across NIH.

The Office of Research Infrastructure Programs (ORIP) is dedicated to supporting the NIH research-related resource programs to support researchers with the infrastructure they need to improve public health. The national non-human primate (NHP) resources which enable the NIH ICOs to fulfill their missions by providing animals, facilities, and expertise required to study models for human disease are a key resource managed by ORIP. The S10 Instrumentation Grant Programs coordinated by ORIP support the purchase of up-to-date instruments to be used on a shared basis, making expensive equipment available to many scientists. In 2020, ORIP solicited grant applications for a wide range of instruments. In the future, ORIP will continue to invest in the research tools and infrastructure needed to advance discoveries across all areas of human health.

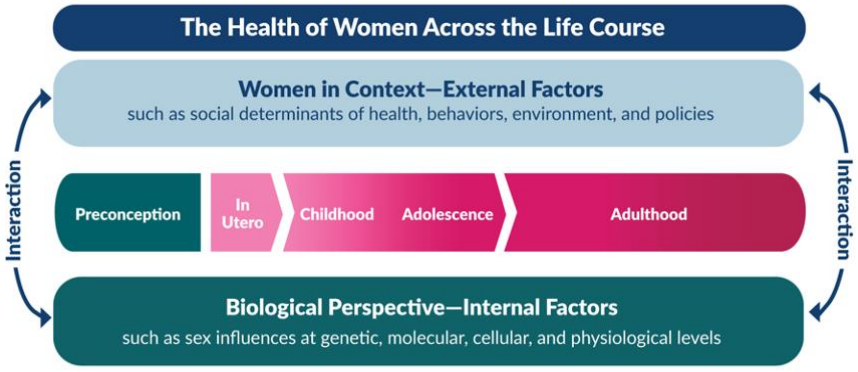
The current COVID-19 pandemic, and the high likelihood of future pandemics, has highlighted the need to expand NHP resources to ensure numbers sufficient for allocation to high-priority studies. NHPs and their specialized containment laboratory space are both very limited resources nationally. NHPs will provide insights into the molecular and cellular mechanisms that underlie infection and pathogenesis of SARS-CoV-2 and other potential pandemic agents, and will be

[24] ods.od.nih.gov/Research/Dietary_Supplement_Research_Centers.aspx

essential for developing and testing therapeutics and vaccines. There are not enough NHPs at present to support both pandemic research and all the existing NIH research for which NHPs are necessary. The FY 2022 request includes $30.0 million to support the expansion of the NHP resource infrastructure at the National Primate Research Centers and Caribbean Primate Research Center (NPRCs/CPRC) located in seven states plus Puerto Rico.

The health of women is affected by many internal and external factors acting across the life course. Thus, consideration of a multidimensional framework is needed to improve the quality of women's lives, reduce their disease burden across the life course, and address health disparities for populations of women at greatest risk for certain diseases. The Office of Research on Women's Health (ORWH) supports NIH-wide research policies and programs that focus on all aspects of women's health.[25] Capturing skills and expertise across the NIH and the extramural community, ORWH leads the development and implementation of the NIH Policy on Sex as a Biological Variable,[26] career development and professional opportunities for Women in Biomedical Careers,[27] and NIH-wide research programs on the health of women.[28] ORWH also hosts workshops throughout the year to enhance collaborations, provide a forum to disseminate research findings, and inform strategic planning efforts. Going forward, ORWH will continue to build on the goals of the *Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women's Health Research*.[29]

The offices of the NIH OD aim to use NIH resources effectively to address the many pressing health needs of the American people. The Office of Evaluation, Performance, and Reporting (OEPR) improves stewardship by advancing approaches to decision-making at NIH based on the highest quality available evidence on the agency's activities and outcomes. In response to the Foundations for Evidence-Based Policymaking Act of 2018, OEPR is guiding the development of a trans-NIH evaluation plan to enhance the agency's capacity to generate and analyze evidence from evaluations and other investigations and integrate findings into decision-making processes. As a part of this process, OEPR is working with stakeholders to develop a systematic and strategic approach to building on NIH's current strengths in evaluation, assessments, and evidence dissemination. Concurrent with this effort, OEPR develops tools and resources to facilitate monitoring and evaluation for continuous learning and improvement.



The multidimensional framework represents the intersection of multiple biological factors in the context of a woman's life over the entire course of her life.

[25] orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_02_21_19_V2_508C.pdf
[26] orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable
[27] orwh.od.nih.gov/career-development-education/nih-working-group-women-biomedical-careers
[28] orwh.od.nih.gov/research/funded-research-and-programs
[29] orwh.od.nih.gov/sites/orwh/files/docs/ORWH_Strategic_Plan_2019_02_21_19_V2_508C.pdf

Alongside these efforts, the Office of Portfolio Analysis (OPA) enables NIH decision-making and research stewardship by providing analytic capabilities, tools, methods, and best practices. By examining the outputs and impact of NIH investments, OPA informs evidence-based decision-making by NIH leadership, ICOs, and other federal agencies and offices, consideration of future investments, and potential approaches to address evolving research needs and opportunities. In response to the COVID-19 pandemic, OPA launched the *iSearch* COVID-19 Portfolio Tool[30] to support analysis of the ongoing and newly emerging portfolio of research awards related to COVID-19 and SARS-CoV-2. This tool is updated daily, allowing NIH staff and the public to explore and learn from the growing set of advances in COVID-19 research in real-time. OPA will continue to develop these tools and implement innovative approaches to studying the biomedical research landscape.

The table below provides the budget levels for the offices within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
Budget Summary
(Dollars in Thousands)

	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY2021
Office of the DPCPSI Director	20,030	23,082	23,452	370
Office of Behavioral & Social Sciences Research	28,932	29,827	30,304	477
Office of AIDS Research	62,256	63,593	63,593	0
Office of Research on Women's Health	45,458	51,480	52,303	824
Office of Disease Prevention	13,330	13,771	13,991	220
Office of Dietary Supplements	26,302	27,113	27,546	434
Office of Research Infrastructure Programs	293,976	299,885	304,684	4,798
Office of Nutrition Research	0	1,050	1,067	17
Common Fund	639,111	648,539	658,539	10,000
Total	**$1,129,395**	**$1,158,339**	**$1,175,479**	**$17,140**

Budget Policy: The FY 2022 President's Budget estimate for this program is $1,175.5 million, an increase of $17.1 million or 1.5 percent compared to the FY 2021 Enacted level. The offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences, Disease Prevention, Dietary Supplements, Infrastructure Resources, Sexual and Gender Minorities, Tribal Health, and Nutrition will continue to serve as focal points for these research areas across NIH, fostering efforts such as a trans-NIH BSSR Coordinating Committee, and providing shared resources, such as the P2P workshop program and Non-Human Program Resources to build capacity in these areas. Offices will leverage this funding to enhance NIH's efficiency for program evaluation, strategic planning, and portfolio analysis to better support evidence based decision-making across the NIH.

[30] icite.od.nih.gov/covid19/search/

Research for Countermeasures against Nuclear, Radiological, and Chemical Threats
The National Institute of Allergy and Infectious Diseases (NIAID) manages both the Radiation and Nuclear Countermeasures Program (RNCP) and the Chemical Countermeasures Research Program (CCRP), with funding provided through the OD. The RNCP supports research and development of medical countermeasures (MCM) and biodosimetry approaches to assess, mitigate, and treat injuries during a radiation public health emergency, to guide them toward U.S. Food and Drug Administration (FDA) approval. In FY 2020, RNCP funded 17 new awards, addressing early and late MCM development, biomarker discovery, a valuable large animal research repository, and dosimetry harmonization. The CCRP supports both fundamental research and early development of MCMs to prevent deaths and/or treat injuries during and after high consequence public health emergencies due to large scale chemical exposure. The CCRP will continue to offer grant, cooperative agreement, and interagency agreement research funding opportunities to engage the academic, industry, and government scientific communities in FY 2022.

Budget Policy: The FY 2022 President's Budget estimate for this program is $103.7 million, an increase of $1.6 million or 1.6 percent compared to the FY 2021 Enacted level. Funding will be used to continue NIH's leadership of the RNCP and the CCRP and efforts toward the development of safe and effective MCMs, targeting areas such as radiation injuries treatment in emergency conditions and after large scale chemical exposures, and supporting innovative research through funding of and engagement with the scientific community.

Developing New Data Science and Artificial Intelligence Tools to Advance Research
NIH leverages innovative computational and data science approaches and techniques to advance and expand research across biomedical and clinical fields and to invest in and improve patient care. Within the OD, the Office of Science Policy (OSP) leads development of data sharing policies and coordinates implementation with the Office of Extramural Research (OER) to support a culture of data stewardship, respect for participant privacy and consent, and encourage policies consistent with findable, accessible, interoperable, reusable (FAIR) data principles. In 2020, OSP finalized the NIH Policy for Data Management and Sharing (DMS Policy), which will require researchers to prospectively submit their plans for managing and sharing data. These plans will describe how data will be managed, how participants' privacy and rights will be respected, and anticipated timelines for data preservation and access. Researchers will be expected to maximize data sharing, acknowledging any limiting legal, ethical, and technical factors. The DMS Policy will go into effect for new and competing awards in 2022.

To unleash the full potential that data science has to offer in aiding scientific discovery and clinical care, NIH must ensure that appropriate infrastructure, resources, and expertise are available to drive advances. The Office of Data Science Strategy (ODSS) is leading efforts to build a trans-NIH data ecosystem that leverages activities across the NIH ICs such as providing researchers access to up to 100 PB of biomedical data in commercial cloud resources, quick search and access to sensitive datasets across NIH platforms, and methods for sharing data such that they meet FAIR principles. ODSS is also leading new partnerships to enhance software sustainability as well as the Data and Technology Advancement (DATA) National Service

Scholars Program to bring industry experts to NIH to work on transformative programs, as laid-out in the 2018 NIH Strategic Plan for Data Science.[31]

Harnessing the enormous progress that NIH has made in studying the fundamental components of human biology will require an understanding of how these components work together. This is the promise of AI. Through leadership and coordination by ODSS, NIH is developing new capability in AI including massive data linkages, convergence of technology, algorithms, and datasets, and new partnerships for training and talent recruitment for a future AI-biomedical workforce. For example, the Common Fund, in partnership with multiple ICs, has launched the Enhancing the Use of Artificial Intelligence for Health Research Program. This program will fulfill the ACD Working Group recommendation to invest in new biomedical datasets to analyze using machine learning techniques. It includes five interdependent initiatives: generation of rubrics to measure amenability to machine learning approaches, development of tools to accelerate AI ready data, enhancement of existing data generation efforts to improve AI-readiness, generation of gold-standard data sets that adhere to these rubrics, and evaluation and updating of existing public biomedical research data using the rubrics. Ultimately, the program will generate new tools and standards to contribute lasting value to biomedical research.

In the future, NIH plans to develop an Artificial Intelligence to Address Chronic Disease initiative to expand on the FY 2021 AI Health Research Program, utilizing AI-amenable datasets from healthy and chronic stages of diseases. Using AI as a method to assess co-morbidity in chronic illness may require integration of diverse data such as imaging, genomics, and electronic health records together with more novel data such as lifestyle, sensor, or nutrition data. The interagency Smart and Connected Health Initiative, led by the National Science Foundation and the NIH, has supported innovative, high-risk disease-agnostic research drawing from multidisciplinary approaches involving computer and information science, engineering, and the biomedical and behavioral sciences with the promise of disruptive transformations in biomedical research. The reissue of this initiative has increased its focus on data science and AI approaches.

Budget Policy: The FY 2022 President's Budget estimate for data science and AI is $105.0 million, equal to the FY 2021 Enacted level. In FY 2022, ODSS will continue to build on the STRIDES Initiative and Trans-NIH collaborations to provide needed data infrastructures and expertise across NIH programs and to NIH-supported researchers. These activities have the potential to transform the use of data generated through NIH-supported work by enhancing accessibility and interoperability for a broader research community, as well as to improve efficiencies by minimizing infrastructure and maintenance costs. This support will enable ODSS to continue to provide training opportunities such as the DATA National Service Scholars Program to build capacity in application of AI to biomedical research.

Policy Initiatives in the Office of the Director: Guiding the Scientific Enterprise, Ensuring Research Stewardship

As the NIH's central office, the OD is responsible for setting policy that affects the entire agency. These policies address the critical, challenging issues faced by the biomedical research

[31] datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf

community by supporting research integrity and responsibility, developing a diverse, skilled biomedical workforce, and guaranteeing proper stewardship of taxpayer investment.

A Policy Response to the COVID-19 Pandemic

As the COVID-19 pandemic grew, NIH recognized the need to support the safety and health of researchers across the biomedical enterprise. OER worked quickly to assure applicants and recipients of NIH funding that the agency was continuing to support them whenever possible.[32] Policies on donating research supplies, application deadlines, and submitting post-submission materials were amended to allow applicants and recipients to operate flexibly in response to the pandemic. Accommodations for the loss of research time for early-stage investigators (ESIs)[33] and research involving human participants[34] and laboratory animal models[35] were quickly announced. OER also extended the administrative flexibilities made available by the Office of Management and Budget (OMB Memos M-20-11, M-20-17, and M-20-26) through the end of the public health crisis. These administrative flexibilities were applied by NIH ICs on a case-by-case basis to help grant recipients through the pandemic.

To assess the response of NIH staff to the COVID-19 pandemic, the Chief Officer for Scientific Workforce Diversity (COSWD) launched the NIH Workplace COVID-19 Impact Survey with the goal of identifying vulnerable groups and potential mitigation strategies to minimize the impact of the pandemic on NIH staff, contractors, and trainees. The Survey found that a large majority of respondents felt they had received the support they needed from NIH during the pandemic (87 percent) and were able to perform their responsibilities very effectively via telework (62 percent). Through the end of 2020, COSWD released reports describing the findings of the survey, including intervention suggestions to better support the NIH workforce. Following lessons learned from the intramural experience, NIH also began surveying how COVID-19 is impacting extramural researchers and their institutions. The results will help inform policy and program decisions as NIH seeks to continue support for the biomedical research enterprise.

Supporting a Diverse and Inclusive Biomedical Workforce: Research Training and Career Development Programs at NIH

NIH recognizes the critical importance of diverse perspectives, background, and skillsets to address complex scientific problems and enhance the impact of science globally. In February 2021, NIH launched the UNITE Initiative to identify and address structural racism within the NIH community and the biomedical research community. The UNITE Initiative, developed with collaborations from across all 27 NIH ICs and many offices from within the OD, is comprised of five workstreams which aim to: understand stakeholder experiences, support new research on health disparities, improve the NIH culture and structure for equity and inclusion, provide transparency and accountability for stakeholders, and remodel the extramural research ecosystem to promote workforce diversity. This effort is spearheaded by the NIH OD with leadership from the Immediate Office of the Director, the Office of the COSWD, and the Office of Management (OM). The UNITE Initiative is beginning a wide reaching effort to achieve racial equity across

[32] grants.nih.gov/policy/natural-disasters/corona-virus.htm
[33] grants.nih.gov/faqs#/covid-19.htm
[34] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html
[35] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-088.html

the biomedical research community by gathering data and information on the current state of equity across the organization. Future activities will include addressing funding disparities, improving recruitment and retention of scientists from underrepresented groups, and countering racism in the NIH workplace, among others.

NIH is committed to enhancing workforce diversity and inclusion. Despite a long history of funding programs to increase diversity in the workforce, there are still significant challenges to address. The Common Fund, in collaboration with COSWD, OER, and other NIH ICOs, implemented the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program,[36] which aims to establish and support scientific environments that benefit from a full range of talent through support for institutions to hire cohorts of faculty committed to promoting diversity and scientific excellence. Looking forward, the ACD Working Group on Diversity is prioritizing the communication of NIH's progress on enhancing diversity and preparing a white paper about individuals with disabilities in the scientific workforce. The upcoming Scientific Workforce Diversity Strategic Plan for 2021-2025 will encompass actionable steps for implementing the recommendations of the ACD Working Group on Diversity and other stakeholders.

Building research capacity and expertise through training and career development programs across the OD fulfills a key part of the NIH mission to develop and maintain a skilled biomedical workforce. The NIH HIV/AIDS Scholar Program, run jointly by OAR and ORIP, aims to support and develop trainees researching HIV/AIDS with non-human primate models. The ODS Research Scholars Program offers a one-year competitive scholarship for intramural early-stage NIH investigators to study dietary supplements and enhance multidisciplinary collaborations and bring diverse expertise to dietary science. ORIP also supports training and career development of veterinary students and veterinarians with the goal of attracting them to biomedical research careers[37] by providing veterinarians and veterinary students, ORIP provides opportunities for them to contribute unique animal and translational research skills which can be applied to human health. OBSSR developed an initiative on Predoctoral Training in Advanced Data Analytics for Behavioral and Social Sciences Research (TADA-BSSR)[38] to develop a cohort of specialized predoctoral candidates who possess advanced competencies in data science analytics to apply to an increasingly complex landscape of behavioral and social health-related big data. Eight T32 awards were made to programs integrating computer science, informatics, mathematics, and statistics into behavioral and social sciences research training.

The Diversity Program Consortium (DPC; also known as Enhancing the Diversity of the NIH-Funded Workforce program)[39] was developed to implement and assess effective approaches to engage, train, and mentor students, enhance faculty development, and strengthen institutional training programs for researchers from underrepresented backgrounds in biomedical research. Funded by the Common Fund and coordinated by COSWD and the National Institute of General Medical Sciences (NIGMS), the DPC consists of several initiatives and programs that analyze and implement effective, evidence-based training and mentoring interventions and disseminate

[36] grants.nih.gov/grants/guide/notice-files/NOT-RM-20-023.html
[37] orip.nih.gov/sites/default/files/ORIP_Training_Fact_Sheet_FINAL_508.pdf
[38] grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-011.html
[39] www.nigms.nih.gov/training/dpc/pages/default.aspx

Strengthening Anti-Harassment Policies at NIH

Harassment in the sciences is a critical area of NIH policy focus. To address this urgent issue, the NIH has worked across ICOs and with external partners to develop policies to end harassment. At NIH, the Office of Human Resources (OHR) and the NIH CIVIL Program have worked with the Trans-NIH Anti-Harassment Steering Committee, chaired by the OD, to expand available trainings and analysis on harassment at NIH. As such, the OD will continue to enact policies which lead to ending harassment and protecting all members of the biomedical workforce.

In 2019, the ACD Working Group on Changing the Culture to End Harassment released its report and recommendations on the implementation of new anti-harassment policies and updates to procedures for handling allegations and findings of harassment. Since the release of that report, the NIH OD has made anti-harassment training available to the public, which may be used by NIH-funded institutions and others to educate on practices to end harassment. Additionally, anyone may now inform NIH of harassment through a publicly available web form. In June 2020, the NIH announced a new policy to close gaps left by previous policies, eliminating the ability for perpetrators of harassment to move NIH funding to a new institution without consequences. With the release of the new policy, NIH is now better able to hold both grantee institutions and investigators accountable to harassment findings, regardless of where they occurred. NIH is committed to continued efforts to end the culture of harassment both within the agency and at NIH-supported institutions.

findings.[40] To support promising faculty who have demonstrated a commitment to diversity and inclusion, the Office of Intramural Research (OIR) and COSWD coordinate the NIH Distinguished Scholars Program,[41] which uses a cohort hiring model to select intramural researchers from diverse backgrounds each year and provide them with mentoring and professional development. OIR also coordinates the Independent Research Scholar Program,[42] which increases workforce diversity among highly competitive pre-tenure-track NIH intramural investigators and improves their scientific leadership skills. Selected applicants are provided technical staff, budget, and mentorship to support their advancement toward tenure-track positions at NIH or elsewhere. The Future Research Leaders Conference is a trans-NIH effort led by the COSWD targeting researchers transitioning into independent careers for recruitment to NIH and enhancing the diversity of the Intramural Research Program (IRP). Since its inception in 2015, a total of 115 invitees have learned about the NIH mission and career opportunities through attendance at the Conference. The next Conference, scheduled for 2021, will continue this outreach to promising early career scientists and promote careers at the NIH.

Within the OIR, the Director's Challenge Innovation Award Program encourages collaborations across the NIH IRP by awarding start-up funds to innovative, high-impact research proposals that will provide some benefit to a wide range of research, infrastructure, or other scientific activity across the agency. Each award is given to a team of researchers representing multiple ICs. In 2020, five awards were given, including the initiation of an NIH Pain Research Center, the development of a trans-NIH Metabolomics and Lipidomics Consortium and eventual Core Facility, and other promising projects with wide-reaching effects.[43]

[40] www.nigms.nih.gov/training/dpc/Pages/DPC-Publications.aspx
[41] diversity.nih.gov/programs-partnerships/dsp
[42] oir.nih.gov/sourcebook/personnel/ipds-appointment-mechanisms/research-fellow/independent-research-scholar-program
[43] oir.nih.gov/sourcebook/awards-fellowships-grant-opportunities/directors-challenge-innovation-award-program/2020-directors-challenge-awards#2020-directors-ferre

The extramural and intramural NIH Loan Repayment Programs (LRPs), established by Congress and led by the OD, are designed to recruit and retain highly skilled professionals to the biomedical workforce.[44] The LRPs repay qualified loan debt in return for a sustained research career and a commitment to engage in biomedical research relevant to the NIH mission. Beginning in FY 2021, a new LRP category will be added that seeks high quality, mission-relevant research ideas designed to pursue major opportunities and gaps in biomedical research and expand critical research in emerging areas of human health.

The NIH Director is able to respond quickly to new and emerging research opportunities and scientific issues deemed high priority with the NIH Director's Discretionary Fund (DDF). Funding is often awarded to projects with potential to improve management, planning, and analytical tools in support of research. In FY 2020, the DDF was used to support select COVID-19 activities including research on MIS-C and support for the Community Engagement Alliance (CEAL) Against COVID-19 Disparities Initiative, which is addressing misinformation about COVID-19 and providing education on clinical research to overcome health disparities related to COVID-19. The DDF also funded a National Academies of Science, Engineering, and Medicine study on the impact of the COVID-19 pandemic on women. In FY 2022, the DDF will continue to support nascent scientific opportunities across the NIH.

The biomedical research enterprise relies on highly trained scientists to develop innovative ideas, apply new knowledge and techniques, and advance scientific understanding of disease to improve public health. Beginning in 2017, with the support of the 21st Century Cures Act, the NIH OD launched the Next Generation Researchers Initiative (NGRI).[45] Through the NGRI and with leadership from the OD and OER, NIH ICs prioritize funding opportunities for early-stage investigators (ESIs). As a result of this initiative, NIH has substantially increased support for ESIs – from less than 600 ESIs in FY 2013 to 1,412 in FY 2020.

The ACD also called for "special funding consideration for 'at-risk' investigators" in its December 2018 report on NGRI.[46] In response, the NIH is developing methods to identify and support meritorious investigators who are at risk for losing all NIH funding and do not have significant research support from other sources. Early data suggest that, since NGRI began, the outlook for at-risk investigators has improved somewhat in 2018 and 2019, but still their funding rates are lower than those for established investigators who are assured of continuing funding for at least one more fiscal year. NIH remains strongly committed to the goals of NGRI to fund more ESIs, protect and retain meritorious at-risk scientists, and enhance the diversity of the biomedical research workforce. In addition, NIH implemented automatic extensions of ESI status for childbirth for one year within the ESI period.[47]

Budget Policy: The FY 2022 President's Budget estimate for this program is $20.1 million, an increase of $0.1 million or 0.7 percent compared to the FY 2021 Enacted level. In FY 2022, the OD will ensure the future of the biomedical workforce by addressing racial disparities and

[44] www.lrp.nih.gov/
[45] grants.nih.gov/ngri.htm
[46] /acd.od.nih.gov/documents/presentations/12132018NextGen_report.pdf
[47] grants.nih.gov/grants/guide/notice-files/NOT-OD-18-235.html

structural racism in biomedical research and at NIH. Through training and career development opportunities, NIH will continue to support the advancement of scientists and clinicians.

Protecting U.S. Biomedical Intellectual Innovation

NIH recognizes the critical role of scientific collaborations based on principles of scientific excellence, integrity, responsibility to the public, and fair competition in advancing its mission. Despite these principles, incidents that threaten the integrity and academic competitiveness of U.S. biomedical research and innovation have occurred.[48] NIH has taken a number of steps to address these risks, including convening the ACD Working Group on Foreign Influences on Research Integrity, coordinated by the OD, to advise on how best to address these issues.[49] NIH, through the OER, has also shared these concerns with over 10,000 institutions within the research community and has contacted over 90 institutions regarding specific concerns about foreign affiliation disclosures, financial conflicts of interest, and/or research support from foreign governments. Further implementation of the ACD Working Group recommendations will help establish best practices across NIH-supported science. Outreach and communication with the research community along with partnerships across the federal government, scientific societies, and NIH-funded institutions will help to integrate these practices into the culture of the biomedical community. Protecting the integrity of NIH-supported science is a priority for the OD to ensure that U.S. institutions and the American public benefit from their investment in biomedical research.

Enhancing Rigor, Reproducibility, and Transparency in Research

The application of scientific rigor to the design and conduct of experiments and the ability to reproduce research findings ensures robust and unbiased methodology, analysis, interpretation, and communication of discoveries. In recent years, NIH has collaborated with organizations across the biomedical enterprise to identify opportunities to align goals, policies, and activities in support of enhancing rigor and reproducibility at all stages of biomedical research. The NIH OD is committed to supporting high quality research through policies and processes that support and incentivize rigorous and reproducible research. To continue these efforts, assess the current landscape, and make recommendations toward improving rigor and reproducibility in animal research, the OD has convened the ACD Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research.[50] The Working Group is tasked with identifying opportunities to improve the application of these principles in research involving animal models, evaluate how animal models are currently developed and used, assess the validation science being applied to animal models, and consider how to best include the principles of rigor, reproducibility, and transparency into research training. Final recommendations from the ACD Working Group will be presented to the NIH Director and the ACD in 2021.

Operations of the Office of the Director: Transforming Culture and Modernizing Processes

As the central office of the NIH, the OD is responsible for providing infrastructure and resources to all of NIH. With this goal, the OD is continually striving to streamline operations and enhance efficiency. Several offices in the OD work to transform NIH culture, improve and maintain critical resources, and increase transparency.

[48] www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research
[49] acd.od.nih.gov/working-groups/foreign-influences.html
[50] www.acd.od.nih.gov/working-groups/eprar.html

Changing NIH Operations in Response to COVID-19

The onset of the COVID-19 pandemic in the United States created a sudden need for clinical and hospital settings to shift focus and develop specialized testing and treatment facilities to provide care for potential surges in local COVID-19 cases. The Office of Research Services (ORS) and Office of Research Facilities (ORF) quickly responded by erecting a drive-thru facility staffed with trained care providers to offer COVID-19 testing to symptomatic NIH staff. To support this testing, the Office of Medical Services (OMS) established a call center to guide symptomatic staff to testing appointments and provide connections to needed medical services. Volunteers from the NIH workforce provided the human infrastructure needed to perform vital contact tracing for any individual who tested positive for COVID-19. ORS partnered with the NIH Clinical Center (CC) to establish a process to test and share results efficiently. Most NIH staff receive test results within 48 hours of being tested. Beginning in August 2020, ORS and the CC coordinated the development and operation of an asymptomatic surveillance screening program, which makes COVID-19 tests accessible to asymptomatic staff.

To care for COVID-19 positive patients at NIH, the OD worked closely with the Clinical Research Center (CRC) to reconfigure 36 rooms with differential air pressures and other infection control mechanisms. These measures are carefully implemented to ensure the safety of patients, clinicians and caregivers, and other building occupants. The OD Division of the Fire Marshal co-led the design of paths and controlled access to the CC with screening for COVID-19 symptoms at each entry.

In March 2020, the NIH quickly transitioned to maximum telework flexibilities to allow staff to work safely from home. This required providing all technological needs for staff to complete work responsibilities with little disruption. All employees with the ability to telework were given the proper equipment including Virtual Private Network (VPN) access, laptops, and monitors. Essential staff who could not telework were organized into shifts to ensure their ability to accomplish mission-critical tasks with reduced likelihood of viral transmission. The OD developed an anonymous crowdsourcing site called OD TalkBack to provide a space for individuals to share coping strategies and creative solutions to the challenges posed by COVID-19. The Trans-NIH Mental Health Response Team, co-led by the OD and the National Institute of Mental Health (NIMH), worked to create and disseminate mental health related resources for staff across NIH.

The NIH Return to the Physical Workspace Framework outlines a phased approach for a safe return to the physical worksite. The Framework uses evidence-based decision-making to meet evolving needs and allow flexibilities for the unique needs of the workforce. Leave and telework use and other behaviors continue to be analyzed by the Office of Human Resources (OHR) throughout the pandemic to inform NIH leadership in determining which staff should return to the worksite and when, as well as the efficacy of ongoing communication strategies. OHR has also provided guidance on flexibilities available to staff and supervisors to ensure safety and consideration for difficult circumstances. The Office of Intramural Training and Education (OITE) has developed new programming, discussion groups, and guidance, for the NIH trainee community. To aid NIH families, three NIH childcare centers have re-opened and OD offices

have continued to provide Childcare Resource and Referral Services,[51] the Back-up Care Program,[52] and Lunch and Learn Webinars focused on Supporting Families During COVID-19.[53]

To track the many efforts now being implemented to address the COVID-19 pandemic and demonstrate good stewardship of resources, the OD has developed a process for planning, tracking, and reporting the NIH response to COVID-19. OER, the OM, and the Office of Budget (OB) have established procedures to track NIH activities for COVID-19. OEPR, in collaboration with other OD offices, developed a process for receiving, coordinating, and tracking incoming requests for information on NIH COVID-19-related activities. Providing a centralized platform for this purpose will enable increased awareness of each ICO's contribution to the COVID-19 response, a searchable repository of NIH efforts, enhance opportunities for collaboration, and improve the understanding of outcomes.

Updating the NIH-Wide Strategic Plan

The NIH-Wide Strategic Plan advances the NIH mission and informs the public of NIH's goals and priorities for the future of biomedical research. As a framework for ongoing and upcoming NIH activities, the Strategic Plan outlines how the NIH will address new challenges for human health, close existing gaps in knowledge, and capitalize on new opportunities for scientific discovery. In 2020, a new NIH-Wide Strategic Plan was developed in a trans-NIH effort guided by OEPR. This process ensured input from across the NIH ICOs and alignment with the individual strategic planning efforts of each IC and trans-NIH initiative. NIH leadership guided the development of the key priorities set forward in the plan. The Strategic Plan was also informed by periods of public comment, during which interested individuals and organizations shared their feedback on the NIH's goals and priorities and suggested new directions.

Modernizing Processes, Communication, and Operations at NIH

The *Optimize NIH* effort, led by the OM, and coordinated as a part of the *Reimagine HHS* initiative, was completed in September 2020. The goal of *Optimize NIH* was to identify areas to increase efficiency and effectiveness across the agency. Throughout its tenure, *Optimize NIH* led updates to many functional areas including committee management, ethics, acquisitions, IT security, property management, Title 42 hiring processes, and travel. Most recently, an award-winning cybersecurity campaign enhanced the NIH-wide adoption of safe cyber practices on the part of NIH staff. Additionally, over 1,800 acquisitions professionals were engaged in an assessment of procurement processes to develop recommendations which were implemented beginning in 2020. *Optimize NIH* launched several new data dashboards including the NIH Conference Travel, Contract Analytics, and IT Security Dashboards to provide operational insight for decision-making. As the *Optimize NIH* effort closes, sustainment will continue as a part of regular NIH activities to ensure the program's long-term benefits.

The OD Strategic Engagement Agenda (OD-SEA), launched in 2019 by OD leadership, is improving efficiency across the OD and enhancing communication and coordination between the OD and ICs to improve engagement and strengthen trans-NIH relationships. Early accomplishments of the OD-SEA include completed needs assessments of OD IT processes, tools, and limitations, which were used to inform new policies to speed the receipt of IT

[51] www.ors.od.nih.gov/pes/dats/childcare/Pages/resourceReferral.aspx
[52] www.ors.od.nih.gov/pes/dats/childcare/Pages/NIHBack-upCareProgram.aspx
[53] www.ors.od.nih.gov/pes/dats/childcare/Pages/parent_seminars.aspx

equipment, enhance customer choice, and increase efficiency of IT services. The OD-SEA is also developing an enterprise-wide administrative platform and enhancing cybersecurity. The OD-SEA has standardized OD requests for information from the OD to reduce administrative burden on the ICs and restructured the NIH Steering Committee to increase open dialogue between the Committee and its supporting working groups and to improve trans-NIH decision-making processes.

In addition to modernizing planning and processes, the OD is consistently working to modernize the infrastructure available to NIH researchers. ORS and ORF have worked diligently to oversee new construction on the NIH main campus in Bethesda and other NIH facilities. Despite COVID-19, several large construction projects have taken place in 2020 and 2021. For example, the Tumor-Infiltrating Lymphocyte Lab was completed with state-of-the-art building systems to ensure patient safety, reliability, and compliance with relevant statutes and recommendations. Additionally, the Center for Cellular Engineering facility will provide space for tissue culture processing and the discovery and production of new pharmaceuticals.

Budget Policy: The FY 2022 President's Budget estimate for OD operations is $413.4 million, an increase of $38.6 million or 10.3 percent compared to the FY 2021 Enacted level. In FY 2022, funding will be used to provide common infrastructure and resources for NIH ICOs, such as continued adaption to the evolving COVID-19 pandemic, facilities and services for NIH staff, and IT equipment and security. The OD will also continue to lead efforts across the agency to streamline processes, improve efficiency, and enhance transparency, such as through OD Strategic Engagement Agenda efforts and release of the next NIH-wide Strategic Plan.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2013	$1,429,161,000		$1,431,341,000	$1,528,181,000
Rescission				$3,056,362
Sequestration				($104,107,715)
2014	$2,046,346,000		$2,031,757,000	$1,400,134,000
Rescission				$0
2015	$2,034,825,000		$1,413,734,000	$1,946,773,000
Rescission				$0
2016	$1,442,628,000	$2,240,565,000	$2,080,214,000	$1,571,200,000
Rescission				$0
2017[1]	$1,623,200,000	$775,639,000	$803,142,000	$1,729,783,000
Rescission				$0
2018[1]	$2,127,666,661	$792,980,000	$697,890,000	$2,526,609,000
Rescission				$0
Supplemental				$50,000,000
2019[1]	$1,808,306,000			$2,117,675,000
Rescission				$0
2020[1]	$1,926,144,000	$2,216,592,000	$2,513,622,000	$2,409,387,000
Rescission				$0
Supplemental				$30,000,000
2021[1]	$2,208,063,000	$2,446,148,000	$2,499,659,000	$2,532,710,000
Rescission				$0
Supplemental				$1,250,000,000
2022[1]	$2,399,859,000			

[1] Includes funding provided in the NIH Innovation Account under the 21st Century Cures Act, after actual and anticipated transfers.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2021 Amount Authorized	FY 2021 Enacted	2022 Amount Authorized	FY 2022 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,283,867,000	Indefinite	$2,394,859,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,283,867,000		$2,394,859,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Amounts Available for Obligation[1,2]
(Dollars in Thousands)

Source of Funding	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation[3]	$2,409,387	$2,532,710	$2,399,859
Secretary's Transfer	0	0	0
Transfer to HHS Office of the Inspector General	-5,000	-5,000	-5,000
Subtotal, adjusted appropriation	$2,404,387	$2,527,710	$2,394,859
OAR HIV/AIDS Transfers	0	1,157	0
Comparative Transfer (ECHO/INCLUDE)[4]	-240,871	-245,000	0
Subtotal, adjusted budget authority	$2,163,516	$2,283,867	$2,394,859
Unobligated balance, start of year	59,290	63,343	0
Unobligated balance, end of year[5]	-63,343	0	0
Subtotal, adjusted budget authority	$2,159,464	$2,347,210	$2,394,859
Unobligated balance lapsing	-124	0	0
Total obligations	$2,159,340	$2,347,210	$2,394,859

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2020 - $103,664 FY 2021 - $110,975 FY 2022 - $113,000

[2] Amounts may not add due to rounding.

[3] Includes $157.0 million in FY 2020, $109.0 million in FY 2021, and $150.0 million in FY 2022 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

[4] Reflects comparable transfer of ECHO/INCLUDE funds to NICHD.

[5] Reflects funds from the NIH Innovation Account not obligated in FY 2020 and available for obligation in FY 2021.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total compensable workyears:				
	Full-time equivalent	952	975	23
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$197	$200	$3
	Average GM/GS grade	13.1	13.0	-0.1
	Average GM/GS salary	$125	$127	$1
	Average salary, Commissioned Corps (42 U.S.C. 207)	$127	$130	$3
	Average salary of ungraded positions	$194	$197	$3
	OBJECT CLASSES	**FY 2021 Enacted**	**FY 2022 President's Budget**	**FY 2022 +/- FY 2021**
	Personnel Compensation			
11.1	Full-Time Permanent	90,735	94,934	4,199
11.3	Other Than Full-Time Permanent	14,261	14,913	652
11.5	Other Personnel Compensation	2,962	3,100	138
11.7	Military Personnel	952	1,003	50
11.8	Special Personnel Services Payments	562	574	13
11.9	**Subtotal Personnel Compensation**	**$109,472**	**$114,524**	**$5,052**
12.1	Civilian Personnel Benefits	40,407	43,409	3,002
12.2	Military Personnel Benefits	937	986	50
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$150,816**	**$158,920**	**$8,104**
21.0	Travel & Transportation of Persons	239	243	4
22.0	Transportation of Things	51	52	1
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	6	6	0
23.3	Communications, Utilities & Misc. Charges	728	741	13
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	87,082	93,019	5,938
25.2	Other Services	118,551	120,685	2,134
25.3	Purchase of goods and services from government accounts	135,074	137,959	2,885
25.4	Operation & Maintenance of Facilities	2,082	2,370	287
25.5	R&D Contracts	45,496	55,225	9,729
25.6	Medical Care	1	1	0
25.7	Operation & Maintenance of Equipment	4,211	4,287	76
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$392,496**	**$413,545**	**$21,049**
26.0	Supplies & Materials	2,365	2,408	43
31.0	Equipment	3,857	3,927	69
32.0	Land and Structures	1,878	1,912	34
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,731,429	1,813,105	81,676
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$2,133,051**	**$2,235,939**	**$102,888**
	Total Budget Authority by Object Class	**$2,283,867**	**$2,394,859**	**$110,992**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
Full-Time Permanent (11.1)	90,735	94,934	$4,199
Other Than Full-Time Permanent (11.3)	14,261	14,913	$652
Other Personnel Compensation (11.5)	2,962	3,100	$138
Military Personnel (11.7)	952	1,003	$50
Special Personnel Services Payments (11.8)	562	574	$13
Subtotal Personnel Compensation (11.9)	**$109,472**	**$114,524**	**$5,052**
Civilian Personnel Benefits (12.1)	40,407	43,409	$3,002
Military Personnel Benefits (12.2)	937	986	$50
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$150,816**	**$158,920**	**$8,104**
Travel & Transportation of Persons (21.0)	239	243	4
Transportation of Things (22.0)	51	52	1
Rental Payments to Others (23.2)	6	6	0
Communications, Utilities & Misc. Charges (23.3)	728	741	13
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:	0	0	0
Consultant Services (25.1)	87,082	93,019	5,938
Other Services (25.2)	118,551	120,685	2,134
Purchases from government accounts (25.3)	135,074	137,959	2,885
Operation & Maintenance of Facilities (25.4)	2,082	2,370	287
Operation & Maintenance of Equipment (25.7)	4,211	4,287	76
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$347,000**	**$358,319**	**$11,320**
Supplies & Materials (26.0)	$2,365	$2,408	$43
Subtotal Non-Pay Costs	**$350,388**	**$361,769**	**$11,381**
Total Administrative Costs	**$501,205**	**$520,689**	**$19,484**

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2020 Final			FY 2021 Enacted			FY 2022 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	824	8	832	898	10	908	919	12	931
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	824	8	832	898	10	908	919	12	931
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	43	-	43	44	-	44	44	-	44
Total:	43	-	43	44	-	44	44	-	44
Total	867	8	875	942	10	952	963	12	975
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2018	13.0
2019	13.1
2020	13.1
2021	13.1
2022	13.0

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Positions[1]

GRADE	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Total, ES Positions	12	13	13
Total, ES Salary	2,337,389	2,557,438	2,600,484
General Schedule			
GM/GS-15	152	156	160
GM/GS-14	200	208	213
GM/GS-13	294	302	306
GS-12	108	118	120
GS-11	54	61	66
GS-10	0	0	0
GS-9	21	26	27
GS-8	2	2	2
GS-7	8	8	8
GS-6	1	1	1
GS-5	3	3	3
GS-4	3	3	3
GS-3	0	0	0
GS-2	2	2	2
GS-1	1	1	1
Subtotal	849	891	912
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	1	1	1
Director Grade	3	4	5
Senior Grade	3	4	4
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	8	10	11
Ungraded	63	65	66
Total permanent positions	687	819	839
Total positions, end of year	932	979	1,002
Total full-time equivalent (FTE) employment, end of year	875	952	975
Average ES salary	194,782	196,726	200,037
Average GM/GS grade	13.1	13.1	13.0
Average GM/GS salary	124,288	125,288	126,786

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.