Office of the Director

CONGRESSIONAL JUSTIFICATION
FY 2023

Department of Health and Human Services
National Institutes of Health

NIH National Institutes of Health
Office of the Director

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

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Director's Overview

The Office of the Director (OD) is the central office of the NIH. As such, the OD maintains primary responsibility for setting NIH policy, as well as for planning, managing, and coordinating across all NIH Institutes, Centers, and Offices (ICOs).

NIH Acting Director Lawrence A. Tabak, D.D.S., Ph.D.

In 2021, the OD coordinated the release of the *NIH-Wide Strategic Plan for Fiscal Years 2021-2025*.[1] This new strategic plan highlights NIH's strategic vision in three areas – research, research capacity, and research conduct – and features five crosscutting themes that overlay NIH's mission: minority health and health equity; women's health; public health challenges across the lifespan; collaborative science; and data science.

Following the path outlined in the Strategic Plan, NIH, under the guidance of the OD, will continue to invest efficiently and effectively in a wide range of basic, translational, clinical, and applied research that builds a strong foundation to overcome scientific challenges inherent to our evolving world. The OD has a unique leadership position. It oversees an extensive variety of NIH-wide initiatives that seek to address the nation's most pressing health concerns, including the COVID-19 pandemic, health equity, and systemic racism.

Ongoing Research to End the COVID-19 Pandemic

As the COVID-19 pandemic has continued to evolve, the NIH has adapted to meet our nation's changing science and health care needs. Despite challenging circumstances, the scientists and staff at the NIH were able to rapidly respond to the growing crisis of COVID-19 by shifting resources to better understand SARS-CoV-2 and COVID-19, quickly identifying and implementing various grant administrative flexibilities to support the research community, and efficiently communicating emerging knowledge and recommendations to the public in coordination with partner HHS agencies. The NIH supported the record-breaking development of safe and effective vaccines for COVID-19 by leveraging critical partnerships and innovative research paradigms such as the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership (PPP). The Rapid Acceleration of Diagnostics (RADx®) effort, a program designed to speed innovation, commercialization, and implementation of SARS-CoV-2 diagnostic testing, has supported companies which have together expanded testing capacity across the United States by more than 150 million tests by early 2021.[2] Ongoing, community-engaged RADx projects are working to ensure communities throughout the United States have access to COVID-19 tests by attempting to understand and alleviate barriers to testing in areas hardest hit by the pandemic.

The intergovernmental partnerships and PPPs leveraged during the pandemic have demonstrated the ability of diverse groups to coordinate large-scale efforts to rapidly achieve public health goals. The pandemic highlighted the urgent need for increased representation of diverse communities across the research process, from study design to implementation, to better engage critical stakeholders. Finally,

[1] nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf
[2] nlmdirector.nlm.nih.gov/2021/03/31/one-year-of-rapid-acceleration-of-diagnostics-and-anticipating-new-challenges/

streamlined administrative processes and policies allowed the NIH and its funded researchers to respond flexibly to changing needs.

As we have seen promising return on investment from initiatives such as ACTIV, the NIH has also launched new initiatives in response to evolving pandemic-related needs within the United States healthcare system, such as the Community Engagement Alliance (CEAL) Against COVID-19 Disparities and the Social, Behavioral, and Economic (SBE) Health Impacts of COVID-19 in Vulnerable and Health Disparity Populations. RADx-Underserved Populations (RADx-UP), a part of the RADx effort that focuses on underserved populations, is also working to eliminate inequities by partnering with the communities most impacted by COVID-19 nationwide. RADx-UP projects seek to understand COVID-19 testing patterns as well as disparities in infection rates, disease progression and outcomes. These programs address key areas of evolving COVID-19 need, including health disparities and inequities that were further exacerbated by the pandemic; vaccine confidence and access, diagnostic testing, and treatment in underserved communities; and the many public health ripple effects of the COVID-19 pandemic.

Building a Diverse Biomedical Workforce

To improve research capacity, we must strive to build a strong biomedical workforce. The NIH has long recognized that the most critical assets in the biomedical research enterprise are its scientists and clinicians, and that diversity is a key component of innovation and achievement in the workforce. Within the OD, the Chief Officer for Scientific Workforce Diversity (COSWD) Office leads NIH's effort to diversify the national scientific workforce and expand recruitment and retention of individuals underrepresented in the biomedical, behavioral, and social science scientific workforce. Additionally, the Office of Equity, Diversity, and Inclusion (EDI) fosters an inclusive culture at the NIH, increases racial, gender, and ethnic representation, provides analyses of representation across the NIH, and manages the agency's civil rights program. Other OD offices, such as the Sexual and Gender Minority Research Office (SGMRO) and the Tribal Health Research Office (THRO) help to coordinate research across the NIH to address health disparities and inequities and ensure diversity in the biomedical research workforce.

This year, the OD has sought to build on the efforts of these important offices. In early 2021, NIH launched the UNITE Initiative, an agency-wide effort committed to ending racial inequities across the biomedical research enterprise.[3] UNITE is comprised of 5 committees with representatives from across OD Offices and all 27 Institutes and Centers (ICs). UNITE will work to improve NIH organizational culture and structure to promote diversity, equity, and inclusion and strive to improve transparency internally and externally on topics relevant to workplace inclusion. UNITE will also address the need for increased health equity research and perform a broad systematic evaluation of NIH extramural policies and processes, to identify and change structures that perpetuate a lack of inclusivity and diversity within the extramural research ecosystem.

Additionally, the OD's Advisory Committee to the Director (ACD) Working Group on Diversity took significant steps within the past year, releasing its final report on racism in science in February 2021.[4] The report provides recommendations to the NIH to best address systemic racism in the workforce through: (1) acknowledging racism and inequities; (2) conducting research to better understand systemic

[3] nih.gov/ending-structural-racism/unite
[4] acd.od.nih.gov/documents/presentations/02142021_DiversityReport.pdf

racism; (3) monitoring acts of bias and changing the culture; and (4) making structural changes to mitigate the impact of bias and racism.

Preparing for Infrastructure, Resource, and Operational Needs for the Future of Research

As the central office of the NIH, OD is responsible for providing critical infrastructure and services to the ICOs to secure the Nation's investment in biomedical research and support consistent and transformative advances in human health. Offices within the OD support NIH-wide initiatives that enhance the agency's ability to drive innovative, multidisciplinary research across the biomedical landscape. Career development opportunities and research infrastructure efforts led by the OD provide trainees and scientists with critical skills and expertise needed to advance – both at NIH and at home institutions – their careers and research programs. The OD leads NIH-wide efforts to improve the productivity of research portfolios through careful analysis and evidence-based decision-making. Employee well-being and support programs, such as ongoing wellness initiatives and childcare-related resources led by the OD, are available to all NIH staff to provide needed assistance to enable the NIH community to drive its mission forward. By providing the tools to collect and analyze data on NIH funded scientific programs as well as the training and support, the OD enables NIH to maintain high levels of research stewardship and ensure informed decision-making on future and ongoing initiatives.

The OD provides scientific and administrative leadership to foster NIH-wide activities through planning, managing, and implementing policies and procedures to facilitate the coordination, award, and management of cutting-edge biomedical research. By guiding NIH's extramural and intramural research activities, health information dissemination and outreach, science policy, legislative activities, technology transfer, and stewardship of public funds, the OD drives NIH's scientific mission. The OD also prioritizes, allocates, and manages funds for administrative services, including budget and financial management, human resources, information technology, procurement, property management, intramural and extramural support, ethics, and administration of equal employment and diversity management practices. The OD is leading reviews of innovative policies and practices brought on by the demands of the COVID-19 pandemic to learn from its successes and challenges and determine how to be more effective and efficient. The OD is preparing for a safe return to work by evaluating resources for staff and facility management, preparing new flexibilities to recruit and retain talented staff, and determining which new operational practices should be codified in preparation for future public health emergencies. Many of these efforts are being led by the Office of Management, which advises, provides leadership, and oversees NIH administration and management, including areas of budget, human resources, facilities, support services, security operations, and logistics.

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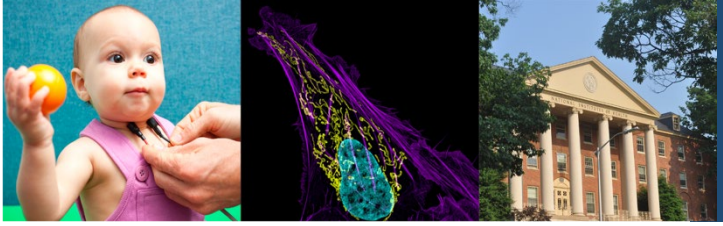


NIH National Institutes of Health
Office of the Director

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, Centers, and Offices (ICOs). The OD provides scientific and operational direction to the ICs by setting NIH-wide policy and procedures; developing and maintaining shared resources; coordinating initiatives, programs, and activities; and anticipating new directions for the biomedical research enterprise.

The NIH Director and the OD play a vital role in shaping the agency's overarching agenda. 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. The OD also provides leadership and support for many NIH-wide initiatives that involve collaboration across ICOs to solve some of the most perplexing health challenges of our time.

NIH Acting Director Lawrence A. Tabak, D.D.S., Ph.D.

OD Offices

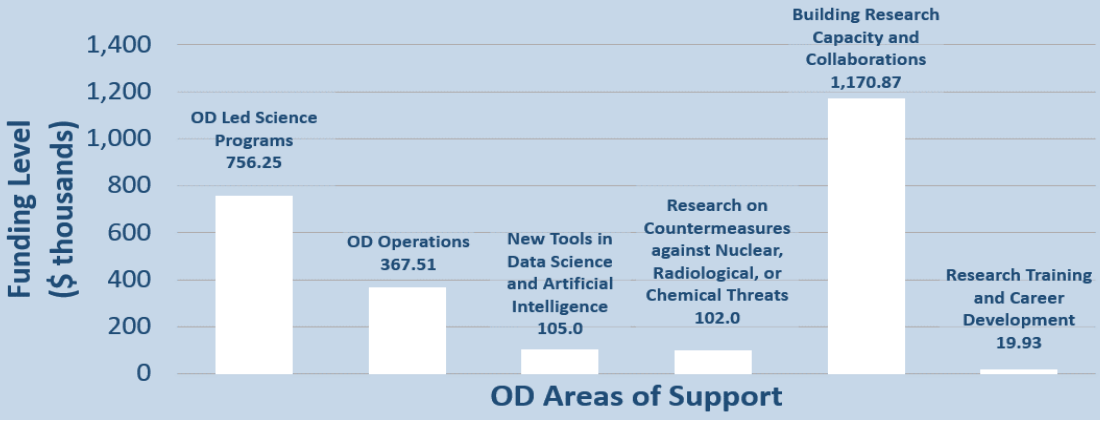
The OD is comprised of a number of scientific, operational, and policy offices that provide resources and tools, program support, and guidance to advance the NIH mission.

Highlights from the Office of the Director

- **NIH responded to COVID-19 by pivoting resources and developing new policies and tools to address the pandemic.** To build on and learn from those innovations, the OD has begun evaluating the COVID-19 response to identify strengths, challenges, and novel best practices to adopt moving forward.
- **The OD is leading NIH-wide efforts to prepare for maintaining operations after the COVID-19 pandemic.** The Strategic Administrative Management Advisory Committee (SAMAC) formed teams of over 120 volunteers from across NIH to develop guidelines for the NIH Future of Work. These teams are charged with developing NIH-wide guidelines that reflect new realities brought on by the COVID-19 pandemic.

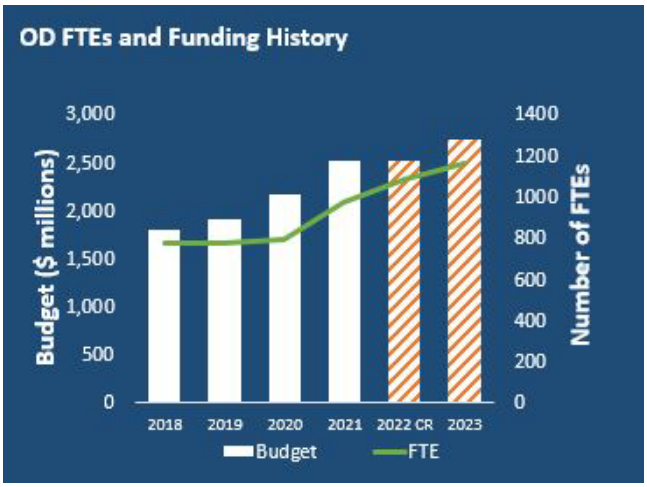
Quick Facts

In FY 2021, the OD employed 968 FTEs and funded over $2.5 billion in scientific research and NIH-wide resources and operations.



Recent Accomplishments

- In July 2021, the NIH released the ***NIH-wide Strategic Plan for Fiscal Years 2021-2025***. The Plan, developed under OD leadership, summarizes NIH's approach to advancing its mission and sets out a vision for direction, capacity, stewardship for biomedical research, and the NIH's highest priorities for the next five years.
- Supported by the OD, the **Advisory Committee to the Director (ACD) Working Group on Diversity** released its final Racism in Science report in February 2021. The Working Group's recommendations to address systemic racism are now being implemented.



Current Activities

- The OD Office of Disease Prevention recently launched **Advancing Prevention Research for Health Equity (ADVANCE),** an NIH-wide initiative to develop new prevention interventions and implement existing evidence-based interventions and preventive services in populations that experience health disparities and inequities.
- The **HEALing Communities Study**, supported by the NIH Helping to End Addiction Long-term[SM] (HEAL) Initiative**,** has engaged 67 communities across the country to help develop community decision-making and action plans to reduce opioid-related deaths by 40 percent. Now, HEALing Communities is working with local partners to develop implementation plans for evidence-based therapies and interventions.
- **Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD)** is led by the Office of Data Science Strategy to establish partnerships between researchers and underrepresented communities to enhance emerging artificial intelligence and machine learning technology.

Future Initiatives

- The OD is working to ensure the NIH is well-positioned to manage future public health challenges or emergencies. The NIH OD and the ICs have begun conducting formal evaluations of pandemic practices to measure their effectiveness, prepare for future public health emergencies, and identify successful policies for the future of biomedical research.
- The Office of Science Policy (OSP) is working to identify and share best practices for developing informed consent language to support human subject data sharing. OSP launched the **Clinical Trial Stewardship Task Force**, which will assess NIH's progress toward clinical trial stewardship reform and identify areas in which additional focus may be needed.

Major Changes in 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 2023 budget request for OD, which is $209.3 million above the FY 2022 CR level for a total of $2,728.7 million.

Office of Nutrition Research (+$96.0 million; total $97.2 million): The FY 2023 budget requests funding to support the objectives of the 2020 – 2030 Strategic Plan for NIH Nutrition Research.

Center for Sexual Orientation and Gender Identity (SOGI) Research (+$2.0 million; total $2.0 million): The FY 2023 budget requests funding to support up to three research FTEs and the establishment of a center for ongoing SOGI research to analyze and build on an ongoing NASEM consensus study on Measuring Sex, Gender Identity, and Sexual Orientation.

All of Us Research Program (+$41.0 million; total $541.0 million): The FY 2023 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.

Firearms Research (+$12.5 million; total $25.0 million): The FY 2023 President's Budget request will enable NIH to increase its research efforts on firearm injury and mortality prevention.

Office of the Chief Officer for Scientific Workforce Diversity (+$16.0 million; total $22.4 million): The FY 2023 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

Office of the Director Budget Mechanism [1,2]

(Dollars in Thousands)

Mechanism	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Grants:								
Research Project		$715,953		$675,058		$734,193		$59,135
Research Centers		$255,683		$304,938		$342,036		$37,098
Other Research		$880,544		$835,677		$901,314		$65,636
Total Research Grants		$1,852,180		$1,815,673		$1,977,543		$161,870
Training		$18,439		$20,992		$19,116		-$1,876
R & D Contracts		$85,296		$92,439		$126,903		$34,464
Intramural Research		$12,946		$12,526		$5,495		-$7,031
Res. Management & Support		$495,244		$520,738		$542,575		$21,838
Construction		$57,500		$57,032		$57,032		$0
Total Other Than Research Grants		$669,425		$703,727		$751,122		$47,395
Subtotal, Labor/HHS Budget Authority		$2,521,605		$2,519,401		$2,728,665		$209,264
Total, OD		$2,521,605		$2,519,401		$2,728,665		$209,264

[1] Includes $109.0 million in FY 2021, $109.0 million in FY 2022, and $419.0 million in FY 2023 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

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

Appropriations Language

OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, $2,302,065,000: 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 $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 up to $30,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 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 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 2023 and 2024 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.

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, $1,085,000,000, 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.

Summary of Changes

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes

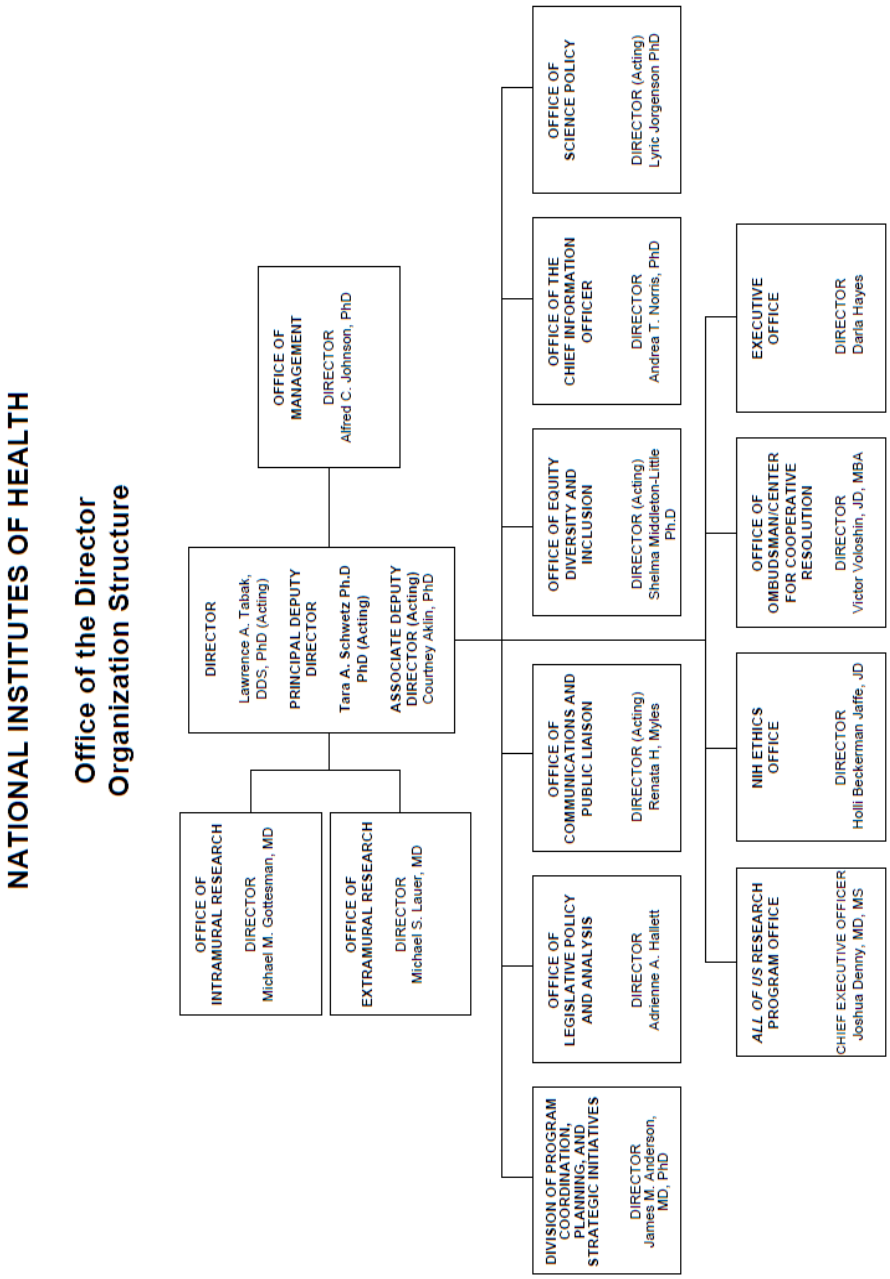
(Dollars in Thousands)

FY 2022 CR	$2,519,401
FY 2023 President's Budget	$2,728,665
Net change	$209,264

CHANGES	FY 2022 CR FTEs	FY 2022 CR Budget Authority	FY 2023 President's Budget FTEs	FY 2023 President's Budget Budget Authority	Built-In Change from FY 2022 CR FTEs	Built-In Change from FY 2022 CR Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2022 pay increase & benefits		$3,566		$3,688		$22
b. January FY 2023 pay increase & benefits		3,566		3,688		$114
c. Paid days adjustment		3,566		3,688		-$14
d. Differences attributable to change in FTE		3,566		3,688		$0
e. Payment for centrally furnished services		0		0		$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		8,960		1,807		$197
Subtotal						$319
2. Research Management and Support:						
a. Annualization of January 2022 pay increase & benefits		$178,693		$196,482		$1,183
b. January FY 2023 pay increase & benefits		178,693		196,482		$6,040
c. Paid days adjustment		178,693		196,482		-$679
d. Differences attributable to change in FTE		178,693		196,482		$12,329
e. Payment for centrally furnished services		3,279		3,344		$66
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		338,766		342,750		$7,412
Subtotal						$26,352
Subtotal, Built-in						$26,671

CHANGES	FY 2022 CR No.	FY 2022 CR Amount	FY 2023 President's Budget No.	FY 2023 President's Budget Amount	Built-In Change from FY 2022 CR No.	Built-In Change from FY 2022 CR Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	370	$472,670	322	$426,884	-48	-$45,786
b. Competing	205	194,431	300	299,352	95	104,921
c. SBIR/STTR	12	7,956	12	7,956	0	0
Subtotal, RPGs	587	$675,058	634	$734,193	47	$59,135
2. Research Centers	156	$304,938	174	$342,036	18	$37,098
3. Other Research	361	835,677	392	901,314	31	65,636
4. Research Training	538	20,992	440	19,116	-98	-1,876
5. Research and development contracts	6	92,439	7	126,903	1	34,464
Subtotal, Extramural		$1,929,104		$2,123,562		$194,458
	FTEs		FTEs		FTEs	
6. Intramural Research	0	$12,526	0	$5,495	0	-$7,350
7. Research Management and Support	1,087	520,738	1,162	542,575	75	-4,514
8. Construction	0	57,032	0	57,032	0	0
9. Buildings and Facilities	0	0	0	0	0	0
Subtotal, Program	1,087	$2,519,401	1,162	$2,728,665	75	$182,593
Total built-in and program changes						$209,264

Organization Chart



NATIONAL INSTITUTES OF HEALTH
Office of the Director

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

	FY 2021 Final	FY 2022 CR Level	FY 2023 President's Budget	FY 2023 +/- FY2022
OD Led Science Programs	**756,250**	**756,250**	**797,250**	**41,000**
INCLUDE Project	65,000	65,000	65,000	0
All of Us Research Program	391,000	391,000	122,000	-269,000
All of Us Research Program - Cures	109,000	109,000	419,000	310,000
BRAIN Initiative	10,000	10,000	10,000	0
Environmental Influences on Child Health Outcomes	180,000	180,000	180,000	0
Foundation for the National Institutes of Health	1,250	1,250	1,250	0
New Tools in Data Science and Artificial Intelligence	**105,000**	**105,000**	**105,000**	**0**
Office of Data Science Strategy	55,000	55,000	55,000	0
Artificial Intelligence to Address Chronic Disease	50,000	50,000	50,000	0
Building Research Capacity and Collaborations	**1,170,871**	**1,162,915**	**1,301,637**	**138,722**
Common Fund	648,539	640,230	658,539	18,309
Office of Nutrition Research	1,050	1,205	97,205	96,000
Firearm Injury and Mortality Prevention Research	12,500	12,500	25,000	12,500
Center for Sexual Orientation and Gender Identity (SOGI) Research	0	0	2,000	2,000
Division of Program Coordination, Planning and Strategic Initiatives	508,782	508,981	518,893	9,913
Research Training and Career Development	**19,926**	**19,956**	**20,124**	**167**
Intramural Loan Repayment and Scholarship	8,513	8,543	8,711	167
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	**102,042**	**102,042**	**102,042**	**0**
OD Operations	**367,515**	**373,236**	**402,611**	**29,375**
Office of the Chief Officer for Scientfiic Workforce Diversity (non-add)	*(6,190)*	*(6,415)*	*(22,415)*	*(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	**$2,521,605**	**$2,519,401**	**$2,728,665**	**$209,264**

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 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	$2,521,605,000	$2,519,401,000	$2,728,665,000	$209,264,000
FTE	968	1,087	1,162	75

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

Overall Budget Policy: The FY 2023 President's Budget request for the Office of the Director is $2,728.7 million, an increase of $209.3 million or 8.3 percent compared with the FY 2022 CR level. The request includes $419.0 million in funding provided by the 21st Century Cures Act. Increases above the CR level are distributed across programmatic and operational areas, as described below. This level includes an increase for the Office of Nutrition Research, the All of Us Research Program, the Office of the Chief Officer for Scientific Workforce Diversity, 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 public health.

Program Descriptions

Scientific Programs of the Office of the Director: Coordination, Direction, and Investments
The OD coordinates and contributes to scientific research activities across the NIH that are led by both the OD and the ICs. To provide 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.

Under OD's leadership, NIH has made exceptional progress toward understanding, diagnosing, treating, and preventing SARS-CoV-2 infection and COVID-19. The *NIH-Wide Strategic Plan*

for COVID-19 Research[5] was updated in early 2021 to reflect NIH progress and the highest priorities in this rapidly evolving pandemic landscape. The plan outlines efforts to address emerging and ongoing challenges, such as Long COVID—also known as Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)—and SARS-CoV-2 variants; to implement accurate and reliable diagnostics, and safe and effective vaccines and therapeutics; and to engage disproportionately affected populations. The plan was developed by the OD, in partnership with the ICOs, and with input from the research community, professional societies, advocacy groups, and the public.

Addressing Vaccine Hesitancy to End the COVID-19 Pandemic

As the COVID-19 pandemic has evolved, the development and distribution of safe and effective vaccines to prevent infection has created the potential to change the course of the pandemic. However, there remain many individuals who have questions about the vaccine and may be hesitant to get vaccinated. To better understand and address vaccine hesitancy, the OD is supporting several ongoing efforts from across NIH which aim to inform vaccine uptake programs. Focusing on groups that experience health disparities, OD and the National Institute on Minority Health and Health Disparities (NIMHD) are together supporting intervention research to determine how best to reduce barriers to access, acceptance, and uptake of vaccines. These research projects consider factors that impact vaccine uptake such as interpersonal, community, cultural, and historical factors associated with health-related beliefs, risk perceptions, and behavior. Research will identify effective interventions, develop successful practices for communication strategies, and find policies that support equitable vaccine distribution, among other goals. Finally, the OD supports the NIH CEAL initiative, led by NIMHD and the National Heart, Lung, and Blood Institute (NHLBI), which works closely with communities most impacted by the pandemic to provide accurate information and encourage people to become informed and take steps to protect themselves and their communities from the pandemic.

Since the earliest days of the pandemic, the NIH has mounted a vigorous research response against COVID-19 in coordination with Congress, the Department of Health and Human Services (HHS), and partners in the private and public sectors. Major NIH efforts launched early on have shown unprecedented success. Established by the NIH and coordinated by the Foundation for the National Institutes of Health (FNIH), the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership (PPP) has moved at an unprecedented speed. ACTIV brings together NIH with its sibling agencies in HHS, including the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), and the Centers for Disease Control and Prevention (CDC); other government agencies, including the Department of Defense (DOD) and Department of Veterans Affairs (VA); the European Medicines Agency; and representatives from academia, philanthropic organizations and numerous biopharmaceutical companies.[6] ACTIV developed a collaborative, streamlined forum to identify preclinical treatments, accelerate clinical testing of the most promising vaccine and treatment candidates, improve clinical trial capacity and effectiveness, and fast-track the evaluation of candidates to enable rapid authorization or approval. Six ACTIV master protocols for COVID-19 treatments are currently underway.[7]

[5] covid19.nih.gov/sites/default/files/2021-05/NIH-Wide-COVID-19-StratPlan_2021_508_1.pdf
[6] nih.gov/research-training/medical-research-initiatives/activ
[7] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials

A working group of ACTIV, the ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) initiative, is focused on identifying emerging variants of SARS-CoV-2.[8] TRACE produces a weekly report that summarizes shifting trends in emerging SARS-CoV-2 variants based on viral sequence data. TRACE leverages the private-public partnership framework of ACTIV to facilitate rapid data sharing from industry and government agencies to characterize the impact of variants on vaccines and therapeutics. Public data is collated from research publications and preprints, as well as unpublished data provided directly by TRACE's industry partners and shared publicly on the National Center for Advancing Translational Science (NCATS) OpenData Portal.[9] Finally, TRACE is generating datasets using standardized protocols and common reference reagents to better understand the impact of each new variant reported on the efficacy of vaccines and therapeutics. ACTIV TRACE is cochaired by the NIH and private sector experts, and facilitated by the FNIH, with participation by the ACTIV PPP.

The RADx®-UP Safe Return to School Diagnostic Testing Initiative

In 2021, the Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) program supported research on COVID-19 diagnostic testing approaches to safely return children and staff to in-person schooling in underserved and vulnerable communities. This Return to School effort included two phases of research support to rapidly accelerate SARS-CoV-2 testing implementation research in school settings and to initiate new cohorts or approaches to build evidence for testing strategies to facilitate the safe return of children to in-person school. Researchers are developing scalable and sustainable strategies that incorporate multiple stakeholders and overlapping policies from local governments and school districts to study key issues related to returning to in-person learning during the COVID-19 pandemic. To date, the Return to School program has funded 16 projects at schools serving racially and ethnically diverse and other underserved populations across the country. Several of these projects include children with medical conditions or intellectual and developmental disabilities who are at greater risk of infection or disease and may not be able to use common risk mitigation measures like masks or social distancing. In August 2021, RADx-UP hosted a webinar with investigators funded through Return to School to present data acquired to date, learn from each other, and support the safe return of children to in-person school. This research is providing communities with needed access to the most up-to-date scientific evidence to weigh the benefits and challenges of implementing different COVID-19 mitigation strategies in ongoing return to school efforts.

NIH efforts have adapted to address timely needs such as health inequities exacerbated by the pandemic. Funding from the OD allocated to the NIH CEAL initiative will foster research in communities that have been hit hardest by the pandemic to help strengthen COVID-19 vaccine confidence and access, as well as testing and treatment.[10] CEAL teams work closely with community leaders and organizations to address the misinformation and mistrust that can slow therapeutic interventions and pandemic recovery.

Another major and ongoing initiative coordinated by the OD is the RADx® effort, a $1.5 billion program designed to address the COVID-19 pandemic by speeding innovation, commercialization, and implementation of diagnostic testing for SARS-CoV-2. RADx Tech and RADx Advanced Technology Platforms (ATP) – two programs within RADx that focus on the acceleration, evaluation, validation, and

[8] nih.gov/research-training/medical-research-initiatives/activ/tracking-resistance-coronavirus-evolution-trace
[9] opendata.ncats.nih.gov/covid19/
[10] covid19community.nih.gov

scale-up of promising testing technologies – have supported companies that collectively expanded testing capacity across the United States by more than 150 million tests and have compressed the typical multi-year tech commercialization process to approximately 6 months.[11] The RADx-UP program supports the development of community-engaged projects across the United States to assess and expand SARS-CoV-2 testing for underserved or vulnerable populations. RADx® Radical (RADx-rad) supports new, non-traditional approaches, including rapid detection devices and home-based testing technologies, that address current gaps in COVID-19 testing. The program will also support new or non-traditional applications of existing approaches to make them more usable, accessible, or accurate. RADx initiatives are working to develop additional research foci to expand and offer new testing opportunities as diagnostic capabilities progress.

The OD collaborates with the ICs on the Collaboration to Assess Risk and Identify Long-term Outcomes for Children with COVID (CARING for Children with COVID). CARING for Children with COVID is developing and funding studies to investigate how COVID-19 impacts children and how to identify patients at risk for multisystem inflammatory syndrome in children (MIS-C), a life-threatening condition marked by severe inflammation of one or more parts of the body.[12]

Additionally, the NIH is dedicated to understanding and reducing the widespread effects of the COVID-19 pandemic within vulnerable communities. The SBE Health Impacts of COVID-19 in Vulnerable and Health Disparity Populations initiative funds research devoted to assessing the best public health efforts to curb the pandemic, the impacts of the pandemic on everyday life and routine health care, and relevant community health efforts. The SBE Initiative released two new funding opportunities in 2021 and, pending availability of funds, is planning several future possible research efforts.[13]

Building Research Collaborations to Address Public Needs

To address the alarming increases in maternal morbidity and mortality within the U.S., the OD Immediate Office of the Director, the OD's Office of Research on Women's Health (ORWH), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) co-lead the NIH-wide Maternal Morbidity and Mortality Task Force (MMTF). The MMTF coordinates the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative, which supports research to reduce preventable causes of maternal deaths and improve health for women before, during, and after delivery, particularly in populations that experience health inequities. In FY 2020, the NIH awarded over $7 million to support 36 projects via IMPROVE and funded 22 administrative supplements totaling over $13 million in FY 2021. IMPROVE released two funding opportunities in FY 2021 that focused on projects designed to address innovative diagnostic technology for improving maternal health outcomes and on improving women's health and maternal health infrastructure in states with limited access to health care.

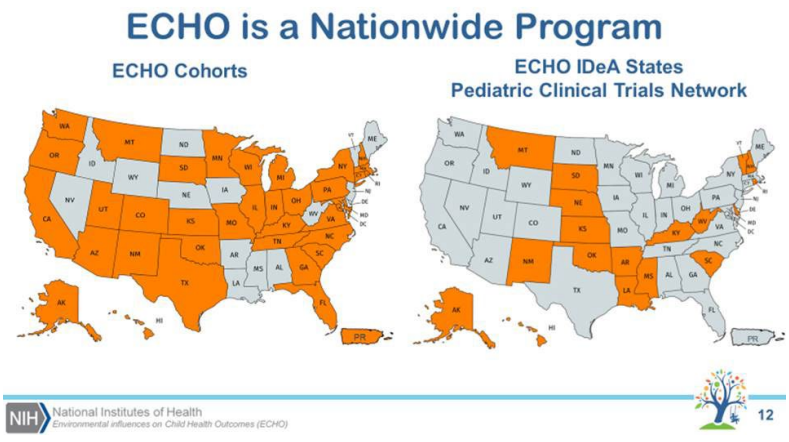
[11] nlmdirector.nlm.nih.gov/2021/03/31/one-year-of-rapid-acceleration-of-diagnostics-and-anticipating-new-challenges

[12] caring4kidswithcovid.nih.gov

[13] obssr.od.nih.gov/news-and-events/news/director-voice/nih-behavioral-and-social-science-covid-19-research-funding

The INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project was launched with Congressional support in June 2018. Led by the OD, and in coordination with 18 ICOs, INCLUDE is an NIH-wide initiative dedicated to investigating critical health and quality-of-life needs for individuals with Down syndrome (DS), including co-morbidities such as Alzheimer's Disease, which commonly affect the DS community. In 2021, INCLUDE will finalize and release a new research plan,[14] setting research goals and objectives in basic research, clinical studies and cohort building, living and aging with DS, and building critical research infrastructure. In FY 2021, INCLUDE released three new funding opportunities designed to encourage exploratory research in DS, adoption of telehealth and mobile health approaches following their success during the pandemic, and whole genome sequencing of research participants with DS.

In addition to the NIH OD, 10 ICs collaborate on the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, a public-private partnership (PPP), focused on innovative technologies which allow researchers to gain a new understanding of the brain to ultimately lead to discoveries in treatments, cures, and preventions for brain disorders. With funding in part from the OD, the BRAIN Initiative has made over 700 awards to hundreds of investigators, totaling approximately $1.3 billion in funds. The BRAIN Initiative is also working to promote diversity in the biomedical workforce, sponsoring a Transition to Independence Award program for under-represented minorities and women scientists and a recent funding opportunity to encourage eligible NIH BRAIN Initiative awardees to apply for research supplements that promote diversity. NIH also recently released a Request For Information to seek input from BRAIN Initiative awardees and the broader scientific community on factors that may contribute to the lack of diversity in research teams.



ECHO is a nationwide program, with cohorts in over 30 states and 16 IDeA states involved in ECHO's ISPCTN.

The Environmental influences on Child Health Outcomes (ECHO) Program is an extramural research program managed by the OD consisting of observational research by ECHO Cohorts and intervention research by the IDeA States Pediatric Clinical Trials Network (ISPCTN). ECHO supports multiple, synergistic, longitudinal cohort studies to investigate how environmental exposures—including physical, chemical, social, behavioral, biological—influence child health and development. For example, a recent publication involving over 8,700 ECHO participants revealed that childhood asthma almost doubles the risk of obesity but use of asthma medications nearly abolishes this risk, reinforcing best practices for children with

[14] nih.gov/include-project/include-project-research-plan

asthma.[15] In response to the pandemic, ECHO researchers are studying how COVID-19-related hardships are affecting the health of pregnant women and children.[16] ECHO's ISPCTN was renewed in FY 2020, assuring access of children living in rural or underserved communities to clinical trials and building pediatric research capacity for IDeA states. ECHO is partnering with the Helping to End Addiction Long-term[SM] (HEAL) Initiative to conduct two clinical trials focused on improving outcomes among newborns exposed to prenatal opioids.[17]

The NIH HEAL Initiative, launched in 2018, is a cross-agency program spanning basic, translational, and clinical research on opioid misuse, addiction, and pain. HEAL aims to support therapeutic development and improved delivery of evidence-based treatment, a task that has become even more urgent since the COVID-19 pandemic fueled a nearly 30 percent increase in overdose deaths in 2020, the highest 12-month increase in decades. To date, the initiative has funded over $1.5 billion to more than 500 research projects to address opioid misuse and pain management.[18] The HEAL research portfolio wraps around a breadth of science from the neuroscience of pain to implementation science on innovative treatments to the science of long-term recovery. HEAL is supporting the Consortium on Addiction Recovery Science (CoARS) in developing resources to support recovery research with a focus on community-based recovery centers, justice-involved youth, family-based recovery, recovery in rural settings, and integrated networks of care. HEAL also bridges the spectrum of clinical settings to meet people where they are, supporting the management of opioid misuse among individuals with low-severity OUD in primary care settings through the Subthreshold Opioid Use Disorder Prevention (STOP) Study, in emergency rooms through the Emergency Department-INitiated bupreNOrphine and VAlidaTIOn Network Trial (ED-INNOVATION), and in justice setting through the Justice Community Opioid Innovation Network (JCOIN).

The HEAL Initiative is also ensuring the scientific future of this work by building increasingly diverse, innovative, and rising research teams. In 2021, HEAL launched new diversity supplements[19] intended to allow principal investigators (PIs) to bring in a new trainee or early career researcher from an underrepresented group to further that individual's career development. Lastly, undergirding these efforts, a HEAL data ecosystem platform is currently under development for accessing HEAL research data, making HEAL and other NIH datasets accessible for investigators and the public while protecting the privacy and confidentiality of research participants.[20,21]

As a not-for-profit organization, the FNIH supports the mission of the NIH by accelerating biomedical discoveries through strategic alliances that leverage researchers from the public, private, and not-for-profit sectors; coordinate and focus scientific efforts to maximize impact; and marshal resources. The Accelerating Medicines Partnership® (AMP®) program is a nimble and powerful PPP that includes the NIH, FDA, multiple biopharmaceutical and life science

[15] pubmed.ncbi.nlm.nih.gov/34561347/
[16] echochildren.org/echo-programs-response-to-covid-19/
[17] heal.nih.gov/research/infants-and-children/act-now
[18] heal.nih.gov/news/heal-research-opioid-public-health-crisis
[19] ninds.nih.gov/Funding/Training-Career-Development/Award/SUP-NIH-HEAL-Initiative-Research-Supplements-Promote
[20] heal.nih.gov/data/public-access-data
[21] heal.nih.gov/files/2021-06/heal-annual-report-2021.pdf

companies, not-for-profit organizations, and other organizations.[22] Managed by the FNIH, AMP seeks to improve our understanding of disease pathways and facilitate better selection of targets for treatment. Projects to date include Alzheimer's disease, type 2 diabetes, Rheumatoid Arthritis and Systemic Lupus Erythematosus, Parkinson's disease, common metabolic diseases, and schizophrenia, with a total investment of over $500 million. Projects to encourage research in heart disease and gene therapy are now under development.

Budget Policy: The FY 2023 President's Budget request for these programs is $281.3 million, an increase of $12.5 million or 4.7 percent compared with the FY 2022 CR level. The OD will utilize the overall funds requested to pursue promising scientific opportunities across a range of critical public health fields. In addition, the OD will continue to lead landmark scientific efforts such as the HEAL Initiative and the INCLUDE Project. The OD will capitalize upon the collective expertise of NIH Institutes and Centers to coordinate trans-NIH efforts, such as IMPROVE and the BRAIN Initiative.

Building Research Capacity and Collaborations Across the Biomedical Enterprise

The Office of Behavioral and Social Sciences Research (OBSSR) is responsible for coordinating the health-relevant behavioral and social sciences and identifying challenges and opportunities to advance these sciences at the NIH. In May 2021, the *Trans-NIH Research Opportunities in the Basic Behavioral and Social Sciences* report was released.[23] This report to the NIH Director and Council of Councils is a follow-up to 2004's *Research Opportunities in the Basic Behavioral and Social Sciences* (bBSSR).[24] OBSSR has convened a report implementation group and is working to engage the bBSSR community internal and external to NIH to identify priorities for the next iteration of its strategic plan.

Several NIH ICOs support violence prevention research and studies on understanding violence perpetration and those affected by violence. The FY 2020 Further Consolidated Appropriations Act (P.L. 116-94) and FY 2021 Consolidated Appropriations Act (P.L. 116-260) each provided $12.5 million of funding to the NIH in 2020 and 2021 to conduct research on firearm injury and mortality prevention by taking a comprehensive approach to studying the underlying causes and evidence-based methods of prevention of firearm injury, including crime prevention. In FY 2021, OBSSR coordinated input from multiple ICOs and funded 10 novel projects with a broad and comprehensive approach to firearm injury and mortality prevention.[25,26]

The mission of the Office of AIDS Research (OAR) is to ensure that NIH HIV/AIDS research funding – between 6-7 percent of the overall NIH budget – is directed at the highest priority research areas and to facilitate maximal return on the investment. In 2020, the NIH released the *FY 2021-2025 NIH Strategic Plan for HIV and HIV Related Research*.[27] The Plan provides a framework for the NIH-wide HIV research agenda and outlines the specific role of OAR in

[22] nih.gov/research-training/accelerating-medicines-partnership-amp
[23] obssr.od.nih.gov/sites/obssr/files/inline-files/bBSSR-WG-report-05042021-508.pdf
[24] obssr.od.nih.gov/sites/obssr/files/Basic-Beh-Report_complete.pdf
[25] obssr.od.nih.gov/about/violence-research-initiatives
[26] obssr.od.nih.gov/news-and-events/news/director-voice/nih-awards-10-grants-addressing-firearm-violence-prevention
[27] oar.nih.gov/about/directors-corner/fiscal-year-2021-2025-nih-strategic-plan-for-hiv-and-hiv-related-research

supporting HIV-related research across the agency. The Plan aligns NIH-supported research with the newly released HIV National Strategic Plan and the U.S. President's Emergency Plan for AIDS Relief.[28,29] Similarly, OAR continues to collaborate with the ICOs, HHS partners, and other stakeholders to advance the goals of the HHS-wide Ending the HIV Epidemic in the U.S. (EHE) initiative, which focuses on 4 key strategies to reduce new HIV infections in the United States by at least 90 percent by 2030: Diagnose, Treat, Prevent, and Respond to Outbreaks. OAR is responsible for monitoring, tracking, and reporting research investments related to EHE across all NIH ICOs.

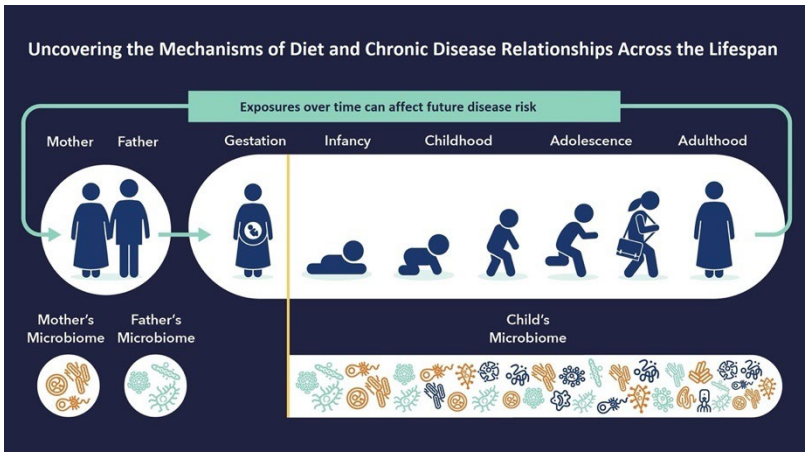
To help improve the health of racial and ethnic minorities and other populations who experience health disparities, the Office of Disease Prevention (ODP) launched the NIH-wide research effort, ADVANCE: Advancing Prevention Research for Health Equity.[30] ADVANCE brings together ICOs to support the development of new prevention interventions and to implement existing evidence-based interventions and preventive services in populations that experience health inequities. This effort will help to mitigate risk factors and enhance preventive services in four broad areas that contribute significantly to health disparities in the United States: cardiometabolic conditions driven by factors such as diet, high blood pressure, and low physical activity; use of alcohol, tobacco, and other drugs; mental health conditions; and cancer.

The Office of Dietary Supplements works to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, supporting research, disseminating research results, and educating the public. Sales of dietary supplements marketed for immune health increased after the emergence of the COVID-19 pandemic, as many people hoped these products might provide protection from infection or reduce disease severity. In May 2021, ODS released a new fact sheet for health professionals, combating misinformation related to dietary supplements, which concluded that data are insufficient to support recommendations for or against the use of any supplement ingredient to prevent or treat COVID-19.[31]

The NIH Common Fund, managed by the Office of Strategic Coordination (OSC), addresses emerging scientific opportunities and challenges in biomedical research that no single ICO can address on its own. The Common Fund supports over 25 scientific programs including the Bridge to Artificial Intelligence (Bridge2AI) program, which sets the stage for the broad adoption of AI in biomedical research.[32] In 2021, Bridge2AI released two opportunities for funding to 1) support a center to integrate, disseminate, and evaluate results of the program and 2) define best practices for generating datasets that are AI-ready and address health challenges that require AI and machine-learning (ML) analysis. Another Common Fund initiative, Transformative Research to Address Health Disparities and Advance Health Equity, launched on an accelerated timeline in FY 2021, resulted from the NIH's UNITE initiative, and is funding bold projects aiming to develop, disseminate, and/or implement innovative and effective interventions that prevent, reduce, or eliminate health disparities and health inequities.[33]

[28] hiv.gov/federal-response/hiv-national-strategic-plan/hiv-plan-2021-2025
[29] state.gov/pepfar/
[30] prevention.nih.gov/research-priorities/health-disparities
[31] ods.od.nih.gov/factsheets/COVID19-HealthProfessional/
[32] commonfund.nih.gov/bridge2ai
[33] commonfund.nih.gov/healthdisparitiestransformation

The Office of Nutrition Research (ONR) plans, coordinates, and tracks progress toward achieving the objectives of the *2020-2030 Strategic Plan for NIH Nutrition Research*.[34] Seven topic-based, NIH-wide Implementation Working Groups[35] have been established to develop specific initiatives, improve coordination, broaden NIH subject matter expertise in nutrition research, lead the implementation of the Strategic Plan. Inequities in nutrition health is an example of one of the timely and important topics being addressed by these groups. The ONR in collaboration with other NIH ICOs, CDC, and the United States Department of Agriculture (USDA), convened a virtual workshop entitled, "Food Insecurity, Neighborhood Food Environment, and Nutrition Health Disparities: State of the Science" in September 2021 to review the state of the science, identify research gaps and opportunities related to food insecurity and the neighborhood food environment, and suggest innovative research strategies that will inform policy and practice to address and prevent diet-related health disparities and promote health equity.[36]

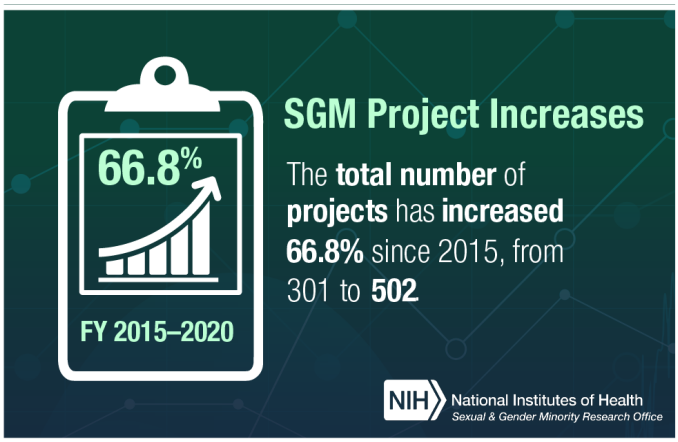


The NIH Office of Nutrition Research supports studies focused on identifying exposures across the lifespan to prevent diet-related chronic diseases and promote health.

The NIH ORWH supports NIH-wide research policies and programs that focus on all aspects of women's health including consideration of sex as a biological variable across the research continuum. In 2021, ORWH published its *Guide for Implementing and Evaluating the 2019–2023 Trans-NIH Strategic Plan for Women's Health Research Across NIH Institutes, Centers, and Offices*. The Guide offers methods, tools, and suggestions to help evaluate implementation efforts for the most recent NIH-wide strategic plan for the health of women.[37] ORWH also supports understudied, underrepresented, and underreported (U3) interdisciplinary women's health research through its U3 Administrative Supplement Program.[38] The U3 program targets research focused on the effects of sex/gender influences at the intersection of several social determinants—including, but not limited to, race and ethnicity, socioeconomic status, education, health literacy, gender identity, and urban/rural residence—in human health and illness. ORWH has continued to build on its successes of the U3 initiative and has more than doubled its funding over the past fiscal year.

[34] dpcpsi.nih.gov/sites/default/files/2020NutritionStrategicPlan_508.pdf
[35] dpcpsi.nih.gov/onr/iwg
[36] labroots.com/ms/virtual-event/food-insecurity-neighborhood-food-environment-nutrition-health-disparities-science
[37] journals.sagepub.com/doi/full/10.1177/21649561211042583
[38] orwh.od.nih.gov/womens-health-research/interdisciplinary-research/u3-interdisciplinary-research

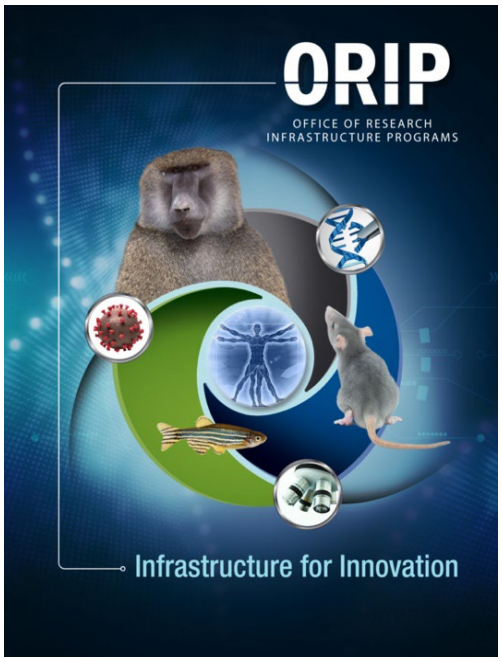
The Sexual & Gender Minority Research Office (SGMRO) continues to coordinate and encourage sexual and gender minority (SGM) research across NIH. In December 2020, NIH commissioned the National Academies of Sciences, Engineering, and Medicine (NASEM) to review current measures and methodological issues related to measuring sex as a non-binary construct, gender identity, and sexual orientation in surveys and research studies, in administrative settings (such as grant and job applications), and in clinical settings (such as doctor's offices or clinical trials). A NASEM panel will release a consensus report in March 2022 with conclusions and recommendations on: 1) guiding principles for collecting data on sex, gender identity, and sexual orientation; and 2) recommended measures for these constructs across different settings. SGMRO continues to implement the *NIH Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities for FY 2021-2025.*[39] The Center for Sexual Orientation and Gender Identity (SOGI) Research will be established to support ongoing studies of and build a consensus on measuring sex, gender identify, and sexual orientation.



The Sexual & Gender Minority Research Office at NIH has supported a dramatic increase in the number of research projects related to sexual and gender minority health across NIH ICOs.

The Tribal Health Research Office (THRO) was established in recognition of the importance of meaningful participation from Tribal nations in NIH programs and policies. THRO coordinates Tribal health research and related activities across all NIH ICOs and serves as the central point-of-contact for gathering input from all 574 federally recognized Tribal nations. In 2021, THRO, in collaboration with the Office of Science Policy (OSP) and NIH Tribal Advisory Committee, drafted the NIH Tribal Consultation Policy (TCP). The Policy reflects NIH's commitment to consistent and meaningful engagement with Tribal Nations on NIH policies, programs, and activities that significantly affect Tribes, such as those related to the COVID-19 pandemic. The NIH TCP will provide a standardized approach for all ICOs to conduct appropriate Consultation on programs, policies, or initiatives that significantly impact Tribes. In response to the Tribal Consultation for COVID-19 Research held in 2020, NIH incorporated Tribal input in the design of the RADx Initiative. In 2021, NIMHD and ODSS held a Tribal Consultation on key issues critical to the establishment of the RADx Initiative's Tribal Data Repository (TDR), including how to shape the TDR's ability to hold and share Tribal data that recognizes Tribal sovereignty.

[39] dpcpsi.nih.gov/sites/default/files/SGMStrategicPlan_2021_2025.pdf



Office of Research Infrastructure Programs at NIH.

Non-human primates (NHPs) have played a key role in helping scientists to understand and develop treatments for many different diseases and conditions, including COVID-19. Through a collaboration between the Office of Research Infrastructure Programs (ORIP) and the National Institute of Allergy and Infectious Diseases (NIAID), NIH provided supplemental funding to support the expansion of domestic rhesus macaque colonies to replace NHPs needed for COVID-19 research and supported the purchase of additional equipment. These funds also were used to provide urgent upgrades to existing biosafety level-3 (BSL-3) laboratories at NIH-supported NHP facilities. Additionally, ORIP is supporting basic pathogenesis studies on PASC in NHP species at multiple facilities, and is part of the new, innovative NIH 5-year preclinical antiviral therapeutics program, which includes support for animal models. ORIP also plays an essential role for NIH's biomedical research community by supporting programs that modernize existing or construct new biomedical research facilities and provide access to advanced scientific instruments and equipment needed for research investigations, including COVID-19 research.

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 2021 Final	FY 2022 CR Level	FY 2023 President's Budget	FY 2023 +/- FY 2022
Office of the DPCPSI Director	23,114	24,066	24,537	472
Office of Behavioral & Social Sciences Research	29,827	29,920	30,507	587
Office of AIDS Research	63,593	62,336	63,593	1,257
Office of Research on Women's Health	51,480	51,588	52,600	1,011
Office of Disease Prevention	13,771	13,904	14,176	273
Office of Dietary Supplements	27,113	27,182	27,715	533
Office of Research Infrastructure Programs	299,885	299,985	305,765	5,781
Office of Nutrition Research	1,050	1,205	97,205	96,000
Center for Sexual Orientation and Gender Identity (SOGI) Research	0	0	2,000	2,000
Common Fund	648,539	640,230	658,539	18,309
Total	**$1,158,371**	**$1,150,415**	**$1,276,637**	**$126,222**

Budget Policy: The FY 2023 President's Budget request for these programs is $1,276.6 million, an increase of $126.2 million or 11.0 percent compared with the FY 2022 CR 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, supporting interdisciplinary research coordination, and providing shared resources to build capacity.

All of Us Research Program

In December 2020, the *All of Us* Research Program began releasing the first genetic results to participants who have donated their biosamples, demonstrating *All of Us'* commitment to return information to its participants.[40] Initially, participants may choose to receive information about their genetic ancestry and traits. *All of Us* is taking a phased approach to the return of genetic results and will offer participants the opportunity to receive additional health-results beginning in spring 2022. As of February 2022, the program has enrolled nearly 466,000 participants, 321,000 of whom have completed the initial steps of the program. More than 50 percent of participants self-report being racial and ethnic minorities and 80 percent report being from communities historically underrepresented in biomedical research.

As of September 2021, the *All of Us* Research Workbench now includes expanded survey and electronic health record information that reflects the program's enrolled participants.[41] More than 1,487 researchers have gained access to the Researcher Workbench, over 1,112 research projects have been launched, and more than 293 institutions have signed on to the Data Use and Registration Agreement.[42] Researchers now have access to information about study participants' experience with the pandemic through survey responses on mental health, social distancing, and economic impacts.[43] The program plans to update the Researcher Workbench approximately twice a year with new participant data and additional records from existing participants, as well as new data types and improved research tools, if available. *All of Us* is continually evolving and improving the research tools and data available to make the platform as accessible, collaborative, and impactful as possible.

All of Us is committed to working with Tribal Nations and respectfully engaging American Indian/Alaska Native (AI/AN) people. In response to Tribal leader input gathered from a nearly two-year consultation process, the program confirmed a set of baseline commitments to Tribal Nations, including specialized education efforts for researchers, increased AI/AN participation in program governance to ensure the perspectives and needs of AI/AN communities are represented.[44] The *All of Us* consultation was one of the most extensive Tribal Consultations that NIH has held to date and was scaled to match *All of Us*' national scope, reflecting a growing momentum across the agency to expand Tribal engagement efforts and strengthen the relationship between the United States and Tribal Nations.

Budget Policy: The FY 2023 President's Budget request for this program is $541.0 million, an increase of $41.0 million or 8.2 percent compared with the FY 2022 CR level. The OD will

[40] allofus.nih.gov/news-events-and-media/announcements/nihs-all-us-research-program-returns-first-genetic-results-participants
[41] researchallofus.org/allofus.nih.gov/news-events-and-media/announcements/researchers-guide-and-drive-workbenchs-first-year
[42] researchallofus.org/institutional-agreements/
[43] allofus.nih.gov/news-events-and-media/announcements/all-us-releases-initial-covid-19-survey-data-researchers
[44] allofus.nih.gov/news-events-and-media/announcements/nih-enhance-tribal-engagement-efforts-precision-medicine-research

continue to lead the *All of Us* Research Program to build one of the most diverse health databases in history, enhance tools for researchers and participants, and innovate approaches for supporting accessible and transparent genetic data.

Research for Countermeasures against Nuclear/Radiological/Chemical Threats

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 provides oversight of the Medical Countermeasures against Radiation Consortium (CMCRC), a network of national research centers working together to develop effective and comprehensive medical countermeasures (MCM) applicable to all subsets of the civilian population in the event of radiological or nuclear emergencies. In 2020, funding for the CMCRC was reissued for the third time since its initial establishment in 2005.

Budget Policy: The FY 2023 President's Budget request for this program is $102.0 million, equal to the FY 2022 CR 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 and support innovative research through funding of and engagement with the scientific community.

Data Science and Artificial Intelligence (AI) Applied to Public Health

To realize the value of biomedical and health related data, NIH supports the data science infrastructure and tools, such as AI and machine learning (ML), to systematically enhance the ability of investigators and clinicians to improve public health while preserving patient privacy and enabling reproducibility of research results. The Office of Data Science Strategy (ODSS), in the OD, leads the implementation of the *NIH Strategic Plan for Data Science*[45] through scientific, technical, and operational collaboration across the NIH ICOs. In parallel, OSP leads the development of data sharing policies and coordinates implementation of these policies with the Office of Extramural Research (OER) to support a culture of data stewardship and respect for participant privacy and consent, and to encourage policies consistent with findable, accessible, interoperable, reusable (FAIR) data principles.

To meet the needs of open-access data to address the COVID-19 pandemic, ODSS is rapidly creating the necessary data infrastructure, including RADx Data Hub, a Tribal Data Repository, and an integrated data ecosystem for the NIH RECOVER Initiative: REsearching COVID to Enhance Recovery (RECOVER), for researchers to easily access and use critical public health data.

Led by ODSS, NIH's Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD)[46] program will broaden the benefits of AI across demographic groups and improve health equity. The newly awarded AIM-AHEAD Coordinating Center[47] will establish a consortium of institutions and organizations that have a

[45] datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf
[46] datascience.nih.gov/artificial-intelligence/aim-ahead
[47] datascience.nih.gov/news/nih-issues-research-opportunity-to-establish-aim-ahead-coordinating-center

core mission to serve underrepresented or underserved groups affected by health inequities to develop a more inclusive basis for AI data and enhance the diversity of leaders in AI for health.

Budget Policy: The FY 2023 President's Budget request for these programs is $105.0 million, equal to the FY 2022 CR level. This support will enable ODSS to continue innovative programs such as the AIM-AHEAD program to enhance diversity in AI and support the data needs of growing, ongoing NIH research programs. 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.

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

The OD is responsible for setting scientific, operational, and management policies that affect the entire agency. These policies aim to address critical issues faced by NIH and the larger biomedical research community by supporting research integrity and responsibility, developing a diverse, skilled biomedical workforce, and guaranteeing proper stewardship of public investments.

Improving Research Policies in Response to COVID-19

Policies directing the support of scientific research at the NIH were affected by changing supply chains, travel restrictions, and limitations to clinical studies, among many other unexpected impacts. Charged with rapidly finding vaccines and therapeutics to end the pandemic, the NIH OD, in collaboration with ICs, developed new models of supporting scientific research which can now be integrated into regular practice.[48] For example, OAR has convened the OAR Task Force on COVID-19 and HIV, to provide input to OAR and foster discussions between OAR and HIV stakeholders on programmatic, scientific, and operational focus areas and action plans at the intersection of HIV and COVID-19. The Task Force has focused on advances made during the pandemic, such as access to COVID-19 care for individuals with HIV and other vulnerable populations, and newly implemented approaches such as telehealth and community involvement in research. Interactions with communities and local leaders through programs like CEAL and the NIH Tribal Consultation on COVID-19 Research were at the forefront during the pandemic. CEAL Teams engage community leaders to provide trustworthy educational tools and host local events to engage with and learn from community members. As the pandemic evolves and the needs of the research community shift, NIH will maintain its close engagements with stakeholders to analytically implement novel policies and practices designed to support scientific and clinical research more effectively.

[48] science.org/doi/10.1126/science.abh3996

Creating an Inclusive and Supportive Culture for Biomedical Research

In response to the 2020 protests for social and racial justice across the United States, NIH revitalized its efforts achieve health equity and advance scientific research for underrepresented communities. The Office of Equity, Diversity, and Inclusion (EDI) rapidly established an Advancing Racial Equity campaign, for the NIH community to engage in self-paced learning and social and racial justice conversations.[49] Led by the OD, the NIH-wide UNITE Initiative was launched to boldly identify and put into action solutions to racial inequities across the biomedical research enterprise. UNITE aims to establish an equitable and civil culture and reduce barriers to racial equity in the biomedical research workforce. To reach this goal, UNITE is facilitating research to identify opportunities, make recommendations, and develop and implement strategies to increase inclusivity and diversity in science. UNITE is composed of 5 committees with representatives from all 27 NIH ICs and the OD. Each committee has a specific, targeted focus: (U)nderstanding stakeholder experiences through listening and learning; (N)ew research on health disparities/minority health/health inequity; (I)mproving the NIH culture and structure for equity, inclusion, and excellence; (T)ransparency, communication, and accountability with NIH's internal and external stakeholders; and (E)xtramural research ecosystem and changing policy, culture, and structure to promote workforce diversity.

Seeking Public Input to Advance Solutions to Racial Disparities in Research

The NIH-wide UNITE Initiative, launched in early 2021, aims to establish an equitable and civil culture within the biomedical research enterprise and reduce barriers to racial equity in the biomedical research workforce. UNITE will facilitate research to increase inclusivity and diversity in biomedical science. In March 2021, UNITE issued a public Request for Information and captured over 1,100 responses from researchers, external partners, and members of the public. The responses provided feedback on practical and effective approaches to improving and strengthening racial equity, diversity, and inclusion across the biomedical research workforce, including NIH's own internal workforce. Responses will also inform efforts to expand the research portfolio to include research on eliminating health disparities and inequities. NIH will identify, develop, and implement policies, procedures, and practices designed to improve the culture and advance structural change in biomedical research. The UNITE initiative has begun a series of internal listening sessions and focus groups to gain input from the NIH community to gain insights into how to best foster diversity and inclusion both internally and externally. External listening sessions will begin in 2022.

In addition to UNITE, NIH seeks input from internal and external advisory groups to guide diversity, equity, and inclusion efforts. The Chief Officer for Scientific Workforce Diversity (COSWD) Office leads NIH's effort to diversify the national scientific workforce and expand recruitment and retention of individuals underrepresented in the scientific workforce. In 2022, COSWD will plans to release its five-year strategic plan which will outline its approach to using evidence to promote diversity, equity, inclusion, and accessibility in the workforce. The conversations between the Anti-Harassment Steering Committee, the Black/African American Senior Scientists, the Supporters of 8 Changes for Racial Equity (8CRE), and NIH leadership led in part by the UNITE Initiative. The Advisory Committee to the Director Working Group on Diversity released its final Racism in Science report in February 2021. Supported by the OD, the report provides recommendations for how NIH can address systemic racism in the workforce.

[49] edi.nih.gov/people/resources/advancing-racial-equity

The Working Group advised that NIH: 1) acknowledge racism and inequities, 2) conduct research to better understand system racism, 3) monitor acts of bias and change the culture, and 4) make structural changes to mitigate the impact of bias and racism. With this critical guidance, NIH commits to creating a work environment free of racism, discrimination, harassment, and other inappropriate behaviors at NIH and in biomedical research and to removing any barriers that may perpetuate structural racism by excluding people of color from professional advancement.

The EDI Office is charged with establishing a model Equal Employment Opportunity (EEO) and evaluating NIH's personnel programs[50] and policies "to ascertain any inequitable opportunities…in the workplace" (EEOC MD-715, §1). Recent demographic data of NIH staff have revealed that Black/African Americans, Native Americans, and Hispanics are underrepresented in certain scientific positions with high compensations and individuals with targeted disabilities are underrepresented (29 CFR 1614.102, 2017). Since 2020 EDI conducted an ongoing NIH-wide barrier analysis to study challenges in hiring and recruitment that result in a lack of equity, diversity, inclusion, and accessibility.

In 2021, EDI began building its analytic capabilities to anticipate and address changes that would identify practices that result in inequitable employment outcomes and actions that may help to overcome barriers. As a result of those efforts, EDI has developed new programs and resources for the NIH including a new Internal EEO Investigations Branch and an upcoming Mediation Program which will aim to conduct mediations for at least half of all EEO complaints filed. EDI is now piloting a new Diversity, Equity, Inclusion, and Accessibility (DEIA) Education Program which will provide practical tools NIH staff to become aware of and advance DEIA across the agency. The DEIA Education Program will provide a safe, inclusive, and effective space to: critically assess and explore triggers and barriers; develop the NIH's capacity to advance DEIA; and increase inclusion, diverse requiting pools, and cultural proficiency.

Training and Career Development Programs: The Future Biomedical Workforce

Support for trainees and early career scientists in biomedical research is key to advancing innovative approaches and transformative discoveries in public health. The NIH recognizes the importance of funding and career development opportunities for early-stage and underrepresented scientists and clinicians to fulfill its mission to develop and maintain the nation's skilled biomedical workforce.

Several training programs at the NIH aim to build the pipeline of researchers with specific scientific expertise. The Predoctoral Training in Advanced Data Analytics for Behavioral and Social Sciences Research (TADA-BSSR) was developed by OBSSR to support a cohort of specialized predoctoral candidates who can apply advanced competencies in data science

[50] Equal employment opportunity covers all personnel/employment programs, management practices, and decisions, including, but not limited to, recruitment/hiring, merit promotion, transfer, reassignments, training and career development, benefits, and separation. (EEOC MD-715, §1(I)(A)(2)(c)).

analytics to an increasingly complex landscape of behavioral and social health-related big data.[51] Coordinated by the ODSS, the Data and Technology Advancement (DATA) National Service Scholar Program offers one- to two-year positions to skilled data scientists to work directly with NIH leadership on high-profile projects, that leverage large datasets to impact biomedical research and policy across fields of study.[52] The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) is a mentored career-development program led by ORWH, designed to connect junior faculty to senior faculty with shared interest in women's health and sex differences research. Since BIRCWH was launched in 2000, over 88 grants to 44 institutions supporting more than 700 junior faculty have been awarded.[53]

The Distinguished Scholars Program, supported by the COSWD in collaboration with the Office of Intramural Research (OIR), aims to cultivate a diverse and inclusive community in the NIH Intramural Research Program (IRP) by providing 15 investigators with mentoring and professional development training to foster career success.[54] Similarly, the Independent Research Scholar Program, developed by the OIR, encourages workforce diversity by advancing postdoctoral scholars committed to building a diverse intramural workplace.[55] By coordinating and funding these and similar programs, the OD works to build a more diverse and inclusive workforce and bring new ideas and perspectives to tackle challenging public health problems facing the country today.

NIH recognizes the many structural and social challenges that early career scientists face during their career path. In many cases, these challenges can drive promising early career researchers and clinicians to other career options. To retain scientists and meet workforce needs, the OD coordinates support for early career scientists. ORWH leads the recently expanded Research Supplements to Promote Re-Entry and Re-integration into Health-Related Research Careers,[56] which offer full- or part-time support for eligible scientists to reenter the workforce after family responsibilities challenges or to transition out of a discriminatory environment to a safe one. Individuals supported by the supplements are expected to apply for independent research support at the end of the supplement period. The OD coordinates the NIH Intramural Loan Repayment Program (LRP) designed to recruit and retain qualified healthcare workers and biomedical researchers by repaying up to $50,000 of educational debt annually in return for committing to NIH-mission relevant research.[57] In FY 2021, the Intramural LRP supported 76 researchers, an increase of 7 percent from the previous year. The Undergraduate Research Scholarship Program, led by the Office of Intramural Training and Education (OITE), provides competitive scholarships for undergraduates from disadvantaged backgrounds who commit to paid research

[51] obssr.od.nih.gov/news-and-events/news/obssr-t32-training-in-advanced-data-analytics-for-behavioral-and-social-sciences-research-grants-awarded#:~:text=This%20new%205%2Dyear%20training,with%20competencies%20in%20data%20science
[52] datascience.nih.gov/data-and-technology-advancement-data-national-service-scholar-program-data-scientists-advancing
[53] orwh.od.nih.gov/career-development-education/building-interdisciplinary-research-careers-womens-health-bircwh
[54] diversity.nih.gov/programs-partnerships/dsp
[55] oir.nih.gov/sourcebook/personnel/ipds-appointment-mechanisms/research-fellow/independent-research-scholar-program
[56] orwh.od.nih.gov/career-development-education/research-supplements-promote-reentry-and-reintegration-health-related
[57] lrp.nih.gov

training and employment at NIH during the summer and following graduation.[58] OITE welcomed 15 new undergraduate scholars to the program in FY 2021.

The NIH Director's Challenge Innovation Award builds on the skills and expertise of the intramural research workforce by identifying and funding projects that foster NIH-wide collaborations in the NIH IRP.[59] The Award offers seed funding from the Office of Intramural Research (OIR) for innovative and impactful research with a high potential to benefit a variety of research, infrastructure, and scientific endeavors across the IRP. The Director's Discretionary Fund further enables the NIH Director to quickly establish and support new and emerging areas of research to address high-priority scientific issues. Together these awards drive innovative research, bolster critical scientific and clinical activities, and enable strategic partnerships within NIH.

The pipeline of highly trained biomedical researchers is a critical component of the scientific enterprise, often bringing new insights, developing innovative methodologies, and advancing the translation of scientific discoveries to support public health in the U.S. With support from the 21st Century Cures Act (P.L. 114-255), the OD launched the Next Generation Researchers Initiative (NGRI) in 2017.[60] Led by the OER, the NGRI increases opportunities for early-stage investigators (ESIs) by enabling NIH ICOs to prioritize funding for ESIs and track the impact of funding decisions on their careers to ensure the strategy for support is effective. NIH is now analyzing NGRI policies to ensure efforts adequately support career development for women and individuals from diverse backgrounds in biomedicine. In FY 2021, NGRI funded 1,513 ESIs, significantly exceeding its goal.

In 2018, NIH updated its NGRI policies to include support for meritorious at-risk investigators, those at risk of losing all NIH funding who do not have research support from other sources. While the outlook for these scientists is better today than in 2018, NIH remains committed to the goals of NGRI to protect and retain meritorious, at-risk scientists. During the COVID-19 pandemic, the OD allowed grant flexibilities for ESIs to accommodate the unusual demands and limitations they faced.[61] The OD will continue to support ESIs and at-risk investigators as the pandemic continues and will use evidence-based approaches to enhance the diversity of the future research workforce.

Budget Policy: The FY 2023 President's Budget request for these activities is $20.1 million, an increase of $0.2 million or 0.8 percent compared with the FY 2022 CR level. In FY 2023, OD will continue support for training and career development opportunities to support the advancement of scientists and clinicians and ensure the future of the biomedical workforce by addressing racial disparities and structural racism in biomedical research.

[58] training.nih.gov/programs/ugsp
[59] oir.nih.gov/sourcebook/awards-fellowships-grant-opportunities/directors-challenge-innovation-award-program
[60] grants.nih.gov/ngri.htm
[61] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-052.html

Enhancing Research Stewardship Practices, Tools, and Policies

Using all possible evidence to support effective, innovative research and policies is a critical goal of the NIH. In response to Title 1: Federal Evidence-Building Activities of the 2020 Evidence Act (P.L. 115-435), NIH is focused on strengthening its capacity to generate and use evidence in decision-making. To implement the Evidence Act, NIH has established several committees composed of members of the NIH Planning and Evaluation community, led by the Office of Evaluation, Performance, and Reporting in the OD. In 2021, the committees gathered detailed information on existing data resources and evaluation tools used by NIH staff, conducted a review of published evaluation competency models to identify competencies relevant to the NIH, and led productive discussions with senior leadership to understand how they define, prioritize, value, and utilize evidence to inform their decision-making. The products of these efforts include a new searchable web-based resource to share data and evaluation tools with NIH staff, an assessment of the evaluation competencies found among staff in the NIH ICOs, and a set of actionable recommendations based upon the identified evidence needs of senior leadership. These recommendations will form the basis of continued efforts to enhance data and tools and build upon existing evaluation competencies in NIH staff.

The Office of Portfolio Analysis (OPA) applies expertise in data science, machine learning, and software engineering to support data-driven decision making and research stewardship at NIH. OPA develops and disseminates validated approaches to analyzing past decision making, measuring the resulting impact, and forecasting the productivity of NIH research portfolios, including their potential for successful translation to the clinic. The OPA serves as a centralized resource for NIH ICOs in conducting large-scale analyses of research programs and scientific advances through training and analytical services. In 2021, OPA released its *Strategic Plan for Fiscal Years 2021-2025,* which outlines its objectives for the next four years: improve the decision makers' ability to use data and tools to optimize research investments; and develop and disseminate metrics and standards to inform best practices for portfolio analysis and science of science research. By pursuing its Plan, the OPA will continue to advance new analytical tools, develop partnerships across NIH, and drive innovations in science of science methodologies.

An important aspect of ensuring proper stewardship of federal research funding is maintaining the quality and availability of scientific results and information. In 2020, the OSP released the NIH Data Management & Sharing Policy, which will go into effect in January 2023.[62] The Policy aims to achieve a cultural shift across the biomedical research enterprise by establishing data management and sharing as standard practices for NIH-supported research that should be planned for as an integral part of the research process. The Policy will apply to all NIH-supported research, regardless of funding level, and will require submission of a Data Management and Sharing Plan to NIH, as well as compliance with that plan. Promoting greater data sharing will ultimately help to advance the rigor and reproducibility of NIH-supported research by sharing data needed to validate and replicate research findings, provide opportunities for new research and collaborations, and promote trust in NIH-supported research by increasing transparency and demonstrating good stewardship of taxpayer funds. NIH's ongoing implementation efforts aim to catalyze these critical opportunities across biomedical and public health research while supporting a smooth transition for funded investigators.

[62] grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

Enhancing Rigor, Reproducibility, and Transparency in Research

Responsible for setting NIH-wide policies on the responsible conduct of research, OD upholds the highest principles for the appropriate use of research results and findings from studies involving human participants. In response to stakeholder feedback, OSP will identify and share best practices for developing informed consent language to support the sharing of data and biospecimens derived from human participants. To begin, OSP released sample language and points to consider when developing informed consents for studies that include data and biospecimen sharing and invited public input on the language and any potential gaps through an RFI.[63] Following receipt of input, the NIH will update the sample informed consent language and points to consider and publish it for voluntary use by investigators and Institutional Review Boards (IRBs). Charged by the NIH Director, OSP has launched the Clinical Trial Stewardship Task Force to revisit a series of policies released in 2016 and ensure stewardship efforts continue to support a robust clinical trials enterprise capable of accelerating the translation of biomedical discoveries into improvements in health. The Task Force will assess NIH's progress toward clinical trial stewardship reform and identify areas in which additional focus may be needed. The Task Force will further the agency's clinical trial stewardship and ultimately issue findings and recommend strategies for future reform efforts.

The effective application of scientific research into clinical and public health practices requires rigorous study design and conduct of experiments, the ability to reproduce research results, and transparency around research methodologies and data analysis. Several NIH-wide efforts are dedicated to establishing and aligning goals, policies, and activities in support of rigorous and reproducible research across biomedical organizations. The OD maintains the Research Methods Resources website, which provides investigators with information on experimental design and analysis for both human and animal studies in basic and applied research.[64] The OD also convened the ACD Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research (WG) to identify opportunities to apply these principles in research involving animal models.[65] The WG presented its final recommendations to the NIH Director in June 2021.[66] The broad recommendations aim to: 1) improve study design and analytic rigor; 2) address bias, incomplete reporting, and questionable research practices; 3) improve relevance and use of animal models; 4) improve methodologic results reporting; and 5) measure and evaluate effectiveness and cost of animal research. The NIH, led by OER, OSP, and ORIP, will now consider best approaches to implement these recommendations across the agency.

Protecting United States Biomedical Intellectual Innovation

NIH research is built on bedrock principles of scientific excellence, unassailable integrity, and fair competition. The NIH expects applicants for and recipients of funding — both domestic and foreign — to abide by these principles. It is critical for NIH-supported institutions and their researchers to be wholly transparent about financial support from and affiliations with international institutions. Such transparency ensures that the NIH's funding decisions are fair and appropriate, and that U.S. institutions and the public benefit from their investment in biomedical research.

[63] grants.nih.gov/grants/guide/notice-files/NOT-OD-21-131.html
[64] researchmethodsresources.nih.gov/
[65] acd.od.nih.gov/working-groups/eprar.html
[66] acd.od.nih.gov/documents/presentations/06112021_ACD_WorkingGroup_FinalReport.pdf

The NIH has implemented recommendations put forward by the ACD Working Group for Foreign Influences on Research Integrity to address concerns about research integrity.[67] The OER works closely with its federal partners, such as the Department of Justice, and White House Office of Science and Technology Policy, to continue developing and implementing strategies that address foreign government interference on intellectual property from NIH-funded extramural research. OER also highlights relevant disclosure policies and describes actions institutions and investigators can take to address undue foreign government interference in NIH-supported research on its Protecting U.S. Biomedical Intellectual Innovation website.[68] Since June 2018, the NIH has identified 540 scientists of possible concern, and has reached out to more than 95 institutions regarding 222 of these scientists. Five cases have led to criminal actions and two civil settlements totalling $6.6 million.

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

The OD serves as the central office of the NIH and as such is responsible for providing infrastructure and resources to its ICOs. To support the NIH mission, the OD endeavors to streamline operations and enhance efficiency and to transform culture, improve and maintain critical resources, and increase transparency across the agency.

Learning and Recovering from the COVID-19 Pandemic

With the onset of the COVID-19 pandemic in the United States, the NIH was able to rapidly and effectively adapt ongoing activities to keep staff, trainees, and contractors safe. This transition included new safety policies and resources for on-site workers and a transition to work from home for many staff, contractors, and trainees. The NIH has developed a dynamic Framework for the Return to Physical Workspaces, which outlines procedures to support the NIH mission and prioritize time sensitive research, patient care responsibilities, and other critical onsite functions while preparing for a safe return to work. The Office of Human Resources has worked closely with the White House Office of Management and Budget, Office of Personnel Management, and HHS to develop the plan and provide data-driven guidance to NIH leadership and staff.

The Office of Research Services (ORS) led a pilot at NIH's Rocky Mountain Laboratories Montana campus, which showed that fully vaccinated staff could safely return to work using masks and other mitigation measures. The Office of Research Facilities (ORF) developed a Standard Operating Procedure for tracking COVID-19 exposed rooms and their remediation status. With this system, OD has managed over 84 SARS-CoV-2 exposures and disinfected over 3,256 rooms since the beginning of the pandemic. In one specifically critical operation, ORF collaborated with the Coast Guard National Strike Force, NIAID, and ORS Division of Occupational Health and Safety to deploy Vaporized Hydrogen Peroxide to neutralize residual virus rapidly and effectively, thus enabling research staff to safely return to work within a few days of the exposure. Within OD, the Division of Logistics Services (DLS) established reliable supply chains for personal protective equipment, medical supplies, and cleaning products to support uninterrupted scientific research, SARS-CoV-2 screening, and clinical care. By

[67] acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf
[68] grants.nih.gov/policy/protecting-innovation.htm

consolidating the demand for supplies and utilizing strategic sourcing methodologies, DLS has become the preferred supply source going forward. These efforts are designed to improve the safety of NIH campuses and inform evidence-based decision-making to ensure staff are able to return to work safely.

A critical part of the safe return to the physical workspace will be widespread uptake of the COVID-19 vaccine. The ORS, in partnership with the NIH Clinical Center, National Institute of Environmental Health Sciences (NIEHS), and the Public Health Service, established a process for staff to receive COVID-19 vaccines and boosters at the Bethesda campus, Research Triangle Park, and Rocky Mountain Laboratories. Between December 2020 and August 2021, the NIH Vaccination Clinic provided 32,190 doses to 16,213 NIH staff members. Five-hundred twenty-four employees with federal partners, including those deploying to the border in support of the HHS Unaccompanied Minors response, were also able to receive vaccines at NIH. OHR regularly monitors and adapts agency guidance and policies governing employee safety at NIH, including support for the development of a mandatory COVID-19 vaccination program. NIH staff are now able to voluntarily notify NIH of receiving a vaccination in the community to ensure compliance with the Safer Federal Workforce Task Force Vaccination Guidelines for Federal Employees and the HHS Vaccination Mandate for staff that work with patients.

Looking ahead, the OD is leading NIH-wide efforts to prepare for maintaining operations after the COVID-19 pandemic. The Strategic Administrative Management Advisory Committee (SAMAC) formed teams of over 120 volunteers from across NIH to develop guidelines for the NIH Future of Work. These teams are charged with considering the specific needs of communities and programs at NIH and developing NIH-wide guidelines for the future of work that reflect new and emerging realities due to the COVID-19 pandemic. Their foci cover a broad topic range including remote work policies, leverageable communication technologies, and telemedicine for clinical trials. SAMAC is working closely with OD offices to ensure consistency and transparency throughout this process. The Office of Financial Management has streamlined and automated processes for payments and invoicing, which have dramatically increased efficiencies and accountability, while supporting NIH biomedical research programs and meeting new financial needs caused by the pandemic. OHR is identifying new best practices for telework, remote work, and workforce scheduling flexibilities to continue to recruit and retain the top scientific, administrative, and executive talent, including addressing any emerging fields needed to support the future of work and maintain employee and patient safety at the NIH during the pandemic and beyond.

The COVID-19 pandemic required many NIH policies to change in response to shifting needs and research capacities across the country. While many of these policy changes are temporary, several of these changes have established new practices and approaches that enable the NIH to achieve its mission of fostering innovative research in support of human health more effectively. To capture these new approaches, ICOs across NIH are conducting formal evaluations of pandemic policies to determine their effectiveness, prepare for future public health emergencies, and identify new policies for the future of biomedical research. An intra-action review to capture the overarching strengths, challenges, and lessons learned from the NIH's COVID-19 response is now ongoing, led by the OD with collaboration from many ICs. This effort will capture changes to workforce capacity and flexibilities, infrastructure, scientific communications, and mission-

driven operations at the NIH. With actionable recommendations following the review, the OD will lead efforts to implement the best practices learned during the COVID-19 response.

Budget Policy: The FY 2023 President's Budget estimate for OD operations is $402.6 million, an increase of $29.4 million or 7.9 percent compared with the FY 2022 CR level. In FY 2023, funding will be used to provide common infrastructure and resources for NIH ICOs, such as continued adaption to the evolving COVID-19 pandemic, the return to on-site facilities and services for NIH staff, and IT equipment and security.

Building on Evidence to Advance the Mission and Improve Decision-Making

In July 2021, the NIH released the *NIH Wide Strategic Plan for Fiscal Years 2021-2025*.[69] The Strategic Plan summarizes NIH's approach to advancing its mission and fulfilling the requirements of the 21st Century Cures Act. The development of the Plan was led and coordinated by the OD, through collaboration between NIH leadership and IC staff and key stakeholders, including the research community, professional societies, advocacy groups, and the public. Included in the Plan is NIH's vision for the direction, capacity, and stewardship of biomedical research and its highest priorities for the next five years. The Plan also serves as an overarching document for the individual strategic plans of the NIH ICOs which address specific, congressionally mandated missions and goals. In developing the Plan, NIH adopted a transparent approach focused on science and good stewardship of research and guided by evidence.

In 2019, the OD launched the OD-Strategic Engagement Agenda (OD-SEA) to improve efficiency and coordination across the OD and enhance communication and collaboration between the OD and the ICOs. A critical goal of the OD-SEA is to improve engagement and strengthen NIH-wide relationships to enable future initiatives and operations with greater efficiency. Within the last year, the OD-SEA has built on early assessments of the OD IT landscape, processes, and existing challenges to inform new policies related to IT equipment procurement and services. The OD has also begun to establish an OD IT Project Management Office to oversee IT-related governance and management of IT systems within the OD. The OD IT PMO will reduce duplication of IT efforts across OD, encourage resource sharing, unify the OD IT infrastructure, and minimize cybersecurity risks. The OD-SEA has also led the implementation of new administrative processes which aim to streamline approval processes, relegate authorities, and centralize tracking and reporting processes to better maintain administrative data. The new processes, as well as many existing processes, will be automated and standardized in a new administrative platform called OD-ENGAGE. OD-ENGAGE will enable real-time reporting and tracking of approvals and business decisions to support more efficient and modern operations. Together, the policies and tools developed by the OD-SEA will improve coordination within OD and facilitate better coordination with ICOs and external stakeholders.

[69] nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	$2,829,985,000	$2,700,813,000	$2,532,710,000
Rescission				$0
2023[1]	$2,733,665,000			

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

Authorizing Legislation

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2022 Amount Authorized	FY 2022 CR	2023 Amount Authorized	FY 2023 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,519,400,600	Indefinite	$2,728,665,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,519,400,600		$2,728,665,000

NATIONAL INSTITUTES OF HEALTH
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Amounts Available for Obligation[1,2]

(Dollars in Thousands)

Source of Funding	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation[3]	$2,532,710	$2,532,710	$2,733,665
Fund balance limitation for 10-Year Pediatric Research Initiative Fund	0	-8,309	0
Secretary's Transfer	-7,262	0	0
Transfer to HHS Office of the Inspector General	-5,000	-5,000	-5,000
Subtotal, adjusted appropriation	$2,520,448	$2,519,401	$2,728,665
OAR HIV/AIDS Transfers	1,157	0	0
Subtotal, adjusted budget authority	$2,521,605	$2,519,401	$2,728,665
Unobligated balance, start of year	63,343	75,945	
Unobligated balance, end of year (carryover)[4]	-75,945	0	0
Subtotal, adjusted budget authority	$2,509,003	$2,595,345	$2,728,665
Unobligated balance lapsing	-173	0	0
Total obligations	$2,508,830	$2,595,345	$2,728,665

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2021 - $84,556 FY 2022 - $101,000 FY 2023 - $103,000

[2] Includes $109.0 million in FY 2021, $109.0 million in FY 2022, and $419.0 million in FY 2023 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

[3] Amounts may not add due to rounding.

[4] Reflects funds from the NIH Innovation Account not obligated in FY 2021 and available for obligation in FY 2022.

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Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022 CR
Total compensable workyears:				
	Full-time equivalent	1,087	1,162	75
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$202	$212	$9
	Average GM/GS grade	13.1	13.1	0.0
	Average GM/GS salary	$130	$136	$6
	Average salary, Commissioned Corps (42 U.S.C. 207)	$134	$140	$6
	Average salary of ungraded positions	$197	$204	$7
	OBJECT CLASSES	**FY 2022 CR**	**FY 2023 President's Budget**	**FY 2023 +/- FY 2022**
	Personnel Compensation			
11.1	Full-Time Permanent	108,105	118,608	10,503
11.3	Other Than Full-Time Permanent	15,598	17,127	1,529
11.5	Other Personnel Compensation	4,538	4,865	327
11.7	Military Personnel	1,449	1,819	369
11.8	Special Personnel Services Payments	1,771	1,838	66
11.9	**Subtotal Personnel Compensation**	**$131,462**	**$144,256**	**$12,794**
12.1	Civilian Personnel Benefits	49,785	54,639	4,854
12.2	Military Personnel Benefits	1,012	1,275	263
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$182,259**	**$200,170**	**$17,911**
21.0	Travel & Transportation of Persons	48	49	1
22.0	Transportation of Things	861	880	19
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	374	382	8
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	105,016	111,664	6,648
25.2	Other Services	144,499	152,640	8,141
25.3	Purchase of Goods and Services from Government Accounts	137,731	131,769	-5,962
25.4	Operation & Maintenance of Facilities	2,707	2,766	60
25.5	R&D Contracts	41,860	64,075	22,215
25.6	Medical Care	55	57	2
25.7	Operation & Maintenance of Equipment	3,260	3,332	72
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$435,128**	**$466,303**	**$31,176**
26.0	Supplies & Materials	9,923	10,141	218
31.0	Equipment	5,407	5,526	119
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,885,399	2,045,213	159,813
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	2	2	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$2,337,142**	**$2,528,495**	**$191,353**
	Total Budget Authority by Object Class	**$2,519,401**	**$2,728,665**	**$209,264**

[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 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022 CR
Personnel Compensation			
Full-Time Permanent (11.1)	$108,105	$118,608	$10,503
Other Than Full-Time Permanent (11.3)	$15,598	$17,127	$1,529
Other Personnel Compensation (11.5)	$4,538	$4,865	$327
Military Personnel (11.7)	$1,449	$1,819	$369
Special Personnel Services Payments (11.8)	$1,771	$1,838	$66
Subtotal Personnel Compensation (11.9)	**$131,462**	**$144,256**	**$12,794**
Civilian Personnel Benefits (12.1)	$49,785	$54,639	$4,854
Military Personnel Benefits (12.2)	$1,012	$1,275	$263
Benefits to Former Personnel (13.0)	$0	$0	$0
Subtotal Pay Costs	**$182,259**	**$200,170**	**$17,911**
Travel & Transportation of Persons (21.0)	$48	$49	$1
Transportation of Things (22.0)	$861	$880	$19
Rental Payments to Others (23.2)	$0	$0	$0
Communications, Utilities & Misc. Charges (23.3)	$374	$382	$8
Printing & Reproduction (24.0)	$0	$0	$0
Other Contractual Services:	$0	$0	$0
Consultant Services (25.1)	$89,495	$87,214	-$2,282
Other Services (25.2)	$144,499	$152,640	$8,141
Purchases from Government Accounts (25.3)	$110,386	$101,943	-$8,443
Operation & Maintenance of Facilities (25.4)	$2,707	$2,766	$60
Operation & Maintenance of Equipment (25.7)	$3,260	$3,332	$72
Subsistence & Support of Persons (25.8)	$0	$0	$0
Subtotal Other Contractual Services	**$350,347**	**$347,895**	**-$2,453**
Supplies & Materials (26.0)	$9,923	$10,141	$218
Subtotal Non-Pay Costs	**$361,553**	**$359,346**	**-$2,207**
Total Administrative Costs	**$543,812**	**$559,516**	**$15,704**

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2021 Final			FY 2022 CR			FY 2023 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	914	8	922	1,027	14	1,041	1,099	17	1,116
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	914	8	922	1,027	14	1,041	1,099	17	1,116
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	46	-	46	46	-	46	46	-	46
Total:	46	-	46	46	-	46	46	-	46
Total	960	8	968	1,073	14	1,087	1,145	17	1,162
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**								
2019	13.1								
2020	13.1								
2021	13.2								
2022	13.1								
2023	13.1								

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Positions[1]

GRADE	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Total, ES Positions	11	15	17
Total, ES Salary	2,160,922	3,035,695	3,598,721
General Schedule			
GM/GS-15	173	192	209
GM/GS-14	232	245	263
GM/GS-13	315	345	343
GS-12	134	149	166
GS-11	53	63	68
GS-10	0	0	0
GS-9	18	27	32
GS-8	2	2	2
GS-7	7	7	9
GS-6	1	1	1
GS-5	2	2	2
GS-4	3	3	3
GS-3	0	0	0
GS-2	1	1	1
GS-1	1	1	1
Subtotal	942	1,038	1,100
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	1	1	1
Director Grade	3	5	6
Senior Grade	2	4	5
Full Grade	1	3	4
Senior Assistant Grade	0	1	1
Assistant Grade	0	0	0
Subtotal	7	14	17
Ungraded	79	84	89
Total permanent positions	904	1,025	1,097
Total positions, end of year	1,039	1,151	1,223
Total full-time equivalent (FTE) employment, end of year	968	1,087	1,162
Average ES salary	196,447	202,380	211,689
Average GM/GS grade	13.2	13.1	13.1
Average GM/GS salary	126,377	130,194	136,183

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