Office of the Director

CONGRESSIONAL JUSTIFICATION
FY 2024

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)

FY 2024 Budget Table of Contents

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General Notes

1. FY 2023 Enacted levels cited in this document include the effects of the FY 2023 HIV/AIDS transfer, as shown in the Amounts Available for Obligation table.
2. Tables in this document do not include supplemental funding, other than the Appropriations History table.
3. Detail in this document may not sum to the subtotals and totals due to rounding.

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Director's Overview

The National Institutes of Health (NIH) Office of the Director (OD) is responsible for the research mission, policies, and administration of the agency. The OD leads and supports NIH-wide initiatives in close partnership with NIH Institutes, Centers, and Offices (ICOs) and their constituents. The OD strives toward making scientific discovery possible and establishes and coordinates NIH-wide strategic priorities and services, providing guidance and resources to lead efforts on behalf of the agency, and to foster collaboration across agency activities.

To support the NIH mission, the OD endeavors to streamline operations, enhance efficiency, transform culture, improve and maintain critical resources and infrastructure, drive scientific research and discovery through integrity and oversight, effect system-wide change, and increase transparency across the agency.

Lawrence A. Tabak, D.D.S., Ph.D. is performing the duties of the NIH Director.

NIH seeks to continually optimize operations across a diverse array of business, administrative, and scientific functions as well as improve the physical and technological infrastructures supporting enterprise-wide operations. In keeping with organizational stewardship, the OD will continue to invest efficiently and effectively in a wide range of basic, translational, and clinical research that builds a strong foundation to overcome scientific challenges in our ever-changing world. The OD holds a unique leadership position that oversees an extensive variety of NIH-wide initiatives that continue to address the nation's most challenging and debilitating health issues through innovative, collaborative, and culturally respectful scientific research that reflects the American population.

Modernizing NIH's Data Ecosystem

NIH envisions a modernized, integrated biomedical data ecosystem, as outlined in its Strategic Plan for Data Science, with the goal of ensuring NIH-funded data is Findable, Accessible, Interoperable, and Reusable (FAIR).[1] A central theme of the Strategic Plan is to enhance responsible data sharing and access to data collected with NIH funding. To this end, the NIH Office of Data Science Strategy (ODSS) catalyzes and provides leadership, strategic guidance, and coordination for NIH-wide data activities.[2] These activities include advancing initiatives that address storage, management, and integration of diverse data to establish a modern and integrated biomedical data ecosystem; establishing partnerships with communities, academic societies, and international partners to promote education, adoption, and implementation of FAIR practices through collaborative projects, workshops, and other activities; and advancing coordination of activities associated with adoption of FAIR data principles that would enable better sharing, discovery, and secondary use of NIH-funded data.

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

In FY 2022, ODSS invested $15 million to enable NIH data repositories to reach maturity and align with the White House Office of Science and Technology Policy (OSTP) Desired Characteristics for a Data Repository, improve the artificial intelligence (AI)-readiness of existing NIH data, establish a DataCite partnership, and enhance researcher training to develop data management in a responsible and ethical manner.[3] Joining the DataCite consortium provides NIH-funded data resources the ability to streamline and easily develop digital object identifiers (DOIs). These DOIs are persistent identifiers that ensure data preservation, enable data citations, and serve as a measure for data reuse. This is important in the context of the new Data Management and Sharing (DMS) Policy and its implementation to enhance discoverability and access of NIH-funded data.[4]

ODSS' partnership with the Data Curation Network also led to the launch of a series of data curation training events.[5] Additional funds helped establish the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative's CloudLab, a platform for learning and exploration of data and analysis. CloudLab primarily provides training opportunities for under-resourced researchers and institutions.[6, 7] Other examples of program initiatives include funding opportunities to support: data repositories and knowledgebases; the NIH data ecosystem Generalist Repository Ecosystem Initiative (GREI); and enabling the adoption and contributions to the Research Data Management Toolkit and the FAIR Cookbook.[8, 9] These efforts are examples of NIH ODSS' commitment to the OSTP's new policy guidance to responsibly empower equitable access to federally-funded research data.[10]

ODSS oversees the development and implementation of the COVID Rapid Acceleration of Diagnostics (RADx®) Data Hub for the RADx initiative.[11] NIH launched the RADx initiative in 2020 to accelerate innovation in the development, commercialization, and implementation of technologies for SARS-CoV-2 testing. The RADx initiative now spans four major programs: RADx Tech, RADx Underserved Populations (RADx-UP), RADx Radical (RADx-rad), and RADx Advanced Technology Platforms (RADx-ATP), with additional efforts on at-home and improved accessibility of tests. A $70 million effort, the COVID RADx Data Hub will provide de-identified data from 197 RADx studies across the 4 RADx programs by coordinating, managing, and providing researchers with workspaces and analytic tools for data analyses to address scientific and public health questions about SARS-CoV-2 and COVID-19. NIH recognized that the COVID RADx Data Hub, launched in FY 2023, did not meet cultural, governance, and sovereignty needs and expectations to support and share de-identified American Indian and Alaska Native (AI/AN) RADx research data. In response, NIH developed an emergency cooperative agreement funding opportunity to provide expedited support for a RADx

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[3] www.whitehouse.gov/wp-content/uploads/2022/05/05-2022-Desirable-Characteristics-of-Data-Repositories.pdf
[4] sharing.nih.gov/data-management-and-sharing-policy
[5] datascience.nih.gov/data-curation-network-event-series
[6] datascience.nih.gov/data-curation-network-event-series
[7] cloud.nih.gov/resources/cloudlab/
[8] rdmkit.elixir-europe.org/
[9] faircookbook.elixir-europe.org/content/home.html
[10] www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf
[11] radx-hub.nih.gov/home

Tribal Data Repository.[12] The NIH expects to make one award (totaling $12 million) for the first sovereignty-based, tribally governed and directed research data repository that will provide responsible data sharing and access to researchers and their collaborators who are generating or interested in working with RADx AI/AN research data. These investments will also lead to a better understanding and development of diagnostics, technologies, and treatments for COVID-19 for all people.

In FY 2024, NIH plans to increase support for strategic data services such as the NIH Research Auth Service,[13] data search tools, and innovative uses of community standards and tools. These efforts are aligned with the new OSTP policy guidance regarding equitable access to federally funded research. Continued support will ensure that ODSS efforts to enhance platform interoperability and protect data security through authorization and authentication are successful in advancing data access and reuse.

Supporting Safe and Respectful Work Environments

NIH has long prioritized supporting a safe and respectful workplace, free from harassment and discrimination, wherever NIH-funded research is conducted. Towards this end, and in response to a 2018 National Academies report and recommendations from the NIH Advisory Committee to the Director (ACD), NIH implemented a number of changes aimed at ending harassment in all its forms – within the agency's workforce, and at the institutions it funds.[14, 15] These efforts focused on three primary areas: 1) demonstrating accountability and transparency, 2) clarifying NIH's expectations that funded institutions ensure a safe workplace free of harassment, and 3) establishing clear channels of communication to NIH for reporting. As part of these efforts, OD created a dedicated phone line and web form that allows for anybody in the biomedical research community to share directly with NIH – anonymously, if desired – information related to a potential case of sexual harassment or other inappropriate behavior.[16] For transparency and accountability, the agency also reports aggregate numbers and outcomes of allegations NIH has received involving projects at NIH-supported institutions since January 2018, with the data updated regularly.[17]

NIH implemented a general provision in the 2022 Consolidated Appropriations Act (P.L. 117-103) that mandates the NIH Director to require NIH-funded institutions to report to the NIH "when individuals identified as principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions."[18] This provision not only enables mandatory reporting to NIH of removals and disciplinary actions, but it also ensures that NIH is notified when the reason for the actions is related to harassment. This is a major step in

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[12] grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-011.html
[13] datascience.nih.gov/researcher-auth-service-initiative
[14] nap.nationalacademies.org/catalog/24994/sexual-harassment-of-women-climate-culture-and-consequences-in-academic
[15] acd.od.nih.gov/documents/presentations/12122019ChangingCulture_Report.pdf
[16] nexus.od.nih.gov/all/2019/06/14/how-to-notify-nih-about-a-concern-that-sexual-harassment-is-affecting-an-nih-funded-activity-at-a-grantee-institution/
[17] grants.nih.gov/grants/policy/harassment/data
[18] www.congress.gov/bill/117th-congress/house-bill/2471/text

ensuring the safety for all involved in NIH-supported research. As Dr. Lawrence Tabak, who performs the duties of the NIH Director, wrote "Wherever NIH research activities take place, our priority will always be to do what we can to eliminate harassment and ensure that the integrity of scientific endeavor is never compromised by the fundamental injustice of workplace harassment."

In addition, OD established the NIH-wide UNITE initiative in 2021 to identify and address structural racism within the biomedical research enterprise, as well as bolster the efforts of the NIH ICOs for improving diversity, equity, inclusion, and accessibility (DEIA).[19] Guided by five committees consisting of staff from across all NIH ICOs, UNITE is committed to ending racial inequities in the greater scientific community via strategic, short- and long-term actions and funding initiatives that will result in significant, lasting change. The UNITE initiative focuses on three primary areas: (1) research on health disparities, minority health, and health equity; (2) the internal NIH workforce, and (3) the external biomedical research workforce, such that these areas intersect and enable greater transparency, accountability, and communications across NIH and the biomedical research community.

Understanding Long-Term COVID-19 Symptoms and Enhancing Recovery

In the third year of the COVID-19 pandemic, our nation and the world are more prepared with tools – like vaccines and treatments – to protect ourselves and our communities from severe illness associated with the virus SARS-CoV-2 and its variants. Most restrictions to mitigate the spread of the virus have lifted, and society is trying to get back to "normal." Potentially for millions of people globally, there is no getting back to "normal" just yet. They are still living with the long-term effects of COVID-19, commonly known as Long COVID, and continue to experience debilitating fatigue, shortness of breath, pain, difficulty sleeping, racing heart rate, exercise intolerance, gastrointestinal and other symptoms, as well as cognitive problems that make it difficult to perform daily activities.[20]

For the past two years, NIH's National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Neurological Disorders and Stroke (NINDS) in coordination with the OD, have been leading NIH's Researching COVID to Enhance Recovery (RECOVER) initiative, a national research program to better understand post-acute sequelae of COVID-19 (PASC), commonly referred to as Long COVID.[21] The initiative studies key topics such as the lingering effects of COVID-19, why new symptoms may develop, and the impact of SARS-CoV-2 infection on other diseases and conditions. Establishing fundamental knowledge will help to determine the underlying biologic basis of Long COVID, identify those at risk for Long COVID, and elucidate therapies to prevent or treat the condition. Those experiencing Long COVID report varying symptoms, making it unlikely that a single therapy will work for everyone, underscoring the need to pursue multiple therapeutic strategies.

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[19] www.nih.gov/ending-structural-racism/unite
[20] covid19.nih.gov/covid-19-topics/long-covid
[21] recovercovid.org/

RECOVER investigators are recruiting more than 17,000 adults (including pregnant people) and more than 18,000 children at hundreds of enrolling sites across the country to take part in cohort studies. An autopsy research cohort may also provide further insight on how COVID-19 affects the body's organs and tissues. In addition, researchers plan to analyze electronic health records from millions of people to better understand how Long COVID and its symptoms change over time. The RECOVER initiative is also utilizing common research protocols, developed with input from patients and advocates, across all the study sites. These protocols allow for consistent data collection, improve data sharing, and accelerate the pace of research. People suffering from Long COVID and their advocates have been and continue to be partners in the RECOVER initiative from its inception, contributing important perspectives and valuable input in the master protocols and research plans.

RECOVER established the National Community Engagement Group to ensure it meets the needs of all people affected by Long COVID. The RECOVER Patient and Community Engagement Strategy outlines all the strategies that RECOVER is using to engage with and gather input from individuals impacted by Long COVID.[22] NIH recently awarded more than 40 administrative supplements to improve understanding of the underlying biology and pathology of Long COVID. The RECOVER initiative will soon announce clinical trials, leveraging data from clinicians and patients in which researchers identified symptom clusters that can be targeted to test various interventions.[23] These trials aim to investigate therapies that are indicated for other non-COVID conditions and novel treatments for Long COVID. Through extensive collaborations across multiple NIH ICOs that contribute to the RECOVER effort, our goal is to have critical answers that will help us to recognize the full range of health outcomes and needs resulting from PASC and, ultimately, enable many people to make a full recovery from COVID-19. We are indebted to the over 10,000 participants who have already enrolled in a registry for RECOVER. Their contributions and the tireless efforts of the RECOVER investigators offer hope for the future to the millions still suffering from Long COVID.

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[22] recovercovid.org/docs/RECOVEREngagementStrategy.pdf
[23] recovercovid.org/pathobiology

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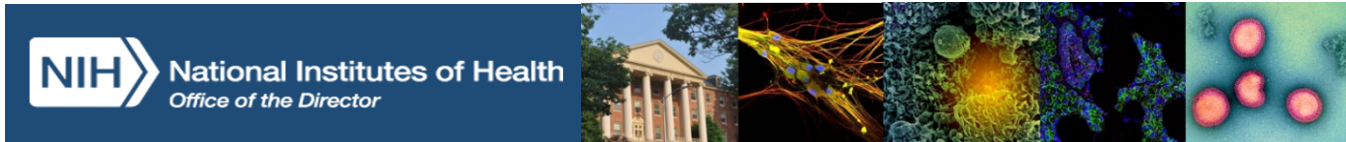
Mission of the Office of the Director

The National Institutes of Health (NIH) Office of the Director (OD) is responsible for the research mission, policies, and administration of the agency. OD leads and supports NIH-wide initiatives in close partnership with NIH Institutes, Centers, and Offices (ICOs) and their constituents. OD strives to make scientific discovery possible and establishes and coordinates NIH-wide strategic priorities and services, providing guidance and resources to lead efforts on behalf of the agency, and to foster collaboration across agency activities.

OD plays a vital role in shaping the agency's overarching agenda and is responsible for seeking input from and working with a wide range of collaborators, including the scientific community, the public, other federal agencies, and Congress. OD also provides leadership and support for many NIH-wide initiatives coordinated across ICOs to solve some of the nation's most challenging and debilitating health issues through innovative, collaborative, and culturally respectful scientific research that reflects the American population.

Lawrence A. Tabak, D.D.S., Ph.D. is performing the duties of the NIH Director.

Highlights from the Office of the Director

- **OD Action Plan.** The OD Action plan established a set of shared goals to move to a One OD focus. The goals outlined in the plan will advance through coordinated efforts, motivation, shared resources, and teamwork. The goals include: strengthening One OD; accelerating OD's role as a leader in diversity, equity, inclusion, and accessibility (DEIA) efforts; embracing new tools and technologies to improve capabilities; and providing for the needs of the workforce.

- **Data Management and Sharing**. NIH has developed supplemental information to the Data Management and Sharing (DMS) Policy to assist researchers in responsible data sharing by establishing 1) operational principles for protecting participants' privacy when sharing scientific data; 2) best practices for implementing these principles; and 3) points to consider for choosing whether to designate scientific data for controlled access.

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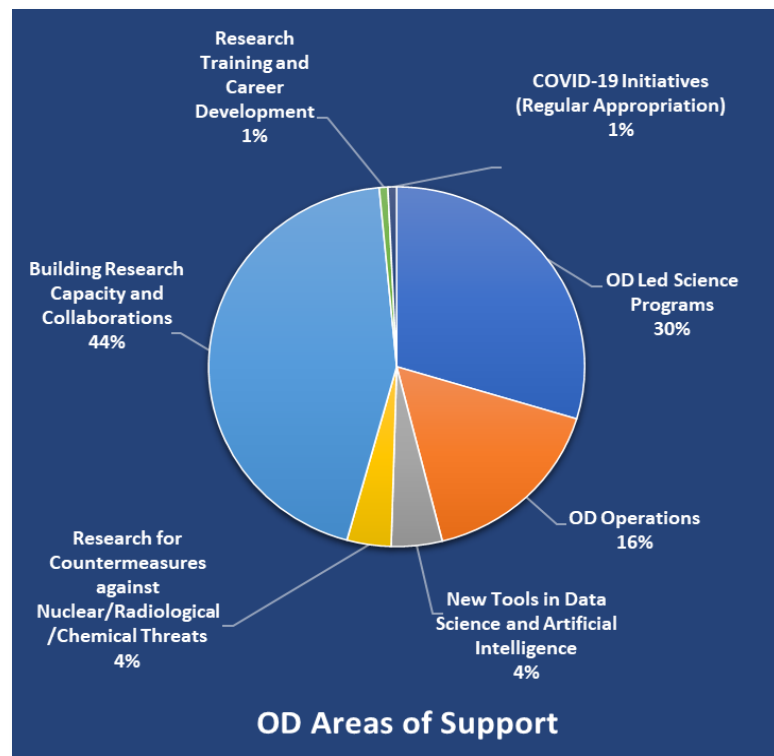
OD Offices: The OD is comprised of a number of scientific, operational, and policy offices that provide resources and tools, program support, and guidance to advance the NIH mission.

Quick OD Facts: In FY 2022, the OD employed 1,059 FTEs and funded over $2.7 billion in scientific research and NIH-wide resources and operations (see chart above for details).
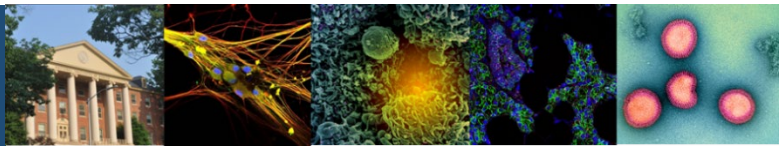
Recent Accomplishments

- **Office of Dietary Supplements (ODS) Strategic Plan.** The strategic planning process for 2022-2026 was a multi-layered process that included program modelling for all ODS programs; priority-setting with staff and key stakeholders; public comment feedback; and NIH/HHS leadership feedback. As a result of the strategic planning process, ODS has reaffirmed its mission and vision statement and added a fifth goal focused on collaboration.

- **Supporting Safe and Respectful Work Environments.** OD implemented several changes aimed at ending harassment in all its forms – within the agency's workforce, and at the institutions it funds. As demonstrated by the 2022 OD Racial and Ethnic Equity Plan (REEP), OD remain committed to enhancing awareness and understanding of equity, diversity, inclusion, accessibility, and civility among OD employees; establishing and maintaining a diverse workforce; and cultivating and supporting a culture of inclusion, diversity, and respect.

OD FTEs and Funding History
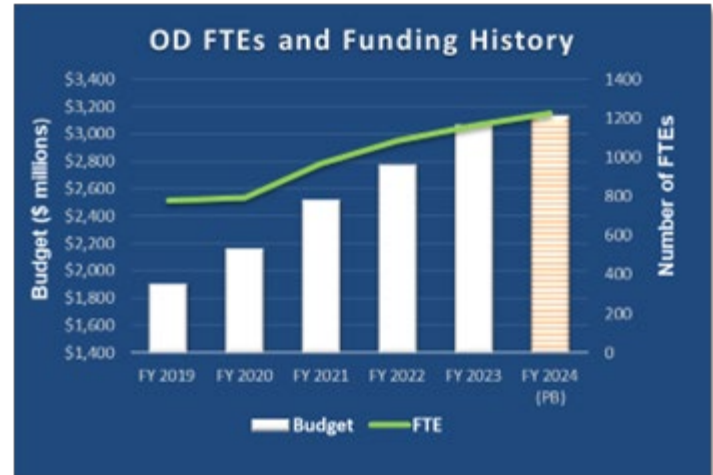
Current Activities

- **Somatic Mosaicism across Human Tissues (SMaHT) Network.** The OD Common Fund-supported research in SMaHT aims to transform our understanding of how somatic mosaicism (variation) in human cells influences health and disease, by supporting analysis of somatic mosaicism in a variety of human tissues and development of novel tools and technologies.

- **NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA).** The Strategic Plan captures activities that NIH will undertake to meet the vision of the Strategic Plan, and will be organized around accomplishments, needs, opportunities, and challenges in addressing DEIA in the NIH workforce, its structure and culture, and the research it supports.

The SMaHT Network will discover how somatic variation contributes to human biology through:

Somatic Variant Discovery
Generating a systematic catalog of human somatic variation from different types of healthy tissues

Technology and Tool Development
Improving our ability to detect and describe somatic variants in small populations of cells

Data Analysis and Organization
Ensuring the somatic variant catalog is accessible, high-quality, and interoperable with other data sets

Future Initiatives

- **Nutrition Research.** The OD Office of Nutrition Research will use increased funding in the FY 2024 request to implement the objectives of the 2020-2030 Strategic Plan for NIH Nutrition Research with the goal of developing specific initiatives, improving coordination, and broadening cross-cutting NIH subject matter expertise in nutrition research. These efforts will support the White House National Strategy on Hunger, Nutrition, and Health, released in September 2022.

- **Building *iSearch* Analytics.** The Office of Portfolio Analysis (OPA) is developing *iSearch* Analytics, a comprehensive portfolio analysis platform that will catalyze the adoption of data-driven decision making. The tool will integrate features of existing OPA tools with enhanced visualization, person disambiguation, and literature expansion to support metascience analytics to improve the accuracy and quality of users' literature and grant searches.

Major Changes in the 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 2024 budget request for OD, which is $67.2 million above the FY 2023 Enacted level for a total of $3,133.4 million.

Office of Nutrition Research (+$120.0 million; total $121.3 million): The FY 2024 budget requests funding to support the objectives of the 2020 – 2030 Strategic Plan for NIH Nutrition Research.

Nonhuman Primate Infrastructure (+$30.0 million; total $30.0 million): The FY 2024 budget request provides funding to implement required updates, repairs, and maintenance to facilities used to house nonhuman primates.

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Budget Mechanism[1,2]
(Dollars in Thousands)

Mechanism	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Grants:								
Research Project		$741,256		$836,205		$901,894		$65,689
Research Centers		$430,182		$475,241		$469,417		-$5,824
Other Research		$890,645		$974,973		$1,025,306		$50,333
Total Research Grants		$2,062,083		$2,286,420		$2,396,617		$110,198
Training		$17,925		$15,686		$11,866		-$3,820
R & D Contracts		$121,522		$150,060		$155,744		$5,685
Intramural Research		$13,327		$6,233		$6,424		$192
Res. Management & Support		$495,538		$527,810		$532,727		$4,917
Construction		$60,940		$80,000		$30,000		-$50,000
Total Other Than Research Grants		$709,251		$779,788		$736,762		-$43,027
Total, OD		$2,772,998		$3,066,208		$3,133,379		$67,171

[1] Of which $150.0 million in FY 2022, $419.0 million in FY 2023, and $235.0 million in FY 2024 is derived by transfer from 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, [$2,642,914,000]
$2,890,779,000: *Provided,* That funding shall be available for the purchase of not to exceed 29
passenger motor vehicles for replacement only: *Provided further*, That all funds credited to the
NIH Management Fund shall remain available for one fiscal year after the fiscal year in which
they are deposited: *Provided further*, That $180,000,000 shall be for the Environmental
Influences on Child Health Outcomes study: *Provided further*, That $722,401,000 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 [$80,000,000] *up to $30,000,000* shall be
used to carry out section 404I of the PHS Act (42 U.S.C. [283K], relating to biomedical and
behavioral research facilities] *283k) with respect to the National Primate Research Centers and
Caribbean Primate Research Center: Provided further*, That $5,000,000 shall be transferred to
and merged with the appropriation for the "Office of Inspector General" for oversight of grant
programs and operations of the NIH, including agency efforts to ensure the integrity of its grant
application evaluation and selection processes, and shall be in addition to funds otherwise made
available for oversight of the NIH: *Provided further*, That the funds provided in the previous

proviso may be transferred from one specified activity to another with 15 days prior [approval of] *notification to* the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years [2023] *2024* and [2024] *2025* no later than 30 days after the date of enactment of this Act: *Provided further*, That amounts made 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[: *Provided further*, That the funds made available under this heading for the Office of Research on Women's Health shall also be available for making grants to serve and promote the interests of women in research, and the Director of such Office may, in making such grants, use the authorities available to NIH Institutes and Centers].

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 the Internal Revenue Code of 1986 (26 U.S.C. 9008), 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. *(Department of Health and Human Services Appropriations Act, 2023.)*

[OFFICE OF THE DIRECTOR]

[(INCLUDING TRANSFER OF FUNDS)]

[For an additional amount for "Office of the Director", $25,000,000, to remain available until September 30, 2024, for necessary expenses directly related to the consequences of Hurricanes Fiona and Ian: *Provided,* That funds appropriated under this heading in this Act may be made

available to restore amounts, either directly or through reimbursement, for obligations incurred for such purposes, prior to the date of enactment of this Act: *Provided further*, That funds appropriated under this heading in this Act may be transferred to the accounts of Institutes and Centers of the National Institutes of Health (NIH): *Provided further*, That this transfer authority is in addition to any other transfer authority available to the NIH.] *(Disaster Relief Supplemental Appropriations Act, 2023.)*

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] *$407,000,000*, to remain available until expended: *Provided*, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further*, That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: *Provided further*, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. *(Department of Health and Human Services Appropriations Act, 2023.)*

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes
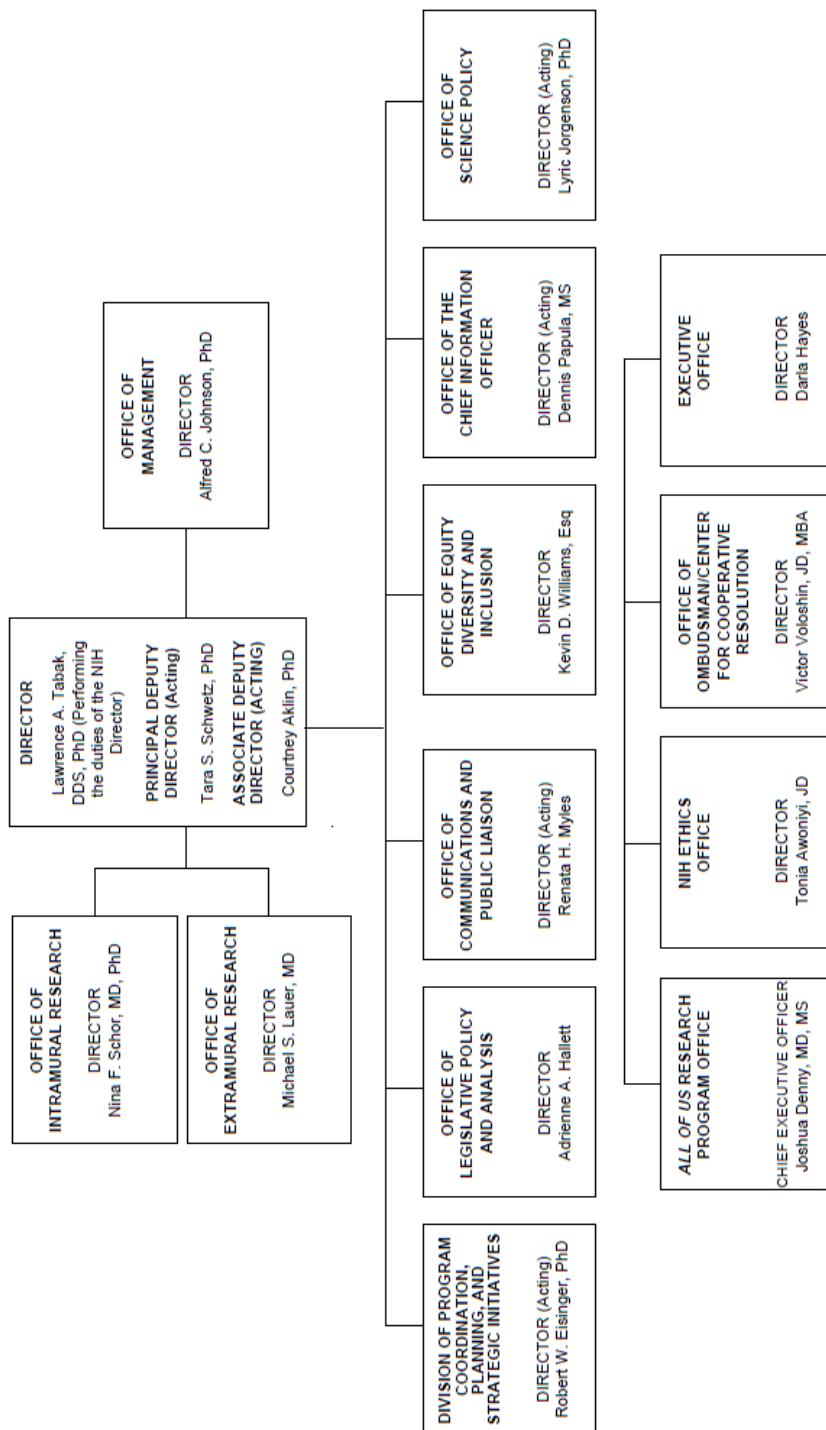
(Dollars in Thousands)

FY 2023 Enacted	$3,066,208
FY 2024 President's Budget	$3,133,379
Net change	$67,171

CHANGES	FY 2023 Enacted FTEs	FY 2023 Enacted Budget Authority	FY 2024 President's Budget FTEs	FY 2024 President's Budget Budget Authority	Built-In Change from FY 2023 Enacted FTEs	Built-In Change from FY 2023 Enacted Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of FY 2023 pay and benefits increase		$4,237		$4,451		$42
b. FY 2024 pay and benefits increase		$4,237		$4,451		$154
c. Paid days adjustment		$4,237		$4,451		$16
d. Differences attributable to change in FTE		$4,237		$4,451		$0
e. Payment for centrally furnished services		$0		$0		$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$1,995		$1,974		$31
Subtotal						$244
2. Research Management and Support:						
a. Annualization of FY 2023 pay and benefits increase		$193,385		$214,420		$2,140
b. FY 2024 pay and benefits increase		$193,385		$214,420		$7,403
c. Paid days adjustment		$193,385		$214,420		$745
d. Differences attributable to change in FTE		$193,385		$214,420		$10,878
e. Payment for centrally furnished services		$0		$0		$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$334,426		$318,307		$7,792
Subtotal						$28,958
Subtotal, Built-in						$29,202

CHANGES	FY 2023 Enacted No.	FY 2023 Enacted Amount	FY 2024 President's Budget No.	FY 2024 President's Budget Amount	Program Change from FY 2023 Enacted No.	Program Change from FY 2023 Enacted Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	393	$434,900	466	$511,097	73	$76,197
b. Competing	415	$388,837	398	$377,914	-17	-$10,923
c. SBIR/STTR	17	$12,469	18	$12,883	1	$414
Subtotal, RPGs	825	$836,205	882	$901,894	57	$65,689
2. Research Centers	165	$475,241	155	$469,417	-10	-$5,824
3. Other Research	506	$974,973	535	$1,025,306	29	$50,333
4. Research Training	417	$15,686	126	$11,866	-291	-$3,820
5. Research and development contracts	10	$150,060	9	$155,744	-1	$5,685
Subtotal, Extramural		$2,452,165		$2,564,228		$112,063
6. Intramural Research	0	$6,233	0	$6,424	0	-$52
7. Research Management and Support	1,162	$527,810	1,225	$532,727	63	-$24,041
8. Construction		$80,000		$30,000		-$50,000
9. Buildings and Facilities		$0		$0		$0
Subtotal, Program	1,162	$3,066,208	1,225	$3,133,379	63	$37,969
Total built-in and program changes						$67,171

OD-16

NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure

DIRECTOR
Lawrence A. Tabak, DDS, PhD (Performing the duties of the NIH Director)

PRINCIPAL DEPUTY DIRECTOR (Acting)
Tara S. Schwetz, PhD

ASSOCIATE DEPUTY DIRECTOR (ACTING)
Courtney Aklin, PhD

OFFICE OF MANAGEMENT
DIRECTOR
Alfred C. Johnson, PhD

OFFICE OF INTRAMURAL RESEARCH
DIRECTOR
Nina F. Schor, MD, PhD

OFFICE OF EXTRAMURAL RESEARCH
DIRECTOR
Michael S. Lauer, MD

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES
DIRECTOR (Acting)
Robert W. Eisinger, PhD

OFFICE OF LEGISLATIVE POLICY AND ANALYSIS
DIRECTOR
Adrienne A. Hallett

OFFICE OF COMMUNICATIONS AND PUBLIC LIAISON
DIRECTOR (Acting)
Renata H. Myles

OFFICE OF EQUITY DIVERSITY AND INCLUSION
DIRECTOR
Kevin D. Williams, Esq

OFFICE OF THE CHIEF INFORMATION OFFICER
DIRECTOR (Acting)
Dennis Papula, MS

OFFICE OF SCIENCE POLICY
DIRECTOR (Acting)
Lyric Jorgenson, PhD

ALL OF US RESEARCH PROGRAM OFFICE
CHIEF EXECUTIVE OFFICER
Joshua Denny, MD, MS

NIH ETHICS OFFICE
DIRECTOR
Tonia Awoniyi, JD

OFFICE OF OMBUDSMAN/CENTER FOR COOPERATIVE RESOLUTION
DIRECTOR
Victor Voloshin, JD, MBA

EXECUTIVE OFFICE
DIRECTOR
Darla Hayes

OD-17

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Activity
(Dollars in Thousands)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
OD Led Science Programs	**807,250**	**822,250**	**822,250**	**0**
INCLUDE Project	75,000	90,000	90,000	0
All of Us Research Program	391,000	122,000	306,000	184,000
All of Us Research Program - Cures	150,000	419,000	235,000	-184,000
BRAIN	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	**120,000**	**135,000**	**135,000**	**0**
Office of Data Science Strategy	70,000	85,000	85,000	0
Artificial Intelligence to Chronic Disease	50,000	50,000	50,000	0
Building Research Capacity and Collaborations	**1,225,252**	**1,316,100**	**1,436,100**	**120,000**
Common Fund	670,001	735,001	735,001	0
Office of Nutrition Research	1,241	1,313	121,313	120,000
Firearm Injury and Mortality Prevention Research	12,500	12,500	12,500	0
Division of Program Coordination, Planning and Strategic Initiatives	541,510	567,285	567,285	0
Research Training and Career Development	**20,213**	**20,427**	**20,427**	**0**
Intramural Loan Repayment and Scholarship	8,800	9,014	9,014	0
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	**104,083**	**105,644**	**105,644**	**0**
OD Operations	**496,200**	**666,787**	**613,958**	**-52,829**
Office of the Chief Scientific Officer for Workforce Diversity (non-add)	*(16,543)*	*(22,462)*	*(22,462)*	*(0)*
Reception and Representation Fund (non-add)	*(10)*	*(10)*	*(10)*	*(0)*
Non-Human Primate Facilities (non-add)	*(0)*	*(0)*	*(30,000)*	*(30,000)*
Biomedical & Behavioral Research Facilities (non-add)	*(70,000)*	*(80,000)*	*(0)*	*-(80,000)*
Total	**$2,772,998**	**$3,066,208**	**$3,133,379**	**$67,171**

Office of the Director

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

Budget Authority (BA):

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
BA	$2,772,998,000	$3,066,208,000	$3,133,379,000	$67,171,000
FTE	1,059	1,162	1,225	63

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

Overall Budget Policy: The FY 2024 President's Budget request for OD is $3,133.4 million, an increase of $67.2 million or 2.2 percent compared with the FY 2023 Enacted level. The request includes $235.0 million from the 21st Century Cures Act, the full authorized level, in support of the *All of Us* program.

The FY 2024 request includes an increase of $120.0 million for the Office of Nutrition Research, to support the White House National Strategy on Hunger, Nutrition, and Health, and to implement the objectives of the 2020-2030 Strategic Plan for NIH Nutrition Research with the goal of developing specific initiatives, improving coordination, and broadening cross-cutting NIH subject matter expertise in nutrition research. Also included in this request is $30.0 million to support the nonhuman primate infrastructure to improve existing facilities used to house nonhuman primates, which require continual updates and maintenance. This level will enable the OD to continue to support diversity, equity, inclusion, and accessibility (DEIA) across biomedical research and bolster scientific integrity and rigor in NIH-funded research. This funding will also support the continuation of critical research, policy, and operational initiatives in support of the NIH mission to advance scientific discovery and improve public health.

Program Descriptions

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

The OD is responsible for overseeing the planning, managing, and coordinating of programs and activities of all the NIH components, including scientific research activities. In addition, the OD provides strategic direction and coordination for key scientific programs.

Continuing the NIH Response to COVID-19
NIH continued a vigorous research response against COVID-19 in FY 2022. As part of this response, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership continues to lead a coordinated clinical research strategy for prioritizing and speeding development of the most promising treatments and vaccine candidates. ACTIV brings NIH together with other operating divisions in HHS, including the U.S. 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 U.S. Department of Defense (DoD) and Department of Veterans Affairs (VA); the European Medicines Agency; and representatives from academia, philanthropic organizations, and biopharmaceutical companies. NIH management of ACTIV clinical trial master protocols for COVID-19 therapeutic interventions continued into 2022.

SARS-CoV-2 continues to mutate wherever there are high rates of viral transmission. As part of ACTIV, the Tracking Resistance and Coronavirus Evolution (TRACE) initiative focuses on identifying emerging variants of SARS-CoV-2. The initiative surveys new viral variants, assesses vaccine and therapeutic resistance, and evaluates the impact of genetic variation on viral biology and on the clinical approaches for preventing and treating illness. ACTIV TRACE aims to prioritize which viral variants should be studied to determine the effectiveness of vaccines and therapeutic candidates in late stages of development against these variants; coordinate data sharing; and confirm testing and periodic public reporting of results to allow confident decision making by the U.S. Government, health professionals, and pharmaceutical organizations. ACTIV TRACE is co-chaired by NIH and private sector experts and facilitated by the Foundation for the National Institutes of Health (FNIH).

As the coronavirus pandemic continues to affect communities across the world, the Environmental influences on Child Health Outcomes (ECHO) Program is committed to protecting the health and safety of its staff and participants while advancing its research mission of enhancing the health of children for generations to come. The ECHO Institutional Developmental Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN) launched the Improving COVID-19 Vaccine Uptake Using mHEALTH Tools (MoVeUP) study to explore parental attitudes about the COVID-19 vaccine and test the effectiveness of a mobile app to help parents learn more about the vaccine for children. The study involved parent focus groups and individual interviews to assess the factors that influence COVID-19 pediatric vaccination decision making. Data from the focus groups and interviews informed development of a mobile health app to help parents learn and decide about vaccinating their children against COVID-19. The ISPCTN is testing this mobile app for its impact on pediatric COVID-19 vaccine uptake. This study includes a focus on participants from rural and underrepresented racial and ethnic communities, which have experienced disproportionately lower vaccination rates and greater hardships due to the COVID-19 pandemic.

Modernizing the Conduct and Impact of Clinical Trials

Increasing representation in research participants
The NIH Office of Extramural Research (OER) has been committed to inclusivity in clinical trial research for over three decades. It is essential to have people from diverse communities

participate in clinical trials to reduce biases, promote social justice and health equity, and produce more innovative science. To account for the diverse lived experiences and exposures of various populations, clinical trials must be appropriately inclusive of racial and ethnic minority groups and other populations experiencing health disparities. Inclusion of diverse populations in clinical trials requires a sustained commitment from the entire scientific community to design trials that answer questions important to diverse populations and provide those affected by the condition under study the opportunity to participate. NIH continues to engage external collaborators such as researchers, patients, their advocates, journals, and industry to address barriers to inclusion of participants in NIH-supported clinical research.

NIH's Inclusion Across the Lifespan policy requires the inclusion of individuals of all ages, including children and older adults, in clinical trials absent compelling scientific or ethical reasons. In April 2022, NIH began reporting data on the age of participants in NIH-supported clinical research. This newly

Launch of Advancing Prevention Research for Health Equity
The Office of Disease Prevention (ODP) launched Advancing Prevention Research for Health Equity (ADVANCE) in 2022. ADVANCE is an NIH-wide initiative to develop new preventive interventions and implement existing evidence-based interventions and preventive services in populations that experience health disparities and inequities. Four NIH-wide ADVANCE workgroups focus on preventive intervention research to address long-standing health disparities and inequities: (1) Cardiometabolic risk factors for acute or chronic disease; (2) Alcohol, tobacco, and other drugs as risk factors; (3) Mental Health as a risk factor; and (4) Cancer screening and preventive services. ADVANCE released two funding opportunity announcements (FOAs) in FY 2022 with plans for the working groups to develop additional FOAs in future years. Seventeen ADVANCE supplements funded in FY 2022 supported research on a variety of prevention topics, including nutrition, physical activity, alcohol and substance use, mental health, violence, and HIV. Potential FY 2024 activities include ODP co-funding for current and future ADVANCE FOAs, training and professional development FOAs to increase the diversity of the scientific workforce in preventive intervention research, and a coordinating center FOA for an NIH-wide network on multi-sectoral preventive interventions that address social determinants of health.
prevention.nih.gov/research-priorities/health-disparities#ADVANCE

available information on age adds to already-reported data on participant sex or gender, race, and ethnicity. Furthermore, NIH also expects that sex as a biological variable will be factored into research designs, analyses, and reporting in clinical studies. These policies and increased data availability will advance NIH's ability to understand who is currently represented in clinical trials and target strategies to close identified gaps.

In addition to these broad efforts, OD supports scientific programs with an explicit focus on increasing representation in clinical trials. OD launched the NIH-wide INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project in support of a FY 2018 Congressional directive to increase participation of people with Down syndrome (DS) and their families in clinical and basic science research and to expand knowledge about DS and its links to other health conditions. Despite the relative frequency of DS in the population, very few clinical studies have examined differences in how commonly used medications affect people with DS. INCLUDE supports research projects, scientific infrastructure, and community building efforts to assemble a large study population of individuals with DS and conduct clinical trials research inclusive of individuals with DS. The INCLUDE project is developing the standards for inclusivity for this population previously not well represented in, if not explicitly excluded from, clinical research.

The ECHO ISPCTN is another program with a focus on reaching populations who may not otherwise be included in clinical research. ECHO ISPCTN's main goal is to address disparities in pediatric research by including children from rural or underserved populations in clinical trials, and by building pediatric research capacity in states with historically low NIH funding. By conducting clinical trials focused in ECHO's five outcome areas (pre-, peri, and postnatal; obesity; upper and lower airways; neurodevelopment; and positive health), this 18-state network helps researchers gain knowledge that will enhance the health of children in IDeA states,[24] states that historically have had low levels of NIH funding. Because ISPCTN includes a presence in rural and other underserved areas, it is well-positioned to address health issues that disproportionately affect those communities. The network provides a broad scope of research not limited to a single population, specialty, or condition. ISPCTN also builds research capacity by strengthening an institution's ability to support biomedical research and enhancing the competitiveness of its investigators in securing future research funding.

The *All of Us* Research Program is a historic effort to collect and study data from one million or more people living in the United States. The program began national enrollment in 2018 and is expected to last at least 10 years.

The *All of Us* Research Program, a longitudinal cohort study that aims to accelerate health and medical breakthroughs to enable individualized prevention, treatment, and care for all of us, also broadly encompasses populations historically underrepresented in biomedical research. *All of Us* is building one of the largest, most diverse health databases of its kind, capable of informing thousands of studies on a variety of health conditions. The program has already enrolled more than half a million participants. More than 50 percent of *All of Us* participants who have completed initial steps of the program identify with a racial and ethnic minority group, and about 80 percent of participants are from populations underrepresented in biomedical research including people over age 65, LGBTQ+ people, those who live in rural areas, people with low income or limited education, and people with disabilities. As of October 2022, researchers are actively conducting more than 2,700 projects on the *All of Us* Researcher Workbench and more than 3,300 researchers from more than 400 institutions have registered to use the resource. Through the Researcher Workbench, registered researchers have access to rich health data from *All of Us* participants including survey responses, physical measurements, electronic health record information, wearables data, and whole genome sequencing. This resource also includes data from nearly 20,000 people who have had SARS-CoV-2 infections, opening new opportunities to study COVID-19 disease prevention, progression, and recovery. In FY 2022, the NIH Common Fund supported 11 new awards to advance *Nutrition for Precision Health, powered by the All of Us*

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[24] www.nigms.nih.gov/Research/DRCB/IDeA/Pages/default.aspx

Research Program.[25] The study will recruit a diverse pool of 10,000 *All of Us* participants to inform more personalized nutrition recommendations.

Engaging and returning results to participants
Participants are essential partners in biomedical research. As NIH prioritizes partnership building and diverse and equitable inclusion practices, it is imperative to connect community needs and research response by increasing engagement with research participants and building robust systems to return research results. The *All of Us* Research Program is committed to returning results in a timely manner both to members of its participant community and to the scientific community broadly. In FY 2022, *All of Us* released its first genomic dataset of nearly 100,000 whole genome sequences, the most diverse of its kind. This included 593 million unique genetic variants and more than 151 million previously unreported genetic variants. The program has started the process to return health-related genetic results in a responsible manner to those participants who express an interest in receiving this information. The program's Genetic Counseling Resource provides participants access to speak with a genetic counselor to understand their results. *All of Us* participants are true partners in this initiative, and the program is ensuring that participants have access to their information, one of its core values.

Community engagement and information sharing are likewise essential to maximize research impact in the response to the human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) epidemic. The NIH Office of AIDS Research (OAR) is developing platforms to disseminate lessons learned and new practices to the community. As an example, community advisory boards (CABs) in all HIV/AIDS clinical trials networks inform study design and procedures. CABs typically include advocates, activists, implementers, and persons with HIV to improve cultural competence through early engagement with communities across the research continuum, from developing the research concept to delivering interventions. OAR has also initiated HIV community listening sessions to gather input from both scientific and non-scientific key partners, which has significantly informed the NIH HIV/AIDS research agenda and broad federal HIV-related initiatives, such as the ongoing Ending the HIV Epidemic in the U.S. (EHE) initiative, the updated National HIV/AIDS Strategy (NHAS) published in December 2021, and the NHAS Federal Implementation Plan published in August 2022. OAR has incorporated this feedback in tangible actions, including stronger partnerships between federal agencies, rapid information dissemination to the public, enhanced support for the workforce, and increased support for early career investigators. OAR further provides resources to all persons interested in HIV/AIDS through two public-facing websites: *HIVinfo.nih.gov* and *ClinicalInfo.hiv.gov.*

BRAIN Initiative®
The NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative aims to develop and apply new tools and technologies to answer fundamental questions about the brain and ultimately to inspire new treatments for brain diseases. NINDS and NIMH are leading partners in the NIH BRAIN Initiative, working with eight other ICOs. With Congressional support, including funding authorized by the 21st Century Cures Act, the BRAIN Initiative has invested over $3 billion in more than 1,300 research projects, engaging scientists from many areas of expertise as well as mathematicians, engineers, physicians in individual labs and inter-

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[25] commonfund.nih.gov/nutritionforprecisionhealth

disciplinary teams. The BRAIN Initiative has led positive change in the culture of neuroscience research through its emphasis on neuroethics, diversity and inclusion, and promoting infrastructure and practices for sharing research data and tools. Furthermore, the BRAIN Initiative promotes scientific advances that provide opportunities to understand the structure and function of the brain at an unprecedented level of detail.

Community Partnerships to Advance Science for Society (ComPASS)
To accelerate the science of health disparities and advance health equity research through new models of community-engaged clinical research partnerships, the NIH Common Fund launched the ComPASS Program. ComPASS aims to develop, share, and evaluate community-led health equity structural interventions that leverage partnerships across multiple sectors to reduce health disparities and to develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies. This program will enable communities and researchers to work collaboratively as equal partners in all phases of the research process to enhance the quality of interventions and advance health disparities research. ComPASS is co-led by the National Institute on Minority Health and Health Disparities, National Institute of Mental Health, National Institute of Nursing Research, the Office of Research on Women's Health (ORWH), and the Tribal Health Research Office (THRO) and will support awards beginning in FY 2023.

Increasing participation and training of underrepresented groups to understand and apply artificial intelligence/machine learning to address health equity
In FY 2021, NIH initiated a new flagship program called the Artificial Intelligence (AI)/Machine Learning (ML) Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) with the goal of ensuring that the benefits of AI/ML in biomedical research are ethically and equitably beneficial across all populations. AIM-AHEAD leverages vast amounts of already collected clinical data to test and develop innovative biomedical research methods. Recent accomplishments include the establishment of AIM-AHEAD fellowship and leadership training opportunities, regionally based outreach activities, and pilot projects that have attracted hundreds of new and underrepresented researchers to join the consortium. In FY 2024, NIH plans to expand investments that enhance diversity in the data used to train AI/ML applications, increase the diversity of AI/ML leaders asking questions about these clinical data, and tailor new training opportunities for a wide range of stakeholders.

Budget Policy: The FY 2024 President's Budget request for these programs is $822.3 million, equal to the FY 2023 Enacted level. The OD will utilize the overall funds requested to pursue promising scientific opportunities across a wide range of critical public health fields.

Expanding Research Tools and Collaborations

New data ecosystem
The Helping to End Addiction Long-term® (HEAL) Initiative developed the HEAL Data Ecosystem to maximize value and broadly disseminate HEAL data and results among researchers, healthcare providers, community leaders and organizations, policy makers, and other stakeholders. HEAL is supporting external data management and sharing experts to help scientists to make their data FAIR in support of the ecosystem. In FY 2021, HEAL funded the HEAL Stewards to work routinely with HEAL research teams to provide best practices for sharing diverse datasets and making data FAIR. HEAL continues to build the HEAL Platform, a cloud-based environment for sharing and analyzing data. In FY 2022, HEAL funded two institutions and their partners to develop bi-directional relationships with communities that may benefit from HEAL research outcomes. The partnership will help ensure data shared through the HEAL Platform are accessible to communities, providers, and policy makers. Across the initiative, HEAL programs are standardizing data collection and terminology to make it discoverable by other researchers.

> **Expansion of START to Increase Efficient Tracking and Reporting**
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> The Office of Evaluation, Performance, and Reporting (OEPR) created the Strategic Tracking and Reporting Tool (START) in 2018 to assist NIH staff in strategic plan development, tracking, and reporting. To date, START has expanded beyond strategic plan tracking and now includes programmatic and executive order tracking in support of more than 40 engagements spanning 8 ICs and 12 NIH OD Offices. OEPR aims to further strengthen and expand NIH's monitoring and reporting efforts by creating new features in START, including the development of a new Evaluation Module to assist agency staff in assessing the implementation and impact of new and established programs and initiatives. OEPR is also modernizing NIH's evidence-building infrastructure by refining its Performance Module, which facilitates collaborative data reporting across the agency. Together, these tools optimize program management and reporting while minimizing resource use and staff burden. The OEPR platform also promotes collaboration among NIH staff and provides infrastructure to foster better data-driven decision-making. START Modules foster efficient and effective management, data-driven decision-making, and responsible and transparent stewardship.
>
> *dpcpsi.nih.gov/oepr/scientific-reporting*

Report on Measuring Sex, Gender Identity, and Sexual Orientation
The NIH Sexual & Gender Minority Research Office (SGMRO) addresses the growing need to develop better measures and methods to accurately capture and understand the health of sexual and gender minority (SGM) populations. In 2020, the SGMRO, along with 18 other NIH components, commissioned the National Academies of Sciences, Engineering, and Medicine (NASEM) to review current measures and methodological issues related to ascertaining sex as a non-binary construct, gender identity, and sexual orientation in surveys and research studies, administrative settings, and clinical settings. In March 2022, NASEM released their consensus report *Measuring Sex, Gender Identity, and Sexual Orientation*.[26] This report is at the center of the SGMRO's efforts to promote increased data collection on sexual orientation, gender identity, and variations in sex characteristics and serves as a key component of the office's technical assistance program for researchers. The SGMRO is currently working with colleagues across NIH and other federal agencies to promote data collection and advance the NASEM report's research recommendations, such as improving conceptual accuracy. SGMRO

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[26] www.nationalacademies.org/our-work/measuring-sex-gender-identity-and-sexual-orientation-for-the-national-institutes-of-health

has given numerous presentations on the report to NIH internal and external audiences, fielding questions and advocating for consideration of its recommendations.

Expert consultations and collaborations
Expanding fundamental knowledge of biological systems and applying that knowledge to the advancement of health requires strategic partnerships with a range of organizations, including other federal agencies, international governments, the private sector, and the public. These partnerships bring enhanced coordination, critical expertise, pooled resources, and novel stakeholder connections to augment NIH efforts. Several offices within the OD provide expert consultation and collaboration to NIH ICOs, other government agencies, and external stakeholders.

The NIH Office of Science Policy (OSP) works across the biomedical research enterprise to ensure NIH policy evolves in tandem with rapidly advancing science and technology. To achieve these aims, OSP partners with the diverse stakeholder community that includes researchers, policymakers, ethicists, research participants, legal scholars, and importantly the American public. Consultation from OSP has also been key to establishing major NIH initiatives such as *All of Us*, RADx, and the Accelerating Medicines Partnership (AMP). OSP helps NIH and its ICOs achieve their mission objectives through activities such as coordinating collaborations with the FNIH; managing NIH's contract with the National Academy of Sciences (NAS); facilitating research collaborations and supporting NIH leadership involvement with the Patient-Centered Outcomes Research Institute (PCORI); and directing the NIH-American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellowship Program. OSP frequently plays a crucial role in across-government policymaking through long-established working relationships with the White House OSTP, partner agencies within HHS, and many other major players in the policy arena.

The Office of Disease Prevention (ODP) assists ICOs with design, analysis, and sample size issues for large projects or initiatives involving randomization of groups or delivery of interventions to groups. These trials face methodological issues beyond those regularly found in traditional randomized controlled trials, and the methods required are often more complex. ODP helps ICO staff plan new initiatives and work with funded projects to strengthen research design, analysis, and sample size methods. These consultations and collaborations improve the methods used in NIH-supported prevention research and enhance rigor and reproducibility. One example is the NIH Health Care Systems Research Collaboratory, where the ODP serves on the Biostatistics and Design Working Group and meets regularly with investigators to strengthen methods on 21 supported trials. ODP also consults on the Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHeR) Alliance at NHLBI, leading a Technical Assistance Working Group that has resulted in substantial improvements in research rigor and reproducibility.

The Generalist Repository Ecosystem Initiative (GREI)
The GREI, supported by NIH, is intended to supplement the domain-specific data repositories that are critical components of the NIH biomedical data ecosystem for data sharing.[27] ODSS

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[27] datascience.nih.gov/data-ecosystem/exploring-a-generalist-repository-for-nih-funded-data

anticipates that this initiative will help researchers find and share data from NIH-funded studies, improve the discoverability of data within and across participating generalist repositories, and lead to increased reproducibility and reuse of data. During FY 2022, the GREI included seven established generalist repositories that work together to establish consistent information capture, develop use cases for data sharing, and train and educate researchers on FAIR data principles and the importance of data sharing. In FY 2024, continued support of GREI will facilitate the implementation of the final NIH Policy for Data Management and Sharing (DMS).

Fast Healthcare Interoperability Resources (FHIR®) standard application programming interface (API) to exchange data between electronic health records
A Common Data Element (CDE) is a standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection. NIH has made significant strides in adopting CDEs and the FHIR standard API for the exchange of health care data. These enhanced capabilities enable the collection, analysis and sharing of clinical and health care data while safeguarding the privacy of participant and patient information. These standards were particularly crucial for COVID-19 studies that illuminated the pathophysiology of the infection, prevalence among diverse populations, and disease outcomes. Continued support in FY 2024 will enhance NIH's commitment to implementing FHIR standards for healthcare interoperability according to the *21ˢᵗ Century Cures Act* Final Rule.

FHIR® standard enables electronic healthcare data exchange through an API. Software developers can seamlessly connect their program to another computer through a FHIR API to transmit electronic health data.

Advancing Critical Research Areas

NIH-Wide Strategic Plan for Research on the Health of Women FY 2024-2028
Every five years, NIH publishes a new strategic plan for research on the health of women to highlight NIH research priorities and serve as a roadmap for achieving its goals. ORWH has initiated the development of the FY 2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women. The goals and objectives to be established by ORWH in this Strategic Plan will serve as a guide for future NIH research efforts to improve the health of all women throughout their entire lifespan. The plan will address a wide range of topics and factors, including recent public health events such as the COVID-19 pandemic, outcomes from the Congressionally directed and ORWH-led Women's Health Conference, scientific advances, new technologies, current health priorities; and feedback from relevant communities including the public. Developing the Strategic Plan is a multi-faceted process, requiring collaboration and coordination among internal and external partners including the Coordinating Committee for Research on Women's Health; the Advisory Committee for Research on Women's Health; staff from other NIH ICOs; and other federal partners. ORWH will leverage a variety of existing data sources to maximize the application of knowledge generated, including ICO implementation of the current 2019-2023 Trans-NIH Strategic Plan for

Women's Health Research.[28] ORWH anticipates publishing the plan in January 2024 and plans to issue a companion Strategic Plan Implementation and Evaluation Guide in 2024.

ACT NOW
The Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) Program aims to inform the clinical care of infants who are exposed to opioids in the womb.[29] Newborns exposed to opioids in the womb are at risk for a condition called neonatal opioid withdrawal syndrome (NOWS). The goal is to generate results that can inform clinical practice guidelines and give newborns with NOWS the best start possible. NOWS symptoms can include tremors; excessive crying and irritability; and problems with sleeping, feeding, and breathing. ACT NOW clinical trials provide an evidence base for the clinical care of infants with NOWS to help inform medical practice and health policy. Supported through the HEAL Initiative, the ACT NOW Program combines the efforts of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Neonatal Research Network and the ECHO Program ISPCTN to include a geographically and racially diverse population. In future work, ACT NOW investigators will plan and conduct a multi-center, randomized controlled clinical trial that further investigates how to optimize care for infants exposed to opioids in utero, while also considering other types of non-drug therapies such as behavioral interventions.

Reducing the burden of obesity, diet-related diseases, and nutrition health disparities
In FY 2021, the NIH Director transferred the Office of Nutrition Research (ONR) to the OD to lead the implementation of the 2020-2030 Strategic Plan for NIH Nutrition Research and to reflect the priority NIH places on innovative, multidisciplinary nutrition research. As part of the office's role in planning, coordinating, and tracking progress toward the objectives of the Strategic Plan, ONR established seven topic-based, NIH-wide Implementation Working Groups to develop specific initiatives, improve coordination, and broaden cross-cutting NIH subject matter expertise in nutrition research. One collaborative project includes the Stimulating Research to Understand and Address Hunger, Food and Nutrition Insecurity Project,[30] which is bringing together scientists from across the country to conduct discovery science and develop innovative interventions to address food insecurity and neighborhood-level access to healthy and affordable foods. Another NIH-wide collaboration is the Advanced Training in Artificial Intelligence for Precision Nutrition Science Research program.[31] This program provides interdisciplinary research training in AI and precision nutrition that will include ML, systems biology, systems science, big data, and computational analytics. The program aims to build a future workforce that will use growing data resources to tackle complex challenges in nutrition science and reduce diet-related diseases and health disparities.

Rates of obesity and other diet-related diseases are skyrocketing, and poor diet quality is now the leading risk factor for death in the United States.[32] ONR is committed to advancing nutrition science to promote health and reduce the burden of diet-related diseases and nutrition health disparities. ONR is leading efforts on two fronts to address this problem. First, barriers within

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[28] orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research

[29] heal.nih.gov/research/infants-and-children/act-now

[30] grants.nih.gov/grants/guide/notice-files/not-od-22-135.html

[31] grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-027.html

[32] jamanetwork.com/journals/jama/fullarticle/2678018

communities and health care systems severely hinder the goal to reduce obesity and other diet-related diseases such as cardiovascular disease, cancer, and diabetes. To address these barriers, ONR is leading the Food as Medicine Networks or Centers of Excellence program, which will support implementation science, intervention, and health quality research in which the health care enterprise is the nexus for coordinating efforts.[33] Second, the Developmental Origins of Health and Diseases (DOHaD) hypothesis reflects a growing concern that exposures during conception, pregnancy, and early life (e.g., food environment, life stress, traumas, medications, health and nutritional status, microbiome ecology, and other environmental exposures) are responsible for future diet-related disease risk. ONR is collaborating with other ICOs on a transformative research program examining the role of diet, food environment, and related environmental exposures through the DOHaD program. This discovery science program will include a comprehensive study of human milk composition, dietary intake, and nutritional status measures and outcomes; answer key mechanistic questions about the developmental origins of some diseases; and ultimately lead to an optimized diet for the health of the mother and child.

Firearm injury and mortality prevention research network and coordinating center
NIH is committed to supporting scientific research to develop, evaluate, and implement effective public health interventions to understand and prevent firearm violence. Firearms deaths constitute an urgent and significant public health crisis. In 2020, 79 percent of all homicides and 53 percent of all suicides involved firearms, and firearm-related injuries became the leading cause of death for children and youth. From 2019 to 2020, the firearm suicide rate remained consistently high, and the firearm homicide rate increased to its highest recorded rate in over 25 years, with widening disparities by race, ethnicity, and socioeconomic status.[34] In FY 2022, under the leadership of the Office of Behavioral and Social Sciences Research, NIH released two new funding opportunities to support a network of research sites to develop, implement, and evaluate innovative interventions to prevent firearm and related violence, injury, and mortality.[35,36] This network of projects focuses on community- and organizational-level interventions to target higher-order structural causes of this violence, expanding the current knowledge base which has focused more on individual-level interventions among those at highest risk. Support for data harmonization and sharing will enhance the impact and generalizability of the findings, and a coordinating center will provide cross-network coordination, communication, analytics, engagement, and dissemination efforts to promote collaboration across research teams.

The table below provides the budget levels for the offices within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). More information about the budget for the Common Fund within DPCPSI appears in the Common Fund section of the NIH Congressional Justification Overview volume.

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[33] dpcpsi.nih.gov/sites/default/files/Day-2-225PM-ONR-Concept-Food-as-Medicine-Lynch-onepagerREV-508.pdf
[34] www.cdc.gov/vitalsigns/firearm-deaths/index.html
[35] grants.nih.gov/grants/guide/pa-files/PAR-22-115.html
[36] grants.nih.gov/grants/guide/pa-files/PAR-22-120.html

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

	FY 2022 Final	FY 2023 Enacted Level	FY 2024 President's Budget	FY 2024 +/- FY 2023
Office of the DPCPSI Director	25,675	27,236	27,236	0
Office of Behavioral & Social Sciences Research	39,923	40,047	40,047	0
Office of AIDS Research	65,489	67,589	67,589	0
Office of Research on Women's Health	60,620	76,648	76,648	0
Office of Disease Prevention	17,321	17,873	17,873	0
Office of Dietary Supplements	27,998	28,500	28,500	0
Office of Research Infrastructure Programs	304,485	309,393	309,393	0
Office of Nutrition Research	1,241	1,313	121,313	120,000
Common Fund	670,001	735,001	735,001	0
Total	**$1,212,752**	**$1,303,600**	**$1,423,600**	**$120,000**

Budget Policy: The FY 2024 President's Budget request for DPCPSI and firearms research programs is $1,436.1 million, an increase of $120.0 million or 9.1 percent compared with the FY 2023 Enacted level. The OD will capitalize on ONR collaborating with NIH Institutes and Centers on a transformative research program examining the role of diet, food environment and related environmental exposures on the DOHaD. This funding will also enable the continuation of Firearm Research activities and allow the DPCPSI offices to continue serving as the focal points for their respective areas of research across NIH.

Research for Countermeasures against Nuclear/Radiological/Chemical Threat
NIAID manages both the Radiation and Nuclear Countermeasures Program (RNCP) and the Chemical Countermeasures Research Program (CCRP) with funding provided through OD. The RNCP supports research and development of approaches to diagnose and treat radiation injuries during a public health emergency and guides promising approaches toward FDA approval. During FY 2022, the RNCP initiated a human safety protocol for a novel oral drug to remove damaging radionuclides from the body and established a research consortium focused on understanding the impact of radiation exposure on immunity. During the past year the RNCP engaged with 35 organizations developing radiation approaches, including ongoing efforts to broker interactions between industry and the FDA to repurpose a licensed blood pressure medication as a therapeutic for radiation-induced lung injury and support novel product development for lethal gastrointestinal complications. Going forward, the RNCP will continue to maintain a strong research infrastructure, fund animal model development and testing to evaluate product safety and efficacy and strengthen collaboration with academic and US government partners through scientific meetings. In FY 2023, the program plans to award contracts for advanced development of candidate approaches and basic research grants to study the role of the microbiome in radiation injuries.

Budget Policy: The FY 2024 President's Budget request for this program is $105.6 million, equal to the FY 2023 Enacted level. Funding will be used to support efforts toward the development of safe and effective medical countermeasures and support innovative research through funding of and engagement with the scientific community.

Advancing Data Science and Artificial Intelligence

AI and ML are data-driven technologies with the potential to significantly advance biomedical research and improve human health. NIH makes a wealth of biomedical data available and reusable to research communities; however, not all of these data can be used efficiently and effectively by AI/ML applications. Making data AI/ML-ready is not simple or formulaic, but rather requires engagement with and feedback from researchers, new practices and capabilities for the ethical development and use of these technologies, and new skills in the biomedical workforce. In FY 2024, ODSS will expand initial investments in these areas with targeted support for strategic opportunities in AI/ML workforce development, ethical AI, and expanding AI methods in biomedicine.

The Common Fund's Bridge to AI program aims to set the stage for widespread adoption of AI approaches to address complex biomedical research challenges through the creation of flagship AI-ready data sets, best practices for ML analysis, software, standards, tools, training materials, and other resources.[37] NIH announced the first Bridge to AI awards in FY 2022; new data sets will likely include voice and other data to identify abnormal changes in the body, data to make new connections between complex genetic pathways and changes in cell shape and function, and data to improve decision-making in critical care settings. This program is supported by the Common Fund and co-led by the National Library of Medicine (NLM), National Eye Institute (NEI), National Human Genome Research Institute (NHGRI), National Center for Complementary and Integrative Health (NCCIH), and National Institute of Biomedical Imaging and Bioengineering (NIBIB).

The Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) is a federal advisory committee that provides recommendations to the NIH Director and serves as a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies, including AI/ML.[38] In FY 2021, the NExTRAC was charged by NIH to first define and characterize the types of research questions that require increasing granularity and aggregation of data about individuals that are likely to be addressed through emerging technologies, and second to consult with diverse stakeholders including scholars and the general public to discuss and assess the value and potential implications of those questions and technologies for individuals, groups, and society. In response to this charge, the NExTRAC formed the Data Science and Emerging Technology Working Group, which presented an update addressing the first part of the charge in FY 2022 by identifying types of research questions that NIH might encounter on these topics, with a focus on the use of novel data from outside of the traditional healthcare system, the use of models and algorithms (including AI/ML), and data linkage and aggregation of disparate datasets from multiple sources. The working group is now moving into the second part of its charge on stakeholder engagement, with an emphasis on community conversations around the types of research questions identified. The NExTRAC expects to publish a report addressing the charge in the summer of 2023, which will help inform NIH's thinking about policies and programs in data science.

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[37] commonfund.nih.gov/bridge2ai
[38] osp.od.nih.gov/biotechnology/main-nextrac/

Budget Policy: The FY 2024 President's Budget request for these programs is $135.0 million, equal to the FY 2023 Enacted level. This support will enable the Common Fund's Bridge to AI program to propel biomedical research forward by setting the stage for widespread adoption of AI that tackles complex biomedical challenges beyond human intuition.

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

As the NIH's central office, the OD is responsible for setting policies that affect the entire agency. These policies seek to address critical challenges faced by NIH and the larger biomedical research community by protecting scientific integrity, developing a diverse, skilled biomedical workforce, driving innovation, and ensuring that the public receives maximum benefit from its investment in NIH.

Bolstering Scientific Integrity

NIH has a long-standing commitment to foster scientific integrity and has developed numerous policies and procedures to ensure the Nation's investment in biomedical research is held to the highest standards. In fostering scientific integrity, NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence based. Public input and accountability are woven throughout NIH processes to assure the public of the credibility of NIH-funded science and its associated scientific findings.

Responsive to the *Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking,* NIH is in the process of updating its compendium of policies and procedures that support scientific integrity.[39] The agency's commitment to scientific integrity goes beyond strengthening its policies and processes and includes the creation of new organizational structures that will support the agency's goals. For example, NIH has designated the NIH Principal Deputy Director and Associate Director of Science Policy, both senior career employees, as the agency's Chief Science Officer (CSO) and Scientific Integrity Official (SIO), respectively. The CSO will serve as principal advisor to the NIH Director on scientific issues and will ensure that NIH's research programs are scientifically and technologically well-founded and conducted with integrity. The CSO will oversee implementation and iterative improvement of policies that affect research integrity overseen by the agency that affect Federal and non-Federal scientists. The SIO will report to the CSO and oversee implementation and the iterative improvement of NIH scientific integrity policies and processes. The SIO will report to the CSO on all matters involving scientific integrity. The SIO will also serve as the appointed NIH official on the HHS Scientific Integrity Council and the National Science and Technology Council (NSTC) Subcommittee on Scientific Integrity, both of which will support agency integrity efforts, including allegations or violations involving high level officials, which can be the most problematic and difficult for a single agency to address.

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[39] www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/

Strengthen Diversity, Equity, Inclusion, and Accessibility Across Biomedical Research

In 2022, the OD coordinated the development of the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA), to delineate NIH's vision for embracing, strengthening, and integrating DEIA across all NIH activities to achieve its mission. The Plan articulates NIH's DEIA priorities for areas of operations, workforce, and research. The Plan also emphasizes approaches that cross over these areas, including transparency and communication, structural and cultural change, and data-informed decision-making. To operationalize the vision set forth in the Strategic Plan for DEIA, OD is coordinating an implementation planning process to prioritize DEIA activities across NIH and track progress toward the goals and strategies outlined in the Plan.

In 2022, the NIH's Chief Officer for Scientific Workforce Diversity (COSWD) team released its Strategic Plan for FY 2022-2026.[40] The plan outlines a bold vision for future efforts and renews the team's charge to lead the science of scientific workforce diversity, using evidence-based approaches to catalyze cultures of inclusive excellence. Over the next five years COSWD activities will promote diversity, equity, inclusion, and accessibility in the biomedical research enterprise through building, disseminating, and acting on evidence. One such activity is the Scientific Workforce Diversity Seminar Series, convened by the COSWD office to share the latest research on scientific workforce diversity topics by engaging with interested professionals and researchers at the NIH and beyond. In addition, COSWD and the Office of Intramural Research (OIR) organized a virtual DEIA in the Workplace workshop series. The workshop sessions provided a judgement-free environment for open discussion where participants learned

NIH established the UNITE initiative to identify and address structural racism within the NIH-supported and the greater scientific community. UNITE aims to establish an equitable and civil culture within the biomedical research enterprise and reduce barriers to racial equity in the biomedical research workforce.

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[40] diversity.nih.gov/about-us/strategic-plan

about DEIA concepts, current statistics, NIH resources, relevant examples, helpful techniques, and best practices, while engaging in small-group discussions and self-reflective activities. This series encouraged participants to challenge the way they look at DEIA within the NIH and define ways to contribute to growing a diverse and inclusive workforce.

Increasing Equitable Access to Research Results

In the spirit of stewardship, accountability, and transparency, NIH has consistently provided the public access to the research it funds. In FY 2020, NIH published the Data Management and Sharing (DMS) Policy to promote the management and sharing of scientific data generated from NIH-funded or -conducted research.[41] The DMS Policy, which went into effect in January 2023, emphasizes the importance of good data management practices and establishes the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research. In preparation for the implementation of the DMS Policy, OER and OSP launched a new website for Scientific Data Sharing.[42] This site serves as a central portal to help scientists understand which sharing policies apply to their research and how to comply with the DMs Policy and provide access to scientific data from NIH-affiliated repositories. In addition, NIH continues to develop resources to help implement the Plan,[43] such as providing information to assist researchers in addressing privacy considerations when sharing human research participant data,[44] and describing considerations and best practices for the responsible and respectful management and sharing of AI/AN participant data.[45]

To further increase the transparency and availability of scientific data and resources, the NIH Office of Portfolio Analysis (OPA), in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) is developing a new public-facing analytical tool: *iSearch* Analytics.[46] The tool will allow for reimagined cluster visualizations with artificial intelligence labels, provide users with person-level data and metrics, and expand the literature beyond what is available in PubMed, including access to pre-prints.

Harnessing New Technologies

Enhancing animal research and developing alternative methods in research
NIH continues to invest in a broad array of research models and systems to advance its mission. The NIH Advisory Committee to the Director (ACD) Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research published recommendations in FY 2021 to bolster confidence in the quality and applicability of research findings from animal studies and to ensure that animal subjects are used with appropriate consideration of ethics and harm–benefit analysis. NIH is working to implement these recommendations to enhance the rigor of NIH-supported research.[47] Building on the recommendations from a workshop on animal models in biomedical research, and in line with the ACD recommendations, the Office of Research

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

[42] sharing.nih.gov/

[43] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html

[44] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-213.html

[45] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html

[46] dpcpsi.nih.gov/sites/default/files/11.15AM-OPA-Update-Santangelo-508.pdf

[47] www.acd.od.nih.gov/documents/presentations/06092022_Animal_Research.pdf

Infrastructure Programs (ORIP) is launching a new program initiative to develop resources and technologies supporting validation of animal models and advancement of rigorous and reproducible preclinical research using animal models.[48] In FY 2022 the Office of Animal Care and Use within OIR launched a research animal handling and techniques training program offering over 150 classes per year and open to all NIH staff, NIH trainees, and students. In addition, NIH is making efforts to reduce administrative burden across the grants process, including as it relates to animal welfare.[49]

Alternative methods may hold promise for reducing reliance on specific animal models for select research studies in the future but remain limited in their ability to generate the whole-of-systems approach needed to understand the complexity of human biology. While advances in model organism approaches, stem cells, organoids, computational models, non-invasive imaging, and other technologies are assisting our understanding of complex human systems, research using vertebrate animals continues to provide the gold standard for understanding diseases and developing therapies and vaccines. At present, rather than replacing animal models, alternative methods provide complementary tools that drive hypotheses that may refine or reduce animal studies necessary in the arsenal for diagnosing, preventing, curing, and treating human disease. Such efforts are outlined in a recent report to Congress describing *Alternatives to Animals in Research and Testing Humane Research Alternatives.* A new FY 2024 Common Fund program may foster further development of non-animal approaches, including cell-based methods, computer modeling/simulation, and human tissue studies.

Data Science and Participant Preferences
In FY 2022, NIH engaged scientific and public communities through webinars, a request for information, and through workshop discussions led by ODSS in collaboration with NLM and OSP, to identify and develop best practices to standardize controlled data access processes.[50] These practices are envisioned to streamline access to data, support the emerging NIH data science infrastructure, and meet the needs of the research community in a manner that preserves the original research participant protections agreed to when the data were collected. Lessons learned from past efforts and reviewing existing and emerging processes and technologies used by NIH ICOs will inform and support the development of new solutions. These solutions will streamline data access, support the emerging NIH data science infrastructure, and meet the needs of the research community in a manner that preserves the original data and takes into account potential cost and burden. These efforts are in line with the White House OSTP's new policy guidance to responsibly empower equitable access to federally funded research.[51] ODSS will continue efforts in FY 2024 to enhance data sharing utility and provide equitable sharing of government funded research data.

Supporting Investigators Throughout their Careers
OD supports many programs to build and strengthen the future of the biomedical workforce. For example, the Undergraduate Scholarship Program (UGSP), led by the Office of Intramural

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[48] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-039.html
[49] nexus.od.nih.gov/all/2022/04/20/reducing-administrative-burden-in-laboratory-animal-research-what-have-we-done-recently-and-whats-coming/
[50] datascience.nih.gov/streamlining-access-to-controlled-data
[51] www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf

Training and Education (OITE), offers competitive scholarships to exceptional college students from disadvantaged backgrounds who are committed to biomedical, behavioral, and social science health-related research careers at NIH. In FY 2022, OITE selected 16 new recipients for the UGSP award and renewed 5 UGSP Scholars. The Common Fund's Early Independence Award supports outstanding junior scientists with the intellect, scientific creativity, drive, and maturity to bypass the traditional postdoctoral training period, launching independent research careers on an accelerated timeline.[52] NIH also began providing funding for childcare costs for Ruth L. Kirschstein National Research Service Awards for Individual Fellows and Trainees. NIH issued 228 childcare cost awards in FY 2021, totaling $572,083, and 196 awards in FY 2022 (as of July), for a total of $509,687.

NIH's Next Generation Researchers Initiative (NGRI) aims to cultivate and support early-stage investigators (ESIs) entering the biomedical and behavioral research workforce. As part of NGRI, NIH ICs prioritize funding for ESIs and track the impact of funding decisions on ESIs, such as subsequent grant submission and success. As a result of this initiative, NIH has substantially increased support for ESIs, increasing from 978 in FY 2016 (before NGRI started) to 1,609 in FY 2022.[53] This new all-time high level of support for ESIs represents a 7.2 percent increase over FY 2020.

Loan repayment is another strategy NIH uses to help build a diverse biomedical research workforce. The Extramural Loan Repayment Program aims to recruit and retain highly qualified biomedical and behavioral scientists to engage in NIH mission-relevant research and funded 1,359 awards (over $93 million). Similarly, the Intramural Loan Repayment and Scholarship Programs aims to develop and manage programs that offer financial incentives and other benefits to attract highly qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of NIH. The Intramural Loan Repayment Program (ILRP) repays outstanding eligible educational debt for postgraduates, who commit to conducting mission-relevant research at NIH. In FY 2022, NIH supported 63 total ILRP awards.

The NIH Data and Technology Advancement (DATA) National Service Scholar program recruits individuals with established data science expertise from industry and academia to serve for one to two years at the NIH and contribute to the acceleration of data science in biomedicine.[54] The program brought onboard the first cohort of scholars in FY 2020 and has supported 13 scholars to date, matched to 12 ICOs. The program expects eight new Scholars matched to seven institutes in FY 2022 and anticipates similar growth each year. Continued support in FY 2024 will help to promote the recruitment of diverse and advanced data science talents to the NIH.

Unique Opportunities to Drive Innovative Research
The NIH Director's Challenge Innovation Award aims to support projects that foster NIH-wide collaborations across the NIH Intramural Research Program (IRP). The award provides seed money from OIR for innovative and high-impact research that may significantly benefit a variety of research, infrastructure, and scientific endeavors across the IRP. In FY 2022, the program

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[52] commonfund.nih.gov/earlyindependence
[53] nexus.od.nih.gov/all/2022/07/18/more-early-stage-investigators-supported-in-fy-2021/
[54] datascience.nih.gov/data-scholars-2022#overview

supported investigator-initiated, collaborative, and interdisciplinary projects that employed engineering and/or physical science approaches to problems in biology and medicine.[55] The Director's Discretionary Fund further enables NIH to rapidly address high-priority research opportunities and respond to new scientific issues. In addition, the Common Fund's High-Risk, High-Reward program supports exceptionally creative scientists proposing innovative and transformative research in any scientific area within the NIH mission through four complementary initiatives: Pioneer Award, New Innovator Award, Transformative Research Award, and Early Independence Award.[56] These awards are intended to support transformative science that is inherently difficult and risky but necessary to accelerate the pace of scientific discovery and advance human health. Together these programs drive innovative research, bolster critical scientific and clinical activities, and enable strategic partnerships across NIH.

In response to high rates of pregnancy-related complications and deaths in the United States, NIH launched the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative in 2020 to address the leading causes of pregnancy-related maternal mortality and severe maternal morbidity (MM/SMM). The IMPROVE initiative includes two Challenge initiatives, in addition to traditional grant funding, that provide innovative approaches to well-defined barriers in maternal health care and research engagement.[57] NICHD, NIBIB, and the NIH OD are co-leading RADx Tech for Maternal Health Challenge, which leverages an innovation funnel approach to accelerate the development of maternal health diagnostic or other remote-sensing technologies (e.g., wearable devices, sensor technologies, smartphone-enabled tools) to enable extension of care and improve health outcomes in maternal care deserts.[58] These technologies will improve access to care in the

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[55] oir.nih.gov/sourcebook/awards-fellowships-grant-opportunities/directors-challenge-innovation-award-program/2022-directors-challenge-awards
[56] commonfund.nih.gov/highrisk
[57] www.nichd.nih.gov/about/org/od/directors_corner/maternal-health-research-Sept2022?utm_medium=email&utm_source=mailchimp&utm_campaign=dir-corner
[58] www.nichd.nih.gov/newsroom/news/091522-RADxTech

The NIH OD Resilience Through Well-Being campaign is an initiative with the shared purpose to empower OD staff to embrace well-being.

postpartum period and complement the use of telehealth in areas without sufficient maternity awards to incentivize participation and reward successful outcomes, the challenge structure provides expert guidance and consultation on maternal health research project design, implementation, and evaluation. The goal is to support successful organizations to compete for federal grant funding and sustain their research capabilities for future efforts.

Budget Policy: The FY 2024 President's Budget request for these activities is $20.4 million, equal to the FY 2023 Enacted level. In FY 2024, OD will continue support for training and career development opportunities to support the advancement of scientists and clinicians and drive innovative research through strategic partnerships across NIH.

Operations and Management in the Office of the Director: Transforming Culture and Modernizing Processes
In FY 2022, as the central, coordinating entity at NIH, NIH OD continued efforts to modernize the workplace, streamline business processes, increase diversity and equity, and optimize research resource usage to ensure that NIH integrates best practices learned during the COVID-19 public health emergency and other previous and ongoing optimization and modernization efforts into the future of how NIH does business.

Implementing a Human-centric Approach in the Future of Work
NIH continued to offer a multitude of novel leave authorities and workplace flexibilities authorized by the HHS Workplace Flexibilities Policy while also meeting NIH's critical scientific mission. In FY 2022, NIH developed the Future of Work, an enterprise-wide initiative to address the evolving work landscape at NIH, including operationalizing

the HHS Workplace Flexibilities Policy that incorporates telework, remote work, and alternative work schedules.[59, 60]

Sponsored by the NIH Strategic Administrative Management Advisory Committee and coordinated by the Office of Strategic Planning and Management Operations, the initiative focuses on workplace flexibilities and other considerations to ensure that NIH maintains a safe, productive, engaging, state-of-the-art, and equitable work environment. Several working groups across administrative focus areas identified organizational priorities and strategic investments to shape the 'Future of Work' at NIH using a human-centric approach that considers staff wellness and equity. Priorities included transforming physical space, leveraging tools and technology to support the future of collaboration and adapting to a hybrid workforce. As a part of FY 2022 Future of Work actions, NIH OD implemented the use of the Nuvolo Space Reservation system that helps NIH OD staff reserve hoteling space for offices, cubicles, touchdown spaces, or conference rooms in the physical workplace. Through Nuvolo, NIH OD aims to modernize and optimize the use of limited workspace resources in a flexible and adaptive manner.

Meeting the Well-Being Needs of NIH OD Staff

As NIH continues to advance science and support the NIH external community, it is imperative to continue to strengthen the potential of the NIH internal community. OD engages in and leads a variety of activities to provide resources for and promote and enhance the well-being of NIH employees, contractors, and trainees. In FY 2022, OD launched a Resilience Through Well-Being campaign that promotes a culture of resilience through a one-stop shop for tools, event information, and actionable resources, including informational videos, workshops, guided meditations, and infographic posters. The campaign provides links to other wellness resources across NIH, including publicly available wellness toolkits focusing on different aspects of well-being, the Center for Cove Resolution's resources for improving individual, interpersonal, and group health, and the NIH Office of Research Services (ORS) Employee Assistance Program.

OD also provides leadership in an NIH-wide Mental Health and Well-Being Action Team that aims to form collaborative networks of well-being experts and initiatives across the agency, share information on NIH services, recommend resources and initiatives that address unmet needs, and support the well-being of staff, contractors, and trainees across NIH. The Action Team helps maintain awareness of resources and services offered across NIH to assist the NIH community in managing stress, building resilience, and stays informed of the needs of key audiences (e.g., those without computer access, those with existing mental health conditions, working off-campus, and others). Through these and other activities OD strives to safeguard the mental health and well-being of the NIH community and promote a safe and inclusive environment.

www.nih.gov/health-information/your-healthiest-self-wellness-toolkits

Increasing Efficiency and Modernizing Operations through the OD Action Plan

The Future of Work aligns with a centralized FY 2022 effort called the NIH OD Action Plan that established a set of shared, high priority goals intended to unify, strengthen, diversify, and modernize NIH OD. The OD Action Plan encompassed four key goals in FY 2022 to build a shared purpose and unity, embrace new tools and technologies to improve capabilities, expand NIH OD's leadership in DEIA efforts, and provide for the needs of the NIH OD workforce so that it may better serve NIH and the public.

Progress made toward these goals in FY 2022 included creating a new mission and values statement and developing and sharing standard operating procedures (SOPs) for functions across NIH OD. As part of this effort, NIH OD continued work to establish an Information Technology

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[59] hr.nih.gov/working-nih/workplace-flexibilities
[60] www.hhs.gov/about/agencies/asa/ohr/hr-library/990-1/index.html

(IT) Project Management Office (PMO) that will implement an IT governance framework and serve as a centralized coordination hub and resource for best practices and SOPs to standardize how IT processes are conducted across NIH OD. Additional advances made toward other NIH OD Action Plan goals include reconfiguring the anti-harassment working group to encompass all DEIA and civility efforts, creating a DEIA scorecard to monitor progress in DEIA efforts, building additional automated budget processes into the newly

The OD Action Plan established a set of shared goals to move OD to a collective One OD focus.

established OD-ENGAGE administrative platform, conducting a workforce analysis to better understand the staffing needs of the NIH OD community, and creating succession plans for each office within NIH OD to ensure continuity in knowledge resources during times of transition.

Enhancing Research Resources
Complementary extramural modernization efforts focused on streamlining and creating efficiencies in research resources and practices. NIH recognizes that advances in technology and cutting-edge techniques for biological system (e.g., modeling, imaging, molecular characterization) have altered investigator resource needs to carry out research. For example, instruments needed to perform research are often too expensive to be obtained by an individual investigator. Accordingly, through opportunities such as the Office of Research Infrastructure Programs (ORIP) S10 Instrumentation Grant Programs, NIH adapted cost-efficient funding models to support the purchase of state-of-the-art instruments for shared use, benefiting thousands of investigators in hundreds of institutions nationwide including both research-intense and minority-serving institutions.[61] Types of instruments supported by S10 funding include, but are not limited to, X-ray diffraction systems, nuclear magnetic resonance and mass spectrometers, DNA and protein sequencers, biosensors, high performance computer clusters, cell-analyzers, and biomedical imagers.

Reception and Representation (R&R) Fund
The NIH OD's R&R Fund is used for expenses related to official NIH reception and representation functions with approval from the NIH director. This refers to specific functions held by the NIH that are attended by domestic or foreign officials and intended to explain or interpret the mission of its programs and the entertainment of foreign officials where the primary purpose of the function is related to a responsibility of the NIH. For example, in FY 2022 NIH held a ceremony to honor Senator Roy Blunt's work in championing research for Alzheimer's disease and related dementias at the opening dedication for a center named in his honor.

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[61] orip.nih.gov/construction-and-instruments/s10-instrumentation-programs

Budget Policy: The FY 2024 President's Budget estimate for OD Operations is $614.0 million, a decrease of $52.8 million or 7.9 percent below the FY 2023 Enacted level. The majority of this reduction is due to redeploying the $80.0 million provided for extramural construction grants in FY 2023 into $30.0 million of support for nonhuman primate infrastructure, as described above. In FY 2024, funding will be used to build modern infrastructure and resources for OD and NIH-wide by increasing efficiency, modernizing processes, and implementing a human-centric approach to the workplace.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	$2,779,120,000
Rescission				$0
2023 [1]	$2,733,665,000	$2,968,813,000	$2,991,665,000	$3,074,514,000
Rescission				$0
Supplemental				$25,000,000
2024 [1]	$3,138,379,000			

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

NATIONAL INSTITUTES OF HEALTH
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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2023 Amount Authorized	FY 2023 Enacted	2024 Amount Authorized	FY 2024 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				$3,066,208,000		$3,133,379,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$3,066,208,000		$3,133,379,000

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

Source of Funding	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Appropriation	$2,779,120	$3,074,514	$3,138,379
Transfer to HHS Office of the Inspector General	-$5,000	-$5,000	-$5,000
Subtotal, adjusted appropriation	$2,774,120	$3,069,514	$3,133,379
OAR HIV/AIDS Transfers	-$1,122	-$3,306	$0
Subtotal, adjusted budget authority	$2,772,998	$3,066,208	$3,133,379
Unobligated balance, start of year	$75,945	$30,108	$0
Unobligated balance, end of year (carryover)	-$30,108	$0	$0
Subtotal, adjusted budget authority	**$2,818,835**	**$3,096,316**	**$3,133,379**
Unobligated balance lapsing	-$1,663	$0	$0
Total obligations	$2,817,172	$3,096,316	$3,133,379

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2022 - $86,236   FY 2023 - $105,000   FY 2024 - $105,000

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Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Total compensable workyears:				
	Full-time equivalent	1,162	1,225	63
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	$210	$221	$11
	Average GM/GS grade	13.3	13.4	0.1
	Average GM/GS salary	$137	$143	$7
	Average salary, Commissioned Corps (42 U.S.C. 207)	$126	$133	$7
	Average salary of ungraded positions	$464	$489	$25
	OBJECT CLASSES	**FY 2023 Enacted**	**FY 2024 President's Budget**	**FY 2024 +/- FY 2023**
	Personnel Compensation			
11.1	Full-Time Permanent	$117,751	$131,671	$13,920
11.3	Other Than Full-Time Permanent	$16,530	$17,432	$902
11.5	Other Personnel Compensation	$5,320	$5,610	$290
11.7	Military Personnel	$1,293	$1,363	$71
11.8	Special Personnel Services Payments	$2,460	$2,594	$134
11.9	**Subtotal Personnel Compensation**	**$143,354**	**$158,670**	**$15,316**
12.1	Civilian Personnel Benefits	$53,813	$59,720	$5,907
12.2	Military Personnel Benefits	$455	$480	$25
13.0	Benefits to Former Personnel	$0	$0	$0
	Subtotal Pay Costs	**$197,622**	**$218,870**	**$21,248**
21.0	Travel & Transportation of Persons	$695	$712	$17
22.0	Transportation of Things	$101	$103	$2
23.1	Rental Payments to GSA	$0	$0	$0
23.2	Rental Payments to Others	$3	$3	$0
23.3	Communications, Utilities & Misc. Charges	$203	$208	$5
24.0	Printing & Reproduction	$0	$0	$0
25.1	Consulting Services	$110,562	$112,989	$2,426
25.2	Other Services	$152,693	$129,770	-$22,923
25.3	Purchase of Goods and Services from Government Accounts	$125,757	$148,140	$22,382
25.4	Operation & Maintenance of Facilities	$2,868	$2,937	$69
25.5	R&D Contracts	$65,616	$62,704	-$2,913
25.6	Medical Care	$85	$88	$3
25.7	Operation & Maintenance of Equipment	$15,601	$15,976	$374
25.8	Subsistence & Support of Persons	$0	$0	$0
25.0	**Subtotal Other Contractual Services**	**$473,186**	**$472,606**	**-$580**
26.0	Supplies & Materials	$3,778	$3,866	$88
31.0	Equipment	$5,076	$5,197	$121
32.0	Land and Structures	$3,847	$3,939	$92
33.0	Investments & Loans	$0	$0	$0
41.0	Grants, Subsidies & Contributions	$2,381,627	$2,427,805	$46,177
42.0	Insurance Claims & Indemnities	$0	$0	$0
43.0	Interest & Dividends	$69	$69	$0
44.0	Refunds	$0	$0	$0
	Subtotal Non-Pay Costs	**$2,868,586**	**$2,914,509**	**$45,923**
	Total Budget Authority by Object Class	**$3,066,208**	**$3,133,379**	**$67,171**

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

NATIONAL INSTITUTES OF HEALTH
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Salaries and Expenses
(Dollars in Thousands)

Object Classes	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel Compensation			
Full-Time Permanent (11.1)	$117,751	$131,671	$13,920
Other Than Full-Time Permanent (11.3)	$16,530	$17,432	$902
Other Personnel Compensation (11.5)	$5,320	$5,610	$290
Military Personnel (11.7)	$1,293	$1,363	$71
Special Personnel Services Payments (11.8)	$2,460	$2,594	$134
Subtotal, Personnel Compensation (11.9)	**$143,354**	**$158,670**	**$15,316**
Civilian Personnel Benefits (12.1)	$53,813	$59,720	$5,907
Military Personnel Benefits (12.2)	$455	$480	$25
Benefits to Former Personnel (13.0)	$0	$0	$0
Subtotal Pay Costs	**$197,622**	**$218,870**	**$21,248**
Travel & Transportation of Persons (21.0)	$695	$712	$17
Transportation of Things (22.0)	$101	$103	$2
Rental Payments to Others (23.2)	$3	$3	$0
Communications, Utilities & Misc. Charges (23.3)	$203	$208	$5
Printing & Reproduction (24.0)	$0	$0	$0
Other Contractual Services			
Consultant Services (25.1)	$77,233	$79,087	$1,854
Other Services (25.2)	$152,693	$129,770	-$22,923
Purchase of Goods and Services from Government Accounts (25.3)	$80,525	$85,223	$4,697
Operation & Maintenance of Facilities (25.4)	$2,868	$2,937	$69
Operation & Maintenance of Equipment (25.7)	$15,601	$15,976	$374
Subsistence & Support of Persons (25.8)	$0	$0	$0
Subtotal Other Contractual Services	**$328,921**	**$312,992**	**-$15,929**
Supplies & Materials (26.0)	$3,778	$3,866	$88
Subtotal Non-Pay Costs	**$333,702**	**$317,885**	**-$15,817**
Total Administrative Costs	**$531,324**	**$536,755**	**$5,431**

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Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2022 Final			FY 2023 Enacted			FY 2024 President's		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	1,010	10	1,020	1,107	13	1,120	1,168	15	1,183
Total:	1,010	10	1,020	1,107	13	1,120	1,168	15	1,183
Reimbursable									
Reimbursable:	39	-	39	42	-	42	42	-	42
Total:	39	-	39	42	-	42	42	-	42
Total	1,049	10	1,059	1,149	13	1,162	1,210	15	1,225
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**								
2020	13.1								
2021	13.2								
2022	13.2								
2023	13.3								
2024	13.4								

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Detail of Positions[1]

GRADE	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Total, ES Positions	13	15	16
Total, ES Salary	$2,601,719	$3,147,876	$3,540,228
General Schedule			
GM/GS-15	196	202	205
GM/GS-14	271	289	303
GM/GS-13	334	355	370
GS-12	126	136	145
GS-11	51	59	66
GS-10	0	0	0
GS-9	19	23	27
GS-8	0	0	0
GS-7	8	9	12
GS-6	0	0	0
GS-5	4	4	4
GS-4	4	4	4
GS-3	3	3	3
GS-2	1	1	1
GS-1	1	1	1
Subtotal	1,018	1,086	1,141
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	1	1	1
Director Grade	3	4	4
Senior Grade	4	5	6
Full Grade	2	2	3
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	11	13	15
Ungraded	76	80	85
Total permanent positions	990	1,094	1,157
Total positions, end of year	1,118	1,194	1,257
Total full-time equivalent (FTE) employment, end of year	1,059	1,162	1,225
Average ES salary	$200,132	$209,858	$221,264
Average GM/GS grade	13.2	13.3	13.4
Average GM/GS salary	$130,776	$136,502	$143,090

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