

# Office of the Director

# CONGRESSIONAL JUSTIFICATION FY 2025

Department of Health and Human Services National Institutes of Health



National Institutes of Health Office of the Director [THIS PAGE INTENTIONALLY LEFT BLANK]

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# NATIONAL INSTITUTES OF HEALTH

#### Office of the Director (OD)

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#### **General Notes**

- 1. FY 2024 Enacted levels cited in this document are based on the Continuing Resolution in effect at the time of budget preparation (Public Law 118-35) and do not include HIV/AIDS transfers.
- 2. Detail in this document may not sum to the subtotals and totals due to rounding.

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#### **DIRECTOR'S OVERVIEW**

#### **Director's Overview**

The National Institutes of Health (NIH) Office of the Director (OD) serves as the central office of NIH and is responsible for guiding 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 partners. 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 and foster collaborations across agency activities.

The OD is uniquely positioned to take on challenging and emerging scientific questions, advance scientific innovation, and promote equitable public health. The OD supports the NIH mission and aims to improve and streamline operations, transform



Monica M. Bertagnolli, M.D., NIH Director

culture, and enhance and maintain critical resources and infrastructure. The OD supports and guides innovative scientific research and discovery through ensuring integrity and appropriate oversight, effects system-wide change, and aims to increase transparency across the agency.

NIH research has responded to many formidable health challenges over the decades, including polio, HIV/AIDS, cancer, maternal health, and most recently, the COVID-19 pandemic. The OD holds a unique leadership position for addressing these health challenges. The OD oversees an extensive portfolio 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. NIH has long prioritized a safe and respectful workplace, free from harassment and discrimination. In support of this, the OD leads and coordinates initiatives that prioritize the health and well-being of all NIH staff and scientists and bolsters the efforts of the ICOs for improving diversity, equity, inclusion, and accessibility (DEIA).

#### Supporting cutting edge scientific research that benefits all Americans

The COVID-19 public health crisis revealed widespread health disparities and inequities and left potentially millions of people globally with long-term health effects of COVID-19. Although many people have been able to recover with treatment interventions, including antivirals and monoclonal antibodies, developing strategies to prevent and treat post-acute sequelae of COVID-19 (PASC), commonly known as Long COVID, remains a public health priority. People suffering from Long COVID have varying symptoms including debilitating fatigue, shortness of breath, pain, difficulty sleeping, racing heart rate, exercise intolerance, loss of smell or change in taste, and brain fog, making it unlikely that a single therapy will work for everyone and underscoring the need to pursue multiple therapeutic strategies. 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 the NIH-wide Researching COVID to Enhance Recovery

(RECOVER) initiative, a national research program to better understand Long COVID.<sup>1</sup> The RECOVER initiative addresses the widespread and diverse impacts of Long COVID through a national research network that includes observational cohort studies, *in silico* studies of electronic health record, clinical trials, and studies of the underlying pathobiology. There are ongoing efforts to examine the biology behind the different symptoms and causes of Long COVID, including the basis for cardiopulmonary, neurological, and cognitive sequelae.

Another important example of health disparity in our Nation is the high rate of pregnancy-related maternal mortality and severe morbidity. In 2021, the U.S. maternal mortality rate increased to 32.9 deaths per 100,000 live births from a rate of 23.8 in 2020 and 20.1 in 2019.<sup>2</sup> Outcomes are more severe for certain population groups, with non-Hispanic Black women experiencing the highest maternal mortality rate at 69.9 deaths per 100,000 live births.<sup>3</sup> NIH efforts to address maternal health are focused on advancing health equity, reducing preventable causes of maternal deaths, and improving health for women and other pregnant people before, during, and after childbirth.

#### Inclusive scientific research to advance American health

The INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project is an NIH initiative led by the OD that engages with ICOs to support scientific research, clinical trials, and cohort studies to better understand critical health and quality-of-life needs for individuals with Down syndrome (DS).<sup>4</sup> The INCLUDE Project continues to expand its research portfolio by releasing innovative funding opportunities and building the field of investigators by enhancing career pathways for trainees and investigators with expertise related to conditions commonly experienced by individuals with DS. Since its launch in 2018, the INCLUDE Project has funded more than 200 research studies spanning all 3 components of the initiative: basic science studies on chromosome 21; large cohort development for individuals with DS; and the inclusion of individuals with DS in clinical trials. People with DS may have a higher chance of certain chronic, health, or life-threatening conditions but are highly protected from other health conditions. The goal of the NIH-wide program is to prevent these health conditions from reducing the capacity of people with DS to lead healthy and optimal lives.

New funding opportunities from the INCLUDE Program will expand basic research approaches and research tools and support a Down Syndrome Cohort Research Site, a Down Syndrome Clinical Cohort Coordinating Center, and a Federated Biobanking resource for the Down Syndrome Cohort Development Program. Enrolling a cross-sectional cohort of individuals with DS, people of different ages, sexes, races, and ethnicities across the lifespan, will capture the broadest array of phenotypes and ages of onset for the co-occurring conditions that many people with DS experience. This information will help to identify critical windows for interventions and will improve the understanding of co-occurring conditions in individuals with DS over time and provide the basis for developing long-term social and health care policies.

<sup>&</sup>lt;sup>1</sup> recovercovid.org/

<sup>&</sup>lt;sup>2</sup> cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf

<sup>&</sup>lt;sup>3</sup> cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm

<sup>&</sup>lt;sup>4</sup> nih.gov/include-project

The food we eat and have access to varies greatly from person to person and can be different depending on our living environment and culture. Our diets can greatly affect our health and even help prevent and fight conditions like high blood pressure, diabetes, stroke, and cancer. Nutrition is important for the prevention and treatment of chronic conditions and disease; however, current dietary recommendations do not consider individual biological differences in how people respond to foods. In 2023, NIH launched the Nutrition for Precision Health (NPH) study, powered by the *All of Us* Research Program, to study how individual people respond to different foods.<sup>5</sup>

To better understand how food and diet can impact health, NIH is working with 14 different sites across the United States to engage 10,000 participants from diverse backgrounds to learn more about how our bodies respond to food.<sup>6</sup> Participants in the study will complete surveys, report their daily diets, and provide blood, urine, and stool samples for lab tests, including microbiome analysis. A subset of research participants will be provided diets selected by researchers but otherwise maintain their regular lives, while other participants will be selected to reside in research centers while on researcher-provided diets. NPH will use artificial intelligence-based approaches to analyze participants' data from the study and information obtained through the *All of Us* Research Program to develop algorithms that predict responses to dietary patterns. The data collected from the study will be accessible through the *All of Us* data platform and will support many other studies on health and disease. The study's findings may one day allow healthcare providers to offer personalized nutritional guidance to improve overall health.

In FY 2025, the NIH Office of Research on Women's Health (ORWH) plans to support a range of new and ongoing activities to enhance research into women's health issues, including increasing the number of hubs in the Maternal and Pediatric Precision in Therapeutics Centers of Excellence (MPRINT) initiative to increase the knowledge, tools, and expertise in maternal therapeutics available to the broader research, regulatory science, and drug development communities; expanding trial capacity for the Maternal-Fetal Medicine Unit Network to advance specific treatment approaches to leading drivers of maternal morbidity and mortality; and establishing clinical trials to test technologies developed through the RADx-Tech Maternal Health Challenge based on levels of readiness of the technology in rural and remote locations. New research will be supported for important topics such as menopause and diabetes, opioid use disorder in pregnant women, and alcohol use during pregnancy, and ORWH will support cross-NIH initiatives to promote sex and gender equity across all domains of research.

#### More comprehensive, timely and inclusive research results achieved through data sharing

The lifeblood of a research institute is its data, and for NIH this includes data that encompasses research across a spectrum ranging from basic science laboratories to large health systems to individual communities where people live and work. Our goal is to realize the full potential of biomedical research and clinical care data to develop new treatments, prevention approaches, and health care delivery methods that improve the lives of all people. It is critically important that

<sup>&</sup>lt;sup>5</sup> commonfund.nih.gov/nutritionforprecisionhealth

<sup>&</sup>lt;sup>6</sup> nutritionforprecisionhealth.org

NIH work with grantees and across other HHS agencies to develop a modern infrastructure that optimally supports data sharing and use.

Through its Office of Data Science Strategy (ODSS), the OD will implement cross-NIH programs that meet the challenges required to deliver more results faster through optimal data sharing and use. In January 2023, a new NIH Data Sharing Policy<sup>7</sup> went into effect. This policy requires every new publicly funded research project to move beyond completing its research aims by adding a description of how the researchers will produce data that can be used by others to uncover new insights, and, when applicable, reproduce their research results. NIH must ensure these data to be standardized, collected, stored, and used. First, NIH will support the 2024 HHS Data Strategy,<sup>8</sup> working with all HHS agencies to integrate data from basic and social science research, public health, and clinical care. A particular emphasis will be placed on obtaining inclusive, diverse, and secure data from all clinical care environments. To do this, the OD is exploring options to expand clinical research capacity to reach communities of all types via a new NIH-wide network focused on primary care. In addition, the OD will partner with all HHS agencies to further develop the electronic health record as a vehicle for engaging the people who represent the full diversity of our society in biomedical research. Second, NIH envisions the National Library of Medicine (NLM) as a focal point to support data sharing and use for biomedical research. Accordingly, NLM's FY 2025 request includes a new \$30.0 million clinical data initiative to develop the tools, computational resources, and datasets necessary to extend NIH clinical research capabilities, including supporting artificial intelligence research and development. In response to user community needs, ODSS will work with NLM to increase capacity for data hosting, build policies, programs, and infrastructure to deliver minimal cost access to open-industry data standards, support broad access to advanced analytics and computational power, and support education and workforce development, particularly for groups not currently represented.

#### Safe, equitable, and respectful work environments

NIH strives toward a diverse, equitable, inclusive, accessible, safe, respectful, and harassmentfree workplace and has taken many substantive actions to assess, support, and enforce policies and initiatives that benefit the NIH intramural and extramural workforce as well as grantees. Consistent with the U.S. Surgeon General's Framework for Workplace Mental Health & Well-Being, NIH prioritizes employee mental and physical wellbeing, protection from harm in the workforce, and connection and community.<sup>9</sup>

NIH holds all community members, regardless of position or status, accountable to ensure that the workplace is free of harassment and other inappropriate conduct. The NIH Civil program provides the entire NIH community with reporting tools and a process to review allegations, identify inappropriate behaviors, and refer findings to NIH management. The NIH-wide Anti-Harassment Steering Committee, chaired by the OD, is regularly informed of NIH Civil work and findings, and responds by making recommendations on the implementation of new anti-

<sup>&</sup>lt;sup>7</sup> grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

<sup>&</sup>lt;sup>8</sup> cdo.hhs.gov/s/hhs-data-strategy

<sup>&</sup>lt;sup>9</sup> hhs.gov/sites/default/files/workplace-mental-health-well-being.pdf

harassment policies and updates to procedures for handling allegations and findings of harassment.

Diversity, Equity, Inclusion, and Accessibility in the workforce are key components of innovation and achievement in all areas of research. To that end, the UNITE Initiative was publicly unveiled in early 2021 as an NIH-wide effort committed to identifying and addressing any racial inequities across the biomedical and behavioral research enterprise.<sup>10</sup> UNITE is a people focused and data driven initiative that works across three content areas-Health Disparities and Minority Health Research (HD/MH), the internal NIH workforce, and the external biomedical and behavioral research workforce. UNITE has received considerable community input on how NIH might advance diversity within the biomedical and behavioral research workforce. Over 1,000 written responses to a public Request for Information (RFI) and an audience of over 1,300 participants across 14 listening sessions have informed UNITE's efforts, leading to the expansion of existing funding opportunities and the development of 3 new funding opportunities to promote and sustain equity within the NIH-supported biomedical and behavioral research ecosystem.<sup>11,12,13</sup> Accountability and communication are a consistent commitment for UNITE, which is tracking facts and figures regarding aggregated diversity, equity, and inclusion-related data and analyses related to funding, the internal NIH staff, and the extramural scientific workforce through a public Data Dashboard.<sup>14</sup>

The NIH Office of Equity, Diversity, and Inclusion (EDI) offers services to NIH staff with the mission of creating a culture of inclusion where diverse talent is leveraged to advance health discovery. EDI is the central location for all NIH employees to file discrimination complaints pursuant to the federal equal employment opportunity (EEO) laws enforced by the Equal Employment Opportunity Commission (EEOC). In addition, EDI provides reasonable accommodation guidance, delivers training courses pursuant to EEOC's requirements, which include the Notification and Federal Employee Antidiscrimination and Retaliation Act, the Prevention of Sexual Harassment, and Anti-Harassment.

The Chief Officer for Scientific Workforce Diversity (COSWD) Office in the OD leads NIH in the science of diversifying the national scientific workforce. In 2023, the COSWD Office announced a new initiative, the NIH Institutional Excellence in Diversity, Equity, Inclusion, and Accessibility (DEIA) in Biomedical and Behavioral Research Challenge Prize Competition. This competition, in collaboration with all 24 ICs that support extramural grants, was developed to recognize and reward institutions whose biomedical, social, and behavioral science departments, centers, programs, or divisions have identified gaps/barriers towards addressing DEIA; as well as those that design, implement, and evaluate interventions to address gaps to achieve sustained improvement in DEIA within their faculty, postdoctoral scholars, and student bodies.

<sup>&</sup>lt;sup>10</sup> nih.gov/ending-structural-racism/unite

<sup>&</sup>lt;sup>11</sup> nih.gov/sites/default/files/research-training/initiatives/ending-structural-racism/unite-rfi-report-508c.pdf

<sup>&</sup>lt;sup>12</sup> nih.gov/sites/default/files/research-training/initiatives/ending-structural-racism/RFI\_UNITE\_external-listening-session-summary-report-508%5B42%5D.pdf

<sup>&</sup>lt;sup>13</sup> nih.gov/ending-structural-racism/launching-new-unite-e-initiatives

<sup>&</sup>lt;sup>14</sup> nih.gov/ending-structural-racism/data-dashboard

In March 2023, NIH released the Fiscal Years 2023-2027 NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA).<sup>15</sup> The five-year strategic plan articulates NIH's commitment to embrace, integrate, and strengthen DEIA across the agency to enhance its operations, research, and workforce. The DEIA Strategic Plan also includes approaches to advance DEIA within the broader biomedical and behavioral research enterprise, including within its workforce and the research NIH supports.

NIH will continue to increase coordinated support for safe, equitable, and respectful work environments. By supporting these goals, NIH will foster scientific innovation, improve the quality of research, and advance opportunities for populations that experience barriers to participate in and benefit from biomedical and behavioral research.

 $<sup>^{15}\</sup> nih.gov/about-nih/nih-wide-strategic-plan-diversity-equity-inclusion-accessibility-deia$ 





# Mission of the Office of the Director

The National Institutes of Health (NIH) Office of the Director (OD) serves as the central office at NIH, responsible for the research mission, policies, and administration of the agency. OD supports NIH-wide initiatives in close partnership with NIH Institutes, Centers, and Offices (ICOs) by providing leadership in planning, managing, and coordinating the programs and activities across the agency. OD strives to enhance scientific discoveries through establishing NIH-wide strategic priorities and services, providing guidance and resources to lead efforts on behalf of the agency, and fostering collaboration across agency activities.

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OD is a critical element in shaping the agency's overarching agenda, seeking input from, and partnering with

a wide range of collaborators, including the scientific community, the public, other federal agencies, and Congress. With this critical perspective, OD identifies needs and opportunities 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 public.

# Highlights from the Office of the Director

The Common Fund Venture Space. The NIH Common Fund is a funding program that supports bold scientific programs to catalyze discovery across all areas of biomedical, behavioral, and social sciences research. The Common Fund Venture Space provides capacity for high-risk, short-term initiatives that are driven by the needs of the ICOs.



Projects in the Common Fund Venture Space will utilize innovative, flexible approaches to support high impact science, including flexibility in funding mechanisms and project timelines.

• ACD Working Group on Catalyzing the Development and Use of Novel Alternative Methods. The Advisory Committee to the Director (ACD) Working Group was charged with identifying high-priority areas for NIH investment in the development and use of novel alternative methods. These methods include approaches such as cell-based and computational methods that hold tremendous promise for increasing the tools available to achieve the NIH mission.

**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 2023, the OD employed 1,134 FTEs and funded almost \$3.1 billion in scientific research and NIH-wide resources and operations (see chart for details).





• Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program. The NIH Common Fund's FIRST program facilitates extramural institutions in building a self-reinforcing community of scientists through the recruitment of a critical mass of early-career faculty who demonstrate a commitment to inclusive excellence. The program announced its third round of awards to recruit diverse cohorts of early-stage research faculty and establish inclusive environments to help those faculty succeed.

 ACD Working Group on Re-envisioning NIH-Supported Postdoctoral Training. An ACD Working Group

was charged with re-envisioning NIH-supported postdoctoral training. This WG is evaluating whether there is evidence to support the perceived decline and shortage in PhDs seeking U.S. postdoctoral training positions and engaging key parties to understand and strengthen the U.S. postdoctoral training system.

- Accelerating Medicines Partnership® (AMP®) Programs. Managed by the Foundation for the National Institute of Health (FNIH), the AMP® program is a public-private partnership between NIH, FDA, multiple biopharmaceutical and life science companies, nonprofit and other organizations, to transform the current model for developing new diagnostics and treatments. The AMP® Heart Failure project focuses on addressing a critical unmet need in cardiovascular health by investigating the syndrome of heart failure with preserved ejection fraction. The AMP® Bespoke Gene Therapy Consortium fosters development of gene therapies intended to treat rare genetic diseases, which affect populations too small for viable commercial development.
- Native Collective Research Effort to Enhance Wellness (N CREW) Program. Sponsored by the Tribal Health Research Office and the National Institute on Drug Abuse, N CREW was recently launched by the

Helping to End Addiction Long-term (HEAL) Initiative<sup>®</sup> to support locally prioritized research, enhance capacity, and improve access to and quality of data for Tribes and Native American Serving Organizations (T/NASOs) to address overdose, substance use, and pain.

 NIH-Wide Advancing Prevention Research for Health Equity (ADVANCE) Network. The Office of Disease Prevention ADVANCE Program will launch a multi-sectoral research network to support high-impact preventive intervention research projects that address leading risk factors for health conditions in populations experiencing health disparities.



#### **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 2025 budget request for the NIH Office of the Director (OD), which is \$21.8 million below the FY 2023 Final level for a total of \$3,044.5 million. This funding level will allow OD to provide leadership to the NIH Institutes and Centers and will support important research programs managed by OD, including the *All of Us* Research Program, the Environmental Influence on Child Health Outcomes study, and the numerous research initiatives of the NIH Common Fund.

<u>All of Us Research Program (equal to FY 2023; total \$541.0 million):</u> The FY 2025 President's Budget request for the *All of Us* Research Program includes \$36.0 million in budget authority (BA) from the 21st Century Cures Act, the full authorized amount, along with \$505.0 million in non-Cures Act BA, to hold the program at the same total funding level of \$541.0 million as in FY 2023. The *All of Us* funding will be used to continue enrollment and retention activities to advance individualized healthcare by building one of the largest, most diverse health databases in the world.

Office of Research on Women's Health (+\$76.4 million; total \$153.9 million): The FY 2025 President's Budget request will enable the Office of Research on Women's Health to fund research in the areas of Maternal and Pediatric Precision in Therapeutics Centers of Excellence, Maternal-Fetal Medicine Unit Networks Trial Capacity, RADx-Tech Maternal Health Clinical Trials, Menopause and Diabetes, Opioid Use Disorder in Pregnant Women, Alcohol Use During Pregnancy, and to support cross-institute initiatives to promote sex and gender equity across all domains of research.

<u>Firearms Research (+\$12.5 million; total \$25.0 million)</u>: The FY 2025 President's Budget will enable NIH to increase its research efforts on firearm injury and mortality prevention.

<u>Office of Research Infrastructure Programs (-\$50.0 million; total \$259.4 million)</u>: The FY 2025 President's Budget request includes a decrease to the number of instrumentation grants funded by the Office of Research Infrastructure Programs.

<u>Extramural Construction Grants (-\$70.0 million; total \$10.0 million)</u>: The FY 2025 President's Budget requests \$10.0 million for extramural construction grants, a reduction of \$70.0 million from the FY 2023 Final level. The remaining funding would be targeted to support nonhuman primate infrastructure.

Mechanism	FY 2023 Final <sup>2</sup>		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Grants:								
Research Project Grants		\$794,839		\$826,238		\$890,768		\$95,929
Research Centers		\$330,768		\$350,703		\$321,634		-\$9,134
Other Research		\$1,008,274		\$768,135		\$929,861		-\$78,413
Total Research Grants		\$2,133,881		\$1,945,075		\$2,142,263		\$8,382
Training		\$16,074		\$11,566		\$12,188		-\$3,886
R & D Contracts		\$91,253		\$100,631		\$111,649		\$20,396
Intramural Research		\$5,025		\$4,883		\$4,983		-\$42
Res. Management & Support		\$731,794		\$743,358		\$763,372		\$31,579
Construction		\$87,999		\$80,000		\$10,000		-\$77,999
Total Other Than Research Grants		\$932,144		\$940,439		\$902,192		-\$29,953
Subtotal, Labor/HHS Budget Authority		\$3,066,208		\$2,885,514		\$3,044,455		-\$21,753
Total, OD		\$3,066,208		\$2,885,514		\$3,044,455		-\$21,753

#### Office of the Director Budget Mechanism<sup>1</sup> (Dollars in Thousands)

<sup>1</sup> Of which \$419.0 million in FY 2023, \$235.0 million in FY 2024, and \$36.0 million in FY 2025 is derived by transfer from the NIH Innovation Account under the 21st Century Cures Act after actual and anticipated transfers.

<sup>2</sup> Includes FY 2023 21st Century Cures Act funding not obligated in FY 2023 and carried over into FY 2024.

#### **Appropriations Language**

# OFFICE OF THE DIRECTOR (INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, \$3,000,855,000: 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 \$153,909,000 shall be available for the Office of Research on Women's Health established under section 486 of the PHS Act: Provided further, That of the funds provided, \$10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director of the NIH may spend up to \$8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act: Provided further, That up to \$10,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283k) with respect to the National Primate Research Centers and Caribbean Primate Research Center: Provided further, That \$5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: Provided further, That the funds

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provided in the previous proviso may be transferred from one specified activity to another with 15 days prior notification to the Committees on Appropriations of the House of Representatives and the Senate: Provided further, That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2025 and 2026 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.

In addition to other funds appropriated for the Office of the Director, \$12,600,000 is appropriated 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.

# 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, \$127,000,000, 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.

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

#### Summary of Changes

(Dollars in Thousands)

	FY 2023 Fi		FY 202 I	5 President's Budget	Built-In Change from FY 2023 Final	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
1. Intramural Research:						
A. Built-in cost changes:						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$4,061		\$4,600		\$52
b. FY 2024 effect of FY 2024 pay & benefits increase		\$4,061		\$4,600		\$157
c. FY 2024 paid days adjustment		\$4,061		\$4,600		\$16
d. Differences attributable to FY 2024 change in FTE		\$4,061		\$4,600		\$0
e. FY 2025 effect of FY 2024 pay & benefits increase		\$4,061		\$4,600		\$49
f. FY 2025 effect of FY 2025 pay & benefits increase		\$4,061		\$4,600		\$101
g. FY 2025 paid days adjustment		\$4,061		\$4,600		\$0
h. Differences attributable to FY 2025 change in FTE		\$4,061		\$4,600		\$0
i. Payment for centrally turnished services		\$0		\$0		\$0
J. Cost of laboratory supplies, materials, other expenses, and		\$964		\$383		\$34
Subtotal IR built in cost changes						\$409
Subtoliti, in out in cost changes						φ+09
2. Research Management and Support:						
A. Built-in cost changes:						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$209,608		\$237,076		\$2,479
b. FY 2024 effect of FY 2024 pay & benefits increase		\$209,608		\$237,076		\$8,154
c. FY 2024 paid days adjustment		\$209,608		\$237,076		\$807
d. Differences attributable to FY 2024 change in FTE		\$209,608		\$237,076		\$13,429
e. FY 2025 effect of FY 2024 pay & benefits increase		\$209,608		\$237,076		\$2,774
f. FY 2025 effect of FY 2025 pay & benefits increase		\$209,608		\$237,076		\$3,817
g. FY 2025 paid days adjustment		\$209,608		\$237,076		\$0
h. Differences attributable to FY 2025 change in FTE		\$209,608		\$237,076		\$4,660
i. Payment for centrally furnished services		\$0		\$0		\$0
j. Cost of laboratory supplies, materials, other expenses, and		\$522.186		\$526.296		\$26 514
non-recurring costs		\$522,180		\$520,270		\$20,514
Subtotal, RMS built-in cost changes						\$62,634
	FY 2	2023 Final	FY 202 I	5 President's Budget	Program FY 2	Change from 023 Final
CHANGES	No.	Amount	No.	Amount	No.	Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	325	\$367,164	377	\$486,252	52	\$119,088
b. Competing	359	\$419,116	308	\$396,233	-51	-\$22,883
c. SBIR/STTR	14	\$8,559	14	\$8,284	0	-\$276
Subtotal, RPGs	698	\$794,839	699	\$890,768	1	\$95,929
2. Research Centers	128	\$330,768	117	\$321,634	-11	-\$9,134
3. Other Research	458	\$1,008,274	356	\$929,861	-102	-\$78,413
4. Research Training	203	\$16,074	42	\$12,188	-161	-\$3,886
<ol><li>Research and development contracts</li></ol>	9	\$91,253	17	\$111,649	8	\$20,396
Subtotal, Extramural		\$2,241,208		\$2,266,100		\$24,892
6. Intramural Research	0	\$5,025	0	\$4,983	0	-\$451
7. Research Management and Support	1,134	\$731,794	1,241	\$763,372	107	-\$31,056
8. Construction		\$87,999		\$10,000		-\$77,999
9. Buildings and Facilities		\$0		\$0		\$0
Subtotal, program changes						-\$84,614
Total built-in and program changes	1,134	\$3,066,208	1,241	\$3,044,455	107	-\$21,753

#### NATIONAL INSTITUTES OF HEALTH

#### Office of the Director Organization Structure



#### **BUDGET AUTHORITY BY ACTIVITY TABLE**

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

#### Budget Authority by Activity

(Dollars in Thousands)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
OD Led Science Programs	822,250	638,250	822,250	0
INCLUDE Project	90,000	90,000	90,000	0
All of Us Research Program	122,000	122,000	505,000	383,000
All of Us Research Program - Cures	419,000	235,000	36,000	-383,000
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	135,000	135,000	135,000	0
Office of Data Science Strategy	85,000	85,000	85,000	0
Artificial Intelligence to Chronic Disease	50,000	50,000	50,000	0
Building Research Capacity and Collaborations	1,318,997	1,318,997	1,358,066	39,069
Common Fund	735,001	735,001	722,401	-12,600
Office of Nutrition Research	1,313	1,313	1,313	0
Firearm Injury and Mortality Prevention Research	12,500	12,500	25,000	12,500
Division of Program Coordination, Planning and Strategic Initiatives	570,183	570,183	609,352	39,169
Research Training and Career Development	20,427	20,427	20,427	0
Intramural Loan Repayment and Scholarship	9,014	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	105,644	105,644	105,644	0
OD Operations	663,889	667,195	603,067	-60,822
Office of the Chief Scientific Officer for Workforce Diversity (non-add)	(22,711)	(22,711)	(22,711)	(0)
Reception and Representation Fund (non-add)	(10)	(10)	(10)	(0)
Non-Human Primate Facilities (non-add)	(0)	(0)	(10,000)	(10,000)
Biomedical & Behavioral Research Facilities (non-add)	(80,000)	(80,000)	(0)	-(80,000)
Total	\$3,066,208	\$2,885,514	\$3,044,455	-\$21,753

#### **Office of the Director (OD)**

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

Budget Authority (BA):

			FY 2025	
			President's	FY 2025 +/-
	FY 2023 Final	FY 2024 CR	Budget	FY 2023
BA	\$3,066,208,000	\$2,885,514,000	\$3,044,455,000	-\$21,753,000
FTE	1,134	1,217	1,241	107

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

<u>Overall Budget Policy</u>: The FY 2025 President's Budget request for the Office of the Director is \$3,044.5 million, a reduction of \$21.8 million or 0.7 percent compared with the FY 2023 Final level. This level includes increases of \$76.4 million for the Office of Research on Women's Health and \$12.5 million for research related to the prevention of firearms injury and mortality, offset by reductions totaling \$120.0 million in grants for extramural construction and research instrumentation. This request also includes \$36 million in 21<sup>st</sup> Century Cures Act authorized funds for the *All of Us* Research Program, a reduction of \$383.0 million from FY 2023. This decrease is offset with an increase of \$383.0 million in non-Cures Act funding, holding *All of Us* equal to the FY 2023 overall funding level of \$541.0 million. The request for OD will support the continuation of 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 provides leadership to the planning, management, and coordination of programs and activities across NIH that are in both the OD and ICs. In addition, the OD provides strategic direction and coordination for key scientific programs.

#### **Maternal Health**

In response to the high and increasing rates of pregnancy-related deaths in the United States, NIH launched the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative to address the leading causes of maternal mortality and severe maternal morbidity (MM/SMM), reduce preventable causes of MM, improve health, and promote health equity.<sup>16</sup> The IMPROVE initiative is an NIH-wide effort, co-led by the *Eunice* Kennedy Shriver National Institute of Child Health and Human Development (NICHD), Office of Research on Women's Health, and National Institute of Nursing Research, that includes research challenge competitions in addition to traditional grant funding. NICHD launched the Connecting the Community for Mental Health Challenge Prize competition to encourage community-based non-profit organizations to develop infrastructure and capabilities to support maternal health research that specifically impact their communities.<sup>17</sup> Participating organizations received training and mentoring in research proposal writing and building maternal health research infrastructure. The Office of Dietary Supplements (ODS) within the OD is cofunding a seven-year Maternal Health Research Center of Excellence (CoE) grant that started in FY 2023. Maternal Health Research CoEs will use integrated multi-level approaches encompassing structural, social, and biobehavioral research strategies to address the multiple contributing factors that lead to adverse maternal health outcomes and health disparities. The Office of Behavioral and Social Sciences Research (OBSSR) led the development of two IMPROVE funding opportunities (RFA-OD-24-001 and RFA-OD-24-002) that focus on intimate partner violence (IPV) research.<sup>18,19</sup> IPV is a leading cause of maternal mortality and other nonfatal health outcomes; however, there is a limited understanding of the risk and protective factors associated with IPV. Through these funding opportunities, NIH aims to support career development and training opportunities to ensure better integration of the research workforces focused on IPV and maternal morbidity and mortality. This integration is critical in order to facilitate innovative research that will ultimately reduce preventable causes of maternal deaths and improve health for women before, during, and after delivery.

Maternal and neonatal infections are one of the top three causes of maternal and newborn deaths globally.<sup>20</sup> A randomized clinical trial, Azithromycin Prevention in Labor Use Study (A-PLUS), was conducted by NICHD's Global Network for Women's and Children's Health Research and co-funded by NICHD and the Foundation for the National Institutes of Health (FNIH).<sup>21</sup> Results from this trial suggest that a single oral dose of the antibiotic azithromycin administered during labor can reduce the occurrence of maternal sepsis and death by approximately one-third in comparison to a placebo control. This study has the potential to inform and update World Health Organization Guidelines to improve the outcomes of mothers in labor globally.

#### **Nutrition and Dietary Intake**

In FY 2021, the NIH Director transferred the Office of Nutrition Research (ONR) to the OD from NIDDK, reflecting the priority NIH places on innovative, multidisciplinary nutrition research. As part of ONR's mission of advancing nutrition science to promote health and to reduce the burden of diet-related diseases and health disparities, the Reducing Nutrition Health Disparities through Food Insecurity and Neighborhood Food Environment Research collaborative project was developed. This research brings together scientists from across the country to develop and test interventions, innovative programs, and observational studies

<sup>&</sup>lt;sup>16</sup> nichd.nih.gov/research/supported/IMPROVE/about

<sup>&</sup>lt;sup>17</sup> nichd.nih.gov/research/supported/challenges/community-maternal-health

<sup>&</sup>lt;sup>18</sup> grants.nih.gov/grants/guide/rfa-files/RFA-OD-24-001.html

<sup>&</sup>lt;sup>19</sup> grants.nih.gov/grants/guide/rfa-files/RFA-OD-24-002.html

<sup>&</sup>lt;sup>20</sup> who.int/publications/i/item/9789241549363

<sup>&</sup>lt;sup>21</sup> fnih.org/our-programs/azithromycin-prevention-in-labor-use-study-a-plus/

addressing food insecurity and neighborhood-level access to healthy and affordable foods. The findings will lead to a better understanding of the effects that food insecurity and neighborhood food environments have on wellbeing, diet-related diseases, and other health outcomes. Barriers

within communities and health care systems severely hinder the goal to reduce dietrelated diseases. To address these barriers, ONR is leading the Food is Medicine Networks and Centers of Excellence program, which will support implementation science, intervention, and health quality research.<sup>22</sup>

Another NIH-wide collaboration is the Common Fund's Nutrition for Precision Health, powered by the *All of Us* Research Program (NPH). Engaging with 14 sites across the U.S. and over 10,000 participants with diverse backgrounds, NPH is investigating individual responses to food and dietary patterns to develop algorithms that can predict food intake responses. This initiative has the potential to lay the groundwork for more personalized nutrition recommendations. The data produced through this collaboration will be available to researchers through the *All of Us* Research Workbench.<sup>23</sup>

After a meal, dietary supplement, or drug is ingested, transporters are responsible for taking up and distributing nutrients, metabolites, or drugs throughout the body. In the case of the developing fetus and newborn infant, the placenta, lactating mammary gland, and blood brain barrier are critical for nutrient and drug transport. At

#### Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)

Advances in data science hold significant promise for improving our understanding of human health and disease, but if used improperly could entrench or exacerbate inequities in health or health care. NIH seeks to better understand the policy and ethical implications of emerging data science technologies, and their potential benefits and risks for research participants, families, communities, researchers, and society. To assist in these efforts. NIH convened NExTRAC, a federal advisory committee that provides a platform for public forum and guidance to the NIH Director on scientific, safety, and ethical issues associated with emerging biotechnologies, to help ensure that research progresses responsibly and meets ethical principles and societal expectations for the Nation's investment in research.

In August 2023, NExTRAC was charged to develop a harmonized and implementable vision and framework for including public voices in the design and planning of NIH-funded clinical research and to define pathways for widespread dissemination of study findings. This framework will outline approaches appropriate for the breadth and diversity of NIH-funded clinical research studies and assess the potential opportunities and challenges of varying levels of engagement activities for different types of clinical research studies, as well as the impact and value of engagement with patients, communities, and the broader public on clinical research. To address this charge, NExTRAC will consult with the ACD and convene public consultations with a wide range of relevant parties. Through this framework and community convenings, the Committee will provide recommendations regarding different engagement methods, the optimal timing for meaningful engagement activities, and equitable and inclusive approaches for engagement.

present, transporters in the human placenta, mammary gland, the developing gut, and the developing brain are not fully understood, despite their critical role in maternal and infant health. To address our limited understanding of transporters in the human placenta and developing gut and brain, two High Impact Research and Research Infrastructure Cooperative Agreement grants were awarded under the Elucidation and Validation of the role of Transporters in the Placenta, Lactating Mammary Gland, Developing Gut, and Blood Brain Barrier initiative.<sup>24</sup> The grants will aid in responding to this critical knowledge gap.

<sup>&</sup>lt;sup>22</sup> dpcpsi.nih.gov/sites/default/files/Day-2-225PM-ONR-Concept-Food-as-Medicine-Lynch-onepagerREV-508.pdf

<sup>&</sup>lt;sup>23</sup> researchallofus.org/data-tools/workbench/

<sup>&</sup>lt;sup>24</sup> grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-003.html

#### **Animal Models Including Non-Human Primate Model Systems**

Animal models of human disease continue to be critical for understanding and improving human health. The OD helps ensure that NIH-supported laboratory animal research is rigorous, ethically conducted, and scientifically valid by serving a key role in the oversight, management, and coordination of animal research policies and programs. The OD has led implementation of recommendations from the Advisory Committee to the NIH Director (ACD) Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research, which provided recommendations in 2021.<sup>25,26</sup> Efforts include workshops, a Notice of Special Interest (NOSI), and Notices of Funding Opportunities (NOFOS; PAR-23-039 and PAR-23-040) from the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) Office of Research Infrastructure Programs (ORIP) aimed at training and promoting development of resources and technologies that validate animal models and enhance their use.<sup>27,28,29</sup> Recommended by the ACD working group, the OD also leads the ACD Working Group on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research, which is charged with identifying high-priority areas for NIH investment in the use and development of novel alternative methods.<sup>30</sup> Novel alternative methods, such as cell-based and digital models, complement animal research and support the 3Rs of animal research (Replacement, Reduction, and Refinement). Recommendations from the working group were released in December 2023.

The OD also coordinates and funds important resources for NIH-supported animal research. Examples of these resources include:

- ORIP's Pilot Centers Program for Precision Disease Modeling Initiative to provide researchers with advanced animal models needed to develop precision therapies for disorders controlled by a single gene, as well as diseases with more complex genetics.<sup>31</sup>
- Research Resource Centers to support availability and validation of animal models, including marmosets and large and long-lived animal models. For example, supported by ORIP, the National Swine Resources and Research Center (NSRRC) serves as a central resource for the creation of genetically modified swine to use in biomedical research as models of human health and disease.
- National Primate Research Centers (NPRCs) facilitate the effective use of nonhuman primates for biomedical and behavioral research by providing the animals, infrastructure, facilities, expertise, and resources required for research in specific disease areas.<sup>32</sup>
- The NIH-supported mouse model resources which developed and characterized mutations in protein-coding genes to better understand the consequences of these

<sup>&</sup>lt;sup>25</sup> acd.od.nih.gov/working-groups/eprar.html

<sup>&</sup>lt;sup>26</sup> acd.od.nih.gov/documents/presentations/06112021\_ACD\_WorkingGroup\_FinalReport.pdf

<sup>&</sup>lt;sup>27</sup> grants.nih.gov/grants/guide/notice-files/NOT-OD-22-039.html

<sup>&</sup>lt;sup>28</sup> grants.nih.gov/grants/guide/pa-files/PAR-23-039.html

<sup>&</sup>lt;sup>29</sup> grants.nih.gov/grants/guide/pa-files/PAR-23-040.html

<sup>&</sup>lt;sup>30</sup> acd.od.nih.gov/working-groups/novel-alternatives.html

<sup>&</sup>lt;sup>31</sup> orip.nih.gov/comparative-medicine/initiatives/precision-disease-modeling

<sup>&</sup>lt;sup>32</sup> orip.nih.gov/resource-directory/national-primate-research-centers

mutations on human health, include the Knockout Mouse Phenotyping Program (KOMP2), the Mutant Mouse Resource & Research Centers (MMRRC), and others.<sup>33,34</sup>

• The Compliance Unit Standard Procedure Sharing Site, a Federal Demonstration Partnership project funded in part by the NIH Office of Extramural Research, is an online repository where participating institutions can share standard procedures used in animal care protocols, including procedures for care and use of non-typical species such as Cephalopods.<sup>35</sup>

#### **Tribal Health**

Across NIH, there is an increasing focus on the health of American Indians and Alaska Natives (AI/AN). The Tribal Health Research Office (THRO) supports NIH efforts to promote opportunities for the next generation of AI/AN researchers and enhance capacity for research in Native American communities while honoring Tribal sovereignty. THRO also assists in disseminating transparent and culturally tailored information about NIH-funded biomedical and behavioral research to AI/AN communities, as well as AI/AN cultural information to NIH staff. To build respectful partnerships and ensure meaningful input and collaboration with Tribal Nations on NIH policies, programs, and priorities, THRO has developed a Tribal Consultation Toolkit that serves as an internal use step-by-step guide for NIH staff to conduct a Tribal Consultation as is required in the NIH Tribal Consultation Policy.<sup>36</sup>

In direct response to priorities identified in Tribal Consultations, NIH co-launched the Native Collective Research Effort to Enhance Wellness (N CREW) Program.<sup>37</sup> N CREW is a highly collaborative program partnership between the NIH and Native American Serving Organizations to directly respond to the drug overdose and addiction public health emergency by supporting Tribally prioritized and culturally tailored research on overdose, substance use, pain, and related issues such as mental health and wellness. For example, as part of the NIH HEAL Initiative®, Enhancing the National Drug Abuse Treatment Clinical Trials Network to Address Opioids Program,<sup>38</sup> a clinical protocol is testing culturally appropriate methods for integrating use of traditional medications into treatments for opioid use disorder in AI/AN communities and has developed and published strategies for a culturally centered implementation intervention.<sup>39</sup>

ODSS is building a diverse data science community, where the advances in data and digital innovations can benefit all populations. In FY 2023, ODSS collaborated with the National Institute of General Medical Sciences (NIGMS) in providing support for the Native American Research Centers for Health (NARCH) program to promote data science capabilities of the AI/AN communities. NARCH supports projects that inform the development of Tribal Research Codes to govern genomic research, support indigenous research governance, develop data repositories, and improve applied biostatistics skills for AI/AN researchers.

<sup>&</sup>lt;sup>33</sup> genome.gov/Funded-Programs-Projects/Knockout-Mouse-Phenotyping-Program-KOMP2

<sup>&</sup>lt;sup>34</sup> mmrrc.org

<sup>&</sup>lt;sup>35</sup> thefdp.org/demonstrations-resources/cusp/

<sup>&</sup>lt;sup>36</sup> dpcpsi.nih.gov/thro/NIH-Tribal-Consultation-Policy

 $<sup>^{37}\</sup> heal.nih.gov/research/research-to-practice/native-collective-research-effort-enhance-wellness-overdose-substance-mental-health-pain$ 

<sup>&</sup>lt;sup>38</sup> heal.nih.gov/research/research-to-practice/enhancing-clinical-trials-network

<sup>&</sup>lt;sup>39</sup> onlinelibrary.wiley.com/doi/full/10.1002/ajcp.12620

The *All of Us* Research Program is a longitudinal cohort study that aims to accelerate health and medical breakthroughs to enable individualized prevention, treatment, and care. *All of Us* is building one of the largest, most diverse health databases of its kind. To support the participation of AI/AN individuals in the *All of Us* program, a series of virtual information sessions for Tribal communities and Urban Indian Organizations was conducted in partnership with THRO. These sessions provided an overview of *All of Us* Tribal engagement activities and scientific process while providing an opportunity for AI/AN communities, AI/AN researchers, and researchers working with AI/AN communities to provide input and guidance on the *All of Us* data gathering and data access process. The *All of Us* program is continuing to build partnerships with AI/AN communities and hosted its third formal Tribal consultation in September 2023 on program developments of importance to Tribal communities. The input shared by Tribal Nations is vital to informing program plans regarding access to, use, and

#### Community Partnerships to Advance Science for Society (ComPASS)

In the United States, health disparities are an ongoing challenge that require structural interventions to address its complex nature. The NIH Common Fund launched the Community Partnerships to Advance Science for Society (ComPASS) program to develop, share, and evaluate community-led health equity structural interventions. The program will enable communities and researchers to work collaboratively as equal partners with the intent that this research will improve health outcomes in communities affected by health disparities, as well as inform policies, systems, and practices to achieve optimal health for all. In 2023, ComPASS issued its first awards for community-led structural intervention projects and a coordinating center. ComPASS also announced funding opportunities for ComPASS Health Equity Research Hubs, as well as partnership in supporting the NIH Build UP Trust Challenge Prize Competition which aims to utilize new and existing strategies to improve NIH engagement with underserved populations.

commonfund.nih.gov/compass

grants.nih.gov/grants/guide/notice-files/NOT-HL-23-087.html protection of data from self-identified AI/AN participants and respect for Tribal sovereignty. In support of those efforts, *All of Us* also announced three awards in September 2023 totaling \$1.5 million. The awards will support outreach and engagement with Tribal and Indigenous communities, strengthen the research infrastructure supporting AI/AN researchers and broaden the base of researchers conducting cultural and ethical research with Tribal communities.

To support opportunities for the next generation of AI/AN researchers, the Tribal Undergraduate to Graduate Research Training and Leadership Experiences Program (TURTLE), developed in partnership between NIGMS and THRO, will provide institutional training grants to Tribes and Tribal Organizations to support the education of AI/AN undergraduate and graduate students. The awards will consist of two phases: a capacity development phase in which the Tribal Organizations can build the administrative

infrastructure needed to support the training grants, followed by the training grant phase in which the Tribe or Tribal Organization will provide stipends, tuition remission, and mentoring to students attending undergraduate and graduate institutions.

# **Office of Women's Health**

The mission of the NIH Office of Research on Women's Health (ORWH) is to: enhance research related to diseases, disorders, and conditions affecting women; help ensure that women are appropriately represented in biomedical research supported by the NIH; and improve the advancement of women in biomedical careers. In FY 2025, ORWH plans to use a requested

budget increase to fund a range of new and ongoing activities to enhance research into women's health issues, as detailed below. The increase will also allow ORWH to support cross-NIH initiatives to promote sex and gender equity across all domains of research.

- Maternal and Pediatric Precision in Therapeutics Centers (MPRINT) of Excellence to expand the number of MPRINT hubs focused in the area of maternal therapeutics, increasing the available knowledge, tools, and expertise in maternal therapeutics to the broader research, regulatory science, and drug development communities.
- **Maternal-Fetal Medicine Unit Networks Trial Capacity** to advance specific treatment approaches to leading drivers of maternal morbidity and mortality, particularly at or immediately following delivery.
- **RADx-Tech Maternal Health Clinical Trials** to conduct clinical trials to test technologies developed through the RADx-Tech Maternal Health Challenge, based on levels of readiness of the technology in rural and remote locations to ensure feasibility, effectiveness, and efficacy.
- Hormonal changes that occur in women years before menopause may contribute to high glucose levels during menopause, and may result in insulin resistance. More research in **Menopause and Diabetes** is needed, especially in underrepresented populations, to understand the mechanisms by which hormonal changes contribute to diabetes management and the contributions of these changes to alterations in body weight, body fat, and other risk factors contributing to diabetes development, particularly if menopause comes early in life.
- Overdose deaths among pregnant women and in the first year postpartum tripled in the past decade. Research in **Opioid Use Disorder in Pregnant Women** would include (1) implementation projects to engage obstetricians, nurses, and primary care physicians in screening for opioid use disorder (OUD) and initiating buprenorphine treatment; (2) implementation research for initiating buprenorphine treatment of pregnant women with an OUD in incarcerated settings; and (3) research projects for strategies that can help improve retention in treatment of pregnant women with OUD.
- New research is needed in **Alcohol Use During Pregnancy** to design and evaluate novel policy, community-based, and health messaging and other behavioral and social science approaches to help women reduce or abstain from drinking during pregnancy, to improve current prevention strategies to reduce use of alcohol in women of childbearing age, and to design and evaluate cost-effective, culturally sensitive interventions aimed at preventing fetal alcohol spectrum disorder (FASD) in high risk and vulnerable, and diverse populations.

# Sexual & Gender Minority Health Summer Intensive Series

In 2023, the Sexual & Gender Minority Research Office (SGMRO), Office of AIDS Research (OAR), and Office of Intramural Training and Education (OITE) cosponsored a Summer Intensive Series.<sup>40</sup> This first-of-its-kind Summer Intensive Series served to educate NIH summer interns and trainees about multiple aspects of sexual and gender minority (SGM) health research and its intersection with science, policy, communication, and community engagement. Participants met weekly to learn from prominent SGM researchers and engage in discussions

<sup>&</sup>lt;sup>40</sup> dpcpsi.nih.gov/sgmro/summer-intensive-series

about SGM health and health disparities research and policy, career options and how to navigate a career in SGM health research, and specific NIH-funded SGM research programs.

#### **Coordinating Research on Community Level Interventions for Firearm and Related Violence, Injury and Mortality Prevention**

Firearms deaths constitute an urgent and significant public health crisis. NIH is committed to supporting scientific research to increase our understanding of public health interventions to prevent different forms of violence, including firearm violence, and the resulting trauma, injuries, and mortality. Violence research cuts across many NIH Institutes and Centers and is coordinated by the Office of Behavioral and Social Sciences Research (OBSSR). Led by OBSSR, NIH supports the Community Firearm Violence Prevention Network consisting of a Coordinating Center and six research projects across the country that are developing, implementing, and evaluating innovative community level interventions in various environmental and cultural settings to prevent firearm and related violence injury and mortality. Additionally, in FY 2024, NIH published two NOFOs focused on advanced training and career development for established NIH investigators in related fields to obtain the necessary skills and expertise to integrate firearm injury prevention work into their research.<sup>41,42</sup> These awards will be in addition to three similar awards made in 2023 and continue to expand the field of qualified researchers and building capacity for the future. NIH is also working with HHS and other federal entities to ensure the research is available to inform ways to implement the U.S. National Plan to End Gender Based Violence.<sup>43</sup>

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.

#### Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) **Budget Summary**

(Dollars in Thousands)

		FY 2024	FY 2025	FY 2025
	FY 2023 Final	CP	President's	+/-
	28,426 40.845	CK	Budget	FY 2023
Office of the DPCPSI Director	28,426	28,426	41,026	12,600
Office of Behavioral & Social Sciences Research	40,845	40,845	40,845	0
Office of AIDS Research	67,589	67,589	67,806	217
Office of Research on Women's Health	77,557	77,557	153,909	76,352
Office of Disease Prevention	17,873	17,873	17,873	0
Office of Dietary Supplements	28,500	28,500	28,500	0
Office of Data Science Strategy	85,000	85,000	85,000	0
Office of Research Infrastructure Programs	309,393	309,393	259,393	-50,000
Office of Nutrition Research	1,313	1,313	1,313	0
Common Fund	735,001	735,001	722,401	-12,600
Total	\$1,391,497	\$1,391,497	\$1,418,066	\$26,569

 <sup>&</sup>lt;sup>41</sup> grants.nih.gov/grants/guide/pa-files/PAR-24-070.html
<sup>42</sup> grants.nih.gov/grants/guide/pa-files/PAR-24-073.html

<sup>&</sup>lt;sup>43</sup> whitehouse.gov/wp-content/uploads/2023/05/National-Plan-to-End-GBV.pdf

**Budget Policy:** The FY 2025 President's Budget request for these programs – consisting of the DPCPSI offices other than ODSS, plus firearms research funding – is \$1,358.1 million, an increase of \$39.1 million or 3.0 percent compared with the FY 2023 Final level. This level reflects an increase of \$76.4 million for ORWH to support the women's health initiatives detailed above along with a \$12.5 million increase in firearms research, offset by a reduction of \$50.0 million in ORIP grants for laboratory instrumentation. In FY 2025, OD will continue to engage in strategic collaborations and support capacity building in order to support a robust and innovative environment for NIH-supported research. DPCPSI offices will continue serving as a focal point to coordinate their respective areas of research across NIH through partnerships with the NIH Institutes and Centers and will foster efforts in areas including nutrition research, women's health, and firearms and related violence research.

#### All of Us Research Program

Nationally launched in 2018, the *All of Us* Research Program is a key component of the Precision Medicine Initiative established in the 21st Century Cures Act (P.L. 114-255). With more than half a million participants who completed the initial steps of the program, *All of Us* provides researchers access to one of the world's largest and most diverse dataset of its kind and has the ability to inform thousands of studies across all sectors of the biomedical research ecosystem and influence a new era in which researchers, health care providers, technology experts, community partners, and the public work together toward the development of individualized health care. The program is building a national infrastructure for biomedical



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.

research by collecting and securing health data from one million people living in the United States who reflect its diversity.

Currently, the All of Us data set is broadly available via the program's Researcher Workbench<sup>44</sup> to researchers from academic, nonprofit, or health care organizations with signed agreements. As of December 2023, the resource is being used by more than 8,400+ registered researchers from 650+ institutions, including 120+ HBCUs and HSIs, and intramural NIH labs with more than 9,020+ ongoing research projects using All of Us data. All of Us is working with 27 other institutes, centers, and offices from across the NIH to support new research on the All of Us Researcher Workbench.

<sup>44</sup> www.researchallofus.org/data-tools/workbench/

All of Us gathers data including physical measurements, survey responses, electronic health records, DNA samples, and data from wearable devices (e.g., Fitbits). Researchers have access to the

most diverse dataset compared to other national and global large-scale biomedical cohorts with nearly 250,000 genome sequences, 313,000 genotyping arrays, and more than 1,000 detailed long-read sequenced genomes. Fitbit device data includes sleep, activity, step count, and heart rate. Sleep data, when used alongside participants' electronic health record data, could be useful for studying how sleep patterns affect overall health and disease progression, including for conditions such as heart disease, high blood pressure, diabetes, depression, and dementia.

The program began testing its secure, cloud-based data platform three years ago with researchers from U.S.-based academic, not-for-profit, and health care institutions. As originally planned, *All of Us* updated its eligibility criteria for data access to engage more researchers and enable additional insights into health and disease. *All of Us* continues to work on expanding access to the Researcher Workbench to additional researchers. In August 2023, *All of Us* began taking applications from international academic, not-for-profit, and health care organizations. In October 2023 *All of Us* awarded \$30 million to establish the Center for Linkage and Acquisition Data (CLAD) to connect new types of information, including health care claims, mortality data, and environmental data, to *All of Us* participant data.<sup>45</sup> The data streams enabled through CLAD will further the program's efforts to build one of the most diverse biomedical data resources that can be used by researchers to gain insights into the biological, environmental, and behavioral factors that influence health.

The All of Us Research Program is committed to supporting early-career researchers, especially those from groups historically underrepresented in the biomedical workforce. Through the All of Us Researcher Academy, the program is helping to train the next generation of researchers with its data set that focuses on providing training, technical assistance, and peer-to-peer learning for health researchers at Minority Serving Institutions.<sup>46</sup> In July 2023, the program selected 6 HBCUs and 1 community college to serve as the second cohort of Institutional Champions, bringing the total of HBCUs being trained by the *All of Us* Research Academy to 13. Additionally, the All of Us Research Hub Summer Institute focuses on teaching high school science faculty about the Researcher Workbench and how to incorporate it into their curriculum. In July 2023, the first Research Hub Summer Institute was held that included 17 high school teachers from 13 states. During the Institute, teachers learned about the Program and guidelines for Workbench access for high school students. They worked with Workbench data from example research questions and collaborated on plans to engage their students in conducting research studies using data from the All of Us Research Project. The teachers reported that they plan to involve approximately 350 high school students in exploring research questions using the All of Us data during the 2023-2024 school year.

*All of Us* continues its effort to increase enrollment to reach a goal of one million or more participants. As of January 2024, *All of Us* has more than 757,000 consented participants from all 50 states, D.C., and Puerto Rico, of which more than 520,000 have completed the initial steps

<sup>&</sup>lt;sup>45</sup> allofus.nih.gov/news-events/announcements/all-us-research-program-establishes-new-center-linkage-and-acquisition-data

<sup>&</sup>lt;sup>46</sup> academy.researchallofus.org/

of the program. Nearly half of participants self-report being racial and ethnic minorities and over 80 percent report being from communities historically underrepresented in biomedical research. In FY 2025, the program will continue efforts to increase enrollment and continue to recruit pediatric participants aged six years and younger and will eventually expand to older children to reach the goal of having people of every age participate in *All of Us*. The participation of children in *All of Us* is important to gain a better understanding of children's health and how children can change and develop over time. Participation from individuals of all ages will provide insight into how health may change across a person's whole life.

# NIH-wide INCLUDE Program on Down Syndrome

The INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project launched as an 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. INCLUDE is an NIH-wide initiative, led by the OD, engaging 17 ICOs, that aims to better understand critical health and quality-of-life needs for individuals with DS. Now entering its fifth year, the INCLUDE Project continues to expand its research portfolio across all three components of the initiative: basic science studies on chromosome 21, large cohort development for individuals with DS, and the inclusion of individuals with DS in clinical trials.

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 inclusive of individuals with DS. The INCLUDE project is developing the standards for inclusivity for this population previously not well represented in clinical research.

#### **Environmental influences on Child Health Outcomes (ECHO) Program**

Understanding the effects of environmental exposures on child health and development is a priority for NIH. The Environmental influences on Child Health Outcomes (ECHO) Program combines observational and intervention research to answer questions about how influences on early human development, even before birth, affect us throughout our lives and across generations.<sup>47</sup> The ECHO Program has two major components: the ECHO Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN) for intervention research and the ECHO Cohort for observational research.

<sup>&</sup>lt;sup>47</sup> nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program



Echo's DASH datasets include deidentified longitudinal data from more than 41,000 participants across the United States and focus on child health outcomes including pre-, peri-, and postnatal outcomes; upper and lower airways health; obesity and its complications; neurodevelopment; and positive health.

The primary goal of the ECHO Cohort is to bring diverse participant populations together into one large cohort so that ECHO investigators and the broader scientific community can address research questions about effects of a broad range of early environmental exposures on child health and development, questions that no smaller study can answer alone.<sup>48</sup> The ECHO Program made 49 awards totaling over \$157 million for the first year of the second 7-year cycle of the ECHO Cohort Consortium.49,50 From September 2023 through

May 2030, the ECHO Cohort Consortium will follow more than 30,000 current ECHO Cohort child and adolescent participants and their families, while adding more than 30,000 new pregnant participants and their offspring. In addition, researchers will follow at least 10,000 women and, when available, their partners, to examine how preconception exposures may influence child health outcomes. The enhanced ECHO Cohort will include about 60,000 total children and adolescents by 2030.

Following this large and diverse population will enhance ECHO's ability to answer solutionoriented questions about the effects of a broad range of early environmental exposures, from society to biology, on child health and development. Scientific opportunities in the second cycle are nearly limitless and may include effects of novel chemicals, addressing health equity, impact of media use, assessing natural experiments, influences of preconception exposures, and consequences of social determinants of health, among others.

This first public-use version of ECHO-wide Cohort data is now available through the Data and Specimen Hub (DASH), a centralized resource established by NICHD that allows researchers to share and access de-identified data from studies via a controlled-access mechanism.<sup>51</sup> This momentous step fulfills both a key strategic goal of the ECHO Program and an obligation to U.S. taxpayers for their investment in this research.<sup>52</sup>

<sup>&</sup>lt;sup>48</sup> nih.gov/echo/echo-cohort-study-sites

<sup>&</sup>lt;sup>49</sup> nih.gov/echo/funding

 $<sup>^{50}\</sup> nih.gov/echo/echo-awards-more-157-million-observational-research-into-environmental-influences-child-health$ 

<sup>&</sup>lt;sup>51</sup> dash.nichd.nih.gov/

<sup>&</sup>lt;sup>52</sup> echochildren.org/dash/?%20utm\_source=homepagebannerdash

There exist many benefits to returning individual research results to participants such as informing clinical decision making and life planning, especially when such information might not otherwise be obtained by the participants.<sup>53</sup> To identify principles and best practices for ethically and feasibly returning individual research results to participants in large-sample studies that include pregnant women and children, ECHO hosted a two-day virtual workshop. The *Return of Individual Research Results to Participants Virtual Workshop* addressed specific considerations for pregnant people and children that differ from other participants, how to facilitate equity when returning results, and how to broaden returned results to include data other than genetic results.<sup>54,55</sup> The Workshop resulted in ECHO identifying best practices for large-sample studies of pregnancy and childhood to return individual research results ethically and feasibly to participants. These practices include specific principles and implications of returning results, consideration of the value of individual results to participants from their own perspective, and identification of cross-cutting themes and research gaps. These will be publicly available on ECHO.nih.gov.

#### The Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN®)

The BRAIN® Initiative brings together federal and non-federal partners with a common goal of revolutionizing our understanding of the human brain by accelerating the development and application of innovative technologies. Collaboratively managed by 10 ICOs whose missions and research portfolios complement the goals of the BRAIN Initiative, the research supported by the BRAIN Initiative has made significant contributions to the field in addition to changing the lives of individuals. The BRAIN® Initiative supports projects such as developing tools to map human brain cells and circuits, using brain stimulation to treat obsessive-compulsive disorder, converting thought to speech, and using brain-machine interfaces to gain use of arms for those with paralysis. In June 2023, the Congressional Neuroscience Caucus hosted an in-person congressional briefing highlighting the groundbreaking research carried out by the BRAIN® Initiative will continue to promote scientific advances in neurotechnology by supporting NOFOs that plan for enhancing diverse perspectives.

#### Foundation for the National Institutes of Health - Recent Activities

The Foundation for the National Institutes of Health (FNIH) is an independent, not-for-profit 501(c)(3) charitable organization that convenes public and private partnerships between the NIH, academia, life science companies, and patient advocacy groups. The FNIH's Biomarkers Consortium leads cross-sector efforts to address the need for the development and the seeking of regulatory approval for disease biomarkers and surrogates. Recently announced study findings from the Biomarkers Consortium's Noninvasive Biomarkers of Metabolic Liver Disease (NIMBLE) project, demonstrated the effectiveness of noninvasive blood tests to diagnose nonalcoholic steatohepatitis (NASH). This is a significant milestone because NASH is a leading cause of liver-related morbidity and mortality. Currently, the only method to diagnose NASH is a liver biopsy which is painful and expensive. By expanding the diagnostic options beyond liver

<sup>&</sup>lt;sup>53</sup> nap.nationalacademies.org/catalog/25094/returning-individual-research-results-to-participants-guidance-for-a-new <sup>54</sup> nih.gov/echo/nih-echo-program-host-return-individual-research-results-participants-virtual-workshop-march-16-17-2023

<sup>&</sup>lt;sup>55</sup> fnih.org/news/the-fnih-announces-study-results-published-in-nature-medicine-showing-that-liver-disease-can-be-diagnosed-using-noninvasive-blood-tests/

biopsies, more healthcare facilities and healthcare professionals would be able to diagnose NASH with greater safety.

The FNIH, in partnership with NHLBI, recently launched a new project to explore the development of an innovative gene therapy approach that could potentially lead to a one-time cure for sickle cell disease (SCD).<sup>56</sup> Hematopoietic stem cell transplantation—in which patients receive blood stem cells from a donor to establish healthy blood production—offers a cure after only 1 procedure, but only about 10 percent of individuals with SCD can find a well-matched donor. This new project explores techniques for delivering gene editing tools to a patient's own hematopoietic stem cells entirely inside of their body, bypassing the need for a cell processing center and related resources to edit cells outside of the body. A successful outcome could not only lead to a cure of SCD at the DNA level but also has the potential to make SCD treatment more broadly available and could be applicable in low-resource settings to other diseases, including HIV.

**Budget Policy:** The FY 2025 President's Budget request for these programs is \$822.3 million, equal to the FY 2023 Final level. The OD will utilize the overall requested funds to pursue promising scientific opportunities across a wide range of critical public health fields. Through efforts such as *All of Us*, the BRAIN Initiative, INCLUDE, and public private partnership convened through the FNIH, the OD will leverage expertise from diverse partners in order to promote improved biological understanding and enhanced human health.

# **Director's Discretionary Fund (DDF)**

The NIH Director's Discretionary Fund (DDF) allows the NIH Director to respond quickly to new and emerging research opportunities and high-priority scientific challenges. Funding is often awarded to projects with potential to improve management, planning, and analytical tools in support of research. In FY 2023, funds were used to support important research on topics including enhancing understanding of COVID-19 immunity and access to COVID-19 testing, improving accessibility for people with disabilities, and reducing health disparities. In FY 2025, the DDF will continue to support critical and nascent scientific opportunities across the NIH.

# **Loan Repayment Programs**

The extramural and intramural NIH Loan Repayment Programs (LRPs), established by Congress and led by the OD, are designed to recruit and retain highly skilled professionals to the biomedical or biobehavioral workforce. The LRPs repay qualified loan debt in return for a sustained research career and a commitment to engage in biomedical research relevant to the NIH mission. The Extramural Loan Repayment funded 1,323 awards (over \$92 million) in FY 2023. 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 2023, NIH supported 63 total ILRP awards.

 $<sup>^{56}\</sup> fn ih.org/news/new-project-to-explore-development-of-innovative-gene-therapy-approach-that-could-potentially-lead-to-one-time-cure-for-sickle-cell-disease$ 

**Budget Policy:** The FY 2025 President's Budget request for the DDF, Loan Repayment Programs, and the Director's Challenge Fund is \$20.4 million, equal to the FY 2023 Final level. The OD will utilize the requested funds to continue supporting training and career development opportunities for biomedical researchers and clinician scientists across the pipeline to ensure a sustainable and competitive U.S. biomedical ecosystem.

## Radiation and Nuclear Countermeasures Program (RNCP) and Chemical Countermeasures Research Program (CCRP)

The Radiation and Nuclear Countermeasures Program (RNCP) and Chemical Countermeasures Research Program (CCRP) are coordinated by NIAID and OD. With the threat of terrorism ever-present and the potential for mass casualty public health emergencies involving accidental exposures to radiation or highly toxic chemicals, RNCP and CCRP support research and development of medical countermeasures (MCMs) against such possibilities. To date, more than 500 therapeutics have been investigated as potential MCMs by the 2 initiatives.

The primary program goal of RNCP and CCRP is the discovery, development, and advancement of promising therapeutics toward licensure as effective MCMs to treat the immediate and/or long-term injuries after radiation or chemical exposure in civilian populations. To accomplish this objective, RNCP supports early through advanced research and development of products to assess, mitigate, and treat radiation injuries. The program played a pivotal role in the successful FDA approval of 3 MCMs and, since 2008, has transitioned 39 products (29 MCMs and 10 devices) to BARDA for more advanced development. In 2023, the RNCP launched a first-of-its-kind Phase 1 safety, tolerability, and pharmacokinetic study for a novel drug to remove internally deposited radionuclides. This is the first clinical trial for an oral capsule agent suitable for mass casualty use.

The civilian chemical threat spectrum includes chemical warfare agents, toxic industrial chemicals, pesticides, pharmaceutical-based agents, and others that have been identified by the United States Government (USG) as Chemicals of Concern (CoC). Altogether, almost 200 highly toxic chemical compounds have been deemed CoCs to date. CCRP supports discovery research and early development of MCMs with the goal of transitioning promising therapeutics to BARDA for advanced development. CCRP has transitioned eight candidate MCMs and three animal models thus far, and recently implemented a NIH-BARDA interagency administered MCM screening program to recruit and support private-public partnerships with the small business biotech community. In FY 2023, CCRP funded 35 new awards to develop both animal and non-animal models of CoC poisoning and evaluation of MCM safety and efficacy.

In 2024, RNCP and CCRP will continue to support a broad range of research activities, including maintenance of a strong research infrastructure, and funding of animal model development and testing to evaluate MCM safety and efficacy.

**Budget Policy:** The FY 2025 President's Budget request for this program is \$105.6 million, equal to the FY 2023 Final level. Funding in FY 2025 will be used to support efforts towards the discovery, development, and advancement of safe and effective medical countermeasures and to support related research and infrastructure efforts.

## **Artificial Intelligence and Machine Learning**

The use of Artificial Intelligence/Machine Learning (AI/ML) presents exciting opportunities to advance biomedical and behavioral research and improve health and health care. AI/ML technologies are data-driven, so lack of diverse data and researchers in the field runs the risk of creating and perpetuating harmful biases that can exacerbate health disparities and inequities. Communities disproportionately affected by diseases and health conditions can provide data needed to inform the field on the most urgent research questions; however, scientists in these communities lack resources to apply AI/ML approaches to these pressing questions.

Coordinated by NIH's Office of Data Science Strategy (ODSS), the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Research Diversity (AIM-AHEAD) program seeks to build mutually beneficial and trusted partnerships with communities currently underrepresented in AI/ML modeling to improve the capabilities of this emerging technology and to address health disparities and inequities.<sup>57</sup> AIM-AHEAD established collaborations with the All of Us Research Program and the National Center for Advancing Translational Sciences (NCATS) National COVID Cohort Collaborative (N3C) to increase researcher diversity in AI/ML by leveraging All of Us and N3C data, training components, mentorship, and infrastructure. These collaborations are efforts of NIH, including ODSS, to provide access to NIH data repositories, platforms, computing tools, and associated training opportunities by reducing barriers for researchers and students from underrepresented groups. The collaborations will increase the number of diverse AIM-AHEAD researchers and students to utilize big-health-related datasets and analytical tools, in addition to empowering them to conduct novel research at the intersection of AI/ML and health disparities in communities historically underrepresented in and underserved by biomedical and behavioral research.

Many challenges limit widespread use of AI/ML technologies, such as cost, capability for application, and access to appropriate infrastructure, resources, and training. The NIH Common Fund's Bridge to Artificial Intelligence (Bridge2AI) program aims to set the stage for adoption of AI approaches to address complex biomedical research challenges through the creation of flagship AI-ready data sets and best practices for ML analysis.<sup>58</sup> Bridge2AI is assembling team members from diverse scientific disciplines and backgrounds to generate tools, resources, and data that are ethically sourced, trustworthy, well-defined, and accessible. Bridge2AI researchers will also create guidance and standards for development of these AI-ready datasets to be used to help solve some of the most pressing challenges in human health. The first awards were made in September 2022 to fund the creation of a Bridge Center for integration, dissemination, and evaluation, as well as support projects generating a wide range of AI-data to address key biomedical and behavioral research challenges.

#### **Enhancing Data Science Capacity in Underserved Communities**

In FY 2023, ODSS collaborated with NIGMS, the National Institute on Minority Health and Health Disparities (NIMHD), and the National Cancer Institute (NCI) to fund activities that

<sup>&</sup>lt;sup>57</sup> aim-ahead.net/what-is-aim-ahead/

<sup>&</sup>lt;sup>58</sup> commonfund.nih.gov/bridge2ai

enhance data science capacity in institutions serving medically underserved communities and underrepresented students. These institutions are expected to increase the data science workforce; develop or expand infrastructure to support data science research, training, and education; and/or build data science partnerships.

# **Policy Initiatives in the Office of the Director:**

As 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 and behavioral research community by ensuring scientific integrity, supporting a diverse, skilled workforce, driving innovation, and ensuring the public receives maximum benefit from its investment in NIH.

# Data Science, Standards, and Sharing

NIH is committed to conducting research according to the highest standards of scientific integrity. NIH has developed policies, procedures, and programs to ensure data generated through its biomedical and behavioral research is managed and shared appropriately. Using evidence-based data science best practices, NIH aims to ensure that scientific findings are objective, credible, and readily available to the public while protecting research participants.

The update of the current NIH Strategic Plan for Data Science outlines the agency's aims to optimize data generated from biomedical and basic research to enhance the nation's understanding of fundamental biology and develop new clinical treatments and diagnostic technologies. The plan also anticipates the development of sophisticated new technologies and an increased quantity and diversity of data available.

ODSS coordinates NIH-wide initiatives to streamline data access and to improve interoperability with clinical data standards. To maximize interoperability, NIH aims to significantly expand use and development of common data elements for translational and clinical studies. In efforts to streamline data access, NIH develops and implements responsible best practices to standardize controlled data access processes and aims to make its research-generated data Findable, Accessible, Interoperable, and Reusable (FAIR), while affording adequate cybersecurity and human subject protections.

NIH supports many important programs related to data science, including the Data Stewardship Program and the Data Repositories and Knowledgebase Program (DRKB). The Data Stewardship Program will support FAIR data management and sharing practices at NIH by establishing a multi-functional Data Management Center of Excellence (DMCOE) to collect relevant best practices and develop knowledge guides. The Data Stewardship Program will also develop a persistent identifier (PID) plan that aligns with NIH's public access policy. The DRKB supports proper management of data resources to advance knowledge discovery, data integration and data reuse as part of a larger effort in data life-cycle analysis, long-term data preservation, and trustworthy data resource governance at NIH. Continued support for these programs and initiatives maintains NIH's commitment to the White House Office of Science Technology and Policy's guidance for equitable access to federally funded research for all. NIH continues to expand research resources and tools available to agency staff, extramural researchers, and the public to advance science and improve the ability to find scientific information and data produced from NIH-funded research. The OD Office of Portfolio Analysis (OPA) is developing *iSearch* Analytics, a comprehensive portfolio analysis platform that will improve the accuracy and quality of users' literature and grant searches by providing the ability to build complex queries and generate data visualizations, as well as access to comprehensive literature and linked datasets. OPA has also developed and validated an AI-based method that scans more than 35 million publications and predicts topics that are likely to produce transformative breakthroughs in biomedicine within the next 2 to 12 years. These predictions can be used to inform scientific research investments that increase the rate of progress in important emerging areas. OPA continues its activities to make researchers and decision makers aware of its tools and resources and to expedite the adoption of these tools into daily work. In 2023, OPA has expanded the visibility and usage of the tools it has created by offering training and tutorials, providing demonstrations to ICOs, and promoting the tools publicly through social media and research products, such as publications and patents.<sup>59</sup> In addition to these tools, NIH is collaborating with the National Science Foundation to develop novel ways to identify research proposals with overlapping aims without the need to share private information or intellectual property. This collaborative approach to portfolio analysis has the potential to improve stewardship of research investments across funding entities by identifying duplication and encouraging collaborations between and among researchers with similar interests.

The Office of AIDS Research (OAR) launched the NIH OAR Data Hub to showcase the HIV/AIDS research portfolio through a dynamic interface that enables users to explore and learn about the HIV/AIDS research portfolio.<sup>60</sup> Intended for scientific investigators, clinicians, the advocacy community, and the general public, the Data Hub leverages and synthesizes publicly available data from NIH RePORT to promote greater understanding of HIV/AIDS research and to enable users to identify research awards relevant to their specific interests.<sup>61</sup> This resource supports broader NIH efforts to disseminate information about the HIV/AIDS research portfolio and its impact and to promote scientific transparency and public accountability.

NIH funding is critical in stimulating new knowledge and discoveries driving innovation across sectors, and the agency is committed to ensuring NIH-funded inventions are accessible to the public. NIH hosted a workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, which focused on how the agency, as a research institution, approaches patenting and licensing of inventions. The workshop panels tracked the path an invention can take from discovery to licensing. Panelists explored how NIH decides what to patent and license, who NIH partners with, and how NIH negotiates those agreements. Panelists shared perspectives on how NIH can best approach these questions to fulfill public health goals. The workshop included an oral public comment period and opportunities for written public comments are available. NIH has made this workshop publicly available to view and will prepare a report summarizing the proceedings of the workshop.<sup>62</sup>

<sup>&</sup>lt;sup>59</sup> dpcpsi.nih.gov/opa/Publications

<sup>&</sup>lt;sup>60</sup> oar.nih.gov/nih-hiv-research-program/data-hub

<sup>&</sup>lt;sup>61</sup> report.nih.gov/

<sup>&</sup>lt;sup>62</sup> videocast.nih.gov/watch=51051

#### **Data Management and Sharing Policy Implementation**

Building public trust in science is an important aspect of public health and the responsible stewardship and sharing of scientific research data with the public is an important part of building trust. NIH has a long-standing commitment to supporting data access and is regularly updating policies to be reflective of this commitment. In January 2023, after several years of communications with the research community, NIH implemented the Data Management and Sharing Policy to promote the sharing of scientific data.<sup>63</sup> Under this policy, NIH expects investigators and institutions to: 1) plan and budget for the managing and sharing of data; 2) submit a data management and sharing plan for review when applying for funding; and 3) comply with the approved data management and sharing plan. The NIH Data Management and Sharing Policy is consistent with the White House Directive on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research that was released in 2022. This policy makes scientific data cited in publications accessible at the time of publication. NIH is continuing to work toward the White House directive goals of ensuring federally funded publications are freely available and publicly accessible without embargo and is currently developing new policies to address this. With the help of partners and the public, NIH is considering ideas gathered through a public listening session and request for information (RFI) on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research.<sup>64</sup> Planning for how scientific data and publications will be managed and ultimately shared is a crucial step in optimizing the reach of scientific research data supported by NIH and will aid in accelerating biomedical research discovery by enabling validation of research results, providing access to high-value datasets, and promoting data reuse for future research studies.

Policies to Harness the Benefits of Emerging Technologies, Prioritizing Public Engagement The scientific, ethical, legal, and social issues at the forefront of biomedical and behavioral research are so complex that it is essential to turn to experts and members of the public to hear their perspectives before developing a policy responsive to their needs. Listening to public input and incorporating it into policymaking is vital to NIH's activities. The Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) is exemplary of these efforts. The NExTRAC is a federal advisory committee that provides recommendations to the NIH director and a public forum for discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. Recently, the NExTRAC was charged to develop a harmonized and implementable vision and framework for including public voices in the design and planning of NIH-funded clinical research, as well as widespread dissemination of study findings.<sup>65</sup> This framework will assess the impact and value of engagement with patients, communities, and the broader public on clinical research, as well as the potential opportunities and challenges of varying levels of engagement activities. As part of this effort, the NExTRAC will consult with the ACD and convene public consultations with a wide range of relevant parties to provide recommendations regarding different engagement methods, the optimal timing for meaningful engagement activities, and equitable and inclusive approaches for engagement.

Engaging the public through RFIs is an essential component of policymaking, and responding to RFIs is one of the most important ways to directly shape NIH policy. Responses to RFIs allow

<sup>&</sup>lt;sup>63</sup> grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

<sup>&</sup>lt;sup>64</sup> grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html

<sup>65</sup> osp.od.nih.gov/wp-content/uploads/2023/09/ENGAGE-Charge\_NExTRAC-Meeting-8.29.2023.pdf

the public to provide their thoughts and insights on NIH's proposed future policy directions. These comments are then posted anonymously for the community to follow the entire policy development process easily and transparently. For example, the ACD Working Group focused on the issue of Novel Alternative Methods (NAMs) published an RFI to help inform the ACD Working Group's recommendations on high-priority areas for future investment.<sup>66</sup> This process provides an opportunity to learn from the research community how NAMs are currently being used to study human biology, circuits, systems, and disease states; approaches for catalyzing the development and validation of new NAMs; and strategies for maximizing the value of NAMs in research. To supplement the RFI, NIH held a virtual workshop on approaches, challenges, and opportunities related to the development of NAMs.<sup>67</sup>

#### **Continuing to Promote Safe and Secure Research**

As NIH continues to support cutting-edge scientific research and technology development, it is critical to continue to prioritize ethics, safety, and security. The United States has a comprehensive biosafety and biosecurity oversight system that balances science and security while safely enabling critical, lifesaving research. As science and technologies advance, it is critical to review and, as needed, update the oversight system to keep pace. For example, to help consider issues associated with conducting research involving gene drive modified organisms (GDMO) safely and responsibly, NIH charged the NExTRAC to consider whether existing biosafety guidance is adequate for contained laboratory research utilizing GDMOs. The NExTRAC made multiple recommendations for strengthening NIH's existing policies and guidance in the report Gene Drives in Biomedical Research. Through a process involving an opportunity for public comments, NIH is proposing to revise the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to include specific considerations and requirements for conducting research involving GDMOs in contained research settings. These revisions will strengthen safe and responsible conduct of this. NIH also continues to support other efforts to strengthen and promote laboratory biosafety and biosecurity. For example, NIH supports the activities of the National Science Advisory Board for Biosecurity (NSABB), a federal advisory committee that addresses issues related to biosecurity and dual use research. NSABB recommendations provided in response to a charge delivered by NIH are helping to inform revisions to two major U.S. biosecurity policy frameworks.

**Budget Policy:** The FY 2025 President's Budget request for these programs is \$135.0 million, equal to the FY 2023 Final level. This funding will enable programs including the Common Fund's Bridge to AI and DPCPSI's Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Research Diversity (AIM-AHEAD) program to propel biomedical research forward by setting the stage for widespread adoption of ethical and trustworthy AI that tackles complex biomedical challenges beyond human intuition.

<sup>&</sup>lt;sup>66</sup> grants.nih.gov/grants/guide/notice-files/NOT-OD-23-140.html

<sup>&</sup>lt;sup>67</sup> osp.od.nih.gov/events/nih-workshop-on-catalyzing-the-development-of-novel-alternatives-methods/

#### **Operations and Management in the Office of the Director:**

In FY 2023, OD continued efforts to modernize the workplace, streamline business processes, increase diversity, equity, and accessibility, 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 in the future of how NIH conducts business.

#### Phase 1 of Future of Work (FOW) Completed

In FY 2022, NIH developed the Future of Work (FOW) initiative, an enterprise-wide initiative to address the evolving work landscape. Sponsored by the NIH Strategic Administrative Management Advisory Committee (SAMAC) and coordinated by the Office of Strategic Planning and Management Operations, FOW focuses on workplace flexibilities and other considerations to ensure that NIH maintains a safe, productive, engaging, state-of-the-art, and equitable work environment.

Last year marked the completion of phase 1 of the NIH FOW initiative.<sup>68</sup> Led by SAMAC and in collaborations and engagement with working groups whose affiliations are across major NIH organizational, scientific, and administrative management entities, this initiative resulted in identification of innovative ideas, organizational priorities, and strategic investments to shape FOW. Recommendations included modernizing administrative functions, enhancing infrastructure support and services, transforming physical space, leveraging tools and technology

#### Future of Work (FOW)

The COVID-19 pandemic brought many societal changes, including the adaption of hybrid and virtual work. As flexible workplaces become the "new normal," it is important to continue evaluating the technology solutions and best practices of hybrid and remote work to identify and address barriers and to foster productive workplaces. In response to this evolving work landscape, NIH developed the Future of Work (FOW) initiative. As part of the completion of FOW phase 1, collaboration and engagement of 7 different working groups, over 140 volunteers, and 25 ICOs resulted in the identification of innovative ideas, organizational priorities, and strategic investments to shape FOW. To date, accomplishments stemming from the working groups include: establishment of initiatives to support a hybrid workplace environment through meeting and collaboration strategies and virtual tools; development of a workforce engagement toolkit and related resources to support NIH's hybrid workplace environment; and a Resource Hub which contains information and deliverables related to the NIH Future of Work phase 1.

to support the future of collaborations, hybrid workforce targeting future workforce characteristics, and creating a resource hub. NIH implemented a variety of innovations related to FOW and plans to continue building on its accomplishments.

#### New Enterprise Technology Transfer System to Consolidate NIH Tech Transfer Data

The NIH Office of Technology Transfer (OTT) has implemented the Enterprise Technology Transfer system (ETT) to serve as a new system of record for all activities performed by ICO's Technology Transfer Offices.<sup>69</sup> ETT was built to automate processes and workflows, improve efficiency by eliminating the need to duplicate work, help support full compliance with security and policy guidelines, provide increased transparency of NIH-wide

approaches for negotiating agreements, and provide flexibility and support to users. ETT consolidates all NIH technology transfer data and provides users a centralized location to access data critical for enabling research, collaborations, and the development of NIH technologies to

<sup>&</sup>lt;sup>68</sup>nihrecord.nih.gov/2022/08/19/teams-recognized-future-work-phase-1

<sup>69</sup> techtransfer.nih.gov/sites/default/files/images/newsletters/0014 - TT Newsletter 042019.pdf

benefit the public. Now the backbone of technology transfer within the Intramural Research Program, ETT improves public health by facilitating the process of moving inventions from the lab to market as seamlessly as possible.

# Use of START for DEIA Strategic Plan Implementation

The NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA) articulates NIH's commitment to embracing, integrating, and strengthening DEIA across all NIH activities.<sup>70</sup> The DEIA Strategic Plan was developed by a working group with members from every ICO to represent the range of NIH's activities across its operations, workforce, and research portfolio. The DEIA Strategic Plan was released in March 2023 to cover fiscal years 2023-2027 and is now in the implementation phase.

The Office of Evaluation, Performance, and Reporting (OEPR) within the Office of the Director, in collaboration with the Immediate Office of the Director (IMOD), is using the Strategic Tracking and Reporting Tool (START) to help operationalize, implement, and track progress toward the DEIA Strategic Plan. START serves both as a resource, bringing together information from across NIH in one platform, and as a tool that allows for data analyses and reporting. Using START to leverage existing information and streamline data collection, an inventory of DEIA-related activities was collected and mapped to the DEIA Strategic Plan. This inventory and the activities in it will be used to help inform progress toward the goals of the DEIA Strategic Plan.

START is currently being used for tracking progress toward other DEIA-related strategic plans including the NIH Minority Health and Health Disparities Strategic Plan, the Trans-NIH Strategic Plan for Women's Health Research, the NIH Strategic Plan for Tribal Health Research, and the NIH Strategic Plan to Advance Research on the Health and Well-being of Sexual & Gender Minorities. OEPR is also exploring with the NIH Office of Equity, Diversity, and Inclusion (EDI) potential ways in which START could be used for EDI's tracking and reporting needs. OEPR is also working with the COSWD Office to use START for tracking and evaluating UNITE activities.

# **Cloud Lab (STRIDES)**

In FY 2022, ODSS received funds to establish the NIH Cloud Lab to support the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative's mission of enabling and modernizing biomedical research through the cloud.<sup>71</sup> Cloud Lab is a cloud sandbox platform offering incentivized cloud access to intramural and extramural researchers for training, cost estimation, exploring new cloud technology, and deploying prototypes. Cloud Lab is currently supporting 316 extramural researchers from the NIGMS-funded IDeA Networks of Biomedical Research Excellence (INBRE) program. In FY 2025, ODSS plans to expand the Cloud Lab to include additional researchers with an emphasis on users from under-resourced and minority serving institutions.

**Budget Policy:** The FY 2025 President's Budget request for OD Operations is \$603.1 million, a \$60.8 million decrease below the FY 2023 Final level. This reduction is due to a reduction of

<sup>&</sup>lt;sup>70</sup> nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf

<sup>&</sup>lt;sup>71</sup> cloud.nih.gov/resources/cloudlab/

\$70.0 million for extramural construction grants, reducing funding for these grants at \$10.0 million in FY 2025. Funding will be utilized by the OD to enhance key infrastructure, streamline processes, modernize resources, and improve efficiencies. Activities will build upon efforts like the Future of Work initiative to implement approaches that best support NIH staff in the workplace.

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

	<b>Budget Estimate</b>	House	Senate	
Fiscal Year	to Congress	Allowance	Allowance	Appropriation
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 <sup>1</sup>	\$2,127,666,661	\$792,980,000	\$697,890,000	\$2,526,609,000
Rescission				\$0
Supplemental				\$50,000,000
2019 <sup>1</sup>	\$1,808,306,000			\$2,117,675,000
Rescission				\$0
2020 <sup>1</sup>	\$1,926,144,000	\$2,216,592,000	\$2,513,622,000	\$2,409,387,000
Rescission				\$0
Supplemental				\$30,000,000
2021 <sup>1</sup>	\$2,208,063,000	\$2,446,148,000	\$2,499,659,000	\$2,532,710,000
Rescission				\$0
Supplemental				\$1,250,000,000
2022 <sup>1</sup>	\$2,399,859,000	\$2,829,985,000	\$2,700,813,000	\$2,779,120,000
Rescission				\$0
2023 <sup>1</sup>	\$2,733,665,000	\$2,968,813,000	\$2,991,665,000	\$3,074,514,000
Rescission				\$0
Supplemental				\$25,000,000
2024 <sup>1</sup>	\$3,138,379,000	\$2,317,059,000	\$3,069,514,000	\$2,890,514,000
Rescission				\$0
2025	\$3,049,455,000			

# **Appropriations History**

<sup>1</sup> Includes funding provided in the NIH Innovation Account under the 21st Century Cures Act, after actual and anticipated transfers.

#### **AUTHORIZING LEGISLATION**

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

#### Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2024 Amount Authorized	FY 2024 CR	2025 Amount Authorized	FY 2025 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$2,885,514,000	Indefinite	\$3,044,455,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$2,885,514,000		\$3,044,455,000

# NATIONAL INSTITUTES OF HEALTH Office of the Director

# Amounts Available for Obligation<sup>1</sup>

(Dollars in Thousands)

			FY 2025
Source of Funding	FY 2023 Final	FY 2024 CR	President's
			Budget
Appropriation	\$3,074,514	\$2,890,514	\$3,049,455
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(\$0)	(\$0)	(\$0)
Other Mandatory financing	(\$0)	(\$0)	(\$0)
Transfer to HHS Office of the Inspector General	-\$5,000	-\$5,000	-\$5,000
Subtotal, adjusted appropriation	\$3,069,514	\$2,885,514	\$3,044,455
OAR HIV/AIDS Transfers	-\$3,306	\$0	\$0
Subtotal, adjusted budget authority	\$3,066,208	\$2,885,514	\$3,044,455
Unobligated balance, start of year	\$30,108	\$25,617	\$0
Unobligated balance, end of year (carryover)	-\$25,617	\$0	\$0
Subtotal, adjusted budget authority	\$3,070,699	\$2,911,131	\$3,044,455
Unobligated balance lapsing	-\$183	\$0	\$0
Total obligations	\$3,070,516	\$2,911,131	\$3,044,455

<sup>1</sup> Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2023 - \$92,286 FY 2024 - \$117,649 FY 2025 - \$118,242

#### **BUDGET AUTHORITY BY OBJECT CLASS**

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

# Budget Authority by Object Class<sup>1</sup> (Dollars in Thousands)

		FY 2024 CR	FY 2025 President's Budget
Total co	mpensable workyears:		
	Full-time equivalent	1,217	1,241
	Full-time equivalent of overtime and holiday hours	1	1
	Average ES salary	\$217	\$223
	Average GM/GS grade	13.2	13.2
	Average GM/GS salary	\$144	\$148
	Average salary, Commissioned Corps (42 U.S.C. 207)	\$127	\$133
	Average salary of ungraded positions	\$169	\$173
	OBJECT CLASSES	FY 2024 CR	FY 2025 President's Budget
	Personnel Compensation		
11.1	Full-Time Permanent	\$135,415	\$145,407
11.3	Other Than Full-Time Permanent	\$18,328	\$19,966
11.5	Other Personnel Compensation	\$5,942	\$6,759
11.7	Military Personnel	\$1,825	\$1,910
11.8	Special Personnel Services Payments	\$2,675	\$2,750
11.9	Subtotal Personnel Compensation	\$164,185	\$176,792
12.1	Civilian Personnel Benefits	\$62,308	\$64,344
12.2	Military Personnel Benefits	\$516	\$541
13.0	Benefits to Former Personnel	\$0	\$0
	Subtotal Pay Costs	\$227,010	\$241,676
21.0	Travel & Transportation of Persons	\$1,495	\$1,528
22.0	Transportation of Things	\$178	\$182
23.1	Rental Payments to GSA	\$0	\$0
23.2	Rental Payments to Others	\$0	\$0
23.3	Communications, Utilities & Misc. Charges	\$99	\$101
24.0	Printing & Reproduction	\$0	\$0
25.1	Consulting Services	\$106,196	\$126,420
25.2	Other Services	\$205,613	\$240,453
25.3	Purchase of Goods and Services from Government Accounts	\$213,225	\$231,616
25.4	Operation & Maintenance of Facilities	\$5,225	\$5,373
25.5	R&D Contracts	\$68,344	\$83,347
25.6	Medical Care	\$388	\$403
25.7	Operation & Maintenance of Equipment	\$20,253	\$20,712
25.8	Subsistence & Support of Persons	\$0	\$0
25.0	Subtotal Other Contractual Services	\$619,243	\$708,325
26.0	Supplies & Materials	\$5,364	\$5,482
31.0	Equipment	\$6,941	\$7,094
32.0	Land and Structures	\$3,397	\$3,472
33.0	Investments & Loans	\$0	\$0
41.0	Grants, Subsidies & Contributions	\$2,021,601	\$2,076,410
42.0	Insurance Claims & Indemnities	\$0	\$0
43.0	Interest & Dividends	\$186	\$186
44.0	Refunds	\$0	\$0
	Subtotal Non-Pay Costs	\$2,658,504	\$2,802,779
	Total Budget Authority by Object Class	\$2,885,514	\$3,044,455

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

# NATIONAL INSTITUTES OF HEALTH Office of the Director

#### Salaries and Expenses

(Dollars in Thousands)

		FY 2025
Object Classes	FY 2024 CR	President's
		Budget
Personnel Compensation		
Full-Time Permanent (11.1)	\$135,415	\$145,407
Other Than Full-Time Permanent (11.3)	\$18,328	\$19,966
Other Personnel Compensation (11.5)	\$5,942	\$6,759
Military Personnel (11.7)	\$1,825	\$1,910
Special Personnel Services Payments (11.8)	\$2,675	\$2,750
Subtotal, Personnel Compensation (11.9)	\$164,185	\$176,792
Civilian Personnel Benefits (12.1)	\$62,308	\$64,344
Military Personnel Benefits (12.2)	\$516	\$541
Benefits to Former Personnel (13.0)	\$0	\$0
Subtotal Pay Costs	\$227,010	\$241,676
Travel & Transportation of Persons (21.0)	\$1,495	\$1,528
Transportation of Things (22.0)	\$178	\$182
Rental Payments to Others (23.2)	\$0	\$0
Communications, Utilities & Misc. Charges	\$00	¢101
(23.3)	\$99	\$101
Printing & Reproduction (24.0)	\$0	\$0
Other Contractual Services		
Consultant Services (25.1)	\$106,196	\$126,420
Other Services (25.2)	\$205,613	\$240,453
Purchase of Goods and Services from	\$180,102	\$207 562
Government Accounts (25.3)	\$189,192	\$207,303
Operation & Maintenance of Facilities (25.4)	\$5,225	\$5,373
Operation & Maintenance of Equipment (25.7)	\$20,253	\$20,712
Subsistence & Support of Persons (25.8)	\$0	\$0
Subtotal Other Contractual Services	\$526,479	\$600,521
Supplies & Materials (26.0)	\$5,364	\$5,482
Subtotal Non-Pay Costs	\$533,615	\$607,814
Total Administrative Costs	\$760,625	\$849,490

#### DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE)

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

# Detail of Full-Time Equivalent Employment (FTE)

Office	F	Y 2023 Fin	al	ŀ	FY 2024 CI	R	FY 2025	President's	s Budget
Onice	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	1,082	11	1,093	1,162	11	1,173	1,183	14	1,197
Total:	1,082	11	1,093	1,162	11	1,173	1,183	14	1,197
Reimbursable									
Reimbursable:	41	-	41	44	-	44	44	-	44
Total:	41	-	41	44	-	44	44	-	44
Total	1,123	11	1,134	1,206	11	1,217	1,227	14	1,241
Includes FTEs whose payroll obligations are supported	d by the N	IH Commo	n Fund.						
FTEs supported by funds from Cooperative Research	0	0	0	0	0	0	0	0	0
and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR				Ave	age GS G	rade			
2021					13.2				
2022					13.2				
2023					13.2				
2024					13.2				
2025					13.2				

#### NATIONAL INSTITUTES OF HEALTH Office of the Director

GRADE	FY 2023 Final	FY 2024 CR	FY 2025
			<b>President's Budget</b>
Total, ES Positions	13	14	15
Total, ES Salary	\$2,687,824	\$3,042,203	\$3,350,770
General Schedule			
GM/GS-15	210	215	216
GM/GS-14	288	295	298
GM/GS-13	369	377	384
GS-12	143	158	164
GS-11	54	59	62
GS-10	0	0	0
GS-9	22	27	30
GS-8	0	0	0
GS-7	8	9	9
GS-6	0	0	0
GS-5	3	3	3
GS-4	4	4	4
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	1,101	1,147	1,170
Commissioned Corps (42 U.S.C.			
207)			
Assistant Surgeon General	1	1	1
Director Grade	2	2	2
Senior Grade	4	4	5
Full Grade	3	3	4
Senior Assistant Grade	1	1	2
Assistant Grade	0	0	0
Junior Assistant	0	0	0
Subtotal	11	11	14
Ungraded	88	92	93
Total permanent positions	1,077	1,146	1,170
Total positions, end of year	1,213	1,264	1,292
Total full-time equivalent (FTE)	1.104	1 0 1 7	1 0 4 1
employment, end of year	1,134	1,21/	1,241
Average ES salary	\$206,756	\$217,300	\$223,385
Average GM/GS grade	13.2	13.2	13.2
Average GM/GS salary	\$137,257	\$144,257	\$148,296

#### **Detail of Positions**<sup>1</sup>

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.