Lawrence A. Tabak, D.D.S, Ph.D.
Performing the Duties of the Director of the NIH

On behalf of the National Institutes of Health (NIH), I am trasmitting the Congressional Justification of the NIH request for the Fiscal Year (FY) 2024 budget. This request for a $51.1 billion total program level, including the new Advanced Research Projects Agency for Health (ARPA-H), furthers NIH's critical mission to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness. Importantly, this budget request will support NIH efforts to cultivate the diverse and inclusive workforce needed to address the health challenges of today, and develop the life-saving medical interventions of tomorrow.

In 2022, the United States and the rest of the world continued to emerge from grip of the global Coronavirus Disease 2019 (COVID-19) Pandemic. However, by utilizing cutting-edge techniques informed by over two decades of NIH-supported basic research, scientists were able to rapidly develop messenger RNA (mRNA) vaccines for COVID-19. Research continues to demonstrate that the vaccines are safe, create a robust immune response, prevent the spread of the disease, and reduce the severity of infection. We also leveraged lessons learned from the COVID-19 pandemic to respond to the mpox public health emergency by swiftly and effectively leveraging previously developed treatments for smallpox. I hope that with continued diligence and emphasis on continued research for prevention and treatment strategies, as well as continued development of vaccine booster approaches, that we will continue to make strides in reducing the terrible impact of COVID-19, and that we will be better prepared for future pandemics.

When I think of all the things our staff has done in addition to the COVID response, it is really quite remarkable; NIH continued supporting its wide and varied research portfolio across the country during the pandemic, while also supporting critical COVID-related activities. NIH's role in furthering medical research and innovation, and how this wise national investment has led to more progress, more hope, and more lives saved, fill me with pride for everything that the NIH workforce is able to accomplish. Our staff continue to amaze me with their diligence and dedication to the NIH mission. With that said, it remains tremendously important to continue to build our workforce, a process which will include supporting early-stage investigators (ESIs). Currently, NIH has reached an all-time record for number of ESI, and these scientists are already making important discoveries. For example, NIH ESIs recently developed a potential non-pharmacological treatment option for neonatal opioid withdrawal syndrome, which previously had no standard of care, pharmacological or otherwise. The success of this cross-institute and nation-wide program is a prime example of how ESIs are important for fresh ideas and perspectives and their continued success ensures the continuation of the research enterprise.

Meanwhile, NIH has pivoted in real-time through the creation of several programs and initiatives and is working to lay the groundwork for a robust and diverse biomedical research enterprise for years to come. The biomedical research enterprise is strengthened when it harnesses the

complete intellectual capital of the nation, bringing diverse perspectives, backgrounds, and skillsets to apply to complex problems. These strengths come from researchers at diverse institutions across the country; with different backgrounds in different scientific disciplines; who rely on a combination of methods, models, and technologies to answer increasingly complex questions about human health and disease.

NIH is making a more concerted effort to promote racial equity and inclusivity in our research workforce, both through the NIH UNITE Initiative and through Institute-specific initiatives. In 2022, UNITE released its Progress Report, which highlighted important strides that have been made since the establishment of UNITE, but also illuminated the continued work that is needed to substantially move the needle in the direction it needs to go. I am deeply appreciative of the continuing efforts at NIH and across the broader biomedical community to further enable diversity, equity, inclusion, and accessibility within the biomedical research workforce and in all the work that NIH supports. The FY 2024 Budget will allow NIH to recruit, train, and empower this cadre of future innovators.

The NIH standard for excellence extends across all of its Institutes, Centers, and Offices (ICOs). While much attention is garnered by our larger institutes, I cannot overstate the tremendous role that is played by our smaller ICOs in fulfilling the NIH goal of improving the health and wellbeing of all Americans. Smaller ICOs support a wide range of critical cross-NIH initiatives spanning a wide range of topics including, but not limited to, chronic pain, innovations in biomedical research, whole-person health, health disparities, and a variety of other topics. For example, several small ICs are involved in the NIH-wide Helping to End Addiction Long-term (HEAL®) initiative, which is making tremendous strides to understand the underlying mechanisms of chronic pain and the development of non-addictive opioid alternatives.

In conclusion, the FY 2024 Budget provides critical resources needed for NIH and its supported researchers across the country to continue accelerating innovative biomedical discoveries that will lead to prevention and treatment of disease.

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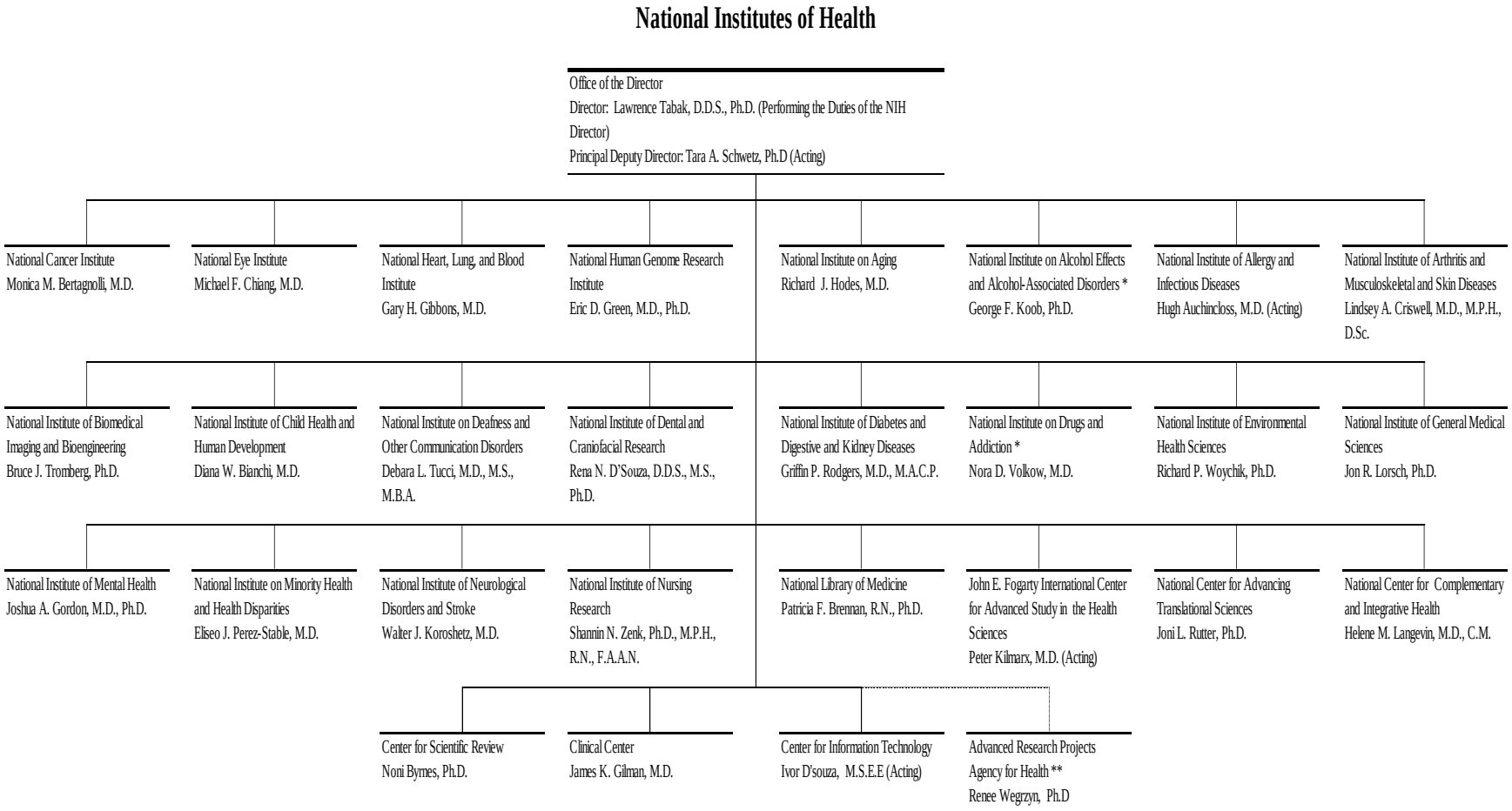
DRUG CONTROL PROGRAMS

General Notes

1. FY 2023 Enacted levels cited in this document include the effects of the FY 2023 HIV/AIDS transfer.
2. Detail in this document may not sum to the subtotals and totals due to rounding.

ORGANIZATION CHART



*The FY 2024 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction and to rename the National Institute on Alcohol Abuse and Alcoholism to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.

**The Director of the Advanced Research Projects Agency for Health (ARPA-H) reports directly to the Secretary of the Department of Health and Human Services.

INTRODUCTION AND MISSION

The mission of the National Institutes of Health (NIH) is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In pursuit of this mission, NIH conducts and supports biomedical research focused on fostering fundamental creative discoveries, innovative research strategies, and their applications towards improving human health.

As the Nation's largest biomedical research agency, NIH plays a critical role in advancing basic and clinical biomedical research to improve human health and lay the foundation for ensuring the Nation's well-being. This role has been more important than ever in the last few years as NIH funded research has contributed to the development of testing, vaccines, treatments, and other measures necessary to face COVID-19, the greatest public health crisis of our generation. NIH also works to develop, maintain, and renew scientific, human, and physical resources that will ensure the Nation's capability to prevent disease and disability. The biomedical research enterprise depends upon not only NIH's support of cutting-edge science and technology, but also its wise investment of tax dollars. Through careful stewardship of public resources in pursuit of its mission, NIH strives to enhance the lives of all Americans.

OVERVIEW OF BUDGET REQUEST

Introduction

For Fiscal Year (FY) 2024, the National Institutes of Health (NIH) requests a total program level of $48.6 billion, an increase of $0.9 billion from the FY 2023 Enacted level. The FY 2024 Budget requests a total of $51.1 billion in funding for NIH and the Advanced Research Projects Agency for Health (ARPA-H). The Budget requests funding for ARPA-H as a separate appropriation within NIH and a detailed request is outlined in the separate ARPA-H Congressional Justification volume.

The budget level is intended to support critical research conducted in service to the NIH mission and support new and ambitious priority investments necessary for improving the health of the Nation. For instance, NIH continues its commitment to fostering discoveries focused on improving health and well-being across the lifespan and will invest to expand mental health research, advancing nutrition science to promote health, and to reduce the burden of diet-related diseases and nutrition health disparities, and drastically reduce maternal mortality rates. Importantly, this request is also critical for NIH to continue to address emerging national health priorities, such as combatting the ongoing overdose crisis, tackling emerging infectious disease outbreaks like influenza and mpox, and reigniting the Cancer Moonshot initiative to end cancer as we know it today.

The NIH proactively pursues scientific opportunities through a variety of collaborations, initiatives, and programs to promote innovative research concepts to tackle our most vexing national challenges. Priority issues such as bolstering diversity in the scientific workforce and reversing the health impacts of climate change remain as critical matters, and NIH approaches these challenges not only by investing in science, but also by investing in infrastructure and people. Strengthening biomedical research ecosystems is critical to ensuring NIH sustains and advances its mission of enhancing health and reducing illness in the decades to come. NIH continues to promote the principles of scientific integrity and rigor within the biomedical research community, with current efforts focused on the research lifecycle to ensure reproducible results in research and to ensure that NIH-funded researchers and staff are held to the highest ethical standards to support the best science. Since the best science often relies on diverse teams and complementary approaches, NIH is investing in new ways to seek out the best and brightest minds to solve the complexities of human health and disease. NIH emphasizes diversity in the scientific questions it explores, the research models it employs, the populations it includes in research studies, its approach to leveraging the investment across the NIH Institutes, Centers, and Offices (ICOs), and, of course, the workforce it aims to cultivate.

Continued support of life-saving research to end the COVID-19 pandemic

The world remains in a critical state as we continue to address the COVID-19 global pandemic, which requires continued investment in a broad array of biomedical research areas. Prior investment proved critical, as NIH leveraged decades of fundamental and translational research in molecular biology and immunology to aid in the development of COVID-19 vaccines, and

continued support is necessary to expand upon our current vaccine and treatment options against emerging viral variants. We are also grappling with a new public health challenge as we begin to understand the long-term effects of the COVID-19 pandemic, including Post-Acute Sequelae of SARS-CoV-2 Infection (PASC, also commonly known as "Long COVID") as well as the mental health effects of the pandemic. Furthermore, NIH continues to use lessons learned during the COVID-19 pandemic to address other public health issues, including the recent mpox Public Health Emergency, and to help prepare for future pandemics.

Continuing COVID-19 research

Millions of Americans have recovered from COVID-19 infections, but unfortunately many people are still dealing with the long-term effects, known as post-acute sequelae of SARS-CoV-2 (PASC, or commonly known as Long COVID). Those who suffer from Long COVID continue to experience debilitating fatigue, shortness of breath, pain, difficulty sleeping, racing heart rate, exercise intolerance, gastrointestinal and other symptoms, as well as cognitive problems that make it difficult to perform at work or school. These symptoms persist long after the initial acute phase of COVID-19 infection has ended. To address this growing public health concern, 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), along with several other NIH Institutes and the NIH Office of the Director (OD), are leading NIH's Researching COVID to Enhance Recovery (RECOVER) initiative, a national research program to understand PASC. The NIH RECOVER initiative funds research aiming to understand how people recover from COVID-19 infection, and why some people do not fully recover and develop Long COVID. The RECOVER initiative brings together patients, caregivers, clinicians, community leaders, and scientists from across the nation to understand, prevent, and treat Long COVID. This consortium represents and supports more than 100 researchers who are leading studies on Long COVID at more than 200 places around the country. These studies have a diverse group of participants, including adults, pregnant people, and children. Currently, over 9,000 adults have enrolled in RECOVER studies.[1] These studies include use of cutting-edge technology to uncover the underlying mechanisms of Long COVID. For example, one study utilized machine learning (ML) to comb through electronic health records looking for signals that may predict whether someone has Long COVID.[2]

COVID-19 and children's health

Although most children infected with SARS-CoV-2 experience only mild illness, the impact that the pandemic has had on children cannot be underestimated. Many children have experienced loss during the pandemic, be it the loss of a family member or loved one due to COVID-19, or the loss of economic, food, or housing security. A study co-sponsored by the National Institute on Drugs and Addiction (NIDA)[3] and published in a paper entitled *COVID-19-Associated Orphanhood and Caregiver Death in the United States* revealed that, as of June 2021, more than 140,000 children in the United States lost a parent or primary caregiver during the pandemic.[4]

[1] recovercovid.org/
[2] pubmed.ncbi.nlm.nih.gov/35589549/
[3] The FY 2024 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.
[4] publications.aap.org/pediatrics/article/148/6/e2021053760/183446/COVID-19-Associated-Orphanhood-and-Caregiver-Death

Sudden parental death can be traumatizing to children and leave families unprepared to deal with the consequences. Early studies on the mental health effects of COVID-19 indicate that children and adolescents experienced higher rates of anxiety and depression during the pandemic period than they did before it.[5] While it is not clear if this effect is due to the pandemic itself (i.e., concern about themselves or loved ones being infected and becoming seriously ill), a reaction to instability that may have been caused by a death or a job loss in the family, or as an indirect consequence of public health measures, it is imperative that we learn from these experiences to properly support children and adolescents as early as possible. Studies to explore these factors and their effects on children will remain an urgent and significant priority.[6] While research shows that children display resilience to early stress or acute trauma, it is clear these experiences can change brain development and affect overall health. Early life exposure to trauma is a risk factor for later health problems, such as substance abuse, mental illness, and heart disease.[7] ICOs across NIH are funding research on exposures and risk factors from childhood trauma, interventions, pediatric intensive care, and long-term health effects. For example, the National Institute of Mental Health (NIMH) is supporting research in children to clarify how, when, and for whom trauma exposure increases risk for adverse physical and mental health outcomes. In one study, researchers are examining developmental changes in children aged 8-14 years to assess how experiences of child abuse are transformed into disruptions of the brain networks underlying emotional and behavioral problems.[8]

As the pandemic continued to evolve, NIH-supported researchers worked to determine the best ways to protect children from the virus and the best practices to get children back into classrooms safely. It has been established that vaccines against COVID-19 are safe and effective ways to prevent COVID-19 infection in children and reduce the severity of infection. Studies supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) have demonstrated that COVID-19 vaccines administered to pregnant and breastfeeding women boost the immunity of not only the mother, but the newborn as well.[9,10] The FY 2024 President's Budget includes $3.0 million in NICHD to sustain increased funding provided in FY 2023 for research on mitigating the effects of COVID-19 on pregnancies, lactation, and postpartum health with a focus on individuals from racial and ethnic minority groups. As children returned to the classroom, studies on the efficacy of masking and testing were crucial in the effort to transition children back to in-person schooling. Launched as part of the NIH Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) program, the NICHD-supported Safe Return to School Diagnostic Testing Initiative helped to develop diagnostic tools and testing approaches in order to facilitate ways of safely returning students and staff to in-person school, with focus on areas with vulnerable populations. Further studies helped to demonstrate that masking, which was critical for initial efforts to return children to in-person schooling, did not interfere with children's ability to follow instructions in class.[11] Additionally, the FY 2024 Budget sustains the FY 2023 Enacted funding level to support research on the impact of COVID-19 on children and on the health impacts of technology and social media use

[5] nida.nih.gov/drug-topics/adolescent-brain/longitudinal-study-adolescent-brain-cognitive-development-abcd-study
[6] pubmed.ncbi.nlm.nih.gov/33353380/
[7] www.cdc.gov/violenceprevention/aces/fastfact.html
[8] reporter.nih.gov/project-details/9986031
[9] pubmed.ncbi.nlm.nih.gov/35129576/
[10] pubmed.ncbi.nlm.nih.gov/33775692/
[11] pubmed.ncbi.nlm.nih.gov/35809337/

on children.

COVID-19 and mental illness

Children are not the only population dealing with the mental health impacts of the COVID-19 pandemic, as the issue affects people of all ages. Mental illnesses are the fifth leading cause of disability in the United States, accounting for 6.6 percent of all disability-adjusted life years in 2019,[12] and the pandemic has only exacerbated this issue. Serious Mental Illness (SMI)[13] is a major, albeit less known, risk factor for COVID-19, and people with SMI are more prone to COVID-19 infection and are more likely to require hospitalization and die from severe COVID-19 infection. NIH supports research on many facets of mental health including rapid interventions to reduce severe suicide risk, funding adaptive interventions to optimize adolescent mental health treatments, and aggregating data to address mental health disparities research gaps. In response to the pandemic, NIH launched a project to support research focused on the social, behavioral, and economic impacts of COVID-19, which supports research on the secondary effects of the pandemic, such as financial hardship, reduced access to health care, and school closures.[14] This initiative includes NIMH-supported research on: the impact of COVID-19 mitigation efforts on socioeconomic disparities in mental health and health care utilization;[15] the effectiveness of digital health apps like Headspace as a just-in-time approach to immediate, personalized behavioral health care;[16] the effectiveness of a digital platform on depression/anxiety symptoms of healthcare workers during the COVID-19 pandemic;[17] and effectiveness, barriers, and facilitators to the implementation of a gold standard exposure treatment for post-traumatic stress disorder in healthcare system employee assistance programs serving frontline healthcare workers.[18] The FY 2024 Budget includes $25.0 million for the impact of COVID-19 on mental health, sustaining the FY 2023 Enacted funding level.

The Community Engagement Alliance (CEAL) Against COVID-19 Disparities works closely with the communities hit hardest by COVID-19.[19] The CEAL research teams focus on COVID-19 awareness and education research, especially among African Americans, Hispanics/Latinos, and American Indians/Alaska Natives —populations that account for over half of all reported cases in the United States. They also promote and facilitate the inclusion and participation of these groups in vaccine and therapeutic clinical trials to prevent and treat the disease. CEAL is comprised of research teams in 21 locations across the country that focus on urgent community-engaged research, and outreach to increase awareness and education within communities impacted by significant health disparities. To bolster research to help communities disproportionately affected by COVID-19, NIH is funding $29 million in additional grants for CEAL to address COVID-19 disparities. This funding was supported by the American Rescue Plan. The awards provide $15 million to 11 teams already conducting research and outreach to help strengthen COVID-19 vaccine confidence and access, as well as testing and treatment, in communities of color. An additional $14 million will fund 10 new research teams to extend the

[12] Institute of Health Metrics and Evaluation. ghdx.healthdata.org/gbd-results-tool accessed October 2021.
[13] nimh.nih.gov/health/statistics/mental-illness
[14] covid19.nih.gov/news-and-stories/covid19-ripple-effects
[15] reporter.nih.gov/search/_E4VoHbiwU293-ndTNu8Kw/project-details/10490467
[16] reporter.nih.gov/search/nG0a0LRnBk2HZbig_DW6ew/project-details/10402904
[17] reporter.nih.gov/search/EMyREeTC3kan_rHKVyS6Fw/project-details/10451636
[18] reporter.nih.gov/search/Wz5OqrJM_keh6fQgmV9ZMg/project-details/10246656
[19] www.nhlbi.nih.gov/news/2020/COVID-19-nih-funds-community-engagement-research-efforts-areas-hardest-hit

reach of COVID-19 community-engaged research and outreach. The FY 2024 request level includes $65.0 million, maintaining the FY 2023 Enacted level, in base funding for CEAL and other COVID-related research initiatives in other ICs, including NIMH, to expand research on the pandemic impacts on mental health, and NICHD, to fund research on COVID effects on pediatric health.

Finally, the rapid successes and generational leaps that have occurred in the field of biomedical research throughout the course of the SARS-CoV-2 pandemic have placed us in a unique position to prepare for the future. We can leverage scientific advances developed during the pandemic, such as mRNA vaccine technology, to address current public health crises such as the HIV epidemic, and future potential pandemic pathogens.

Pandemic Preparedness

The FY 2024 Budget provides $20 billion in mandatory funding to the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), NIH, and Administration for Strategic Preparedness and Response (ASPR) to carry out priorities for national pandemic preparedness. Within this total, $2.69 billion is allocated to NIH. These funds will allow NIH to conduct and support preclinical and clinical research on vaccines and therapeutics (including host-tissue-directed therapies) to provide protection against prototype or representative pathogens selected from a preliminary group of around 10 viral families of concern. It will invest in expanding laboratory capacity (including biosafety level 3 and 4 laboratories) and pilot lot manufacturing in compliance with FDA's Current Good Manufacturing Practice (cGMP) regulations, as well as its network of clinical trial sites that have been so critical to addressing the COVID-19 pandemic. Finally, NIH will develop next-generation diagnostics to fill critical gaps, such as the need for affordable at-home tests that are equally reliable to lab-based PCR tests. For more information on the Department-wide pandemic preparedness mandatory proposal, please find the detailed narrative in the Public Health Social Services and Emergency Fund Congressional Justification.

Mpox response

As mpox emerged as the latest global public health threat, NIH utilized lessons learned from the public health responses to the HIV and COVID-19 pandemics to help guide the response to the outbreak. NIAID played a key role in the development of a currently available vaccine to prevent mpox virus disease, as well as antiviral treatments previously developed for smallpox that can be repurposed for use against mpox, NIH continues to invest in methods of treatment and prevention of mpox infection. NIAID sponsors a clinical trial evaluating alternative strategies for administering the JYNNEOS mpox vaccine, which is approved by the FDA for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection. The testing of this alternative strategy could help increase the number of available doses of the vaccine.[20] The Institute also supports a Phase 3 clinical trial evaluating the antiviral, tecovirimat, also known as TPOXX, an FDA-approved treatment for smallpox. Investigators will gather data to determine if participants receiving tecovirimat heal more quickly, and if the treatment mitigates pain associated with infection as well as the progression of severe disease.[21]

[20] www.niaid.nih.gov/news-events/clinical-trial-evaluating-monkeypox-vaccine-begins

[21] www.niaid.nih.gov/news-events/us-clinical-trial-evaluating-antiviral-monkeypox-begins

Ensuring health at all stages of life for all people

Many public health challenges affect people of various ages and populations differently. NIH supports biomedical and behavioral research applicable to the full spectrum of public health challenges and needs, such as acute and chronic illness, persistent and emerging infectious diseases, cancers, substance abuse disorders, Alzheimer's disease and related dementias, the health impacts of environmental exposures, and many more. NIH continues to invest in research that ensures the well-being of every American across their lifespan, regardless of their background, race, age, gender, sexual orientation, or health status.

Ensuring health at all stages of life

Children and adolescent brain development

The Adolescent Brain Cognitive Development (ABCD) Study is the largest long-term study of adolescent brain and cognitive development in the United States. Researchers have enrolled nearly 12,000 youth ages 9-10 in the study and will track their biological and behavioral development over 10 years as they transition from adolescence into young adulthood. By integrating neuroimaging with genetics, neuropsychological, behavioral, and other health assessments, this study will shed light on how substance use and other experiences during adolescence affect brain development and later health outcomes such as drug use and addiction. To date, more than 300 papers have been published using ABCD study data on a range of topics including psychiatric symptoms and the impacts of the COVID-19 pandemic, and their interactions with brain structure and function. A similar study, the HEALthy Brain and Child Development (HBCD), looks at young children in the first decade of life beginning with the prenatal period. The HBCD study, supported by HEAL, NIDA, and several other NIH Institutes and Centers, is now underway at 25 research sites across the country. A range of scientific specialists, similar to that in the ABCD study, is involved in this effort, including experts in obstetric care and in infant neuroimaging.

Maternal health/IMPROVE Initiative

One ongoing NIH focus area of health disparities of ongoing NIH focus is maternal mortality and morbidity. In response to rising maternal mortality (MM) in the United States, the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative will support research on how to mitigate preventable MM, decrease severe maternal morbidity (SMM), and promote health equity in the United States. The initiative invests in studies to promote an integrated understanding of biological, behavioral, sociocultural, and structural factors that contribute to maternal morbidity and mortality and engages communities in the development of solutions to address the needs of pregnant and postpartum individuals. IMPROVE includes a special emphasis on populations disproportionately affected by MM/SMM (e.g., African Americans/Blacks, American Indians/Alaska Natives, women of advanced maternal age), as well as those who experience health disparities or limits in access to care The research projects will incorporate local community needs and perspectives to expand and complement existing research efforts by developing, implementing, and evaluating community-tailored interventions to address health disparities in SMM/MM, as well as investigate biological,

behavioral, sociocultural, and structural risk factors and mechanisms of the leading causes of SMM/MM. Through this multidimensional strategy, IMPROVE aims to build an evidence-based approach to reducing SMM/MM and its associated health disparities. In FY 2020 and 2021, NIH awarded over $20 million to support 58 projects via IMPROVE. In FY 2022, NIH received a $30 million increase to build the IMPROVE program into a major initiative. One cross-cutting NIH IMPROVE funding opportunity was announced in FY 2021 to identify biological, behavioral, sociocultural, and structural factors that contribute to disparities in maternal health. The initiative also encourages researchers to investigate the potential effects of emerging infections, such as SARS-CoV-2. The FY 2024 Budget request for IMPROVE is $30.0 million, maintaining the FY 2023 Enacted funding level within NICHD.

Health of older adults

NIH continues to support a wide range of research on issues that primarily affect older adults. One area of major emphasis is research on Alzheimer's disease and related dementias. The National Institute on Aging (NIA) supports and conducts research to better understand the aging process, as well as the diseases, conditions, and needs associated with growing older. The Institute is also the primary federal agency supporting and conducting Alzheimer's disease and related dementias research. Since its inception in 1974, NIA has conducted and supported research designed to improve quality of life for aging Americans and identify strategies and treatments to effectively prevent, delay the onset of, or slow the progression of age-related diseases, including dementia. NIA plays a lead role in implementation of the National Alzheimer's Project Act's national plan to accelerate research on Alzheimer's disease and related dementias, and to provide better clinical care and services for people living with dementia and their families. NIA leads the development of implementation research milestones in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS) and other NIH Institutes and Centers, as well as with extensive input from a variety of sources and perspectives outside of NIH. Central to this process was a series of research summits organized by NIH that brought together leading experts and innovators from academia, industry, and advocacy groups. These included the 2021 NIH *Alzheimer's Research Summit: Path to Precision Medicine for Treatment and Prevention*, during which leading scientists and other innovators, public health advocates, and other stakeholders met for a virtual summit showcasing progress in Alzheimer's disease research.[22] Participants also identified gaps and opportunities toward the goal of precision medicine for Alzheimer's treatment and prevention.

NIA also supports a strong portfolio of research initiatives and collaborative efforts to address Alzheimer's and related dementias. The Alzheimer's Disease Neuroimaging Initiative (ADNI) is a public-private partnership established to develop a multi-site longitudinal, prospective, naturalistic study of normal cognitive aging, mild cognitive impairment, and early Alzheimer's disease.[23] NIA has also supported recent studies, including a large-scale study of brain proteins that has helped researchers discover Alzheimer's disease-related changes in the brain that demonstrate the roles of certain proteins in gene progression,[24] and an analysis of Alzheimer's

[22] nia.nih.gov/research/dn/2021-nih-alzheimers-research-summit-agenda
[23] adni.loni.usc.edu/
[24] pubmed.ncbi.nlm.nih.gov/35115731/

study participant data that highlights racial disparities in Alzheimer's disease diagnosis and symptomatic presentation.[25]

Ensuring health for all people

Women's health

The NIH Office of Research on Women's Health (ORWH) has initiated the development of the FY 2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women. Every 5 years, NIH publishes a new strategic plan on research on the health of women to highlight NIH research priorities and goals in this area and serve as a roadmap for achieving these goals. The strategic plan is developed through collaboration and coordination with members of the Coordinating Committee for Research on Women's Health (CCRWH); the Advisory Committee for Research on Women's Health (ACRWH); and staff from NIH ICOs. The goals and objectives created in this Strategic Plan integrate ORWH's and ICO missions and serve as a guide for future NIH research efforts to improve the health of all women throughout the entire life course. Recent public health events (*e.g.,* the COVID pandemic) have had significant effects on the health of women. These considerations, as well as outcomes from the congressionally directed and ORWH-led Women's Health Conference[26]; scientific advances; new technologies; current health priorities; and feedback from a range of stakeholders, including the public, will be factored into the development of the next NIH-Wide Strategic Plan for Research on the Health of Women. Development of the Strategic Plan is a multi-faceted process, requiring coordination among internal and external partners engaging in many interrelated tasks. ORWH will leverage a variety of existing data sources to maximize the application of knowledge generated through ICO efforts, including their implementation of the current 2019-2023 Trans-NIH Strategic Plan for Women's Health Research.[27] In addition, ORWH has expanded its collaborative reach by including other federal partners such as the Health Resources and Services Administration (HRSA), FDA, CDC, Agency for Healthcare Research and Quality (AHRQ), Department of Veterans Affairs (VA), and Office of the Assistant Secretary for Health (OASH). To ensure a targeted release in January 2024, ORWH created a model that follows the plan development from conception to creating strategic goals, objectives, and metrics, and ultimately publication. ORWH will publish the plan in January 2024 with a companion Strategic Plan Implementation and Evaluation Guide following in July 2024.

Health disparities

The FY 2024 Budget request continues to place an emphasis on addressing the marked health disparities of the nation's racial and ethnic minority, rural, low-income, and other underrepresented populations, as well as disparities within the biomedical research enterprise. The request sustains the cumulative funding increases of $95.0 million for health disparities research provided in FY 2022 and FY 2023 appropriations for the National Institute on Minority Health and Health Disparities (NIMHD) and several other institutes.

[25] pubmed.ncbi.nlm.nih.gov/34854531/
[26] orwh.od.nih.gov/research/2021-womens-health-research-conference
[27] orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research

Type 1 Diabetes
Evidence suggests that rates of type 1 diabetes are rising worldwide; in the United States, data show that the prevalence of type 1 diabetes increased by 21 percent between 2001 and 2009. The incidence of type 1 diabetes has increased by 1.9 percent annually between 2002 and 2015, with higher increases observed in minority populations. The Special Diabetes Program for type 1 diabetes research has enabled the establishment of a unique, extraordinarily collaborative, and scientifically comprehensive research strategy. Continued funding will enable the NIH to support ongoing research consortia and clinical trials networks at a scientifically optimal scale toward meeting their long-term scientific goals, including The Environmental Determinants of Diabetes in the Young (TEDDY) study, Type 1 Diabetes TrialNet, and the Human Islet Research Network (HIRN). In December 2020, the Special Diabetes Program was extended at a level of $150.0 million per year for FY 2021-2023. The FY 2024 Budget proposes reauthorization of the Special Diabetes Program for type 1 diabetes research through FY 2026 for an annual amount of $250 million in FY 2024, $260 million in FY 2025, and $270 million in FY 2026.[28]

Promoting the public good

The NIH portfolio is designed with the flexibility to address current public health needs, emerging areas of scientific opportunity, and public health emergencies. A critical focus of the NIH mission is readiness to address new and emerging public health needs rapidly, comprehensively, and efficiently. From the emergence of HIV/AIDS in the 1980s to the more recent outbreaks such as COVID-19 and mpox, NIH has been at the forefront of the global research response. NIH is also working to tackle other public health crises such as the ongoing opioid epidemic and community violence. NIH's role in combatting emerging threats involves identifying and understanding the root causes of the threats and their effects on the body, assessing novel interventions and treatments, and conducting and supporting clinical trials.

21st Century Cures Act
The Budget provides $407.0 million in the Innovation Account for 21st Century Cures Act (Cures Act) programs in FY 2024, the full Cures Act authorized level, down from $1,085.0 million in FY 2023. The NIH request proposes to increase non-Cures funding for the *All of Us* and BRAIN programs to maintain the same total funding level, combining Cures Act and non-Cures Act funding, as enacted in FY 2023. In addition, NIH proposes to fund the Cancer Moonshot – for which authorized Cures funding ends in FY 2023 – at $716.0 million, an increase of $500.0 million from the level provided in FY 2023.

All of Us
With a total request of $541.0 million in FY 2024, identical to the FY 2023 Enacted level, the *All of Us* Research Program will continue its mission to accelerate health research and medical breakthroughs to enable individualized prevention, treatment, and care. *All of Us* aims to deliver one of the largest and richest biomedical data sets that is available and secure, and to catalyze an ecosystem of communities, researchers, and funders to make *All of Us* data an indispensable part of health research. *All of Us* is on its

[28] The final FY 2023 funding level for Type 1 Diabetes is $141.450 million, reflecting the 5.7 percent reduction of $8.550 million for Budget Control Act sequestration.

way to enrolling one million or more participants, and as of February 14, 2023, more than 599,000 participants had consented to join the program and more than 414,000 participants had completed all steps in the initial protocol. In excess of 3,600 researchers across more than 435 institutions have registered to access *All of Us* data.

BRAIN Initiative®

The NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is an ambitious program to develop and apply new tools and technologies to answer fundamental questions about the brain and ultimately to inspire new treatments for brain diseases. NINDS and NIMH are leading partners in the NIH BRAIN Initiative®, working with eight other ICOs. The BRAIN Initiative® has invested over $3 billion in more than 1,300 research projects, engaging scientists from many areas of expertise as well as mathematicians, engineers, physicians in individual labs and inter-disciplinary teams. The BRAIN Initiative® has also led positive change in the culture of neuroscience research through its emphasis on neuroethics, diversity and inclusion, and promoting infrastructure and practices for sharing research data and tools.

With total funding requested at $680 million, identical to the FY 2023 Enacted level, the BRAIN Initiative® promotes scientific advances that provide opportunities to understand the structure and function of the brain at an unprecedented level of detail. Researchers throughout neuroscience are rapidly adopting these advances, and the BRAIN Initiative® is both dramatically enhancing existing methods and developing entirely new technologies to study and manipulate brain circuits. BRAIN Initiative® activities will continue to be guided by the three overarching priorities as recommended in the BRAIN® 2.0 Working Group reports published in 2019[29]: (1) stay on course to accomplish the original goals set out in the BRAIN® 2025 report (published in 2014[30]) (2) ensure sufficient funds for new projects each year to continue the pace of innovation of the Initiative and pursue emerging opportunities across all mission areas; and (3) launch large-scale transformative projects that will significantly change the trajectory of neuroscience research and the treatment of human brain disorders. The BRAIN Initiative® will also continue to work to shift the research culture within neuroscience through its emphasis on neuroethics, diversity and inclusion in the research community, and data sharing practices to enable and enhance the scientific and technological advances from this initiative.

Cancer Moonshot

The National Cancer Institute (NCI) FY 2024 Cancer Moonshot Initiative supports priority investments that advance the ambitious goal of the Reignited Cancer Moonshot. As announced by President Biden in February 2022, the Reignited Cancer Moonshot sets a bold new goal of cutting America's age-adjusted cancer death rate by 50 percent over the next 25 years. To achieve the President's goal, this Cancer Moonshot request will provide NCI with funding to discover, develop, test, and deliver new strategies to prevent, detect, and treat cancer – including new treatments with fewer side effects –

[29] braininitiative.nih.gov/strategic-planning/acd-working-groups/brain-initiative%C2%AE-20-cells-circuits-toward-cures

[30] braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf

together with approaches to more widely and equitably disseminating current standards of cancer care. The FY 2024 proposal fully aligns with the following seven pillars the Biden Administration announced in 2022 for the Cancer Moonshot –

- Diagnose cancer sooner
- Prevent cancer
- Address inequities
- Target the right treatments to the right patients
- Speed progress against the most deadly and rare cancers, including childhood cancers
- Support patients, caregivers, and survivors
- Learn from all patients.

To advance these priorities, the budget proposes major new investments for NCI. These investments will double accrual of patients to clinical trials that NCI sponsors or supports to assure that we achieve the Cancer Moonshot's 25-year goal, while also transforming the meaning of cancer.

To support these objectives, NIH requests $716.0 million in FY 2024, an increase of $500.0 million from the FY 2023 Enacted level, to achieve President Biden's Cancer Moonshot goals. Because FY 2023 marks the final authorization of appropriations of Moonshot funding for NCI under the Cures Act, $216.0 million of the FY 2024 amount will enable NCI to sustain research that will make vital scientific contributions to the seven pillars of the Cancer Moonshot. The budget also proposes to extend the Cures Act Cancer Moonshot authorization through 2026, providing $1.448 billion in mandatory funding in each of FY 2025 and FY 2026 to advance Cancer Moonshot goals.

HEAL Initiative®

The public health crisis of opioid misuse, addiction, and overdose in America continues to evolve rapidly and overlaps with other public health challenges, including that of untreated chronic pain and the national mental health crisis. Since early in the COVID-19 pandemic, studies have found increases in the use of many kinds of drugs, including fentanyl, cocaine, heroin, methamphetamine, cannabis, and alcohol. In 2021, there were over 107,000 drug overdose deaths in the United States.[31] More than 2 million Americans have opioid use disorder (OUD), and 10 million Americans misuse opioids. Additionally, more than 25 million Americans experience daily pain, putting them at increased risks for opioid use and misuse.[32] At the same time, rates of depression and anxiety continues to rise, and the grief, trauma, and physical isolation that many have experienced during the COVID-19 pandemic have continued to drive these trends.

NIH launched the Helping to End Addiction Long-term® (HEAL) Initiative, in 2018 to provide scientific solutions to the opioid crisis and offer new hope for individuals, families, and communities affected by this devastating crisis. HEAL continues to address these evolving issues. This cross-cutting NIH effort spans basic, translational, clinical, and implementation

[31] www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[32] www.ncbi.nlm.nih.gov/pmc/articles/PMC6688196/pdf/collins-1536332.pdf

science on opioid misuse, addiction, and pain. HEAL has funded over $2.0 billion in research, representing more than 600 research projects across the United States. These projects aim to identify new therapeutic targets for both pain and opioid use disorder, reduce the risk of opioids through nonpharmacological strategies for pain management, and improve opioid addiction treatment in a variety of settings.

Since the launch of HEAL, COVID-19 has collided with the opioid crisis in profound ways. Since the declaration of a public health emergency for COVID-19, overdoses increased 42 percent in May 2020 compared to May 2019.[33] The COVID-19 pandemic caused significant disruption to pain management and OUD/substance use disorder (SUD) treatment and recovery services. Furthermore, the rise of non-prescribed fentanyl in combination with other drugs requires new approaches to combat overdose in the United States.[34] In order to continue to respond to these evolving challenges, the FY 2024 request includes funding for the HEAL Initiative® of $635.6 million, maintaining the FY 2023 Enacted level. In addition to continued emphasis on the research ongoing under the HEAL Initiative®, NIDA and the National Institute of Neurological Disorders and Stroke (NINDS) have been funding targeted research to ensure we understand how best to respond to the specific challenges posed by COVID-19 itself and the impact of the opioid crises overall.

Opioid use is not the only alarming trend in addiction and overdose. The misuse of stimulants, such as methamphetamine, is also increasing, and deaths attributed to using these combinations are likewise increasing. Prevention and treatment strategies are needed for both opioid use disorder and co-occurring conditions such as mental health conditions and polysubstance use for a range of at-risk populations and in various settings. Recently launched HEAL programs aim to develop safe and effective treatments, as well as define approaches to improve treatment access and retention in various settings.

Universal flu vaccine

The influenza virus remains a deadly and costly pathogen, placing a substantial health and economic burden on the United States and across the world each year. In the United States, the CDC estimates that the disease burden of influenza has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations, and between 12,000 and 56,000 deaths annually since 2010, all of which results in an estimated $27 billion in health costs. Current influenza vaccination strategies rely on the development of an annual vaccine targeting the circulating strains that are anticipated to spread in the United States.

NIH supports a research portfolio with the ultimate goal of developing a universal influenza vaccine to generate robust, long-lasting protection against multiple subtypes of influenza, eliminating the need to update the vaccine each year and protect against newly emerging strains with pandemic potential. NIH-funded researchers are making progress toward this goal by utilizing several novel approaches to develop vaccine candidates for clinical testing. Building upon the success of mRNA vaccines developed during the COVID-19 pandemic, NIH is working to expand this concept to the development of a universal influenza vaccine. Additionally, NIH-supported researchers are actively identifying and developing novel adjuvants for influenza

[33] emergency.cdc.gov/han/2020/han00438.asp
[34] pubmed.ncbi.nlm.nih.gov/33031013/

vaccines to increase their immunogenicity and effectiveness. In 2022, a new Phase 1 clinical trial was launched at the NIH Clinical Center to assess the safety and efficacy of a novel universal flu vaccine candidate comprised of four strains of non-infectious, chemically inactivated, low pathogenicity avian flu virus.[35] Continued investment in this research will enable the development of universal influenza vaccines to protect millions of people from infection. The FY 2024 budget request includes $270.0 million for universal influenza vaccine research, the same as the FY 2023 Enacted level.

Ending the HIV Epidemic (EHE)

HIV disproportionately affects populations and geographic areas throughout the United States. In 2016 and 2017, 50 percent of newly diagnosed HIV infections in the United States occurred in 48 counties, some territories, and 7 states which have a significant and disproportionate occurrence of HIV in rural areas. The EHE initiative aims to reduce new HIV infections in the United States by 75 percent by 2025 and to end the HIV epidemic by 2030. As part of the initial EHE response, the NIH Centers for AIDS Research (CFARs) and the HIV/AIDS Research Centers (ARCs) built on existing relationships with local health authorities, community-based groups, and other HHS agencies involved in the EHE initiative, including the CDC and HRSA.[36] With these partners, researchers have identified and evaluated strategies to diagnose new cases of HIV, help connect people living with HIV or at risk of HIV acquisition with medical care and HIV prevention services, and ensure they continue to receive care to treat or prevent HIV. These locally focused activities have used proven HIV treatment and prevention tools including antiretroviral therapy that suppresses HIV to undetectable levels, which benefits people living with HIV and prevents sexual transmission of the virus to others (Undetectable = Untransmittable); pre-exposure prophylaxis (PrEP), a single pill that can reduce the risk of acquiring HIV by more than 95 percent when taken daily; and emergency post-exposure prophylaxis (PEP), which can prevent HIV infection if begun within 3 days of exposure and taken for an additional 28 days. As the original halfway point of this initiative approaches, it is clear that an expanded, diversified response is required to reach communities and populations that continue to be disproportionately affected by HIV. NIH includes 27 ICOs with expertise to reach these populations with renewed efforts; this multi-institute response is centrally coordinated within the NIH OD in the Office of Aids Research (OAR). The request sustains the level for EHE into FY 2024 and reflects plans to expand implementation research to additional types of awardees.

The next steps in NIH's EHE response will include multiple synergistic and coordinated efforts that draw on lessons learned from past and ongoing CFAR and ARC projects, the perceived gaps in research infrastructure and workforce needs in many EHE and high HIV-burden jurisdictions, and a recognition of the persistent racial inequities in health access to HIV prevention and treatment services. Moving forward, NIH is keen to support novel research and study designs that are flexible and nimble in responding and addressing shifts in the HIV epidemic as they develop; those that incorporate new, innovative, and readily deployable technology resources; and those that intentionally include demographically diverse populations. Information dissemination and implementation science research studies are equally critical and will be prominent focus areas for NIH moving forward. Further, NIH is committed to increasing

[35] www.nih.gov/news-events/news-releases/trial-potential-universal-flu-vaccine-opens-nih-clinical-center
[36] www.nih.gov/news-events/news-releases/nih-bolsters-funding-hiv-implementation-research-high-burden-us-areas

research capacity and developing a sustainable and diverse HIV research workforce, not just in EHE jurisdictions but beyond, to ensure that 2025 EHE targets are met. To this end, NIH will pursue the inclusion of minority-serving institutions and diverse investigators. Strategies demonstrated to be implementable at additional, larger scale research locations will be shared as best practices to inform efforts in high HIV-burden jurisdictions.

Community violence research

Violence is a widespread public health problem that has profound impacts on lifelong health, opportunity, and well-being and is a leading cause of death and injury in the United States. In particular, when firearms are involved with violent events, the risk for injury and mortality and acute or chronic physical, mental, and behavioral health conditions increases. In 2019, firearms accounted for three quarters of all homicides and half of all suicides among people ages 65 and under.[37] In 2020, firearm injury became the leading cause of death among children and youth aged 1 to 19,[38] and 79 percent of all homicides and 53 percent of all suicides involved firearms. From 2019 to 2020, the firearm homicide rate increased about 35 percent, to its highest recorded rate in over 25 years. NIH is committed to supporting scientific research to develop, evaluate, and implement effective public health interventions to better understand and prevent violence, including firearm violence, and the resulting trauma, injuries, and mortality. Since FY 2020, with the support of specific appropriations, NIH has funded research to further our understanding of risk for firearm injury and mortality as well as the development and implementation of innovative interventions to prevent firearm violence. With $12.5 million in funding provided to NIH in FY 2022 to conduct research on firearm injury and mortality prevention, NIH supported a network of research sites that will develop, implement, and evaluate innovative community level interventions to prevent firearm and related violence, injury and mortality (CLIF-VP)[39] and a Coordinating Center that will provide cross-network coordination, communication, analytics, engagement, and dissemination efforts.[40] These projects cover a range of types of violence (e.g., suicide, intimate partner violence, youth violence) and diverse populations (e.g., African American youth, older adults, Alaska Native populations, firearm owners). In addition to the Community Violence Interventions (CVIs) focus in the CLIF-VP network, several projects awarded in FY 2021 include CVI and seek to develop or evaluate CVIs to reduce the risk of future firearm violence and identify barriers for the implementation of these interventions. These CVI projects include emergency department-based interventions at the point of care, place-based interventions that include vacant lot reuse, and comprehensive programs that focus on service provision and community engagement among particularly high-risk populations. In FY 2023, NIH will fund a research network that will develop, implement, and evaluate community or organizational level interventions to prevent firearm and related violence, injury, and mortality. The FY 2024 request for firearm research is $12.5 million, maintaining the FY 2023 Enacted level.

[37] Centers for Disease Control and Prevention. (2020). National Center for Health Statistics. Underlying Cause of Death 1999-2019 on CDC WONDER Online Database. wonder.cdc.gov/ucd-icd10.html

[38] Goldstick, J.E. (2022). Current Causes of Death in Children and Adolescents in the United States. The New England Journal of Medicine, 386:1955-1956. www.nejm.org/doi/full/10.1056/NEJMc2201761; Kegler, S.R., Simon, T.R., Zwald, M.L., et al. Vital Signs: Changes in Firearm Homicide and Suicide Rates — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:656–663. dx.doi.org/10.15585/mmwr.mm7119e1

[39] grants.nih.gov/grants/guide/pa-files/PAR-22-115.html

[40] grants.nih.gov/grants/guide/pa-files/PAR-22-120.html

Health impacts of climate change

As climate change continues to be an ongoing crisis, the risks to human health will grow, exacerbating existing health threats and creating new public health challenges. Global climate change is already directly and indirectly affecting human health in the United States and around the world. Impacts occur through changes to climate systems such as temperature, air and water quality, and extreme weather events, as well as through changes to the geography and timing of exposures. Climate change contributes to or exacerbates a wide range of health impacts, including non-communicable disease, injury and trauma, and infectious diseases. Although climate change affects everyone, certain populations are especially vulnerable to various impacts due to social determinants of health, including life stage, sex, underlying health status, access to health care, education, and economic, racial, and ethnically driven disparities. In this way, the climate change and health agenda is inextricably linked to health equity. Climate change impacts are the concern of NIH as a whole and are often at the intersection of multiple NIH ICOs. For this reason, NIH has developed an 'all of NIH' approach to building a solutions-driven climate change and health strategic framework that will build on past research investments.[41] The NIH strategic framework will seek to understand the health impacts and factors that contribute to individual and community susceptibility, strengthen capacity for needed research and the development of a transdisciplinary workforce, and promote community-engaged research, translation, and dissemination to maximize efforts and outcomes among the United States and global communities most urgently affected. The FY 2024 Budget request includes an increase of $25.0 million above FY 2023 appropriations to boost research on the human health impacts of climate change.

Developing targeted prevention and treatment

In the United States, an estimated 52.9 million adults struggle with a mental illness, which may be significantly impairing and life-threatening. Mental illnesses are the fifth leading cause of disability in the United States. One of the most tragic outcomes of untreated mental illness is suicide, which accounted for the loss of over 45,000 American lives in 2020 alone. In recognition that the country is in the midst of an unprecedented mental health crisis, the NIH request includes a $200.0 million increase for mental health research. This funding, which supports the White House Report on Mental Health Research Priorities, includes $20.0 million in increased funding to support studies of social media's impact on mental health, $130.0 million to accelerate better diagnostics, improved treatments, and enhanced precision of mental health care, and $50.0 million to support a new Precision Psychiatric Initiative to address the pressing need to identify and refine techniques to find the right mental health treatment for each individual.

Precision Psychiatric Initiative

In recent years, the field of precision medicine has grown at a rapid pace. One size does not fit all when it comes to treating disease, and the use of genetic analysis and biomarkers have allowed practitioners to provide an individualized treatment approach. This approach to treatment and prevention is rapidly growing in the fields of psychiatry, pediatrics, nutrition and more to provide early and effective intervention to prevent more serious disease.

[41] www.nih.gov/climateandhealth

While effective treatments exist, finding the right treatment for a specific individual is a trial-and-error process that leads to unacceptable delays in receiving effective treatment. The two components of the Precision Psychiatric Initiative will address two parallel areas of need – biomarker development and precision diagnostics.

- *An Innovation Funnel Approach to Accelerating Biomarker Development for Depression*. Research has generated promising leads and putative biomarkers that may accelerate the process of matching patients to the treatments that will be most effective for them, but these research leads have yet to impact clinical care. To address this gap, NIH requests $20.0 million for the first year of a 6-year initiative to launch an innovation funnel for depression biomarker development. Based on the remarkably successful RADx initiative for COVID-19 test development, the goal of this initiative is to deliver highly sensitive and specific biomarkers to guide treatment decisions for major depression. NIMH will implement a stage-gated, milestone-based prize competition for biomarker developers, consisting of 3 phases: (1) biomarker viability assessment with retrospective secondary data analysis (9 months); (2) deep dive assessment (competition phase; 15 months); and (3) test of efficacy in a large scale prospective clinical trial with a focus on generalizability for health equity/underserved populations (4 years). At each phase, a judging review panel consisting of internal and external experts will make recommendations on whether each project should advance to the next stage. This initiative will involve cooperation with the FDA and other HHS operating divisions. NIMH expects about 60 to 100 preliminary inquiries for stage 1 to be funneled into 4 to 8 finalists completing stage 3.

- *Data-driven Refinement of Precision Diagnostics***.** Current approaches to understanding and treating mental disorders are largely based on longstanding diagnostic criteria that rely on patient self-reporting and clinician judgment. These approaches do not incorporate modern understanding of brain-behavior relationships and do not allow precise, objective characterization of individual patients to inform treatment selection. The Budget request includes $30.0 million for the first year of a 5-year initiative to foster a Data-driven Refinement of Precision Diagnostics. This initiative will support studies that follow large (100,000+) cohorts of individuals over time using novel behavioral and physiological methods to better predict patient prognosis and optimize treatment. The initiative will utilize NIH-wide cohorts, including the *All of Us* research program, to provide both statistical power and equitable representation of the full diversity of the U.S. population. This data-driven approach will combine innovative methods for assessing behavior (such as mobile-device based measurement of cognition and activity) with detailed clinical information from electronic health records to identify the longitudinal relationships among mental health symptoms, biological systems, behavior, and day-to-day functioning. These different types of data will be used to detect patterns of clinical trajectories and treatment response and, in a second phase of the initiative, will be incorporated into quantitative clinically relevant tools to be tested for use by clinicians in making treatment recommendations for individual patients, leading to better understanding of mental disorders and more effective treatment.

Transforming nutrition science

To reflect the priority NIH places on innovative, multidisciplinary nutrition research, in FY 2021, the NIH Director moved the Office of Nutrition Research (ONR) to the NIH OD. As part of ONR's role in planning, coordinating, and tracking progress toward achieving the objectives of the 2020-2030 Strategic Plan for NIH Nutrition Research[42], seven topic-based, NIH-wide Implementation Working Groups have been established to develop specific initiatives, improve coordination, and broaden cross-cutting NIH subject matter expertise in nutrition research. ONR and these groups are leading the implementation of the Strategic Plan. The FY 2024 Budget request for ONR is $121.2 million, an increase of $120.0 million above the FY 2023 Enacted level, for the OD to support the objectives of the Strategic Plan. These efforts will support the White House National Strategy on Hunger, Nutrition, and Health, released in September 2022.

Another NIH-wide initiative is the Food as Medicine Networks or Centers of Excellence program. Rates of obesity and other diet-related diseases are skyrocketing, and poor diet quality is now the leading risk factor for death in the United States. Food as Medicine is an umbrella term for programs that respond to the critical link between diet and health involving the provision of healthy food, but notably have health care organizations as their nexus. Unfortunately, barriers currently exist both in communities and within health care systems that severely limit the goal to reduce obesity and other diet-related diseases (e.g., cardiovascular disease, cancer, and diabetes). These innovative programs will support implementation science, and intervention and health quality research on culturally sensitive Food as Medicine and other strategies to improve public health and address these barriers.

Nutrition science research will also complement the Artificial Intelligence (AI) for Chronic Disease initiative, given that most chronic diseases are diet related. The complexity of human nutrition demands that cutting-edge data science and system science methods be employed to move this field into the 21st century. The requested funds will support new training programs in AI for Precision Nutrition that will focus on integration of the domains of precision nutrition, AI including machine learning, systems biology, systems science, Big Data, and computational analytics. The goal is to build a future workforce that will be able to use growing data resources to tackle complex biomedical challenges in nutrition science.

ONR is also collaborating with the NIH ICOs on a transformative research program examining the role of diet, food environment and related environmental exposures on the Developmental Origins of Health and Diseases (DOHaD). There is increasing concern that food environment, life stress, traumas, medications, health and nutritional status, microbiome ecology, and related environmental exposures are responsible for future diet-related disease risk. This discovery science program will also include a comprehensive study of human milk composition, dietary intake, and nutritional status measures and outcomes, answer mechanistic questions about the developmental origins of disease, and ultimately, lead to an optimized diet for the health of the mother and child.

[42]dpcpsi.nih.gov/onr/strategic-plan

Inspiring the next generation of scientists

Scientific advancement requires a cadre of diverse minds ready to tackle complicated scientific problems. Just as the development of the polio vaccine inspired a new generation of scientists, the development of lifesaving COVID-19 vaccines will inspire a new generation of young minds with diverse backgrounds and experiences to pursue careers in biomedical science and discover the preventions and cures of tomorrow. NIH supports the training and development of the next generation of scientists who will bring diverse perspectives, skillsets, and backgrounds, and it begins with an NIH commitment to instituting new plans and programs to support diversity, equity, and inclusion in our workforce and beyond.

DEIA Strategic Plan

The purpose of the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA) is to articulate NIH's vision for embracing, integrating, and strengthening DEIA across all NIH activities to achieve the NIH mission. The Strategic Plan will capture activities that NIH will undertake to meet the vision of the Strategic Plan, and will be organized around accomplishments, needs, opportunities, and challenges in addressing DEIA in the NIH internal and extramural workforce, its structure and culture, and the research it supports. The NIH-Wide Strategic Plan for DEIA is being developed in part as a response to directives in the House FY 2022 appropriations report on a diversity strategic plan[43] and is responsive to *Executive Order 14035* and the *Government-Wide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce*.[44] The NIH-Wide Strategic Plan for DEIA will highlight NIH's ongoing and future efforts to foster DEIA within the biomedical and health research enterprise. The Framework for the NIH-Wide Strategic Plan for DEIA, below, articulates NIH's priorities in three key areas: 1) Grow and sustain DEIA through structural and cultural change; 2) implement organizational practices to center and prioritize DEIA in the workforce; and 3) advance DEIA through research.

UNITE: Inspiring the next generation of scientists

To take on issues as pervasively entrenched in the scientific enterprise as structural and systemic racism, UNITE works across three domains—the internal NIH workforce, the external biomedical workforce, and advancing health disparities and mental health (HD/MH) research.

Through the NIH Common Fund, UNITE launched the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program to enhance and maintain scientific environments that cultivate and benefit from a full range of talent. UNITE efforts have led to the expansion of the Science Education and Partnership Awards program with 17 NIH ICOs joining the National Institute of General Medical Sciences (NIGMS) in focusing on projects that generate resources to increase career opportunities for underrepresented groups from diverse backgrounds, including those underrepresented in biomedical research as well as outreach to these groups in the kindergarten through grade 12 (K-12) Science, Technology, Engineering, and Math (STEM) community. Via UNITE efforts, NIH is also developing a DEIA prize competition to reward and recognize institutions of higher education for innovative interventions that enhance faculty and

[43] www.congress.gov/116/crpt/hrpt450/CRPT-116hrpt450.pdf

[44] www.whitehouse.gov/briefing-room/presidential-actions/2021/06/25/executive-order-on-diversity-equity-inclusion-and-accessibility-in-the-federal-workforce/

student DEIA. Finally, UNITE is anticipating the release of three concepts approved by the National Advisory General Medical Sciences Council to enhance the participation of underrepresented groups in biomedical and behavioral research and a fourth concept approved by The National Advisory Council for the National Institute on Minority Health and Health Disparities (NIMHD) to enhance research capacity at minority-serving institutions (MSIs).

STEM Education Training

NIGMS support for STEM education and training starts at the earliest stages of the career pathway. An effective means of helping youth imagine their future selves in a biomedical research career is to acquaint and involve them in the research process. Thus, NIGMS's Science Education Partnership Award (SEPA) supports projects that build interactive educational resources that both capture the imaginations of pre- K-12 students and stimulate the types of scientific curiosity and inquiry-based approaches used in biomedical research.[45] Many of these projects provide opportunities for students to be involved in citizen science projects that aim to understand and address issues that affect their individual communities. In addition, they provide opportunities to interact with current biomedical research professionals from diverse backgrounds as role models: one SEPA program, for instance, pairs veterinarians from a nationwide "superhero" League of VetaHumanz with local schools or community centers that support underserved students.[46] To help educators find free science education content, NIGMS recently launched a STEM teaching resources website. The website includes NIH-wide teaching materials as well as those from SEPA programs, categorized by different health and research topic areas.[47]

In addition to its early outreach efforts, NIGMS promotes access to research experiences by supporting training programs with a strong mentorship component across all educational stages. Research and career development programs at the undergraduate level, for instance, can help set the trajectory of a student's career by allowing them to succeed in the laboratory, thereby allowing individuals to visualize a potential future in scientific research. Participants in diversity-oriented programs like the Maximizing Access to Research Careers (MARC) and Undergraduate Research Training Initiative for Student Enhancement (U-RISE) programs often comment on how they were inspired seeing people from backgrounds like their own conducting—and succeeding in—science.[48,49]

Finally, achieving a diverse and productive workforce means supporting critical phases of the career development pathway, including key transition points between one stage of the pathway and the next. The Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program, which focuses on the transition from postdoctoral scholar to independent investigator, combines individual awards with a cohort-based mentoring program that has

[45] nigms.nih.gov/capacity-building/division-for-research-capacity-building/science-education-partnership-awards-(sepa)
[46] biobeat.nigms.nih.gov/2022/06/the-league-of-vetahumanz-encouraging-kids-to-use-their-powers-for-good/
[47] science.education.nih.gov/
[48] nigms.nih.gov/training/MARC/Pages/USTARAwards.aspx
[49] nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx

attracted and retained a diverse class of fellows.[50,51] Following the success of this program, NIGMS is developing a similar cohort-based program to support trainees during the transition from graduate school to postdoctoral training.

Short-Term Research Experience Program to Unlock Potential (STEP-UP)
To enhance the biomedical research workforce and nurture the next generation of scientists, it is critical to start early, with opportunities that can inspire young people from diverse backgrounds to pursue research careers. Recognizing that talent is everywhere, while opportunity is not, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) launched the STEP-UP program over two decades ago to make research opportunities accessible to high school and undergraduate students, with a focus on students from groups underrepresented in research. STEP-UP provides a hands-on summer research and mentoring experience, reaching students throughout the country and in U.S. territories in the Pacific and Caribbean. Additional components of the program include a symposium at which students present their research results, and continued mentorship after the summer. With NIDDK grant support, academic and non-profit institutions across the country serve as STEP-UP coordinating centers to identify mentors, coordinate student recruitment, help students find sites where they can pursue research without having to travel far from their home or school, and manage other aspects of the program. Early evaluation results of STEP-UP from the first two decades of the program showed that many of the program's participants have pursued careers as researchers, physicians, and physician-scientists. Building on this success, NIDDK recently renewed the program as an important component of the Institute's multifaceted efforts to develop a talented and diverse biomedical research workforce.

Tackling the undiscovered

A fundamental aspect of biomedical and behavioral research is the understanding that there is a multitude of untapped knowledge remaining to be discovered. NIH proactively pursues scientific opportunities through a variety of programs that promote cutting-edge, innovative research concepts that could steer science in new directions. This includes innovative mental health research to novel discoveries in precision medicine and rare and undiagnosed diseases. Additionally, NIH encourages team science and cross-disciplinary collaboration to propel research progress, further scientific advances, and improve human health.

The NIH Director's Challenge Innovation Award
The NIH Director's Challenge Innovation Award is a program designed to identify and fund projects that foster trans-NIH collaborations across the NIH Intramural Research Program (IRP). The program seeks to fund innovative, high-impact projects that require the cooperation of researchers in more than one of NIH's Institutes and Centers. The award provides seed money from the NIH Office of Intramural Research (OIR) for innovative and high-impact research that shows significant benefit to a variety of research, infrastructure, and/or scientific endeavors throughout the IRP. In FY 2022, the program supported investigator-initiated, collaborative, and

[50] nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx
[51] In its first two years, the MOSAIC program supported 82 scholars, 76 percent of whom were women, and 71 percent from under-represented backgrounds.

interdisciplinary projects that employ engineering and/or physical science approaches to problems in biology and medicine. The program made six 2-year awards, ranging in amount from $194,000 to $250,000 per year.

Undiagnosed Disease Network
The FY 2024 budget request includes $18.0 million in NINDS to support the transition of the NIH Undiagnosed Diseases Network (UDN). The UDN was housed in the NIH Common Fund through FY 2022, and needs dedicated funding in NINDS since Common Fund projects have time-limited support. The UDN, which builds on the success of the Undiagnosed Diseases Program at the NIH Clinical Center, is a nationwide network of clinicians and researchers who use both basic and clinical research to uncover the underlying disease mechanisms associated with rare and undiagnosed conditions. It has been estimated that approximately 25 million Americans suffer from a rare disorder. The UDN pioneered a new personalized medicine model for helping patients who have historically been the most difficult for the medical community to diagnose, taking advantage of cutting-edge technologies such as genomic sequencing, metabolomics and assessing patient variants in model organisms to give clinicians new, powerful information to help understand the cause of extremely rare diseases.

Infrastructure to tackle the undiscovered

A critical aspect of NIH supporting the discovery of novel diagnostics, therapeutics, and cures to disease is having facilities, infrastructure, and ecosystems that can support state-of-the-art imaging, discover tumors at the earliest stage possible, safely develop novel treatments such as cellular therapy, and more.

Buildings and Facilities
Facilities must co-evolve with science for NIH to achieve its full potential. A major component of the NIH Building and Facilities (B&F) program is the Repair & Improvement (R&I) program, which enables NIH to maintain and improve the performance of existing facilities throughout their life cycle. As the responsible steward of its approximately 275 facilities, a key aspect of NIH's strategy is to sustain the condition of existing facilities to prevent premature deterioration and the curtailment of research. These investments help reduce the likelihood and consequences of building emergencies associated with NIH's Backlog of Maintenance and Repairs (BMAR) of nearly $3.8 billion across all campuses as of the end of FY 2022. NIH requests a funding level for B&F of $350.0 million, maintaining the FY 2023 Enacted level. This level is designed to address the pressing campus-wide infrastructure needs identified in the independent review of the facility needs of NIH's main campus in 2019 by the National Academies of Sciences, Engineering, and Medicine (NASEM). In addition to the B&F appropriation, NIH has received support for critical infrastructure projects in recent years from targeted allocations from the Nonrecurring Expenses Fund (NEF). In FY 2024, NIH is requesting a total of $120.1 million in NEF funding for five critical infrastructure projects on the Bethesda campus.

NIH plans to execute various modernization and repair projects to NIH's research hospital, replace research animal facilities with a centralized and more efficient facility, improve facilities that advance computational and data science, replace temporary and obsolete administrative

support facilities with permanent buildings, improve the energy and water efficiency of buildings, and support the co-evolution of science and buildings. In addition, NIH proposes new authority to transfer IC appropriations to the B&F Account, subject to a 1 percent cap. This authority would provide needed flexibility in the case of unexpected facilities requirements, such as the extensive renovations required after the major flooding in Buildings 35 and 35A in late December of 2022. The costs of responding to these events, which compromise IC intramural research space, hinder NIH's ability to use the B&F appropriation for BMAR-reducing projects as it is intended. The transferred funds would be available over the five-year period of availability of funds directly appropriated to the B&F account, which is necessary because the general one-year period of availability of appropriations for Institutes and Centers is not sufficient for construction projects.

Modernizing data ecosystems

NIH promotes the management and sharing of scientific data generated from NIH-funded or conducted research, and NIH has several policies that establish expectations for sharing data that results from research. However, sharing data also requires appropriate infrastructure to ensure data can be found, accessed, and used appropriately, and NIH has several ongoing efforts to enhance or modernize the data ecosystem. To that end, NIH stores and facilitates access to many datasets, both open and controlled, with the goal of accelerating new discoveries and maximizing taxpayer investment in the collection of these datasets. Datasets that are shared through controlled-access mechanisms reflect the NIH's commitment to protect sensitive data obtained from – and honor the informed consent provided by – human participants in NIH studies.

NIH has created multiple, controlled-access data repositories to meet the needs of various researcher communities. However, as the data access landscape continues to evolve, opportunities remain to improve efficiency and harmonization among repositories to make NIH data more findable, accessible, interoperable, and reusable (FAIR) and to ensure appropriate oversight when data from different resources are combined. To address these issues while ensuring necessary protections remain in place – and to identify other issues – the NIH Controlled Data Access Committee Working Group organized a series of webinars and a Request for Information to seek community feedback. Insights and observations from these efforts will be synthesized and shared with the NIH Data Science Policy Council and the NIH Scientific Data Council. Additionally, through the Clinical Research Informatics Strategic Planning Initiative (CRISPI), NIH has begun the development of a long-term strategic plan that will produce recommendations to guide the evolution of the infrastructure (both systems and services) that will be needed to support clinical research across the NIH Intramural Research Program. Critical factors will include strong policies on data sharing and governance, interoperability of the clinical-research ecosystem, and adequate funding for support and maintenance of the systems and services for clinical investigators.

Cybersecurity

NIH is requesting $265.0 million in funding, the same as the FY 2023 Enacted level, to continue the trans-NIH multi-year activities to improve the overall cybersecurity posture of NIH and to meet the standards and requirements set forth in the President's Executive Order on Improving the Nation's Cybersecurity, issued on May 12, 2021, and subsequent memoranda and Department of Homeland Security/Cybersecurity and Infrastructure Security Agency (CISA)

directives. The funding will support pro-active, risk-based cybersecurity protections necessary to keep up with the increasing threats to NIH and the cybersecurity challenges and attacks that threaten the privacy and security of NIH's data and overall operations. Specific funding is needed to support trans-NIH cybersecurity investments and improvements to support the 27 NIH ICs and the OD in three broad areas of requirements.

- Enable better prevention, detection, assessment, and remediation of cybersecurity threats. A high priority is NIH's multi-year initiative to implement a Zero Trust Architecture across the NIH network and operating environments, including on-premises and cloud platforms.
- Continue improvements in tools and capabilities to protect all NIH data, systems, and services, and reduce the cyber-attack surface.
- Expand, enhance, and deploy capabilities for NIH-wide continuous monitoring, risk mitigation, and incident response.

Nonhuman primate infrastructure

The National Primate Research Centers (NPRCs) are national resources serving not only NIH-funded investigators, but other federally funded investigators, as well as researchers in private foundations and the pharmaceutical industry. The NPRCs supported many SARS-CoV-2 projects over the last few years. Beyond the need for nonhuman primates in responding to emerging infectious diseases, the NPRCs are critical for understanding a wide range of human diseases and the development of vaccines and therapeutics. Nonhuman primate models have led to critical advances in metabolism, developmental biology, diabetes, obesity, aging, organ transplantation, and cardiovascular and neurologic diseases, among many others. More recent applications of nonhuman primate models have been in the fields of regenerative medicine and gene therapy.

The NIH request includes $30.0 million for improvements to nonhuman primate infrastructure. This request would provide necessary funding to improve facilities used to house nonhuman primates, which require continual updates and maintenance. The funds would be distributed by soliciting applications from NIH grantees to improve existing facilities, not to establish new nonhuman primate facilities. Several nonhuman primate facilities have existed for over 60 years and housing enclosures require frequent repair and replacement. New construction for research facilities would include animal holding rooms, necessary updated equipment including centrifuges, ultrasound devices, clinical analyzers, and veterinary clinical support areas to provide proper care of the nonhuman primates. In addition to housing, nonhuman primates require clinical/veterinary care, and psychological and environmental enrichment, which necessitates highly skilled technical staff and additional resources. NIH would support expansion at existing NIH-supported facilities to leverage the current investments. The NIH Office of Research Infrastructure and Programs (ORIP) supports a well-coordinated national consortium of seven NPRCs and other breeding colonies that collectively address research needs and trends, best husbandry practices, maintenance of genetic diversity, standardization of animal models, scientific rigor, and reproducibility.

Advanced Research Projects Agency for Health (ARPA-H)
ARPA-H's vision is to empower all Americans to realize their health potential. In pursuit of that vision, ARPA-H's mission is to innovate high-impact health solutions to well-defined problems and thus to demonstrate what health futures are possible for all. ARPA-H will pursue its mission through pivotal investments in novel technologies and broadly applicable platforms, capabilities, and resources—driving biomedical innovation from the molecular to societal—to create solutions that have the potential to transform important areas of medicine and health for the benefit of all patients. ARPA-H seeks to realize dynamic health solutions across various levels and varying maturity, speed application and implementation of breakthroughs to serve all patients, and support "user-driven" ideas to solve hard problems with tangible but innovative solutions.

ARPA-H is growing and promoting a culture that is administratively and scientifically nimble, with a relentless drive to catalyze health breakthroughs that benefit all Americans and that cannot readily be accomplished through traditional research or commercial activity. Dr. Renee Wegrzyn, the newly appointed Director of ARPA-H, will be responsible for driving the agency's nascent research portfolio and associated budget. The budget is expected to support programs to develop capabilities to address a broad range of challenges across the health ecosystem including prevention, detection, and treatment of some of the most intractable diseases including cancer. The requested funding will support the continued establishment of ARPA-H mission offices, the recruitment of program managers, and creation of high-impact programs, and the translation of successes into viable health solutions. A detailed request is outlined in the ARPA-H Congressional Justification volume.

Ensuring Stewardship of Publicly Funded Research

As a steward of public resources, NIH has a responsibility to uphold public trust and confidence in the agency. In addition to fostering innovative research, NIH must endeavor to ensure that all of its operations and the research it supports are conducted efficiently, responsibly, ethically, and with integrity. NIH demonstrates effective stewardship by supporting the most meritorious biomedical and behavioral research possible.

Scientific Integrity
NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is held to the highest standards. In accordance with the January 2021 Presidential Memorandum on Restoring Government Trust through Scientific Integrity and Evidence-Based Policymaking, NIH is updating its compendium of these policies and procedures and will specifically include procedures regarding the reporting and addressing of political interference. The updated Compendium of NIH Policies and Procedures for Promoting Scientific Integrity will be submitted to Office of Science and Technology Policy (OSTP) for review within 60 days after the publication of the OSTP Scientific Integrity Framework which was released in January 2023.[52] The updated NIH Compendium includes a definition of political interference which was developed by the HHS Scientific Integrity Working Group, on which NIH sits, and is expected to

[52] whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf

be published after OSTP review and any subsequent revisions are made and approved. Scientific integrity trainings on these procedures will be updated to correspond with the approved updated compendium language. Further, the agency has designated the NIH Principal Deputy Director and Associate Director of Science Policy, both senior career employees, as the agency's Chief Science Officer (CSO) and Scientific Integrity Official (SIO), respectively. Collectively, they will ensure that NIH's research programs are scientifically and technologically well-founded and conducted with integrity.

Rigor and Reproducibility

NIH has embarked on a series of initiatives in recent years to enhance the quality, efficiency, accountability, transparency, and translatability across all supported research.[53] This includes releasing policies to enhance reproducibility of NIH-supported research through rigor and transparency, increasing the focus of rigor in grant review, and actively engaging with the research community to identify and develop research methodologies that could improve the reproducibility and translatability of laboratory research.

While NIH has multiple ongoing efforts to enhance reproducibility through rigor and transparency across the biomedical research enterprise, there are unique aspects of animal research that require additional attention. For example, there are specific considerations around selecting appropriate animal models for translation to findings that inform human biology and disease. Animal researchers are also required to consider the "3Rs" of research – replacement, reduction, and refinement. In 2019, the NIH Director charged the Advisory Council to the Director (ACD) to make recommendations to enhance the reproducibility and rigor of animal research focused on improving experimental design, optimizing translational validity, enhancing training, and increasing the transparency of research studies involving animal models.[54] In response to this charge, the ACD established a working group on *Enhancing Rigor, Transparency, and Translatability in Animal Research* with the overarching goal to enable all stakeholders to have full confidence in the quality and applicability of research findings from animal studies, and to ensure that animal subjects are used with appropriate consideration of ethics, welfare, and harm benefit analysis. This ACD Working Group released its final report in June 2021 with recommendations for: (1) improving study design and data analysis; (2) addressing incomplete reporting and questionable research practices; (3) improving selection, design, and relevance of animal models; (4) improving methodological documentation and results reporting; and (5) measuring and evaluating the costs and effectiveness of these efforts.[55] The agency is actively evaluating the recommendations and determining strategies for their implementation that consider the complexity and diversity of research supported by NIH.

In late 2022, NIH announced a new ACD Working Group on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research. These novel alternative methods which include *in chemico, in vitro,* and *in silico* approaches, can complement traditional animal models and in some cases, may help refine or replace the need for animal models in certain types of research studies. The new working group is being set up to explore options and to make recommendations on where novel alternative methods are positioned to be most

[53] grants.nih.gov/policy/reproducibility/index.htm
[54] acd.od.nih.gov/working-groups/eprar.html
[55] acd.od.nih.gov/documents/presentations/06112021_RR-AR%20Report.pdf

applicable or beneficial, especially in terms of advancing our understanding of human health. The establishment of this working group acts on the recommendation included in the ACD Working Group on *Enhancing Rigor, Transparency, and Translatability in Animal Research*'s June 2021 report.

Data Sharing
In November 2021, NIH sought out public input on the future of the NIH Genomic Data Sharing (GDS) Policy. There is growing interest in the use of human data elements that might be considered identifiable, which cannot currently be submitted to NIH genomic data repositories, and in the ability to match participants' data across repositories or with data from other sources. NIH sought feedback on whether or not it should permit these activities, and if so, what additional protections may be necessary. To ensure consistency of operations and protections, NIH is proposing core principles for NIH-supported genomic data repositories and platforms.

Under NIH's new Policy for Data Management and Sharing, all NIH-supported research will be expected to maximize appropriate sharing of scientific data generated during the research. To improve the management and sharing of data from NIH-supported research, NIH and other agencies agreed to leverage the Subcommittee on Open Science of the National Science and Technology Council to identify a consistent set of desirable characteristics for data repositories that all agencies could incorporate into the instructions they provide to the research community for selecting data repositories. By establishing common expectations, agencies intend to reduce the complexity for the research community–including investigators, program officers, data managers, librarians, and others–in complying with Federal data sharing policies. Federal agencies can also use this set of characteristics to develop or identify suitable repositories for particular types of data.

Conclusion

The Nation's investment in NIH is born from the recognition that a healthy population is a productive and thriving population. NIH seeks to foster a culture of scientific minds with diverse backgrounds, and ideas; a culture that endeavors to handle science with the highest standards of rigor and integrity to achieve the NIH mission of improving the health and wellbeing of all Americans.

NIH investments in research stimulate increased private investment. A $1.00 increase in public basic research stimulates an estimated additional $8.38 of industry R&D investment in a particular research area after 8 years.[56] In rural states, each $1.00 of NIH spending generated an average $1.80 of total economic impact. This economic activity then generates significant revenues for state and local governments, an average of $22 million per state in 2017 for applicable taxes and fees paid by businesses and employees.[57]

[56] sciencepolicy.colorado.edu/students/envs_5100/Toole2007.pdf
[57] www.unitedformedicalresearch.org/wp-content/uploads/2019/03/NIH-Research-Rural-States-Executive-Summary-FINAL-3.13.19.pdf

A healthier nation is a more productive and economically sound nation. Each permanent one percent reduction in cancer deaths alone has been approximated to have a value of nearly $500 billion to current and future generations of Americans. A full cure could be worth more than three times today's GDP.[58] As seen with the COVID-19 response, the benefits of NIH research can be felt in the near term through development of novel health interventions, and continue well into the future as transformations in the diagnosis, prevention, and treatment of disease today become standard practice tomorrow.

[58] ucema.edu.ar/u/je49/capital_humano/Murphy_Topel_JPE.pdf

OVERVIEW OF PERFORMANCE

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Investments in basic biomedical and behavioral research make it possible to understand the causes of disease onset and progression, design preventive interventions, develop better diagnostics, and discover new treatments and cures. Realizing the benefits of fundamental biomedical discoveries depends on supporting research to translate and effectively disseminate that knowledge to aid the development and adoption of new diagnostics, therapeutics, and preventive measures to improve health.

The FY 2024 budget request reflects the Agency's longstanding commitment to invest strategically using performance-based analysis, as emphasized in the Government Performance and Results Act (GPRA) (P.L. 103-62), as amended by the GPRA Modernization Act of 2010 (P.L. 111-352). Through the continuous evaluation and strategic management of its research portfolio, NIH focuses on funding research that shows the greatest promise for improving the overall health and well-being of the American people. In addition, NIH continually seeks to identify and address high-priority scientific opportunities and emerging public health needs. By managing its research portfolio to support key research priorities, NIH ensures the most effective use of funds to achieve the greatest impact on the health and welfare of the Nation. In particular, NIH's strong peer-review process, site visits, performance monitoring, program evaluation, and performance-based contracting enable the Agency to ensure that its investments generate results for the American people.

NIH strives to achieve transparency and accountability by regularly reporting results, achievements, and the impact of its activities. NIH supports a wide spectrum of biomedical and behavioral research and engages in a full range of activities that enable research, its management, and the communication of research results. Because of this diversity and complexity, NIH uses a set of performance measures that is representative of its activities and is useful for tracking progress in achieving performance priorities. This representative approach has helped NIH to share progress of its performance priorities with HHS, the rest of the Executive Branch, the Congress, and the public.

Collectively, the NIH performance measures reflect the Agency's overall goals to: 1) advance the full continuum of biomedical research; 2) strengthen the scientific workforce and biomedical research infrastructure; 3) facilitate the communication of research findings and transfer of knowledge to other sectors for further development; and 4) enhance internal management processes, policies, and systems to support programmatic and organizational oversight. Furthermore, the measures support the Administration's goal of protecting and improving the health and well-being of the American people. They reflect NIH's ongoing efforts to address a variety of public health challenges and to further the U.S.'s biomedical research enterprise, including the need to identify effective prevention interventions for substance use disorders; support the development of diagnostic technologies and antiviral drugs to enhance pandemic preparedness; leverage health information technologies to improve minority health and reduce health disparities; and diversify and foster the next generation of biomedical and behavioral scientists.

Performance Management

Performance management at NIH is an integrated and collaborative process to ensure that the Agency is achieving its mission to conduct and support research to improve public health. At the Agency level, the NIH Director sets priorities, monitors performance, and reviews results across the 27 Institutes and Centers (ICs) and the Office of the Director (OD). OD is the central office responsible for setting policy for NIH, and for planning, managing, and coordinating the programs and activities of all NIH components. The NIH Director provides leadership to the ICs and helps identify needs and opportunities, especially for efforts that involve multiple ICs. ICs and OD offices carry out priority setting, performance monitoring, and progress reviews, and also make adjustments based on progress achieved in their respective areas of science. In addition to the performance management processes that occur for the NIH research program, there are equivalent processes for research capacity-building programs and administrative management functions.

The NIH performance framework includes: 1) priority setting with input from key stakeholders; 2) implementation and management of activities that support priorities; 3) monitoring and assessment of progress, and identification of successes and challenges; 4) oversight by IC leadership and OD office directors in assessing overall progress toward priorities and identification of best practices, appropriate next steps, and corrective actions (as needed); 5) incorporation of regular feedback from IC and OD office leadership to enhance activities; 6) regular reviews of priorities, progress, and outcomes by the NIH Director and IC Directors; and 7) regular review of performance and priorities by external expert review groups including grant peer-review groups, Advisory Councils, and ad hoc working groups.

Qualitative and quantitative information is used to monitor progress and help to identify successes, as well as obstacles in achieving short- and long-term goals. Supporting high-quality research is a process of adapting to new developments or newly identified barriers, or shifting resources to pursue promising unanticipated results that may provide critical new information. Moreover, the impact of research may not be immediately known and may depend on additional development or on advances in other fields. Despite these challenges, NIH leadership is able to manage performance effectively by using the best available information to assess progress toward achieving priorities and making appropriate adjustments.

All scientific research carried out through NIH support is subjected to a rigorous and consistently applied review process. For example, the Extramural Research Program, which accounts for the majority of NIH-funded research, utilizes two levels of peer review. The first level, in which scientific excellence is assessed, consists of chartered scientific review groups composed of outside experts in particular scientific disciplines. The second level, in which public health relevance is assessed, is conducted by National Advisory Councils of the ICs. For the Intramural Research Program, the progress of individual scientists and their laboratories is evaluated once every four years by Boards of Scientific Counselors composed of external experts. These reviews enable ongoing assessments of all intramural labs and the accomplishments of the scientists who contribute to them. It is through this well-honed system of peer review that NIH

maintains its focus on supporting research of the highest possible quality with the greatest potential of furthering NIH's mission.

The NIH approach to performance management is undergirded by the NIH Governance Structure. That structure includes the NIH Steering Committee and standing Working Groups.[59, 60] Ad-hoc working groups are established, as needed, to address emerging issues. The premise of the structure is that shared governance, which depends on the active participation of the IC Directors with the NIH Director, will foster the collaborative identification of corporate issues and a transparent decision-making process. With active participation by the IC Directors in NIH-wide governance, NIH can maximize its perspective and expertise in the development and oversight of policies common to NIH and its ICs. Through the governance process, corporate decisions are made; these may be long-term and strategic (e.g., facilities planning, budget strategy, and research policy direction) or short-term and tactical (e.g., stipend levels, resource allocations, and compliance oversight). This process does not include issues related to the setting of scientific priorities, which is reserved for meetings of all IC Directors. The NIH Director meets with the IC Directors on a bi-weekly basis, and scientific initiatives are discussed, as well as major management issues that affect the Agency. In addition, scientists – from within and outside the Agency – are invited to present on new or emerging research opportunities. The NIH Director stays informed of priorities through regular meetings with IC and OD Office Directors. Similarly, the IC Directors monitor performance through regular meetings with the Division Directors and Scientific/Clinical Directors in their respective ICs.

Based on these reviews, leadership and their staff take appropriate actions to support research activities. For example, the reviews may lead to the development of new award programs for early-career researchers, the development of new funding announcements for promising research areas, or new collaborations across NIH and/or with other Federal and non-Federal partners. The NIH Director and senior leadership receive regular updates on the progress of the priorities, provide feedback, and incorporate the latest information into the NIH's overall planning and management efforts. This constant feedback loop enables NIH to make critical adjustments periodically to align activities and target resources in support of its research priorities.

[59] The NIH Steering Committee is composed of the NIH Director, Deputy Director (ex-officio), the Directors of the National Cancer Institute, National Heart, Lung, and Blood Institute, and National Institute of Allergy and Infectious Diseases, as well as a balance of Directors from the smaller and medium-sized institutes.

[60] The standing working groups are: Extramural Activities Working Group; Diversity, Equity, Inclusion, and Accessibility Working Group; Facilities Working Group; Management and Budget Working Group; Scientific Data Council; Data Science Policy Council; Clinical Center Governing Board; Board of Scientific Directors; Enterprise Information Technology Council; and Research Services Working Group.

ALL PURPOSE TABLE

(Dollars in Thousands)[1,2]	FY 2022 Final[7]	FY 2023 Enacted[7]	FY 2024 President's Budget[7]	FY 2024 +/- FY 2023
Total, NIH Program Level	**$46,177,990**	**$49,178,485**	**$51,098,124**	**$1,919,639**
Less mandatory and funds allocated from different sources:				
PHS Program Evaluation	1,309,313	1,412,482	1,948,109	535,627
Mandatory Type 1 Diabetes Research[3]	141,450	141,450	250,000	108,550
Total, NIH Discretionary Budget Authority	**$44,727,227**	**$47,624,553**	**$48,900,015**	**$1,275,462**
Interior Budget Authority	82,540	83,035	83,035	0
Total, NIH Labor/HHS Budget Authority	**$44,644,687**	**$47,541,518**	**$48,816,980**	**$1,275,462**
Total, NIH Program Level, excluding ARPA-H	**$45,177,990**	**$47,678,485**	**$48,598,124**	**$919,639**
Pandemic Preparedness Mandatory via PHSSEF (non-add) [4]	*$0*	*$0*	*$2,690,000*	*$2,690,000*
Number of Competing RPGs	*11,333*	*10,961*	*10,414*	*-547*
Total Number of RPGs	*42,596*	*43,620*	*44,410*	*790*
FTE[5]	*18,689*	*20,366*	*20,943*	*577*
Nonrecurring Expenses Fund:[6]				
ORF/ORS/NIAID Support Facilities, Rocky Mountain Laboratories, MT		*40,650*		*-40,650*
Electrical Power Reliability, Building 10		*22,490*		*-22,490*
Replace Cooling Towers 18, 19 and Chillers 17, 18, 19			*40,000*	*40,000*
Building 11 Provide Sprinkler Protection			*11,370*	*11,370*
Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C			*29,300*	*29,300*
Repair Parking Garages, Bethesda			*13,360*	*13,360*
Electrical Power Reliability for the CCC			*26,100*	*26,100*

1 Numbers may not add due to rounding.

2 Includes 21st Century Cures Act funding.

3 Amounts in FY 2022 and FY 2023 reflect a reduction of $8.550 million for Budget Control Act sequestration.

4 The FY 2024 budget also provides $20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, NIH will receive $2,690 million.

5 Includes 4 NIH FTEs funded by PHS trust funds in FY 2022 through FY 2024.

6 The FY 2022 NEF notification to Congress on June 17, 2021 did not include any allocation for NIH. The NEF CJ indicates the amounts HHS intends to notify for in FY 2024; these amounts are planned estimates and subject to final approval.

7 Reduced by a transfer of $5.0 million from OD to the HHS Office of Inspector General.

IMPACT OF BUDGET LEVEL ON PERFORMANCE

Programs and Measures (Dollars in Millions, except where noted)	**FY 2023 Enacted**	**FY 2024 President's Budget**	**FY 2024 +/- FY 2023**
Research Project Grants	$26,806.076	$27,089.942	1.1%
Competing Average Cost (in thousands)	$602.000	$581.000	-3.5%
Number of Competing Awards (whole number)	10,961	10,414	-5.0%
Estimated Competing RPG Success Rate	19.9%	18.6%	-1.3%
Research Centers	$2,909.362	$2,921.580	0.4%
Other Research	$3,298.628	$3,489.145	5.8%
Training	$1,033.972	$1,050.644	1.6%
Research & Development Contracts	$3,828.668	$3,946.840	3.1%
Intramural Research	$5,012.040	$5,056.584	0.9%
Research Management and Support	$2,304.890	$2,491.369	8.1%
Common Fund (non-add)	*$735.001*	*$735.001*	*0.0%*
Advanced Research Projects Agency for Health (ARPA-H)[1]	$1,500.000	$2,500.000	*66.7%*
Buildings & Facilities Appropriation	$350.000	$350.000	0.0%
Other Mechanisms[2,3]	$2,134.849	$2,202.020	3.1%
Total, Program Level[4]	**$49,178.485**	**$51,098.124**	**3.9%**
Total, Program Level excluding ARPA-H	$47,678.485	$48,598.124	1.9%
Mandatory Pandemic Preparedness via PHSSEF (non-add) [5]		*$2,690.000*	*NA*

[1] FY 2023 reflects the amount transferred from the HHS Office of the Secretary.

[2] Includes Office of the Director-Other, Buildings and Facilities funding in the National Cancer Institute, and Superfund Research activities funded from the Interior appropriations bill.

[3] Amounts in each year reflect directive transfer of $5.0 million to the HHS Office of Inspector General.

[4] Includes discretionary budget authority received from Labor/HHS appropriations bill and the Interior appropriations bill (Superfund). Also includes program evaluation financing and mandatory budget authority derived from the Type 1 Diabetes account.

[5] The FY 2024 budget also provides $20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund (PHSSEF) chapter. Of this total, NIH will receive $2,690 million.

APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, **[**$7,104,159,000**]***$7,820,159,000*, of which *$716,000,000 shall remain available until expended, and of which* up to $30,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, **[**$3,982,345,000**]***$3,985,158,000*.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to dental and craniofacial diseases, **[**$520,163,000**]***$520,138,000*.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, **[**$2,300,721,000**]***$2,303,098,000*.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

For carrying out section 301 and title IV of the PHS Act with respect to neurological disorders and stroke, **[**$2,588,925,000**]***$2,739,418,000*.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to allergy and infectious diseases, **[**$6,562,279,000**]***$6,561,652,000*.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, $3,239,679,000, of which **[**$1,412,482,000**]***$1,948,109,000* shall be from funds available under section 241 of the PHS Act: *Provided*, That not less than $425,956,000 is provided for the Institutional Development Awards program.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, **[**$1,749,078,000**]***$1,747,784,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, **[**$896,549,000**]***$896,136,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, **[**$913,979,000**]***$938,807,000. (Department of Health and Human Services Appropriations Act, 2023.)*

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For necessary expenses for the National Institute of Environmental Health Sciences in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9660(a)) and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, $83,035,000. *(Department of the Interior, Environment, and Related Agencies Appropriations Act, 2023.)*

[NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES]

[For an additional amount for "National Institute of Environmental Health Sciences", $2,500,000, to remain available until expended, for necessary expenses in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9660(a)) and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986 related to the consequences of major disasters declared pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.) in 2022.**]** *(Disaster Relief Supplemental Appropriations Act, 2023.)*

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, **[**$4,407,623,000**]***$4,412,090,000*.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to arthritis and musculoskeletal and skin diseases, **[**$685,465,000**]***$687,639,000*.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

For carrying out section 301 and title IV of the PHS Act with respect to deafness and other communication disorders, **[**$534,333,000**]***$534,330,000*.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, **[**$197,693,000**]***$197,671,000*.

NATIONAL INSTITUTE ON ALCOHOL [ABUSE AND ALCOHOLISM] *EFFECTS AND ALCOHOL-ASSOCIATED DISORDERS*

For carrying out section 301 and title IV of the PHS Act with respect to alcohol **[**abuse and alcoholism, $595,318,000**]** *misuse, alcohol use disorder, and other alcohol-associated disorders, $596,616,000*.

NATIONAL INSTITUTE ON [DRUG ABUSE] *DRUGS AND ADDICTION*

For carrying out section 301 and title IV of the PHS Act with respect to **[**drug abuse, $1,662,695,000**]** *drugs and addiction, $1,663,365,000*.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, **[**$2,112,843,000**]***$2,455,653,000*.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, **[**$663,200,000**]***$660,510,000*.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, **[**$440,627,000**]***$440,625,000*.

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to complementary and integrative health, **[**$170,384,000**]***$170,277,000*.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

For carrying out section 301 and title IV of the PHS Act with respect to minority health and health disparities research, **[**$524,395,000**]***$525,138,000*.

JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart 2 of part E of title IV of the PHS Act), **[**$95,162,000**]***$95,130,000*.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, **[**$497,548,000**]***$495,314,000*: *Provided,* That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, **[**2024**]**

2025: *Provided further,* That in fiscal year **[**2023**]** *2024,* the National Library of Medicine may enter into personal services contracts for the provision of services in facilities owned, operated, or constructed under the jurisdiction of the National Institutes of Health (referred to in this title as "NIH").

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, $923,323,000: *Provided,* That up to $70,000,000 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network: *Provided further,* That at least $629,560,000 is provided to the Clinical and Translational Sciences Awards program.

OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, **[**$2,642,914,000**]***$2,890,779,000*: *Provided,* That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: *Provided further,* That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: *Provided further,* That $180,000,000 shall be for the Environmental Influences on Child Health Outcomes study: *Provided further,* That $722,401,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: *Provided further,* That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: *Provided further,* That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for

in section 2354(a)(5)(B) of the PHS Act: *Provided further,* That **[**$80,000,000**]** *up to $30,000,000* shall be used to carry out section 404I of the PHS Act (42 U.S.C. **[**283K), relating to biomedical and behavioral research facilities**]** *283k) with respect to the National Primate Research Centers and Caribbean Primate Research Center*: *Provided further,* That $5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further,* That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior **[**approval of**]** *notification to* the Committees on Appropriations of the House of Representatives and the Senate: *Provided further,* That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years **[**2023**]** *2024* and **[**2024**]** *2025* no later than 30 days after the date of enactment of this Act: *Provided further,* That amounts made available under this heading are also available to establish, operate, and support the Research Policy Board authorized by section 2034(f) of the 21st Century Cures Act**[**: *Provided further,* That the funds made available under this heading for the Office of Research on Women's Health shall also be available for making grants to serve and promote the interests of women in research, and the Director of such Office may, in making such grants, use the authorities available to NIH Institutes and Centers**]**.

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, $12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986 (26

U.S.C. 9008), for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act. *(Department of Health and Human Services Appropriations Act, 2023.)*

[OFFICE OF THE DIRECTOR]

[(INCLUDING TRANSFER OF FUNDS)]

[For an additional amount for "Office of the Director", $25,000,000, to remain available until September 30, 2024, for necessary expenses directly related to the consequences of Hurricanes Fiona and Ian: *Provided*, That funds appropriated under this heading in this Act may be made available to restore amounts, either directly or through reimbursement, for obligations incurred for such purposes, prior to the date of enactment of this Act: *Provided further*, That funds appropriated under this heading in this Act may be transferred to the accounts of Institutes and Centers of the National Institutes of Health (NIH): *Provided further*, That this transfer authority is in addition to any other transfer authority available to the NIH.**]** *(Disaster Relief Supplemental Appropriations Act, 2023.)*

BUILDINGS AND FACILITIES

For the study of, construction of, demolition of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, $350,000,000, to remain available through September 30, **[**2027**]** *2028*.

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

For carrying out section 301 and part J of title IV of the PHS Act with respect to advanced research projects for health, $2,500,000,000, to remain available through September 30, 2026.

NIH INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, **[**$1,085,000,000**]** *$407,000,000,* to remain available until expended: *Provided,* That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further,* That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: *Provided further,* That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. *(Department of Health and Human Services Appropriations Act, 2023.)*

GENERAL PROVISIONS

SEC. 216. Not to exceed **[**$100,000,000**]** *1 percent* of funds appropriated by this Act to the *offices,* institutes, and centers of the National Institutes of Health may be **[**used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed $5,000,000 per project**]** *transferred to and merged with funds appropriated under the heading "National Institutes of Health—Buildings and Facilities": Provided, That the use of such transferred funds shall be subject to a centralized prioritization and governance process: Provided further, That the Director of the National*

Institutes of Health shall notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days in advance of any such transfer: Provided further, That the transfer authority provided in this section is in addition to any other transfer authority provided by law.

SEC. 237. (a) The Public Health Service Act (42 U.S.C. 201 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), the Comprehensive Smoking Education Act (15 U.S.C. 1331 et seq.), the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1101 et seq.), the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10101 et seq.), and title 5 of the United States Code are each amended—

(1) by striking "National Institute on Drug Abuse" each place it appears and inserting "National Institute on Drugs and Addiction"; and

(2) by striking "National Advisory Council on Drug Abuse" each place it appears and inserting "National Advisory Council on Drugs and Addiction".

(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 464H(b)(5), by striking "National Institute of Drug Abuse" and inserting "National Institute on Drugs and Addiction";

(2) in sections 464L, 464M(a), 464O, and 494A, by striking "drug abuse" each place it appears and inserting "drug use";

(3) in section 464L(a), by striking "treatment of drug abusers" and inserting "treatment of drug addiction";

(4) in section 464M(a), by striking "prevention of such abuse" and inserting "prevention of such use";

(5) in section 464N—

(A) in the section heading, by striking "DRUG ABUSE RESEARCH CENTERS" and inserting "DRUGS AND ADDICTION RESEARCH CENTERS";

(B) in subsection (a)—

(i) in matter preceding paragraph (1), by striking "National Drug Abuse Research Centers" and inserting "National Drugs and Addiction Research Centers"; and

(ii) in paragraph (1)(C), by striking "treatment of drug abuse" and inserting "treatment of drug addiction"; and

(C) in subsection (c)—

(i) by striking "DRUG ABUSE AND ADDICTION RESEARCH" and inserting "DRUGS AND ADDICTION RESEARCH CENTERS";

(ii) in paragraph (1), by striking "National Drug Abuse Treatment Clinical Trials Network" and inserting "National Drug Addiction Treatment Clinical Trials Network"; and

(iii) in paragraph (2)(H), by striking "reasons that individuals abuse drugs, or refrain from abusing drugs" and inserting "reasons that individuals use drugs or refrain from using drugs"; and

(6) in section 464P—

(A) in subsection (a)—

(i) in paragraph (1), by striking "drug abuse treatments" and inserting "drug addiction treatments"; and

(ii) in paragraph (6), by striking "treatment of drug abuse" and inserting "treatment of drug addiction"; and

(B) in subsection (d)—

(i) by striking "disease of drug abuse" and inserting "disease of drug addiction";

(ii) by striking "abused drugs" each place it appears and inserting "addictive drugs"; and

(iii) by striking "drugs of abuse" and inserting "drugs of addiction".

(c) Section 464N of the Public Health Service Act (42 U.S.C. 285o–2), as amended by subsection (b)(5), is further amended by striking "drug abuse" each place it appears and inserting "drug use".

(d) Any reference in any law, regulation, map, document, paper, or other record of the United States to the National Institute on Drug Abuse shall be considered to be a reference to the National Institute on Drugs and Addiction.

SEC. 238. (a) The Public Health Service Act (42 U.S.C. 201 et seq.) and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4541 et seq.) are each amended—

(1) by striking "National Institute on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Institute on Alcohol Effects and Alcohol-Associated Disorders"; and

(2) by striking "National Advisory Council on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Advisory Council on Alcohol Effects and Alcohol-Associated Disorders".

(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 464H—

(A) in subsection (a)—

(i) by striking "prevention of alcohol abuse" and inserting "prevention of alcohol misuse"; and

(ii) by striking "treatment of alcoholism" and inserting "treatment of alcohol-associated disorders"; and

(B) in subsection (b)—

(i) in paragraph (3)—

(I) in subparagraph (A), by striking "alcohol abuse and domestic violence" and inserting "alcohol misuse and domestic violence";

(II) in subparagraph (D), by striking "abuse of alcohol" and inserting "misuse of alcohol";

(III) by striking subparagraph (E) and inserting "(E) the effect of social pressures, legal requirements regarding the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages on the incidence of alcohol misuse, alcohol use disorder, and other alcohol-associated disorders,"; and

(ii) in paragraph (5), by striking "impact of alcohol abuse" and inserting "impact of alcohol misuse";

(2) in sections 464H(b), 464I, and 494A, by striking "alcohol abuse and alcoholism" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";

(3) in sections 464H(b) and 464J(a), by striking "alcoholism and alcohol abuse" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders"; and

(4) in section 464J(a)—

(A) by striking "alcoholism and other alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";

(B) in the matter preceding paragraph (1), by striking "interdisciplinary research related to alcoholism" and inserting "interdisciplinary research related to alcohol-associated disorders"; and

(C) in paragraph (1)(E), by striking "alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders".

(c) Any reference in any law, regulation, map, document, paper, or other record of the United States to the National Institute on Alcohol Abuse and Alcoholism shall be considered to be a reference to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.

Language Provision to be Changed[61]	Explanation/Justification
NATIONAL CANCER INSTITUTE For carrying out section 301 and title IV of the PHS Act with respect to cancer, **[**$7,104,159,000**]** *$7,820,159,000*, of which *$716,000,000 shall remain available until expended, and of which* up to $30,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.	This proposed revision provides no-year authority for funding specifically set aside for Cancer Moonshot, consistent with the period of availability of Cancer Moonshot funding previously provided through the 21st Century Cures Act.
NATIONAL INSTITUTE ON ALCOHOL [ABUSE AND ALCOHOLISM] ***EFFECTS AND ALCOHOL-ASSOCIATED DISORDERS*** For carrying out section 301 and title IV of the PHS Act with respect to alcohol **[**abuse and alcoholism, $595,318,000**]** *misuse, alcohol use disorder, and other alcohol-associated disorders, $596,616,000*.	This revision reflects the proposal to change the name of the National Institute on Alcohol Abuse and Alcoholism to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.
NATIONAL INSTITUTE ON [DRUG ABUSE] ***DRUGS AND ADDICTION*** For carrying out section 301 and title IV of the PHS Act with respect to **[**drug abuse, $1,662,695,000**]** *drugs and addiction, $1,663,365,000*.	This revision reflects the proposal to change the name of the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.
OFFICE OF THE DIRECTOR That **[**$80,000,000**]** *up to $30,000,000* shall be used to carry out section 404I of the PHS Act (42 U.S.C. **[**283K), relating to biomedical and behavioral research facilities**]** *283k) with respect to the National Primate Research Centers and Caribbean Primate Research Center*	This proposed revision changes the Office of the Director's extramural grant proviso to provide up to $30,000,000 for the National Primate Research Centers and Caribbean Primate Research Center for necessary improvements to nonhuman primate infrastructure.

[61] Language changes are relative to the Consolidated Appropriations Act, 2023 (P.L. 117-328).

Language Provision to be Changed[61]	Explanation/Justification
OFFICE OF THE DIRECTOR That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior **[**approval of**]** *notification to* the Committees on Appropriations of the House of Representatives and the Senate	This proposed revision changes "approval of" to "notification to" for funds transferred for the Office of the Inspector General.
OFFICE OF THE DIRECTOR **[**: *Provided further,* That the funds made available under this heading for the Office of Research on Women's Health shall also be available for making grants to serve and promote the interests of women in research, and the Director of such Office may, in making such grants, use the authorities available to NIH Institutes and Centers**]**	This proposed revision removes the proviso for Office of Research on Women's Health grant-making authority. This proviso, first added in FY 2022 enacted appropriations, is unnecessary as the Office of the Director already has the authority to make grants.
ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH *For carrying out section 301 and part J of title IV of the PHS Act with respect to advanced research projects for health, $2,500,000,000, to remain available through September 30, 2026.*	This provision provides the appropriation for the Advanced Research Projects Agency for Health (ARPA-H) within the National Institutes of Health, consistent with the new ARPA-H authorization, in contrast to FY 2023 enacted appropriations where ARPA-H funding was provided within the HHS Office of the Secretary.
GENERAL PROVISIONS SEC. 216. Not to exceed **[**$100,000,000**]** *1 percent* of funds appropriated by this Act to the *offices,* institutes, and centers of the National Institutes of Health may be **[**used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed $5,000,000 per project**]** *transferred to and merged with funds appropriated under the heading "National Institutes of Health—Buildings and Facilities": Provided, That the use of such transferred funds shall be subject to a centralized prioritization and governance process: Provided further, That the Director of the National Institutes of Health shall notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days in advance of any such transfer: Provided further, That the transfer authority provided in this section is in*	This proposed revision to the existing Section 216 general provision would allow the transfer of IC appropriations to the Buildings and Facilities appropriation, subject to a 1 percent cap. This would allow IC contributions to facilities projects where the timing of the project obligations requires the funds to be available beyond the normal one-year period of availability of IC appropriations.

Language Provision to be Changed[61]	Explanation/Justification
addition to any other transfer authority provided by law.	
GENERAL PROVISIONS *SEC. 237. (a) The Public Health Service Act (42 U.S.C. 201 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), the Comprehensive Smoking Education Act (15 U.S.C. 1331 et seq.), the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1101 et seq.), the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10101 et seq.), and title 5 of the United States Code are each amended—* *(1) by striking "National Institute on Drug Abuse" each place it appears and inserting "National Institute on Drugs and Addiction"; and* *(2) by striking "National Advisory Council on Drug Abuse" each place it appears and inserting "National Advisory Council on Drugs and Addiction".* *(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—* *(1) in section 464H(b)(5), by striking "National Institute of Drug Abuse" and inserting "National Institute on Drugs and Addiction";* *(2) in sections 464L, 464M(a), 464O, and 494A, by striking "drug abuse" each place it appears and inserting "drug use";* *(3) in section 464L(a), by striking "treatment of drug abusers" and inserting "treatment of drug addiction";* *(4) in section 464M(a), by striking "prevention of such abuse" and inserting "prevention of such use";* *(5) in section 464N—* *(A) in the section heading, by striking "DRUG ABUSE RESEARCH CENTERS" and*	This new general provision would authorize the proposed name change for the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.

Language Provision to be Changed[61]	Explanation/Justification
inserting "DRUGS AND ADDICTION RESEARCH CENTERS"; *(B) in subsection (a)—* *(i) in matter preceding paragraph (1), by striking "National Drug Abuse Research Centers" and inserting "National Drugs and Addiction Research Centers"; and* *(ii) in paragraph (1)(C), by striking "treatment of drug abuse" and inserting "treatment of drug addiction"; and* *(C) in subsection (c)—* *(i) by striking "DRUG ABUSE AND ADDICTION RESEARCH" and inserting "DRUGS AND ADDICTION RESEARCH CENTERS";* *(ii) in paragraph (1), by striking "National Drug Abuse Treatment Clinical Trials Network" and inserting "National Drug Addiction Treatment Clinical Trials Network"; and* *(iii) in paragraph (2)(H), by striking "reasons that individuals abuse drugs, or refrain from abusing drugs" and inserting "reasons that individuals use drugs or refrain from using drugs"; and* *(6) in section 464P—* *(A) in subsection (a)—* *(i) in paragraph (1), by striking "drug abuse treatments" and inserting "drug addiction treatments"; and* *(ii) in paragraph (6), by striking "treatment of drug abuse" and inserting "treatment of drug addiction"; and* *(B) in subsection (d)—* *(i) by striking "disease of drug abuse" and inserting "disease of drug addiction";* *(ii) by striking "abused drugs" each place it appears and inserting "addictive drugs"; and* *(iii) by striking "drugs of abuse" and inserting "drugs of addiction".* *(c) Section 464N of the Public Health Service Act (42 U.S.C. 285o–2), as amended by subsection (b)(5), is further amended by striking "drug abuse" each place it appears and inserting "drug use".* *(d) Any reference in any law, regulation, map, document, paper, or other record of the*	

Language Provision to be Changed[61]	Explanation/Justification
United States to the National Institute on Drug Abuse shall be considered to be a reference to the National Institute on Drugs and Addiction.	
GENERAL PROVISIONS *SEC. 238. (a) The Public Health Service Act (42 U.S.C. 201 et seq.) and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation* *Act of 1970 (42 U.S.C. 4541 et seq.) are each amended—* *(1) by striking "National Institute on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Institute on Alcohol Effects and Alcohol-Associated Disorders"; and* *(2) by striking "National Advisory Council on Alcohol Abuse and Alcoholism" each place it appears and inserting "National Advisory Council on Alcohol Effects and Alcohol-Associated Disorders".* *(b) Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—* *(1) in section 464H—* *(A) in subsection (a)—* *(i) by striking "prevention of alcohol abuse" and inserting "prevention of alcohol misuse"; and* *(ii) by striking "treatment of alcoholism" and inserting "treatment of alcohol-associated disorders"; and* *(B) in subsection (b)—* *(i) in paragraph (3)—* *(I) in subparagraph (A), by striking "alcohol abuse and domestic violence" and inserting "alcohol misuse and domestic violence";* *(II) in subparagraph (D), by striking "abuse of alcohol" and inserting "misuse of alcohol";* *(III) by striking subparagraph (E) and inserting "(E) the effect of social pressures, legal requirements regarding the use of alcoholic beverages, the cost of such*	This new general provision would authorize the proposed name change for the National Institute on Alcohol Abuse and Alcoholism to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.

Language Provision to be Changed[61]	Explanation/Justification
beverages, and the economic status and education of users of such beverages on the incidence of alcohol misuse, alcohol use disorder, and other alcohol-associated disorders,"; and *(ii) in paragraph (5), by striking "impact of alcohol abuse" and inserting "impact of alcohol misuse";* *(2) in sections 464H(b), 464I, and 494A, by striking "alcohol abuse and alcoholism" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";* *(3) in sections 464H(b) and 464J(a), by striking "alcoholism and alcohol abuse" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders"; and* *(4) in section 464J(a)—* *(A) by striking "alcoholism and other alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders";* *(B) in the matter preceding paragraph (1), by striking "interdisciplinary research related to alcoholism" and inserting "interdisciplinary research related to alcohol-associated disorders"; and* *(C) in paragraph (1)(E), by striking "alcohol problems" each place it appears and inserting "alcohol misuse, alcohol use disorder, and other alcohol-associated disorders".* *(c) Any reference in any law, regulation, map, document, paper, or other record of the United States to the National Institute on Alcohol Abuse and Alcoholism shall be considered to be a reference to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.*	

BUDGET MECHANISM TABLE

(Dollars in Thousands)[1,2,3]	FY 2022 Final[9]		FY 2023 Enacted[9]		FY 2024 President's Budget[9]		FY 2024 +/- FY 2023 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	29,423	$17,056,649	30,768	$18,487,622	32,055	$19,393,431	1,287	$905,808
Administrative Supplements[3]	*(3,151)*	494,802	*(3,260)*	476,969	*(2,879)*	385,306	*(-381)*	-91,663
Competing	11,333	$6,668,939	10,961	$6,599,170	10,414	$6,047,419	-547	-$551,751
Subtotal, RPGs	40,756	$24,220,390	41,729	$25,563,761	42,469	$25,826,156	740	$262,395
SBIR/STTR	1,840	1,202,743	1,891	1,242,315	1,941	1,263,786	50	21,471
Research Project Grants	42,596	$25,423,133	43,620	$26,806,076	44,410	$27,089,942	790	$283,866
Research Centers:								
Specialized/Comprehensive	1,043	$2,114,324	1,107	$2,277,684	1,151	$2,374,503	44	$96,819
Clinical Research	73	441,087	58	338,841	36	258,134	-22	-80,707
Biotechnology	45	72,777	44	68,863	45	70,033	1	1,170
Comparative Medicine	47	144,037	46	140,771	45	135,706	-1	-5,065
Research Centers in Minority Institutions	22	74,230	25	83,204	25	83,204	0	0
Research Centers	1,230	$2,846,455	1,280	$2,909,362	1,302	$2,921,580	22	$12,218
Other Research:								
Research Careers	4,966	$930,003	5,142	$961,412	5,173	$976,015	31	$14,603
Cancer Education	75	20,668	76	21,508	74	21,078	-2	-430
Cooperative Clinical Research	261	473,265	297	504,493	346	644,352	49	139,859
Biomedical Research Support	158	104,783	149	103,257	149	93,549	0	-9,708
Minority Biomedical Research Support	228	77,191	158	57,578	88	35,948	-70	-21,630
Other	2,394	1,504,305	2,562	1,650,379	2,627	1,718,202	65	67,823
Other Research	8,082	$3,110,215	8,384	$3,298,628	8,457	$3,489,145	73	$190,517
Total Research Grants	51,908	$31,379,803	53,284	$33,014,066	54,169	$33,500,667	885	$486,601
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	4,107	$196,143	4,233	$206,087	4,226	$210,006	-7	$3,919
Institutional Awards	13,298	770,860	14,092	827,886	13,922	840,638	-170	12,753
Total Research Training	17,405	$967,003	18,325	$1,033,972	18,148	$1,050,644	-177	$16,672
Research & Develop. Contracts	2,736	$3,681,591	2,725	$3,828,668	2,752	$3,946,840	27	$118,172
(SBIR/STTR) (non-add)[3]	*(100)*	*(84,165)*	*(109)*	*(96,991)*	*(113)*	*(95,203)*	*(4)*	*(-1,788)*
Intramural Research		$4,828,314		$5,012,040		$5,056,584		$44,544
Res. Management & Support		2,160,226		2,304,890		2,491,369		186,479
Res. Management & Support (SBIR Admin) (non-add)[3]		*(9,188)*		*(11,133)*		*(13,051)*		*(1,919)*
Office of the Director - Appropriation[3,4]		*(2,772,998)*		*(3,066,208)*		*(3,133,379)*		*(67,171)*
Office of the Director - Other		1,798,512		2,021,814		2,088,985		67,171
ORIP (non-add)[3,4]		*(304,485)*		*(309,393)*		*(309,393)*		*(0)*
Common Fund (non-add)[3,4]		*(670,001)*		*(735,001)*		*(735,001)*		*(0)*
ARPA-H		1,000,000		1,500,000		2,500,000		1,000,000
Buildings and Facilities[5]		280,000		380,000		380,000		0
Appropriation[3]		*(250,000)*		*(350,000)*		*(350,000)*		*(0)*
Type 1 Diabetes[6,7]		-141,450		-141,450		-250,000		-108,550
Program Evaluation Financing[6]		-1,309,313		-1,412,482		-1,948,109		-535,627
Subtotal, Labor/HHS Budget Authority		**$44,644,687**		**$47,541,518**		**$48,816,980**		**$1,275,462**
Interior Appropriation for Superfund Research		82,540		83,035		83,035		0
Total, NIH Discretionary Budget Authority		**$44,727,227**		**$47,624,553**		**$48,900,015**		**$1,275,462**
Type 1 Diabetes[7]		141,450		141,450		250,000		108,550
Total, NIH Budget Authority		**$44,868,677**		**$47,766,003**		**$49,150,015**		**$1,384,012**
Program Evaluation Financing		1,309,313		1,412,482		1,948,109		535,627
Total, Program Level		**$46,177,990**		**$49,178,485**		**$51,098,124**		**$1,919,639**
Pandemic Preparedness Mandatory via PHSSEF (non-add)[8]		*(0)*		*(0)*		*(2,690,000)*		*(2,690,000)*

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

2 Includes 21st Century Cures Act funding and excludes supplemental financing.

3 All numbers in italics and brackets are non-add.

4 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as non-adds. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

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

6 Number of grants and dollars for mandatory Type 1 Diabetes (T1D) and NIGMS Program Evaluation financing are distributed by mechanism above; therefore, T1D and Program Evaluation financing amounts are deducted to provide subtotals for Labor/HHS Budget Authority.

7 Amounts in FY 2022 and FY 2023 reflect a reduction of $8.550 million for Budget Control Act sequestration.

8 The FY 2024 budget also provides $20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, NIH will receive $2,690 million.

9 Reduced by a transfer of $5.0 million from OD to the HHS Office of Inspector General.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2023 Amount Authorized	FY 2023 Amount Appropriated	FY 2024 Amount Authorized	FY 2024 President's Budget
National Institutes of Health Activity:				
1. Biomedical Research under Section 301 and Title IV of the PHS Act:				
General Authorization: Section 402A(a)(1) of the PHS Act[1]	TBD	46,361,400	TBD	47,850,489
General Authorization: Section 499A(s) of the PHS Act	TBD	1,500,000	500,000	2,500,000
Pediatric Research Initiative: Section 402A(a)(2) of the PHS Act[2]	12,600	12,600	TBD	12,600
2. Superfund Research Program: Section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and Section 126(g) of the Superfund Amendments and Reauthorization Act of 1986	Indefinite	83,035	Indefinite	83,035
3. 21st Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	419,000	419,000	235,000	235,000
BRAIN Initiative: Section 1001(b)(4)(B)	450,000	450,000	172,000	172,000
Cancer Moonshot: Section 1001(b)(4)(C)	216,000	216,000	0	0
4. Special Diabetes Programs: Section 330B(b) of the PHS Act[3]	150,000	141,450	TBD	250,000

[1]The authorization of appropriations expired as of September 30, 2020.

[2]The authorization of appropriations expires as of September 30, 2023.

[3]The amount for the Special Diabetes Programs in the FY 2023 Amount Appropriated column reflects the reduction due to sequestration.

APPROPRIATIONS HISTORY

FY 2024 Congressional Justification
National Institutes of Health
Appropriations History

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2015	$30,353,453,000		$30,084,304,000	$30,311,349,000 [2]
FY 2016	$31,311,349,000 [3]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [4]
FY 2017	$33,136,349,000 [5]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [6]
FY 2018	$26,919,710,000 [7]	$35,184,000,000	$36,084,000,000	$37,311,349,000 [8]
FY 2019	$34,766,707,000 [9]	$38,564,000,000	$39,312,349,000	$39,313,000,000 [10]
FY 2020	$34,367,629,000 [9]	$41,154,000,000	$42,084,000,000	$41,690,000,000 [11]
FY 2021	$39,133,215,000 [9]	$42,071,000,000	$43,536,500,000	$42,940,500,000 [12]
FY 2022	$51,957,703,000 [13]	$49,520,540,000	$48,007,431,000	$46,182,990,000 [14]
FY 2023	$62,507,703,000 [15]	$47,542,035,000	$48,042,035,000	$49,183,485,000 [16]
FY 2024 PB	$51,103,124,000 [17]			

[1] Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special Type 1 Diabetes Research mandatory funding included. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019, $492,000,000 in FY 2020, $404,000,000 in FY 2021, $496,000,000 in FY 2022, $1,085,000,000 FY 2023, and $407,000,000 in the FY 2024 Request.

[2] Includes Program Evaluation Financing of $715,000,000. Excludes Ebola-related funding.

[3] Includes Program Evaluation Financing of $847,489,000.

[4] Includes Program Evaluation Financing of $780,000,000. Excludes Ebola-related and Zika-related funding.

[5] Includes Program Evaluation Financing of $847,489,000.

[6] Includes Program Evaluation Financing of $824,443,000.

[7] Includes Program Evaluation Financing of $780,000,000.

[8] Includes Program Evaluation Financing of $922,871,000. Excludes supplemental hurricane funding of $50,000,000 to the Office of the Director for extramural construction.

[9] Includes Program Evaluation Financing of $741,000,000.

[10] Includes Program Evaluation Financing of $1,146,821,000. Does not reflect $5,000,000 transfer from NIH to the HHS Office of the Inspector General (OIG) or hurricane disaster supplemental of $1,000,000 for National Institute of Environment Health Sciences.

[11] Includes Program Evaluation Financing of $1,230,821,000. Does not reflect $5,000,000 transfer from NIH to HHS OIG. Also does not reflect three COVID-19 supplementals totaling $3,587,400,000: $836,000,000 in P.L. 116-123, $945,400,000 in P.L. 116-136, and $1,806,000,000 in P.L. 116-139 that was provided to NIH through directive transfer from the PHSSEF.

[12] Includes Program Evaluation Financing of $1,271,505,000. Does not reflect $5,000,000 transfer from NIH to HHS OIG. Also does not reflect COVID-19 supplemental of $1,250,000,000 in P.L. 116-260 for the Office of the Director.

[13] Includes Program Evaluation Financing of $1,271,505,000 and reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account. Does not reflect $5,000,000 transfer from NIH to HHS OIG.

[14] Includes Program Evaluation Financing of $1,309,313,000 and reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account. Also reflects $1,000,000,000 for the Advanced Research Projects Agency for Health provided to NIH through transfer from HHS Office of the Secretary (OS). Does not reflect $5,000,000 transfer from NIH to HHS OIG.

[15] Includes Program Evaluation Financing of $1,271,505,000 and reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account. Does not reflect $5,000,000 transfer from NIH to HHS OIG.

[16] Includes Program Evaluation Financing of $1,412,482,000 and reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account. Also reflects $1,500,000,000 for the Advanced Research Projects Agency for Health provided to NIH through transfer from HHS OS. Does not reflect $5,000,000 transfer from NIH to HHS OIG or supplemental hurricane funding totaling $27,500,000 in P.L. 117-328.

[17] Includes Program Evaluation Financing of $1,948,109,000. Does not reflect $5,000,000 transfer from NIH to HHS OIG.

APPROPRIATIONS NOT AUTHORIZED BY LAW

	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2023
NIH Labor/HHS Budget Authority[1]	FY 2020	$36,472,442,775	$40,954,400,000	$46,361,400,000

[1]Appropriations under general authorization of appropriations in Section 402A(a)(1) of the PHS Act. Excludes appropriations related to the Cures Act, the Gabriella Miller Pediatric Research Initiative, and the Advanced Research Projects Agency for Health.

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2022 Final[3]	FY 2023 Enacted[3]	FY 2024 President's Budget[3]	FY 2024 +/- FY 2023
Program Level[1,2]	$46,177,990	$49,178,485	$51,098,124	$1,919,639
Program Level, excluding ARPA-H[1,2]	$45,177,990	$47,678,485	$48,598,124	$919,639
FTE	18,689	20,366	20,943	577

[1] All columns exclude supplemental funds.

[2] Includes 21st Century Cures Act funding, Mandatory Type 1 Diabetes, and Superfund in all years; includes NIGMS Program Evaluation funding of (in thousands) $1,309,313 in FY 2022, $1,412,482 in FY 2023, and $1,948,109 in FY 2024 PB.

[3] Reduced by transfer to the HHS Office of Inspector General ($5.0 million).

Authorizing Legislation: For existing NIH program, Section 301 and Title IV of the Public Health Act, as amended.

Allocation Methods: Competitive Grants; Contract; Intramural; Other

NIH Contributions and Scientific Advances Towards Improving Human Health

NIH seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. To achieve these goals, NIH supports research on the causes, prevention, and treatments of human diseases and disorders; processes in healthy development and aging; and methods for collecting and disseminating data and health information. To achieve its mission, NIH invests over $47 billion annually in research programs designed to enhance health, lengthen life, and reduce illness and disability.

In 2022, NIH-funded scientists continue to make ground-breaking contributions across the full arc of biomedical science from basic and translational research to clinical research studies. As the coronavirus disease 2019 (COVID-19) pandemic has evolved, NIH has begun adopting new approaches, learned during the pandemic, to enhance mission-critical scientific research and funding. These lessons learned are advancing research in other areas and contributing to preparations for future public health emergencies. Examples of these critical efforts and scientific research areas are described below.

Looking beyond the COVID-19 Pandemic

The demands of the COVID-19 pandemic spurred an unprecedented level of innovation and creativity in the biomedical research enterprise. In response, NIH was able to support the record-breaking development of safe and effective diagnostic tests and vaccines for COVID-19 by leveraging critical partnerships and developing inventive research paradigms.

NIH research efforts have adapted throughout the pandemic to address emerging needs such as ongoing questions on the biological impact of new viral variants, the long-term effects of the pandemic and COVID-19 cases, and preparations for future public health crises and infectious pandemics. The Researching COVID to Enhance Recovery (RECOVER) Initiative was launched to study how affected individuals recover from COVID-19 infection and why some develop Long COVID, also known as post-acute sequalae of SARS-CoV-2 (PASC).[62] RECOVER is led by a consortium and series of committees including closely engaged representative subject matter experts from NIH Institutes, Centers, and Offices (ICOs), patients, caregivers, community leaders, and outside scientific and medical experts. The Initiative supports research designed to identify effective treatments for and potential ways to prevent Long COVID. This year a study supported by the RECOVER Initiative applied machine learning to electronic health records of individuals with Long COVID to reliably predict whether a person with COVID-19 is likely to develop Long COVID.[63] This advance will allow researchers to rigorously investigate critical questions about individual risk factors for Long COVID and enable other RECOVER Initiative studies to identify people with or at risk of Long COVID for participation.

The potential of new emerging infectious diseases will continue to threaten public health in the United States and globally. NIH, led by the National Institute of Allergy and Infectious Diseases (NIAID), has coordinated research on effective countermeasures to potential pandemic pathogens for over two decades. To leverage this experience and expertise, NIH is pursuing

[62] recovercovid.org/

[63] directorsblog.nih.gov/2022/06/07/using-artificial-intelligence-to-advance-understanding-of-long-covid-syndrome/

pandemic preparedness on multiple levels. First, the NIAID Pandemic Preparedness Plan aims to characterize and increase research on pathogens of concern, shorten gaps between the emergence of a pathogen and the implementation of diagnostics, therapeutics, and vaccines, and eliminate gaps in infrastructure and technology to expand pre-clinical and clinical testing.[64] The Pandemic Response Repository through Microbial and Immune Surveillance and Epidemiology (PREMISE) Program will pair virologic and immunologic surveillance to facilitate development of diagnostics and medical countermeasures (MCMs). Preparedness efforts will include continued development of research infrastructure such as pre-clinical testing facilities and clinical trial networks. Finally, NIH will align roles, integrate internal and external preparedness efforts, and enhance or create new communication channels to ensure rapid mobilization of resources.

As the pandemic has evolved, public health needs have changed, and NIH is now able to review its response and begin to implement the new practices to innovate biomedical research administration. The partnerships leveraged during the pandemic, both within and outside of NIH, demonstrated the unique ability of interdisciplinary groups to coordinate large scale efforts. Streamlined administrative processes and policies allowed NIH and funded researchers to respond flexibly to changing needs. To fulfill its mission, NIH will identify lessons learned and implement best practices from the pandemic to support research programs that aim to understand the foundational biology of new organisms and emerging diseases, the role of behavioral and social factors, and their potential impact on human health. Building on these and other advances made during the COVID-19 crisis, NIH will continue to act swiftly to turn discoveries into health.

Addressing Health Disparities and Inequities in Biomedical Research

Health disparities, preventable differences in health status and outcomes that adversely impact certain populations, are a key focus of NIH's mission to improve health in the United States. NIH is dedicated to improving minority health, reducing health disparities, and removing barriers to health disparities research. Only by researching the influence of environment, social determinants, and other underlying mechanisms which lead to differential health outcomes can differences in health be prevented. Efforts across NIH are underway to study mechanisms to reducing disparities in all areas of health.

At NIH, the National Institute on Minority Health and Health Disparities (NIMHD) is the leading institute on research to improve minority health and reduce health disparities through collaborating across NIH and the federal government to advance promising studies. NIMHD supports all aspects of this research including genetic, molecular, and biologic science to clinical, behavioral, and translational research, as well as research on health systems, workforce development, and environmental justice. In 2023, NIMHD will launch the HDPulse Interventions Portal, an expansion of the HDPulse online resource for data to enhance minority health, to share proven interventions to reduce health disparities to inform community interventions.[65]

Many other NIH Institutes and Centers (ICs) lead efforts to advance health disparities research and address inequities within their scientific and medical areas of interest. For example, the National Institute of Nursing Research (NINR) dedicates one third of its budget to research on

[64] www.niaid.nih.gov/research/pandemic-preparedness
[65] www.nimhd.nih.gov/docs/hdPulse_factsheet.pdf

eliminating health disparities.[66] The National Heart, Lung, and Blood Institute (NHLBI) actively supports the Multi-Ethnic Study of Atherosclerosis (MESA), the Strong Heart Study in American Indian men and woman, and the Hispanic Community Health Study of health and disease in Hispanics and Latinos in the U.S. among many other research programs focused on health inequities.[67]

Diversity in the workforce is a key component of innovation and achievement in all areas of research, including health disparities research. To that end the NIH UNITE Initiative was launched in early 2021 as an NIH-wide effort committed to ending racial inequities across the biomedical research enterprise. It is composed of five committees, each with a specific, targeted focus: (U)nderstanding stakeholder experiences through listening and learning; (N)ew research on health disparities/minority health/health inequity; (I)mproving the NIH culture and structure for equity, inclusion, and excellence; (T)ransparency, communication, and accountability with NIH's internal and external stakeholders; and (E)xtramural research ecosystem and changing policy, culture, and structure to promote workforce diversity. To support research on health inequities, the UNITE Initiative will review NIH's research portfolio to identify and make recommendations for addressing research gaps, review systems for measuring and tracking health disparity research, and support research on behavioral, biological, and social determinants of health, structural racism, and discrimination.

NIH will continue to increase coordinated support for research on health disparities and approaches to reducing them and enhance opportunities for scientists and trainees from diverse backgrounds and life experiences. By supporting these goals, NIH will foster scientific innovation, improve the quality of research, and advance opportunities for health disparity populations to participate in and benefit from biomedical research.

Major collaborations across the agency support critical research areas

To achieve their research goals, NIH ICOs often leverage existing strengths and resources by collaborating in innovative and creative ways to develop multidisciplinary approaches to answer complex and crucial questions about human health and preventing disease. NIH-wide collaborative efforts have led to the development of special initiatives and innovative research programs across the agency.

The ultimate examples of NIH-wide collaboration came with the emergence of the COVID-19 pandemic. NIH quickly responded to this public health challenge by establishing new multi-ICO programs, including the Accelerating COVID-19 Therapeutics Interventions and Vaccines (ACTIV) partnership and the Rapid Acceleration of Diagnostics (RADx^{SM}) initiative. As the pandemic continues to evolve, the Community Engagement Alliance (CEAL) Against COVID-19 Disparities and RECOVER: Researching COVID to Enhance Recovery initiatives leverage expertise from across the agency to engage communities hit hardest by the pandemic and advance research on Long COVID. Other NIH-wide collaborations support research in a variety of areas critical for science and health. The INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Project for Down syndrome research, the approximately 30 Common Fund initiatives, and the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative are examples of creative collaborations designed to bring together diverse expertise and advance critical, interdisciplinary research.

[66] www.ninr.nih.gov/researchandfunding/desp
[67] www.nhlbi.nih.gov/science/health-disparities-and-inequities

Partnerships with other federal entities, non-profit and private organizations, and academic institutions strengthen NIH's ability to meet unique research and scientific challenges. The Accelerating Medicines Partnership® (AMP®) program partnership with the Foundation for the NIH (FNIH) and the U.S. Food and Drug Administration (FDA) increases efficiencies and improves the process of identifying potential therapeutic targets. The Advisory Committee to the Director (ACD), which consists of external members from a range of backgrounds and organizations, guides program development, resource allocation, and NIH policy, and identifies promising research areas where NIH can make valuable contributions. NIH now has a unique opportunity to collaborate with the newly established Advanced Research Projects Agency for Health (ARPA-H). ARPA-H will support transformative research to drive biomedical breakthroughs from the molecular to societal.

NIH will continue to facilitate partnerships across ICOs, federal agencies, and other organizations to leverage infrastructure and scientific strengths to effectively advance biomedical research and public health. By answering the call of urgent public health needs, closing gaps in health disparities, and capitalizing on foundational research investments, NIH will continue turning discovery into health.

Modernizing Data Sharing in Biomedical Research

NIH's new Data Sharing and Management (DMS) Policy went into effect in January 2023 to ensure proper stewardship of research funding and maintain the quality and availability of scientific information.[68] By releasing this DMS Policy, NIH aims to lead a cultural shift across the biomedical research enterprise. Establishing standard practices for data management and sharing as an integral part of research supported by NIH will accelerate discovery, enhance rigor and reproducibility, provide broad access to important data sets, and promote data reuse for future studies. The DMS Policy applies to all NIH-supported research regardless of funding level and requires submission of a Data Management and Sharing Plan to NIH, as well as compliance with that plan. Promoting greater data sharing will ultimately help to advance needed validation and replication of research findings, provide opportunities for new research and collaborations, and promote trust in NIH-supported research by increasing transparency.

The Office of Science Policy (OSP) leads NIH's ongoing implementation efforts, which aim to catalyze these critical opportunities across biomedical and public health research while supporting a smooth transition for funded investigators. Building off successful engagement efforts in 2021 such as a workshop on strategies for successful data management and sharing,[69] NIH continued to gather feedback from the research community and share resources in advance of the DMS Policy's implementation. In 2022, NIH published a list of Frequently Asked Questions to clarify the requirements of the DMS Policy, how it interacts with previous data sharing expectations, and unique considerations for data derived from studies with human participants.[70] NIH also released a request for public comment to gather feedback on drafted Supplemental Information to the DMS Policy that promotes responsible management and sharing of data collected from American Indian/Alaska Native study participants.[71] This year,

[68] sharing.nih.gov/data-management-and-sharing-policy
[69] www.nationalacademies.org/event/04-29-2021/changing-the-culture-of-data-management-and-sharing-a-workshop
[70] sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm
[71] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-064.html

NIH is also investing in efforts to improve the readiness of NIH-supported data and existing repositories to align with FAIR (Findable, Accessible, Interoperable, and Reusable) Principles and will release additional resources on budgeting for data sharing, protecting participant privacy, and harmonizing the DMS Policy with existing expectations. As NIH implements the DMS Policy, the agency will continue to engage with researchers, participants, and others to provide clear guidance and resources to all stakeholders.

Advancing the Field of Community Violence Research

In addition to the many diseases and disorders studied by NIH, the agency supports a broad range of behavioral and community health research including studies on violence prevention. Violence presents a significant public health challenge which impacts both physical health and well-being and increases the risk of other health concerns. It is a leading cause of death and non-fatal injuries in the United States especially among young people and racial/ethnic minority, sexual and gender minority (SGM) and disability populations. As a research agency, NIH is committed to increasing the understanding of effective violence prevention interventions. In 2019, the NIH-wide Violence Research Working Group convened representative experts from ICOs across NIH to examine NIH's violence research portfolio and identify gaps and opportunities in research priorities. The Working Group, led by the Office of Behavioral and Social Sciences Research (OBSSR), serves as a coordinating body and a resource for the ICOs supporting violence prevention research. Most recently, the OBSSR collaborated with ICOs to support research on the role of violence in health outcomes and effective mechanisms for violence-related screenings in healthcare settings.[72]

Currently, little is known about the best implementation strategies to optimize the effectiveness, adoption, and scale-up of existing evidence-based violence prevention strategies. In 2022, NIH launched two new solicitations for research on firearms mortality and injury prevention. The first of these funding opportunities will support two-part studies on potential community level interventions for preventing firearm related violence.[73] Research projects will be integrated into the Community-Level Interventions for Firearm Violence Prevention (CLIF-VP) Research Network, whose members will collaborate with NIH and each other to advance cross-project activities. The second funding opportunity aims to identify a Coordinating Center for the CLIF-VP Research Network to ensure effective management and coordination of the Network, support data harmonization and sharing in an approved repository, engage stakeholders in research, and communicate research advances to the public.[74] Once established, this Research Network will result in a greater understanding of successful community-based violence prevention and intervention strategies that aim to modify characteristics of the environment to lower risk. This knowledge will allow communities to target resources toward eliminating high-level factors increasing violence risk, focus on individuals who will benefit most, and prevent later negative health outcomes.

Scientific breakthroughs ushered by NIH

The NIH ICOs support basic, translational, and clinical research in specific areas of health, the human body, and disease to fulfill the NIH mission of enhancing public health and advancing scientific breakthroughs. The unique approaches to research taken by each ICO have led to

[72] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-167.html
[73] grants.nih.gov/grants/guide/pa-files/PAR-22-115.html
[74] grants.nih.gov/grants/guide/pa-files/PAR-22-120.html

critical scientific discoveries. Select highlights from the many accomplishments supported by the ICOs this past year are provided below:

- A clinical trial, which was sponsored by NIAID and conducted at the NIH Clinical Center, recently showed that a single injection of a monoclonal antibody known as L9LS was highly effective at protecting adults exposed to malaria.[75] If the treatment advances through later phase clinical trials, it has the potential to significantly reduce morbidity and mortality in children, healthcare workers, and others in malaria-endemic regions.

- In 2022, scientists at the National Institute on Alcohol Effects and Alcohol-Associated Disorders (NIAAA) released a new definition of recovery from alcohol use disorder (AUD) that establishes the groundwork for future recovery-related research. With input from key researchers, clinicians, and recovery specialists, the new definition recognizes recovery as an ongoing process and will enable more precise measures of recovery and effective collaborations across research studies.[76]

- To enhance research on chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy, two rare but devastating neuromuscular diseases, researchers supported by the National Center for Advancing Translational Sciences (NCATS) created 3-D tissue chips to model the biology of each disease. The chips have provided preclinical data for authorization of clinical trials and have opened new avenues to develop innovative therapies for other rare diseases.[77]

- Researchers at the National Human Genome Research Institute (NHGRI) collaborated with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the European Bioinformatics Institute to identify more species of microorganisms residing on human skin than ever before.[78] This catalog, which was made possible by advances in bioinformatics and laboratory equipment, will significantly enhance research on skin diseases and disorders.

These and other discoveries by NIH-funded investigators deliver new treatments, cures, and innovative prevention mechanisms to communities and patients across the world. In FY 2024, NIH will continue to make bold investments in novel ideas and enable the scientific workforce with cutting-edge resources and opportunities.

Maternal health and growth of the IMPROVE Initiative

U.S. rates of maternal deaths (approximately 700 each year) and complications are higher than in any other developed country and continue to rise, with the highest rates of maternal deaths occurring in non-Hispanic Black and American Indian or Alaska Native populations. In FY 2022, NIH received a $30.0 million increase in funding for the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative. IMPROVE seeks to build an evidence-based approach to reducing severe maternal morbidity (SMM) and maternal

[75] www.nih.gov/news-events/news-releases/monoclonal-antibody-prevents-malaria-us-adults-nih-trial-shows
[76] www.niaaa.nih.gov/news-events/research-update/niaaa-scientists-unveil-new-definition-recovery-aud
[77] ncats.nih.gov/news/releases/2022/researchers-create-3-D-model-for-rare-neuromuscular-disorders-setting-stage-for-clinical-trial
[78] www.genome.gov/news/news-release/NIH-researchers-find-thousands-of-new-microorganisms-living-on-human-skin

mortality (MM) and associated health disparities, including geographical, racial, and ethnic disparities. Led by the NIH Maternal Mortality Task Force, IMPROVE in FY 2022 released three funding opportunities that will develop components of a national network of Maternal Health Research Centers of Excellence. The network will support research projects that incorporate local community needs and perspectives to develop, implement, and evaluate community-tailored interventions to address health disparities in SMM and MM, as well as investigate biological, behavioral, sociocultural, and structural risk factors of the leading causes of SMM and MM.

FY 2022 maternal health research lent insight into causes of death or increasing morbidity during pregnancy and postpartum. One NIH-funded study found that more than 20 percent of deaths during pregnancy and the first year after childbirth are due to drug use, suicide, or homicide, with the number of deaths from these causes increasing between 2010 and 2019.[79] The prevalence of pregnancy-associated deaths because of drug use increased 190 percent during this time period. Another study revealed that women who experienced complications related to developing high blood pressure, or hypertension, during pregnancy had a 63 percent increased risk for developing cardiovascular disease later in life.[80] Early screening and monitoring in four targeted areas—blood pressure, cholesterol and glucose levels, and body mass index—could provide personalized targets to help delay or possibly prevent future cardiovascular events. Recognizing social, structural, or genetic risk factors that could contribute to an increased risk for SMM or MM has the potential to provide opportunities for earlier interventions to decrease or prevent related adverse events or death.

To align and support these and other collaborative maternal health initiatives, NIH remains actively engaged in coordinated efforts across the federal government, including the HHS Task Force on Research Specific to Pregnant Women and Lactating Women,[81] the White House Blueprint for Addressing the Maternal Health Crisis[82] and Maternal Health Interagency Policy Committee, and the establishment of HHS agency priority goals for maternal health.

Innovations in mental health research and treatment

Scientific and clinical advances are rapidly advancing mental health care in the United States. Progress in basic science has led to new tools and resources which enable investigators to gain significant insight into the complex interactions between the brain, environment, and disease. Intervention research continues to enhance the understanding and effectiveness of evidence-based care in a broad range of settings. The National Institute of Mental Health (NIMH) supports innovative research to transform the understanding and treatment of mental illness to pave the way for prevention, recovery, and cure. In 2022, NIMH-funded investigators discovered common biological mechanisms between autism spectrum disorder and congenital heart disease,[83] clarified risk factors and potential prevention strategies for child suicide,[84] and tested the effectiveness of existing care programs including the Veterans Health Administration

[79] journals.lww.com/greenjournal/Fulltext/2022/02000/Pregnancy_Associated_Deaths_Due_to_Drugs,_Suicide,.5.aspx

[80] jacc.org/doi/10.1016/j.jacc.2022.03.335

[81] nichd.nih.gov/about/advisory/PRGLAC

[82] whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf

[83] www.nimh.nih.gov/news/research-highlights/2022/autism-and-congenital-heart-disease-share-underlying-molecular-network

[84] www.nimh.nih.gov/news/research-highlights/2021/understanding-the-characteristics-of-suicide-in-young-children

Recovery Engagement and Coordination for Health–Veterans Enhanced Treatment (REACH VET) program.[85] These and other innovations continue to improve mental health care for those in greatest need.

NIMH has adapted to new challenges such as the COVID-19 pandemic and growing socioeconomic disparities which have increased the need for mental health care by increasing overall stress, worsening symptoms of existing mental illness, and preventing effective administration of care. NIMH has released two urgent funding opportunities to address questions related to the intersection of mental health, COVID-19, and HIV[86] and to secondary impacts of the pandemic.[87] This research will meet the changing needs of the populations as the pandemic evolves and will lay groundwork for responding to future emergencies.

Looking into the future, NIMH will continue to partner with other ICOs and federal agencies, through initiatives like UNITE, the Accelerating Medicines Partnership® Program - Schizophrenia (AMP® SCZ), and the Hub to Reduce the Burden of Suicide among Urban American Indian and Alaska Native Youth. By contributing to and leading these efforts the NIMH advances interdisciplinary approaches to addressing disease with mental health components. Research priorities for FY 2023 and beyond include expansions to collaborative implementation science, improvements to mental health care to underserved populations, and exploration innovations to mental health services. Each of these efforts has the potential to deliver incredible advances to mental health science and care.

Reignite the Cancer Moonshot

With the passage of the 21st Century Cures Act in 2016, the Beau Biden Cancer Moonshot was launched with the goal to accelerate scientific discovery in cancer research, foster collaborations, and improve data sharing. The initiative made tremendous progress in its initial years, funding over $1 billion in research and over 240 studies across more than 70 scientific initiatives to date. In its first iteration, the Cancer Moonshot has focused on four main themes: collaborative research; open access publications; robust data sharing; and elimination of cancer health disparities. Many Moonshot programs, such as Partnerships for Accelerating Therapies, have been established as networks to leverage partner strengths and increase engagement with study participants. To increase transparency and data access, studies supported by the Moonshot programs are made immediately publicly available, resulting in more than 1,000 scientific papers published. Data sharing through the Cancer Moonshot has been enabled by enhanced support for infrastructure, such as the National Cancer Institute (NCI) Cancer Research Data Commons (CRDC), which leverages cloud computing to connect data with available analytical tools, and the Center for Cancer Data Harmonization, which is developing a standard model for harmonizing data across repositories. Finally, reducing cancer disparities is a key focus of all Moonshot programs. For example, many research consortia are creating better pre-clinical models and protocols for diverse patient populations.

The many research initiatives across the Cancer Moonshot have already made significant progress toward their goals. Current research priorities for FY 2023 include expanding immunotherapy by discovering novel immune targets and cell-based therapies for cancer

[85] www.nimh.nih.gov/news/research-highlights/2022/study-shows-reach-vet-program-effective-for-veterans-at-high-risk-for-suicide
[86] grants.nih.gov/grants/guide/pa-files/PAR-22-112.html
[87] grants.nih.gov/grants/guide/pa-files/PAR-22-113.html

treatments through research networks. Through the Cancer Moonshot, NIH will address the unique challenges of pediatric cancers by supporting research on fusion oncoproteins, which drive childhood cancers. Delivering targeted early detection and prevention strategies will reduce cancer risk and health disparities. NIH, in collaboration with other federal agencies, will develop a program to examine multicancer detection tests that are capable of detecting cancers early when the most effective treatment options are available to patients. Finally, in FY 2023, NIH will pursue implementation of proven strategies for detecting and treating cancer in underserved, rural, and minority populations, such as the application of artificial intelligence for detection in areas where access to care is limited.

In early 2022, the Biden-Harris Administration reignited the Cancer Moonshot with the new goals of reducing the death rate from cancer by 50 percent over 25 years and of improving the lives of individuals living with and surviving cancer. By shifting the focus to the experience of having and being treated for cancer, Cancer Moonshot will extend ongoing efforts to speed scientific discoveries and treatments. In the coming years, NIH will leverage the large community of investigators and other collaborators engaged in Cancer Moonshot programs to identify and pursue new methods to prevent and treat cancer and halve the cancer death rate.

Transforming nutrition science

Nutrition plays a fundamental role in human health. If carefully managed, proper nutrition can attenuate disease symptoms and progression, and reduce overall disease risk. Research into how the body reacts to and absorbs nutrients, how nutrient levels are regulated throughout the body, and how high or low levels of nutrients affect health enhance our understanding of the overall impact of diet on health and may lead to improved clinical recommendations and expectations for a healthy lifestyle. Guided by the goals and objectives of the *Strategic Plan for NIH Nutrition Research*,[88] the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Office of Nutrition Research (ONR) lead the coordination and management of nutrition research programs at NIH.

One such program, Nutrition for Precision Health, is a collaborative effort by NIDDK, the NIH Common Fund, and the NIH *All of Us* Research Program, that leverages the vast *All of Us* data resources to develop predictive tools for determining how an individual's response to food might affect their health.[89] In 2022, NIH announced investment in 14 new scientific awards to build a consortium including clinical centers, a dietary assessment center, a metabolomics and clinical assays center, a microbiome and metagenomics center, a multimodal data modeling and bioinformatics center, and a research coordinating center. These many components of the consortium will work together to answer questions important to both *All of Us* participants and the general public. Nutrition is not one-size-fits-all. By understanding how our nutrition interacts with other individual health factors like genetics, gut microbiome, and social environments, the program will further precision nutrition and enable researchers to improve health and prevent disease.

Protecting health amid a changing climate

The changing climate is now a critical public health concern. Climate change negatively impacts health and well-being by worsening chronic diseases, increasing the likelihood of exposures to infectious diseases, impairing air and water quality, and risking access to medical care and

[88] dpcpsi.nih.gov/onr/strategic-plan
[89] commonfund.nih.gov/nutritionforprecisionhealth

resources. Extreme weather events such as floods and heat waves become more frequent and intense, leaving whole communities at risk. The impact of climate change differs across populations depending on socioeconomic status, life stage, and other adaptive capabilities. NIH aims to expand investments in scientific research and policy to identify and mitigate the range of health outcomes triggered or exacerbated by climate change.

As the leader in studying the impact of the environment on human health, the National Institute of Environmental Health Sciences (NIEHS) will lead collaborative efforts to fund research on climate change and human health and adaption. Most recently, the NIH Climate Change and Health Initiative, a collaboration of eight ICs, released the Climate Change and Health Initiative Strategic Framework, which outlines how NIH will invest in research in the short and long term to address the challenges of global climate change.[90] The Framework, published in 2022, explains how NIH will strengthen research by expanding capabilities in scientific workforce development, prioritizing equity, and building partnerships with other organizations working in this space. Priorities identified in the Framework include developing the research infrastructure and workforce, creating new partnerships to achieve greater impact, enhancing research translation to ensure findings are actionable, and identifying risks and benefits to mitigating or adapting to climate change.

To enable research partnerships and engage with the public, NIEHS will dedicate support to a Research Coordinating Center and the Alliance for Community Engagement (ACE-CH), in FY 2023. The Research Coordinating Center will develop a climate change and health community of practice to foster interdisciplinary, inclusive collaborations and provide data and project management services to networked research efforts.[91] Simultaneously, the ACE-CH will maximize engagement and participatory research to achieve climate justice and health equity.[92] The ACE-CH will empower two-way conversations between researchers and participating underserved communities to understand and reduce health disparities. The future of climate research will depend on strong collaborations and a shared commitment between researchers and communities to build new technologies, interventions, and knowledge to manage the impact of climate change.

Advancing research on pain and opioid addiction

The crisis of opioid misuse, addiction, and overdose in the United States is growing, exacerbated by the COVID-19 pandemic, with more drug overdose deaths today than at any point in modern history. The NIH Helping to End Addiction Long-term (HEAL) Initiative aims to identify and develop new therapeutic targets for pain and opioid use disorder, reduce the risk of opioids through nonpharmacological strategies for pain management, and improve opioid addiction treatment. By the end of FY 2021, HEAL had funded over $2 billion in research, representing more than 600 research projects across the United States. HEAL was launched as an NIH-wide program in 2018 to build on the existing research efforts across multiple ICs to address the historic rise in opioid misuse and addiction and better understand pain in the United States by advancing multidisciplinary research across basic, translational, clinical, and implementation science. HEAL research efforts align with the HHS Overdose Prevention Strategy to address the needs of people who live with pain and use drugs. Research supported by HEAL builds on past achievements in basic science of medication development for pain and substance use disorders,

[90] www.nih.gov/sites/default/files/research-training/initiatives/climate-change/nih-climate-change-framework.pdf
[91] grants.nih.gov/grants/guide/rfa-files/RFA-ES-22-003.html
[92] www.nhlbi.nih.gov/sites/default/files/media/docs/ACE_CH_ROA_6_08_2022_FINAL.pdf

pharmacological approaches to pain management, integration of mental health into primary care, and testing of multimodal and multidisciplinary systems of care for pain and addiction. A critical goal of this research is to advance health equity and acknowledge the role of the environment in drug use, chronic pain, and related health outcomes.

Today, HEAL is addressing the many crosscutting issues exposed by the COVID-19 pandemic by prioritizing new research on diversity, equity, and inclusion in research and healthcare and enhancing access to novel telehealth practices for those with co-occurring disparities or limited health and technical literacy. In February 2023, HEAL hosted its fourth annual Investigator Meeting, convening more than 400 researchers, federal officials, and people with lived experiences of opioid use to share recent research findings and identify opportunities to advance HEAL goals.[93] HEAL is also supporting community-engaged research and increasing dissemination of findings to reach researchers, participants, and communities in meaningful ways. In May 2022, HEAL solicited applications for a Research Dissemination and Engagement Center expected to be supported by the end of 2022.[94]

Looking ahead to FY 2024 and beyond, HEAL will support new research on novel approaches to preventing drug use, treating pain and addiction, and reversing overdose. Top priorities for HEAL include advancements to our understanding of polysubstance use, such as the health effects of taking multiple drugs at the same time. HEAL-supported research will work to find tailored treatment approaches for a variety of environments, including primary care settings, and work with health systems to design and test personalized treatments. These personalized treatments could include combination therapies like medication, counseling, and integrative treatments, in addition to support for providers to recognize and treat polysubstance use and complications of drug use. Other research priorities for HEAL include health disparities in treatment for opioid use disorder, neonatal opioid exposure and maternal health, and integrated pain and mental health treatments. HEAL will continue to assess progress made by its older programs and consider how support for research infrastructure and ongoing studies could be leveraged to move in these and other emerging research directions.

[93] heal.nih.gov/news/events/fourth-heal-investigator-meeting
[94] heal.nih.gov/files/2022-05/dissemination-engagement-center-roa.pdf

FUNDING HISTORY (FIVE YEAR FUNDING TABLE)

Fiscal Year	Amount[1, 2]
2020	$41,690,000,000
2021	$42,940,500,000
2022[3,4]	$46,182,990,000
2023[3,5]	$49,183,485,000
2024 Budget Request	$51,103,124,000

[1] Appropriated amounts include discretionary budget authority received from both Labor/HHS appropriations that fund ICs as well as the Interior, Environment & Related Agencies appropriation that supports NIH Superfund Research activities. Also includes mandatory budget authority derived from the Special Type 1 Diabetes account. Includes NIGMS Program Evaluation financing of $1,146,821,000 in FY 2019, $1,230,821,000 in FY 2020, $1,271,505,000 in FY 2021, $1,309,313,000 in FY 2022, $1,412,482,000 in FY 2023, and $1,948,109,000 in the FY 2024 request. Includes CURES amounts of $492,000,000 in FY 2020, $404,000,000 in FY 2021, $496,000,000 in FY 2022, $1,085,000,000 in FY 2023, and $407,000,000 in the FY 2024 request.

[2] Excludes supplemental appropriations and permissive and directive transfers unless otherwise noted.

[3] Reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account.

[4] Reflects $1,000,000,000 for the Advanced Research Projects Agency for Health provided to NIH through transfer from HHS Office of the Secretary (OS).

[5] Reflects $1,500,000,000 for the Advanced Research Projects Agency for Health provided to NIH through transfer from HHS OS.

SUMMARY OF REQUEST NARRATIVE

The FY 2024 President's Budget (PB) request provides a program level of $51.1 billion for NIH, including the Advanced Research Projects Agency for Health (ARPA-H), which is $1.9 billion more than the FY 2023 Enacted level of $49.2 billion. The FY 2024 program level excluding ARPA-H is $48.6 billion, which is an increase of $0.9 billion, or 1.9 percent, over the FY 2023 Enacted level.

The following summary references program level funding, which is the sum of discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriations ($48.8 billion in FY 2024); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research Program ($83.0 million in FY 2024); mandatory budget authority provided for Type 1 Diabetes research ($250.0 million in FY 2024)[95]; and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act ($1,948.1 million in FY 2024).

The FY 2024 Budget provides $20.0 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund (PHSSEF) Congressional Justification. Of this total, $2.7 billion is allocated to NIH. This allocation is not included in the program level total above.

The primary budget mechanisms discussed below include allocations by mechanism of Program Evaluation Financing and Type 1 Diabetes funds. The Superfund Research program and ARPA-H are a lump-sum amount within the NIH mechanism tables.

In FY 2024, NIH will continue providing upfront funding for certain research projects, as appropriate, to facilitate efficient management of resources across multiple years. In general, NIH discretionary research project grants are awarded for more than one year and funded incrementally; each year's commitment is obligated from that year's appropriation. Grants are classified as Competing in the first year of award or renewal, and Non-competing in the remaining years of each award. Certain categories of NIH grants are awarded for multiple years with the full funding provided up front. This includes the NIH Director's New Innovator Award (DP2) and the NIH Research Enhancement Award (R15). The latter consists of two programs, the Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions, and the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. In addition, full funding can be provided up front for other NIH grants and cooperative agreements as appropriate in special circumstances. Situations that may benefit from such an approach can include, but are not limited to, appropriations for new programs, rapid increases in funding, or variable outyear funding streams (e.g., under the 21st Century Cures Act). The use of upfront funding for new programs makes some base funding available for competing awards in the following year. Up-front funding has increased over the last few years, due in part to the large Congressional increases for Alzheimer's disease research.

[95] The final FY 2023 funding level of $141.450 million for Type 1 Diabetes reflects the 5.7 percent reduction for Budget Control Act sequestration.

Research Project Grants (RPGs)
The FY 2024 President's Budget provides $27.1 billion for RPGs, which is $0.3 billion more than the FY 2023 Enacted level. This amount would fund 10,414 Competing RPGs, or 547 fewer than the FY 2023 Enacted level. It would also support 32,055 Noncompeting RPGs, 1,287 more than the FY 2023 Enacted level. In addition, the projected average cost for Competing RPGs of approximately $581,000 would be 3.5 percent below the FY 2023 Enacted level projected average cost of $602,000.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) RPGs.** The FY 2024 President's Budget provides $1,263.8 million for SBIR/STTR program grants, which is $21.5 million above the FY 2023 Enacted level. The statutory minimum set-aside requirement of 3.65 percent for NIH-wide SBIR/STTR support is achieved in FY 2024.

Research Centers
The FY 2024 President's Budget provides $2,921.6 million for Research Centers, which is $12.2 million more than the FY 2023 Enacted level. This amount would fund 1,302 grants, 22 more than the FY 2023 Enacted level.

Other Research
The FY 2024 President's Budget provides $3,489.1 million for this mechanism, which is $190.5 million more than the FY 2023 Enacted level. This amount would fund 8,457 grants, which is 73 more than the number of awards projected in the FY 2023 Enacted level.

Training
The FY 2024 President's Budget provides $1,050.6 million for research training, which is $16.7 million above the FY 2023 Enacted level. This amount would fund 18,148 Full-Time Trainee Positions (FTTPs), which is 177 fewer than planned for in the FY 2023 Enacted level, and would continue to fund the new childcare subsidy allowance for individual and institutional trainees that was phased in starting in FY 2021.

Research & Development (R&D) Contracts
The FY 2024 President's Budget provides $3,946.8 million for R&D contracts, which is $118.2 million more than the FY 2023 Enacted level. The requested amount would fund an estimated 2,752 contracts, or 27 more than the FY 2023 Enacted level.

- **SBIR/STTR R&D Contracts.** The FY 2024 President's Budget includes a $95.2 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts.

Intramural Research (IR)
The FY 2024 President's Budget provides $5,056.6 million for IR, which is $44.5 million more than the FY 2023 Enacted level.

Research Management and Support (RMS)
The FY 2024 President's Budget provides $2,491.4 million for RMS, which is $186.5 million more the FY 2023 Enacted level.

Office of the Director (OD)
The FY 2024 President's Budget provides $3,133.4 million for OD, which is $67.2 million more than the FY 2023 Enacted level.

- **Common Fund (CF)**
  Funding of $735.0 million is allocated for CF-supported programs. This amount maintains the FY 2023 Enacted level.

- **Office of Research Infrastructure Programs (ORIP)**
  Funding of $309.4 million is allocated for ORIP. This amount maintains the FY 2023 Enacted level.

- **Other**
  The $2,089.0 million allocated for OD components other than the Common Fund or ORIP is a net increase of $67.2 million from the FY 2023 Enacted level.

Advanced Research Projects Agency for Health (ARPA-H)
The FY 2024 President's Budget provides $2.5 billion to support ARPA-H, an increase of $1.0 billion from the FY 2023 Enacted level.

Buildings & Facilities (B&F)
The FY 2024 President's Budget provides $380.0 million for infrastructure sustainment projects associated with the B&F program, which maintains the FY 2023 Enacted level. This amount includes $350.0 million for NIH's Buildings and Facilities appropriation, and $30.0 million within the appropriation for the National Cancer Institute (NCI) for facility repair and improvement activities at NCI's Frederick, Maryland, facility.

Superfund Research Program
The FY 2024 President's Budget provides $83.0 million for the Superfund Research Program, which is equal to the FY 2023 Enacted level.

Program Evaluation Financing
The FY 2024 President's Budget provides $1,948.1 million for Program Evaluation Financing purposes in NIGMS, which is a $535.6 million increase over the FY 2023 Enacted level.

OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
SRO-2.4 By 2025, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding one new treatment option per year. (Outcome)	FY 2022: Investigators initiated testing of one new treatment option for a disorder affecting language. Target: Initiate testing one new potential treatment option for a disorder affecting language. (Target Met)	Initiate testing one new treatment for a disorder affecting hearing.	Initiate testing one new treatment for a disorder affecting balance.	N/A
SRO-2.8 By 2023, advance the development of three novel drug or biologic therapeutic candidates for Alzheimer's disease (AD) or related dementias toward the point of entry into Phase 1 human studies. (Output)	FY 2022: Investigational New Drug (IND)-enabling studies were completed for two new candidate therapeutics. Target: Complete IND-enabling studies for 2-3 new candidate therapeutics. (Target Met)	Advance the development of three novel drug or biologic therapeutic candidates for AD or related dementias toward the point of entry into Phase 1 human studies.	N/A	N/A
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	FY 2022: Enrollment is not complete due to regulatory hurdles in other countries. Target: Complete enrollment of two open label extension studies (HPTN 083 and HPTN 084) investigating the safety and efficacy of the long-acting injectable antiretroviral drug cabotegravir (CAB LA).	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	(Target Not Met)			
SRO-2.10 By 2022, develop methods for the regeneration of functional tissues of the human dental, oral, and craniofacial complex to enable initiation of human Phase 1 clinical trials. (Outcome)	FY 2022: Three projects submitted complete applications for Investigational New Drugs and Devices following successful interactions with FDA under the pre-investigational new drug and device application and pre-request for designation consultation programs. Two additional projects are conducting pilot studies prior to consultation with FDA and final design of pre-clinical trials. Target: One FDA application for a tissue regeneration combination product will be approved and one Phase 1 clinical trial protocol will be developed. (Target Met)	N/A	N/A	N/A
SRO-2.13 By 2023, advance the development of 1-2 new drugs and/or other therapeutic candidates for neurological diseases from lead optimization or device development toward the point of preparedness for first-	FY 2022: Studies on eight therapeutic drug or device candidates have demonstrated efficacy in preclinical disease models. Target: Demonstrate efficacy of trial-ready formulation of 1-2 therapeutic or device	Advance the development of 1-2 new drugs and/or other therapeutic candidates for neurological diseases from lead optimization or device	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
in-human studies. (Output)	candidates in preclinical disease models. (Target Exceeded)	development toward the point of preparedness for first-in-human studies.		
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2022: Researchers continued preclinical research to identify which brain regions (e.g., prefrontal cortex, nucleus accumbens, and amygdala) and signaling molecules (e.g., oxytocin and vasopressin) contribute to social alcohol misuse among adolescents. Target: Continue preclinical research to identify brain-based predictors of alcohol use initiation and misuse among adolescents. (Target Met)	Conduct preclinical and clinical studies to better understand the predictors and consequences associated with adolescent alcohol misuse.	Examine the neurobiological mechanisms that underlie the relationship between childhood trauma and increased risk of alcohol misuse during adolescence and adulthood.	N/A
SRO-3.2 By 2022, establish the feasibility of using one emerging technology to safely and non-invasively obtain real-time data on human placenta development and function during pregnancy. (Outcome)	FY 2022: Researchers established the feasibility of using two separate and distinct emerging technologies to safely and non-invasively obtain real time data on human placenta development and function during pregnancy. The first used ultrasound paired with blood oxygen-level dependent magnetic resonance imaging, and	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	the second used sequencing of placental RNA (ribonucleic acid) present naturally in maternal blood. Target: Establish the feasibility of using one emerging technology to safely and non-invasively obtain real time data on human placenta development and function during pregnancy. (Target Exceeded)			
SRO-4.9 By 2026, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2022: Researchers conducted two clinical trials to test medications to prevent opioid overdose death. Target: Conduct a clinical trial of a medication for relapse prevention of OUD or overdose. (Target Met)	Complete a Phase 2 trial of a long-acting formulation of an opioid antagonist.	Conduct Phase 1 clinical trials of at least two anti-opioid vaccines.	N/A
SRO-4.15 By 2025, develop, refine, and evaluate the effectiveness of evidence-based intervention strategies for facilitating treatment of alcohol misuse in underage populations. (Output)	FY 2022: Researchers conducted studies to evaluate the feasibility and effectiveness of delivering computer-based alcohol screening and brief interventions to adolescents in primary care settings. Target: Evaluate the	Evaluate the effectiveness of an alcohol intervention in reducing alcohol misuse among emerging adults outside of college settings.	Continue a clinical trial to evaluate the effectiveness of screening and brief intervention in primary care for reducing alcohol	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	effectiveness of a digital-based alcohol screening and brief intervention for adolescents. (Target Met)		misuse among underage populations.	
SRO-5.2 By 2025, develop or evaluate the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD). (Outcome)	FY 2022: Researchers conducted two studies to test the effectiveness of prevention interventions focused on electronic nicotine delivery systems in schools, via social media and electronic cigarette advertising restrictions. Target: Conduct 1-2 studies to test the effectiveness of prevention interventions focused on electronic nicotine delivery systems (including vaping). (Target Met)	Launch 1-2 clinical trials testing approaches to prevent opioid and other substance misuse by intervening on social determinants of health.	Launch 1-2 pilot studies to develop novel strategies to prevent substance use among youth and young adults informed by epidemiological research.	N/A
SRO-5.3 By 2023, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease. (Output)	FY 2022: The Alzheimer's Disease Sequencing Project (ADSP) consortium continued analysis of Discovery Follow-up Studies in ethnically diverse cohorts. The consortium continued confirmation of genomic regions of interest from the Discovery Phase and Discovery Follow-Up Phase in ethnically diverse cohorts and	Identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	identified genomic elements that underpin the progression of Alzheimer's disease and related dementias. The consortium continued quality control checks and harmonization of phenotypic data with genetic data across multiple studies. The consortium began analysis of genetic data using artificial intelligence/ machine learning approaches. Target: Continue analysis of ADSP Discovery Follow-Up Study in ethnically diverse cohorts. Continue confirmation of genomic regions of interest from Discovery Phase and Discovery Follow-Up Phase in ethnically diverse datasets. Continue harmonization of phenotypic data with ADSP genetic data across multiple types of study approaches from large epidemiology and clinical cohorts that are outside of the ADSP. Begin analysis of ADSP genetic data using artificial intelligence approaches.			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	(Target Met)			
SRO-5.8 By 2022, obtain pre-clinical and clinical data from newly initiated and current studies to evaluate 1-2 HIV vaccine candidate(s). (Outcome)	FY 2022: Primary analysis of laboratory data from a Phase 2b vaccine efficacy study was completed, and additional immune correlates analyses were performed. Target: Analyze laboratory data from a Phase 2b vaccine efficacy study. (Target Exceeded)	N/A	N/A	N/A
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	FY 2022: In a preclinical mouse model, researchers successfully demonstrated the feasibility of an ultrasound technique to temporarily open the blood-brain barrier (which actively prevents foreign substance, like drugs, from entering the brain) for drugs to be delivered to the brain. Target: Evaluate the feasibility and safety of one pre-clinical prototype technology that uses acoustic, optical, or electromagnetic waves to manipulate cells for treatment of a specific disease.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	(Target Met)			
SRO-5.15 By 2025, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations. (Outcome)	FY 2022: Researchers demonstrated the effectiveness of a suicide and alcohol prevention intervention for adolescents living in rural Alaska Native communities. Target: Develop and/or evaluate preventive interventions to address underage alcohol use among specific underserved populations. (Target Met)	Evaluate a culturally appropriate family-based intervention to prevent and reduce underage drinking among an underserved population.	Develop and/or evaluate a preventive intervention to address alcohol use in underage populations.	N/A
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	FY 2022: Researchers tested three interventions to enhance end-of-life and palliative care. Target: Develop and test at least three effective interventions to enhance end-of-life and palliative care by: improving quality of life for patients; providing support for family members and informal caregivers; and/or facilitating shared decision-making. (Target Met)	N/A	N/A	N/A
SRO-5.18 By 2026, enhance understanding of how five health	FY 2022: The app *¡Hola Bebé, Adiós Diabetes!* was	Assess the feasibility of using data	Identify barriers and enhancers to	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
information technologies can be applied effectively to improve minority health or to reduce health disparities. (Output)	successfully launched, but completion of effectiveness testing has been delayed due to the COVID-19 pandemic. Target: Determine if a mobile phone app is effective in promoting physical activity or reducing weight among racial and ethnic minority populations. (Target Not Met)	mining, natural language processing, and/or other technological advances to improve health or healthcare for individuals who experience health disparities.	adoption of health information technologies, such as clinical decision aids, from the perspective of physicians who care for populations who experience health disparities.	
SRO-5.19 By 2026, establish a formalized funding pathway for the development, validation, and regulatory review of diagnostic technologies to enhance surveillance and pandemic preparedness. (Outcome and Efficiency)	FY 2022: NIH supported the development of technologies that led to two at-home COVID-19 tests, five point-of-care COVID-19 tests, and two lab-based COVID-19 tests. All nine tests received an FDA emergency use authorization for marketability. Target: Receive FDA authorization for marketability for three home, point-of-care, or lab-based diagnostics. (Target Exceeded)	Receive FDA authorizations or approvals for two home, point-of-care, or lab-based diagnostics, at least one of which addresses accessibility needs of people with disabilities.	Receive FDA authorization or approval (including updated authorization or approval) for at least two home, point-of-care, or lab-based diagnostics, at least one of which is fully accessible to people with disabilities.	N/A
SRO-5.20 By 2026, advance the preclinical or clinical development of 10 antivirals for current or future	FY 2022: Researchers advanced the preclinical development of multiple antiviral therapeutic candidates.	Advance preclinical or clinical development of	Advance preclinical or clinical development of two	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
infectious disease threats. (Outcome)	Target: Advance preclinical or clinical development of one antiviral therapeutic. (Target Exceeded)	two antiviral therapeutics.	antiviral therapeutics.	
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2022: The GRADE Study found that a long-acting form of insulin (insulin glargine) and an antidiabetic drug that increases insulin levels (liraglutide) performed the best at maintaining blood glucose levels in the recommended range for people with type 2 diabetes, out of the four FDA medications tested in the study. Target: Analyze the primary outcome results from Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study. (Target Met)	Determine the long-term durability of diabetes remission following bariatric surgery compared with medical/lifestyle intervention.	N/A	N/A
SRO-6.2 By 2025, advance 1-2 new or repurposed compounds that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	FY 2022: NIH supported a clinical study to evaluate the efficacy of ketamine combined with motivational enhancement therapy to reduce the number of heavy drinking days in adults seeking treatment for alcohol use disorder.	Evaluate a candidate compound for the treatment of alcohol use disorder in a preclinical and/or clinical study.	Conduct a clinical study to evaluate a candidate compound for the treatment of alcohol use disorder in individuals with a co-	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	Target: Evaluate the efficacy of a candidate compound used in combination with a behavioral therapy for the treatment of alcohol use disorder. (Target Met)		occurring mental health condition.	
CTR-7 By 2022, engage a national community in the development, dissemination, and implementation of a comprehensive national strategy to address the burden of Chronic Obstructive Pulmonary Disease (COPD) in the US. (Output)	FY 2022: Submissions from COPD community stakeholders, which capture activities that support implementation of the COPD National Action Plan, were monitored and analyzed. Target: Analyze Action Plan implementation activities reported by stakeholders. (Target Met)	N/A	N/A	N/A
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2022: Award rate to comparison group reached 9.8 percent Target: N ≥ 10 percent (Target Not Met)	N ≥ 10 percent	N ≥ 10 percent	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2022: Award rate to comparison group reached 16.3 percent and exceeded target by 6.3 percent. Target: N ≥ 10 percent	N ≥ 10 percent	N ≥ 10 percent	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	(Target Exceeded)			
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (Output)	FY 2022: NBS finalized FedRamp Cloud requirements and selected Oracle Cloud Infrastructure as the cloud service provider. Target: (Development) Initiate development of planned business modules to build capacity and functionality of the NBS. (Target Met)	(Development) Identify or initiate development effort for the implementation of the G-Invoicing platform.	(Development) Transition NBS portfolio to a FedRAMP-certified cloud service provider.	N/A
CBRR-18 By 2023, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	FY 2023: The Harmonized Cognitive Assessment Protocol (HCAP) has been developed and validated for dementia assessment for use in large nationally representative samples in several countries, including U.S., Mexico, England, Chile, China, India, and parts of South Africa. Target: Develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Target Met) FY 2022: The follow-up HCAP assessment to provide new data on the	(Note: FY 2023 Target was met early in FY 2022; see results in the second column.)	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	incidence and prevalence of dementia and Alzheimer's disease and related dementias (ADRD) in the U.S. was initiated. FY 2022: Initiate a follow-up HCAP assessment to provide new data on the incidence and prevalence of dementia and ADRD in the U.S. (Target Met)			
CBRR-25 Increase the total number of mentored research career development experiences for trainees from diverse backgrounds, including groups underrepresented in biomedical research, to promote individual development and to prepare them for a range of research-related careers. (Output)	FY 2022: Trainees from diverse backgrounds received a total of 3,972 career development experiences across all career stages. Target: 3,545 career experiences across all career stages. (Target Exceeded)	3,550 career experiences across all career stages.	3,600 career experiences across all career stages.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
CBRR-26 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA (Institutional Development Award) Networks of Biomedical Research Excellence (INBRE) program in order to sustain a pipeline of undergraduate students who will pursue health research careers. (Output)	FY 2022: An estimated 1,490 undergraduate students participated in mentored research experiences, consistent with 2021 level. Target: Sustain the number of undergraduate mentored research experiences from FY 2021 level. (Target Met)	Sustain the number of undergraduate mentored research experiences from FY 2022 level.	Sustain the number of undergraduate mentored research experiences from FY 2023 level.	N/A
CBRR-28 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting research on brain and behavior. (Output)	FY 2022: Brain tissue from 39 new donors was obtained. Samples were distributed to 22 researchers. Target: Collect brain tissue from an additional 40 new donors and distribute tissue samples or data derived from tissue to 20 researchers studying mental or neurological disorders. (Target Not Met)	Collect brain tissue from an additional 30 new donors and distribute tissue samples or data derived from tissue to 20 researchers studying mental or neurological disorders.	Collect brain tissue from an additional 30 new donors and distribute tissue samples or data derived from tissue to 20 researchers studying mental or neurological disorders.	N/A
CBRR-30 By 2025, expand the use of program-focused versus target-focused award mechanisms by National Institute of General Medical Sciences (NIGMS) investigators. (Output)	FY 2022: Out of 4,381 investigators supported by R01 or MIRA/R35 grants, 2,057 were MIRA/R35 investigators (47 percent). This is an increase of 6 percentage points from 41 percent in FY 2021.	Expand NIGMS investigator participation in the Maximizing Investigators' Research Award (MIRA) program by 2	Expand NIGMS investigator participation in the Maximizing Investigators' Research Award	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	Target: Expand NIGMS investigator participation in the Maximizing Investigators' Research Award (MIRA) program by 2 percentage points. (Target Exceeded)	percentage points.	(MIRA) program by 2 percentage points.	
MPO-1 Reduce the footprint of office and warehouse space in NIH's owned and leased facilities portfolio by one percent annually to comply with guidelines in the Office of Management and Budget (OMB) Memorandum M-12-12, Promoting Efficient Spending to Support Agency Operations. (Output and Efficiency)	FY 2022: The usable square footage of rentable office and warehouse space was reduced by 6.4 percent. Target: Reduce one percent of FY 2021 usable square feet. (Target Exceeded)	Reduce one percent of FY 2022 usable square feet.	Reduce one percent of FY 2023 useable square feet.	N/A
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2022: NIH's Client Services Division Metrics Unit evaluated the return-on-investment on shared recruitments versus standard recruitments and found that shared recruitments continually outperform their counterpart. Target: Assess the shared recruitment approach, using data gathered in first year of full-time	Examine key area to enhance recruitment: Examine use of advanced applicant assessments to help improve the quality of applicant pools for highly skilled positions at the NIH and determine whether or not there is an	Examine key area to enhance recruitment: Examine use of resources created specifically to assist Human Resources Specialists with the promotion of vacancies to underrepresen ted groups,	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	practice, to determine if hiring goals are being met. (Target Met)	impact on hiring and retention.	veterans, etc. in an effort to increase awareness of NIH opportunities among diverse populations and determine whether or not there is an impact on the diversity of NIH's applicant pools.	
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors (BSC). (Output)	FY 2022: 25 percent of Principal Investigators were reviewed resulting in approximately 25 percent of resources recommended to be reallocated. Target: Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources. (Target Met)	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line-item projects so it is completed within 100 percent of the final approved project cost. (Ongoing) (Output)	FY 2022: 22 of the 28 active projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100 percent of the final	24 Active Projects	32 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	approved cost. Target: 28 Active Projects (Target Not Met)			
MPO-8 Manage design and construction of capital facility projects funded by B&F so that no more than 10 percent of the projects may incorporate plus or minus 10-percent adjustments of the approved scope. (Ongoing) (Output)	FY 2022: NIH managed the design and construction of 26 of the 28 funded projects within plus or minus 10 percent adjustment to the scope. Target: 28 Active Projects (Target Not Met)	24 Active Projects	32 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2022: Obligated 47 percent of eligible service contracting dollars to PBC. Target: Obligate the FY 2022 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2023 goal of eligible service contracting dollars to PBC.	Obligate the FY 2024 goal of eligible service contracting dollars to PBC.	N/A
MPO-11 Verify 70 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	FY 2022: The NIH's Shared Instrumentation Grant (S10) Program awarded 123 grants in FY 2020. Of the 123 grant awards, 88 instruments (72 percent) were installed within 24 months of the Notice of Award date. Target: Verify 60 percent of awarded state-of-the-	Verify 60 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 24 months after award.	Verify 65 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 24	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
	art instruments are installed at NIH-supported research institutions across the nation 24 months after award. (Target Met)		months after award.	

GRANT AWARDS TABLE

	FY 2022 Final[3,a]	FY 2023 Enacted[3,a]	FY 2024 President's Budget[3,a]
Number of Awards	51,908	53,284	54,169
Average Award (in Whole $s)	$604,527	$619,587	$618,447
Range of Awards (in Whole $s)[1,2]	$1,000 to $30,393,525	$1,000 to $39,534,706	$1,000 to $38,397,646

[1] Award range excludes minimum values of zero to under $1,000 related primarily to no-cost extensions and co-funded actions.

[2] Award maximum estimates are based on an extrapolation from the most recent historical actual while accounting for expected budget policies applicable to each future fiscal year. The actual year-to-year fluctuations are roughly eight million dollars, plus or minus.

[3] Includes 21st Century Cures Act funding.

[a] Figures do not include any awards or funding related to ARPA-H.

NEF NARRATIVE

Budget Summary

(Dollars in Thousands)

	FY 2022[2]	FY 2023[3]	FY 2024[4]
Notification[1]	--	$63,140	$120,130

[1] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.
[2] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2021.
[3] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on September 23, 2022.
[4] The NEF CJ indicates the amounts HHS intends to notify for FY 2024; these amounts are planned estimates and subject to final approval.

Authorizing Legislation:
Authorization…….Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method…….……...…..Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions. Since FY 2016, the NEF has provided support for eight projects delivering important improvements on NIH clinical infrastructure, largely focused on the NIH Clinical Center on the Bethesda campus.

Budget Allocation FY 2024

In FY 2024 NIH will receive $120.13 million in NEF funding for five projects:

Improve Clinical Center Complex Electrical Power Reliability
One of NIH's highest facility-related priorities is to support the safety and reliability of the infrastructure that provides utility services to patient-related areas of the Clinical Center Complex (CCC) on the Bethesda Campus. The CCC is composed of three major structures including the original Building 10, the Ambulatory Care Research Facility (ACRF), and the Clinical Research Center (CRC) built in 1952, 1980, and 2005, respectively. This four-phase project consists of three major initiatives in order to achieve electrical power reliability in the CCC, including: 1) new electrical risers and associated equipment; 2) electrical vault decommissioning; and 3) upgrades to existing vaults. This utility project will replace and upgrade aging services with safe, state-of-of the art, cost effective, contiguous, and secure electrical systems. The three initiatives are to be completed in four phases. This FY 2024 NEF project carries out Phase 2 of the program, which will replace Vault 9, rebuild Vault 6, remove the existing freight elevator, and create new floors and electrical rooms, extend the electrical busducts from the West vault to the newly created electrical rooms, and decommission Vault 4.

Replacement of Cooling Towers 18, 19 and Chillers 17, 18, 19
In all, there are six chillers that require replacement under the Building 11 R22 Chiller Replacement program – Chillers 16, 17, 18, 19, 20 and 21. These chillers need to be replaced to eliminate use of R22 refrigerant, which is being phased out; to improve efficiency in serving newer buildings with more efficient heating, air conditioning, and ventilation systems; and because the cooling towers are beyond their lifespan and under capacity to serve current campus needs.

This project replaces three of the six chillers (Chillers 17, 18 and 19) along with their associated cooling towers. The project will include required electrical updates, replacement of the chillers and cooling towers, and expansion of the Building 11 substation to house the variable frequency drives and other equipment associated with the chillers.

Sprinkler Protection in Building 11
This project will provide sprinkler protection in the NIH Central Utility Plant (CUP), Building 11. The CUP is a nearly 70-year-old, 290,488 gross square feet (gsf) building that provides chilled water and steam to cool, heat, and humidify nearly 12 million gsf of space at the NIH Bethesda Campus. The current infrastructure is over 40 years old and is at the end of its useful life; the necessity for an overhaul to the CUP's current sprinkler system is based on the requirements of the National Fire Protection Association (NFPA) 101, Life Safety Code.

The scope of this project is to install a fully code compliant fire sprinkler system in all required areas of the facility. These areas include the main plant, hallways, mechanical spaces, etc. Included in the scope is selective demolition and restoration of ceilings and other disturbed finishes from the sprinkler installation.

Replacement of Steam and Chilled Water Lines from Vault 2 to Vault 31C
This project will design and replace failed, underground steam, chilled water and domestic water piping from existing Valve Vault - 2 (VV2) to existing Valve Vault 31C (VV31C) within a new, underground walkable utility tunnel on the Bethesda campus, Maryland. The west side of the campus steam loop is formed by existing direct-buried pipe. Not only has the trench collapsed, but multiple segments of the existing aging underground piping in this area have failed and require replacement. By connecting to existing steam tunnel on the east side of the loop, the repair will provide for the final west leg of a continuous walkable tunnel, connecting to the ends of the existing Northeast tunnel between VV-2 and VV-31C.

Repair of Bethesda Campus Parking Garages
This project is a three-phase repair/restoration program of four multi-level parking (MLP) garages located on the Bethesda campus. One of these garages is the Building 10 ACRF garage, part of which is located directly beneath the 15-story ACRF Building, and in which the parking garage columns also support the ACRF building.

The MLP garages on the Bethesda campus were built at different times, so their condition and service life vary. However, all have common issues - the structures are deteriorating due to lack of maintenance and poor drainage. To correct and mitigate garage deterioration and safety issues, NIH plans a garage repair/restoration program that will provide for a complete remediation of the parking structures (including stairs towers) to include concrete and drainage repairs as well as any other repair necessary to ensure the safety and structure integrity of the parking garage system; and provide a 25-year maintenance and repair plan for the expected service life of each

garage. The plan will prioritize the preventative maintenance, repair, and rehabilitation needs for the entire garage system on a yearly basis.

FY 2024 NEF Planned Projects

FPAA Number	Project Title	Requested Amount
N-15-011	Electrical Power Reliability for the CCC	$26.10M
N-19-011	Replace Cooling Towers 18, 19 and Chillers 17, 18, 19	$40.0M
N-21-006	Building 11 Provide Sprinkler Protection	$11.37M
N-19-010	Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C	$29.30M
N-20-008	Repair Parking Garages, Bethesda	$13.36M

Budget Allocation FY 2023

In FY 2023 NIH received $63.140 million in NEF funding for the following projects:

$22.49 million of FY 2023 NEF funding was allocated to Phase 3 of the CCC Electrical Power Reliability program, as mentioned above. Phase 3 of this project, funded with FY 2023 NEF funding, will extend the life safety, emergency, and normal power bus ducts from the East Vault to the "A" Wing of Building 10. The project will provide a new tower on the south side of the "A" Wing for the bus duct risers and closets and offer distribution to all "A" Wing floors. Additionally, the work will upgrade Vault 8 to four 2000 kVA transformers and Vault 9 to four 2500 kVA transformers.

$40.65 million of FY 2023 NEF funding was allocated to the NIAID Support Facility (Building J), at Rocky Mountain Laboratories (RML) in Hamilton, Montana. Building J is a multistory addition to existing NIAID Building J for departmental functions including Microscopy, Intramural Administrative Management Branch (IAMB), Acquisition Management and Operations Branch (AMOB), Office of Cyber Infrastructure and Computational Biology (OCICB), and NIH Police. The existing facilities housing the essential support functions of these programs have remained unchanged for many years, while the scientific structure being supported continues to expand. All areas of services have had additional demands placed on them and additional staff have been hired without adequate facilities available to house and support them. The current deficient facilities negatively affect the ability to provide the central support functions and consequently, negatively affect the scientific mission of NIH at RML.

Budget Allocation for FY 2021 and earlier years

$212.4 million of FY 2020 and $225.0 million of FY 2021 NEF funding was allocated to NIH for the development of enhanced bridging documents and the design build (D/B) construction of the Surgery, Radiology and Lab Medicine Building (SRLM) on the Bethesda campus. This project, the most critical project on NIH's five-year Buildings and Facilities Plan, will construct a new addition and repurpose two floors of the west laboratory wing of the CRC. The project will include the Clinical Center's Surgical (Department of Perioperative Medicine and

Interventional Radiology – DPM/IR), Radiology (Radiology and Imaging Sciences – RADIS) and the Laboratory Medicine (Department of Laboratory Medicine - DLM) departments now located in the 1982-era ACRF wings S&T and the NCI research laboratories located on floors 1W and 3W of the CRC West laboratory wing. These departments involve some of the most advanced and technology dependent cutting-edge programs supporting NIH's Translational Research initiatives. The project is focused on developing a facility that supports medical research initiatives to improve the nation's health and strengthen NIH's biomedical research capacity in close proximity to the CRC. The most recent "Building Condition Index" conducted by the NIH has the ACRF in the POOR category. Some of the major deficiencies include the following: 1) functional space inadequacies/inefficiencies; 2) routes of circulation are not efficient; 3) facility has numerous limitations restricting the flexibility/adaptability to address growth and change; 4) infrastructure systems are deficient and unreliable (major areas of concern include normal and emergency power, communication systems, heating, cooling, and ventilation); and 5) structural problems (light steel structure) result in unacceptable vibration levels in some areas of the building. The total project will consist of 630,000 gross square footage (GSF), including new construction of 527,000 GSF and 103,000 GSF of renovation. The new wing will be an eight-story above-grade structure (with interstitial floors), plus one floor below grade and a mechanical penthouse. A below grade Cardiovascular Intervention Program (CIP) suite is also planned. The addition is located on the west end of the CRC-West Laboratory Wing. Once the new addition is completed, two floors of the West Lab wing (1W and 2W) will be renovated after the existing NCI Research Labs are moved to the new addition.

$12.6 million of FY 2020 NEF funding was allocated to the NIH for the Building Automation System (BAS) Replacement, Building 10, Bethesda. The project is to upgrade and replace the obsolete Johnson Controls, Inc. (JCI) Building Automation System (BAS) of NIH Bethesda campus Building 10 CRC with a new state-of-the-art, cost-effective, contiguous, simple, and secure system.

$63.54 million of FY 2019 NEF funding was allocated to the NIH for construction of the Utility Vault and Patient Parking Garage on the Bethesda campus, providing a new, 330,000 GSF, Utility Vault and Multi-Level Parking Garage to serve the NIH Clinical Center. The project also includes several 'enabling' tasks for the proposed SRLM project described above, including a new 2MW generator and switchgear for the SRLM Building and the Clinical Data Center, replacement of electrical duct bank currently serving the CRC which is in the footprint of the new SRLM building, a new CO2 storage tank, a new electrical feeder from Building 63 to the utility vault and parking garage, and utility vault housing for the future Building 59 and 59A (emergency generators and switchgear) replacement.

$19.5 million of FY 2019 NEF funding was allocated to the NIH for Phase 1 of the Electrical Power Reliability program to replace failing and unreliable electrical power systems in the CCC on the Bethesda campus. As noted above, this program consists of three major initiatives, to be completed in four phases. Phase 1 will replace the most critical Vault 10 in the ACRF and provide critical immediate upgrades to Vaults 6 through 9.

$35.27 million of FY 2017 NEF funding was allocated for the replacement of R22 Refrigerant Chillers. This project involves replacing two existing York 5,000-ton dual steam turbine/electric driven chillers (CH-21 FY 2016, CH-16 FY 2017) in Building 11 with four new 3,000-ton variable speed electric chillers, two in FY 2017 and two in FY 2018. Due to the efficiency

achieved in the current chilled water upgrades accomplished between 2013 and 2015 and the additional efficiency and capacity of the four new chillers, the remaining four R22 chillers will not have to be replaced. The refrigerant removed from the demolished chillers will be used as backup for the four remaining chillers if needed.

$16.48 million of FY 2017 NEF funding was allocated for Emergency Generators to support the CUP. The Cogeneration (COGEN) Plant at NIH, which runs on natural gas, is unique in that it is believed to be the most efficient source of electrical power and steam from a stand-alone system in the world. The plant has the capability of delivering 22 megawatts of power to various substations on the Bethesda Campus, which in turn feeds the CUP. This project is to direct the new emergency power generator or generators (2000 KW total) toward the startup of the COGEN plant should a loss of power occur from the local Utility. This system will guarantee uninterrupted cooling and steam service to the most critical facilities on campus.

$162.1 million of FY 2016 NEF funding was allocated to the NIH for the Renovation of the E-Wing in the NIH Clinical Center (Building 10). This project replaces failing infrastructure in Building 10 by converting former patient care and laboratory space on Floors 2 through 13 to build out laboratory, laboratory support space, and offices for personnel in the clinical research programs of numerous Institutes and Centers (ICs).

$10 million of FY 2015 NEF funding was allocated for National Institute of Environmental Health Sciences (NIEHS) Net-Zero Energy Warehouse in Research Triangle Park, North Carolina. Creating this government-owned warehouse facility replaced an off-site leased facility, eliminating the need to pay for a continuing lease, and provided an increased level of security for the warehouse.

Exhibit A

(In millions of dollars)

NIH Nonrecurring Expense Fund (NEF) Overview									
Project	FY2016 Received $M	FY2017 Received $M	FY2018 Received $M	FY2019 Received $M	FY2020 Received $M	FY2021 Received $M	FY2022 Received $M	FY2023 Received $M	FY2024* Planned $M
E-Wing Renovation, Building 10, Bethesda, MD	$ 162.10								
R22 Refrigerant Chillers Replacement, Bethesda, MD		$ 35.27							
Emergency Power Generators to Assure Chilled Water, Bethesda		$ 16.48							
Surgery, Radiology and Lab Medicine Building (SRLM), Bethesda, MD					$ 212.40	$ 225.00			
ORF/ORS/NIAID Support Facilities, RML, MT								$ 40.65	
Electrical Power Reliability, Building 10, Bethesda. MD				$ 19.50				$ 22.49	$ 26.10
Building Automation System (BAS) Replacement, Bldg 10, Bethesda, MD					$ 12.60				
Utility Vault and Patient Parking Garage, Bethesda, MD				$ 63.54					
Replace Cooling Towers 18,19 and Chillers 17,18,19									$ 40.00
Building 11 Provide Sprinkler Protection									$ 11.37
Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C									$ 29.30
Repair Parking Garages, Bethesda									$ 13.36
Totals:	$ 162.10	$ 51.75	$ -	$ 83.04	$ 225.00	$ 225.00	$ -	$ 63.14	$ 120.13

*The NEF CJ indicates the amounts HHS intends to notify for in FY 2024; these amounts are planned estimates and subject to final approval.

BUDGET REQUEST BY IC (SUMMARY TABLE)

(Dollars in Thousands)[1]	FY 2022 Final[5,6]	FY 2023 Enacted[5,6]	FY 2024 President's Budget[6]
NCI	$6,909,626	$7,317,241	$7,820,159
NHLBI	$3,810,371	$3,985,158	$3,985,158
NIDCR	$501,207	$520,138	$520,138
NIDDK[2]	$2,347,681	$2,444,548	$2,553,098
NINDS	$2,607,190	$2,809,418	$2,825,418
NIAID	$6,322,180	$6,561,652	$6,561,652
NIGMS[3]	$3,092,373	$3,239,679	$3,239,679
NICHD	$1,681,231	$1,747,784	$1,747,784
NEI	$863,752	$896,136	$896,136
NIEHS[4]	$924,702	$996,842	$1,021,842
NIA	$4,222,634	$4,412,090	$4,412,090
NIAMS	$657,873	$687,639	$687,639
NIDCD	$514,882	$534,330	$534,330
NIMH	$2,220,670	$2,341,653	$2,541,653
NIDA	$1,596,123	$1,663,365	$1,663,365
NIAAA	$574,910	$596,616	$596,616
NINR	$180,841	$197,671	$197,671
NHGRI	$636,479	$660,510	$660,510
NIBIB	$424,588	$440,625	$440,625
NIMHD	$459,777	$525,138	$525,138
NCCIH	$159,282	$170,277	$170,277
NCATS	$882,265	$923,323	$923,323
FIC	$86,849	$95,130	$95,130
NLM	$477,506	$495,314	$495,314
OD	$2,772,998	$3,066,208	$3,133,379
ARPA-H	$1,000,000	$1,500,000	$2,500,000
B&F	$250,000	$350,000	$350,000
Total, NIH Program Level	**$46,177,990**	**$49,178,485**	**$51,098,124**
Special Type 1 Diabetes Research (mandatory)	-$141,450	-$141,450	-$250,000
PHS Program Evaluation	-$1,309,313	-$1,412,482	-$1,948,109
Interior Appropriation (Superfund Research)	-$82,540	-$83,035	-$83,035
Total, NIH Labor/HHS Budget Authority	**$44,644,687**	**$47,541,518**	**$48,816,980**
Pandemic preparedness (mandatory) (non-add)	---	---	*$2,690,000*

[1] Includes funding derived by transfer from the NIH Innovation Account under the 21st Century Cures Act.
[2] Includes Type 1 Diabetes mandatory funding as shown later in the table.
[3] Includes Program Evaluation financing as shown later in the table.
[4] Includes Interior appropriation for Superfund Research activities as shown later in the table.
[5] Amounts reflect HIV/AIDS transfers across ICs under the authority of the Office of AIDS Research.
[6] Reflects directive transfer of $5.0 million from OD to the HHS Office of Inspector General.

APPROPRIATIONS ADJUSTMENT TABLE FOR FY 2022

Appropriations Adjustments Table for FY 2022

(Dollars in Thousands)	FY 2022 Enacted	Type 1 Diabetes Sequestration	Permissive Transfer (NIH Innovation Account)[3]	OIG Transfer[4]	HIV/AIDS Transfer[5]	ARPA-H Transfer[6]	FY 2022 Final
NCI	$6,718,522		$194,000		-$2,896		$6,909,626
NHLBI	$3,808,494				$1,877		$3,810,371
NIDCR	$501,231				-$24		$501,207
NIDDK[1]	$2,353,926	-$8,550			$2,305		$2,347,681
NINDS	$2,535,370		$76,000		-$4,180		$2,607,190
NIAID	$6,322,728				-$548		$6,322,180
NIGMS	$3,092,373						$3,092,373
NICHD	$1,683,009				-$1,778		$1,681,231
NEI	$863,918				-$166		$863,752
NIEHS[2]	$924,709				-$7		$924,702
NIA	$4,219,936				$2,698		$4,222,634
NIAMS	$655,699				$2,174		$657,873
NIDCD	$514,885				-$3		$514,882
NIMH	$2,140,976		$76,000		$3,694		$2,220,670
NIDA	$1,595,474				$649		$1,596,123
NIAAA	$573,651				$1,259		$574,910
NINR	$180,862				-$21		$180,841
NHGRI	$639,062				-$2,583		$636,479
NIBIB	$424,590				-$2		$424,588
NIMHD	$459,056				$721		$459,777
NCCIH	$159,365				-$83		$159,282
NCATS	$882,265						$882,265
FIC	$86,880				-$31		$86,849
NLM	$479,439				-$1,933		$477,506
OD	$3,125,120		-$346,000	-$5,000	-$1,122		$2,772,998
B&F	$250,000						$250,000
ARPA-H	$0					$1,000,000	$1,000,000
Total, NIH Program Level	**$45,191,540**	**-$8,550**	**$0**	**-$5,000**	**$0**	**$1,000,000**	**$46,177,990**
Less funds allocated from different sources:							
Mandatory Type 1 Diabetes Research	-$150,000	$8,550					-$141,450
PHS Program Evaluation	-$1,309,313						-$1,309,313
Total, NIH Discretionary Budget Authority	**$43,732,227**	**$0**	**$0**	**-$5,000**	**$0**	**$1,000,000**	**$44,727,227**
Interior Budget Authority	-$82,540						-$82,540
Total, NIH Labor/HHS Budget Authority	**$43,649,687**	**$0**	**$0**	**-$5,000**	**$0**	**$1,000,000**	**$44,644,687**

[1]Includes Type 1 Diabetes.

[2]Includes Superfund Research activity.

[3]Reflects redistribution of NIH Innovation account for the 21st Century Cures Act.

[4]Reflects directive transfer of $5.0 million from OD to the HHS Office of Inspector General.

[5]Reflects HIV/AIDS transfers across ICs under the authority of the Office of AIDS Research.

[6]Reflects transfer of $1,000.0 million from HHS Office of the Secretary to NIH.

APPROPRIATIONS ADJUSTMENT TABLES FOR FY 2023

Appropriations Adjustments Table for FY 2023

(Dollars in Thousands)	FY 2023 Enacted	Type 1 Diabetes Sequestration	Permissive Transfer (NIH Innovation Account)[3]	OIG Transfer[4]	HIV/AIDS Transfer[5]	ARPA-H Transfer[6]	FY 2023 Operating Level
NCL	$7,104,159		$216,000		-$2,918		$7,317,241
NHLBI	$3,982,345				$2,813		$3,985,158
NIDCR	$520,163				-$25		$520,138
NIDDK[1]	$2,450,721	-$8,550			$2,377		$2,444,548
NINDS	$2,588,925		$225,000		-$4,507		$2,809,418
NIAID	$6,562,279				-$627		$6,561,652
NIGMS	$3,239,679						$3,239,679
NICHD	$1,749,078				-$1,294		$1,747,784
NEI	$896,549				-$413		$896,136
NIEHS[2]	$997,014				-$172		$996,842
NIA	$4,407,623				$4,467		$4,412,090
NIAMS	$685,465				$2,174		$687,639
NIDCD	$534,333				-$3		$534,330
NIMH	$2,112,843		$225,000		$3,810		$2,341,653
NIDA	$1,662,695				$670		$1,663,365
NIAAA	$595,318				$1,298		$596,616
NINR	$197,693				-$22		$197,671
NHGRI	$663,200				-$2,690		$660,510
NIBIB	$440,627				-$2		$440,625
NIMHD	$524,395				$743		$525,138
NCCIH	$170,384				-$107		$170,277
NCATS	$923,323						$923,323
FIC	$95,162				-$32		$95,130
NLM	$497,548				-$2,234		$495,314
OD	$3,740,514		-$666,000	-$5,000	-$3,306		$3,066,208
B&F	$350,000						$350,000
ARPA-H	$0					$1,500,000	$1,500,000
Total, NIH Program Level	**$47,692,035**	**-$8,550**	**$0**	**-$5,000**	**$0**	**$1,500,000**	**$49,178,485**
Less funds allocated from different sources:							
Mandatory Type 1 Diabetes Research	-$150,000	$8,550					-$141,450
PHS Program Evaluation	-$1,412,482						-$1,412,482
Total, NIH Discretionary Budget Authority	**$46,129,553**	**$0**	**$0**	**-$5,000**	**$0**	**$1,500,000**	**$47,624,553**
Interior Budget Authority	-$83,035						-$83,035
Total, NIH Labor/HHS Budget Authority	**$46,046,518**	**$0**	**$0**	**-$5,000**	**$0**	**$1,500,000**	**$47,541,518**

[1]Includes Type 1 Diabetes.

[2]Includes Superfund Research activity.

[3]Reflects redistribution of NIH Innovation account for the 21st Century Cures Act.

[4]Reflects directive transfer of $5.0 million from OD to the HHS Office of Inspector General.

[5]Reflects HIV/AIDS transfers across ICs under the authority of the Office of AIDS Research.

[6]Reflects transfer of $1,500.0 million from HHS Office of the Secretary to NIH.

BUDGET MECHANISM TABLE

(Dollars in Thousands)[1,2,3]	FY 2022 Final[9]		FY 2023 Enacted[9]		FY 2024 President's Budget[9]		FY 2024 +/- FY 2023 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	29,423	$17,056,649	30,768	$18,487,622	32,055	$19,393,431	1,287	$905,808
Administrative Supplements[3]	*(3,151)*	494,802	*(3,260)*	476,969	*(2,879)*	385,306	*(-381)*	-91,663
Competing	11,333	$6,668,939	10,961	$6,599,170	10,414	$6,047,419	-547	-$551,751
Subtotal, RPGs	40,756	$24,220,390	41,729	$25,563,761	42,469	$25,826,156	740	$262,395
SBIR/STTR	1,840	1,202,743	1,891	1,242,315	1,941	1,263,786	50	21,471
Research Project Grants	42,596	$25,423,133	43,620	$26,806,076	44,410	$27,089,942	790	$283,866
Research Centers:								
Specialized/Comprehensive	1,043	$2,114,324	1,107	$2,277,684	1,151	$2,374,503	44	$96,819
Clinical Research	73	441,087	58	338,841	36	258,134	-22	-80,707
Biotechnology	45	72,777	44	68,863	45	70,033	1	1,170
Comparative Medicine	47	144,037	46	140,771	45	135,706	-1	-5,065
Research Centers in Minority Institutions	22	74,230	25	83,204	25	83,204	0	0
Research Centers	1,230	$2,846,455	1,280	$2,909,362	1,302	$2,921,580	22	$12,218
Other Research:								
Research Careers	4,966	$930,003	5,142	$961,412	5,173	$976,015	31	$14,603
Cancer Education	75	20,668	76	21,508	74	21,078	-2	-430
Cooperative Clinical Research	261	473,265	297	504,493	346	644,352	49	139,859
Biomedical Research Support	158	104,783	149	103,257	149	93,549	0	-9,708
Minority Biomedical Research Support	228	77,191	158	57,578	88	35,948	-70	-21,630
Other	2,394	1,504,305	2,562	1,650,379	2,627	1,718,202	65	67,823
Other Research	8,082	$3,110,215	8,384	$3,298,628	8,457	$3,489,145	73	$190,517
Total Research Grants	51,908	$31,379,803	53,284	$33,014,066	54,169	$33,500,667	885	$486,601
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	4,107	$196,143	4,233	$206,087	4,226	$210,006	-7	$3,919
Institutional Awards	13,298	770,860	14,092	827,886	13,922	840,638	-170	12,753
Total Research Training	17,405	$967,003	18,325	$1,033,972	18,148	$1,050,644	-177	$16,672
Research & Develop. Contracts	2,736	$3,681,591	2,725	$3,828,668	2,752	$3,946,840	27	$118,172
(SBIR/STTR) (non-add)[3]	*(100)*	*(84,165)*	*(109)*	*(96,991)*	*(113)*	*(95,203)*	*(4)*	*(-1,788)*
Intramural Research		$4,828,314		$5,012,040		$5,056,584		$44,544
Res. Management & Support		2,160,226		2,304,890		2,491,369		186,479
Res. Management & Support (SBIR Admin) (non-add)[3]		*(9,188)*		*(11,133)*		*(13,051)*		*(1,919)*
Office of the Director - Appropriation[3,4]		*(2,772,998)*		*(3,066,208)*		*(3,133,379)*		*(67,171)*
Office of the Director - Other		1,798,512		2,021,814		2,088,985		67,171
ORIP (non-add)[3,4]		*(304,485)*		*(309,393)*		*(309,393)*		*(0)*
Common Fund (non-add)[3,4]		*(670,001)*		*(735,001)*		*(735,001)*		*(0)*
ARPA-H		1,000,000		1,500,000		2,500,000		1,000,000
Buildings and Facilities[5]		280,000		380,000		380,000		0
Appropriation[3]		*(250,000)*		*(350,000)*		*(350,000)*		*(0)*
Type 1 Diabetes[6,7]		-141,450		-141,450		-250,000		-108,550
Program Evaluation Financing[6]		-1,309,313		-1,412,482		-1,948,109		-535,627
Subtotal, Labor/HHS Budget Authority		**$44,644,687**		**$47,541,518**		**$48,816,980**		**$1,275,462**
Interior Appropriation for Superfund Research		82,540		83,035		83,035		0
Total, NIH Discretionary Budget Authority		**$44,727,227**		**$47,624,553**		**$48,900,015**		**$1,275,462**
Type 1 Diabetes[7]		141,450		141,450		250,000		108,550
Total, NIH Budget Authority		**$44,868,677**		**$47,766,003**		**$49,150,015**		**$1,384,012**
Program Evaluation Financing		1,309,313		1,412,482		1,948,109		535,627
Total, Program Level		**$46,177,990**		**$49,178,485**		**$51,098,124**		**$1,919,639**
Pandemic Preparedness Mandatory via PHSSEF (non-add)[8]		*(0)*		*(0)*		*(2,690,000)*		*(2,690,000)*

1 All Subtotal and Total numbers may not add due to rounding.
2 Includes 21st Century Cures Act funding and excludes supplemental financing.
3 All numbers in italics and brackets are non-add.
4 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as non-adds. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.
5 Includes B&F appropriation and monies allocated pursuant to appropriations acts provisions such that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
6 Number of grants and dollars for mandatory Type 1 Diabetes (T1D) and NIGMS Program Evaluation financing are distributed by mechanism above; therefore, T1D and Program Evaluation financing amounts are deducted to provide subtotals for Labor/HHS Budget Authority.
7 Amounts in FY 2022 and FY 2023 reflect a reduction of $8.550 million for Budget Control Act sequestration.
8 The FY 2024 budget also provides $20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, NIH will receive $2,690 million.
9 Reduced by a transfer of $5.0 million from OD to the HHS Office of Inspector General.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING TYPE 1 DIABETES

FY 2024 Budget Authority by Object Class Including Type I Diabetes Funds[1]

(Dollars in Thousands)[1]

Object Classes	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel Compensation			
Full-Time Permanent (11.1)	$1,332,077	$1,436,174	$104,097
Other Than Full-Time Permanent (11.3)	647,853	691,039	43,186
Other Personnel Compensation (11.5)	81,135	86,349	5,214
Military Personnel (11.7)	18,723	19,756	1,033
Special Personnel Services Payments (11.8)	237,756	250,798	13,042
Subtotal Personnel Compensation (11.9)	**$2,317,544**	**$2,484,117**	**$166,573**
Civilian Personnel Benefits (12.1)	773,523	829,955	56,432
Military Personnel Benefits (12.2)	4,623	4,890	266
Benefits to Former Personnel (13.0)	0	0	0
Total Pay Costs	**$3,095,691**	**$3,318,961**	**$223,271**
Travel & Transportation of Persons (21.0)	41,250	42,063	812
Transportation of Things (22.0)	7,880	7,975	95
Rental Payments to GSA (23.1)	30,466	32,551	2,085
Rental Payments to Others (23.2)	8,364	8,562	198
Communications, Utilities & Misc. Charges (23.3)	266,293	273,520	7,227
Printing & Reproduction (24.0)	292	279	-13
Consultant Services (25.1)	1,525,889	1,528,233	2,344
Other Services (25.2)	1,791,925	1,792,141	216
Purchase of goods and services from government accounts (25.3)	3,348,285	3,478,192	129,907
Operation & Maintenance of Facilities (25.4)	35,287	35,730	443
R&D Contracts (25.5)	2,726,995	3,771,413	1,044,418
Medical Care (25.6)	37,752	38,677	925
Operation & Maintenance of Equipment (25.7)	185,144	182,144	-3,000
Subsistence & Support of Persons (25.8)	3	3	0
Subtotal Other Contractual Services (25.0)	**$9,651,280**	**$10,826,532**	**$1,175,253**
Supplies & Materials (26.0)	249,992	243,752	-6,240
Equipment (31.0)	194,727	169,226	-25,501
Land and Structures (32.0)	404,620	405,144	524
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	33,731,740	33,738,037	6,297
Insurance Claims & Indemnities (42.0)	0	0	0
Interest & Dividends (43.0)	373	377	4
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$44,587,277**	**$45,748,019**	**$1,160,741**
Total Budget Authority	**$47,682,968**	**$49,066,980**	**$1,384,012**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Program Evaluation financing, and supplemental appropriations.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING SSF AND MF

FY 2024 Budget Authority by Object Class Including Service and Supply Fund and Management Fund[1]

(Dollars in Thousands)[1]

Object Classes	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel Compensation			
Full-Time Permanent (11.1)	$1,800,093	$1,929,627	$129,534
Other Than Full-Time Permanent (11.3)	697,418	743,299	45,880
Other Personnel Compensation (11.5)	123,205	130,705	7,501
Military Personnel (11.7)	31,268	32,983	1,715
Special Personnel Services Payments (11.8)	245,279	258,730	13,451
Subtotal Personnel Compensation (11.9)	**$2,897,264**	**$3,095,344**	**$198,080**
Civilian Personnel Benefits (12.1)	977,625	1,044,239	66,614
Military Personnel Benefits (12.2)	5,359	5,666	306
Benefits to Former Personnel (13.0)	0	0	0
Total Pay Costs	**$3,880,248**	**$4,145,249**	**$265,001**
Travel & Transportation of Persons (21.0)	43,991	44,819	828
Transportation of Things (22.0)	10,274	10,388	114
Rental Payments to GSA (23.1)	102,507	105,384	2,877
Rental Payments to Others (23.2)	73,321	74,230	909
Communications, Utilities & Misc. Charges (23.3)	383,378	391,856	8,477
Printing & Reproduction (24.0)	305	292	-13
Consultant Services (25.1)	796,787	778,556	-18,231
Other Services (25.2)	3,319,491	3,323,877	4,386
Purchase of goods and services from government accounts (25.3)	788,342	887,282	98,940
Operation & Maintenance of Facilities (25.4)	185,458	187,469	2,011
R&D Contracts (25.5)	2,728,142	3,772,567	1,044,425
Medical Care (25.6)	72,373	73,096	723
Operation & Maintenance of Equipment (25.7)	438,627	436,782	-1,845
Subsistence & Support of Persons (25.8)	3	3	0
Subtotal Other Contractual Services (25.0)	**$8,329,222**	**$9,459,631**	**$1,130,409**
Supplies & Materials (26.0)	451,687	445,487	-6,199
Equipment (31.0)	254,282	228,912	-25,369
Land and Structures (32.0)	421,576	422,253	677
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	33,731,740	33,738,037	6,297
Insurance Claims & Indemnities (42.0)	0	0	0
Interest & Dividends (43.0)	436	440	5
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$47,652,438**	**$48,825,602**	**$1,173,164**
Total Budget Authority	**$47,682,968**	**$49,066,980**	**$1,384,012**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Program Evaluation financing, and supplemental appropriations.

SALARIES AND EXPENSES

FY 2024 Budget Authority by Object Class Including Type I Diabetes Funds[1]
Salaries and Expenses / Administrative Expenses

(Dollars in Thousands)[1]

Object Classes	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel Compensation			
Full-Time Permanent (11.1)	$1,332,077	$1,436,174	$104,097
Other Than Full-Time Permanent (11.3)	647,853	691,039	43,186
Other Personnel Compensation (11.5)	81,135	86,349	5,214
Military Personnel (11.7)	18,723	19,756	1,033
Special Personnel Services Payments (11.8)	237,756	250,798	13,042
Subtotal Personnel Compensation (11.9)	**$2,317,544**	**$2,484,117**	**$166,573**
Civilian Personnel Benefits (12.1)	773,523	829,955	56,432
Military Personnel Benefits (12.2)	4,623	4,890	266
Benefits to Former Personnel (13.0)	0	0	0
Total Pay Costs	**$3,095,691**	**$3,318,961**	**$223,271**
Travel & Transportation of Persons (21.0)	41,250	42,063	812
Transportation of Things (22.0)	7,880	7,975	95
Rental Payments to Others (23.2)	8,364	8,562	198
Communications, Utilities & Misc. Charges (23.3)	266,293	273,520	7,227
Printing & Reproduction (24.0)	292	279	-13
Other Contractual Services:			
Consultant Services (25.1)[2]	1,252,085	1,270,122	18,037
Other Services (25.2)	1,791,925	1,792,141	216
Purchase of goods and services from government accounts (25.3)[2]	2,203,960	2,287,259	83,299
Operation & Maintenance of Facilities (25.4)[2]	35,283	35,726	443
Operation & Maintenance of Equipment (25.7)	185,144	182,144	-3,000
Subsistence & Support of Persons (25.8)	3	3	0
Subtotal Other Contractual Services	**$5,468,400**	**$5,567,395**	**$98,994**
Supplies & Materials (26.0)	249,992	243,752	-6,240
Subtotal Non-Pay Costs	**$6,042,472**	**$6,143,545**	**$101,073**
Total Salaries and Expense / Administrative Costs	**$9,138,163**	**$9,462,507**	**$324,344**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Program Evaluation financing, and supplemental appropriations.

[2] Excludes obligations from accounts (OC 25.1, 25.3 and 25.4) supporting Program Evaluations and Inter-agency Agreements related to the Research and Development Contracts mechanism.

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE)

Institutes and Centers	FY 2022 Actual	FY 2023 Estimate	FY 2024 Estimate
NCI	3,182	3,320	3,468
NHLBI	899	966	966
NIDCR	239	252	252
NIDDK	685	706	756
NINDS	601	632	707
NIAID	2,099	2,180	2,180
NIGMS	185	209	219
NICHD	538	602	602
NEI	286	290	290
NIEHS	638	685	685
NIA	518	600	650
NIAMS	233	242	250
NIDCD	130	140	140
NIMH	579	589	597
NIDA	396	398	416
NIAAA	206	238	238
NINR	82	111	111
NHGRI	352	385	385
NIBIB	106	129	160
FIC	57	61	61
NIMHD	80	210	210
NCCIH	86	100	110
NCATS	262	298	298
NLM	654	741	741
OD	1,059	1,162	1,225
ARPA-H	---	135	152
Central Services:			
OD - CS	843	870	911
CC	1,815	2,035	2,035
CSR	451	464	510
CIT	207	247	247
ORS	495	539	541
ORF	726	830	830
Subtotal Central Services[1]	**4,537**	**4,985**	**5,074**
PHS Trust Fund (non-add)[2]	*4*	*4*	*4*
CRADA (non-add)[3]	*3*	*3*	*3*
Total	**18,689**	**20,366**	**20,943**

[1] Reflects FTE associated with Central Services positions whose payroll costs are financed from the NIH Management Fund and the NIH Service and Supply Fund.

[2] PHS Trust Fund positions are incorporated within the IC's Direct-funded civilian FTE category and are treated as non-add values.

[3] CRADA positions are distributed across multiple ICs and are treated as non-add values.

PROGRAMS PROPOSED FOR ELIMINATION

The FY 2024 request for the National Institutes of Health does not propose any programs for elimination.

PHYSICIAN'S COMPARABILITY ALLOWANCE WORKSHEET

		FY 2021 Actual	FY 2022 Actual	FY 2023 Estimate[1]	FY 2024 Estimate
1) Number of Physicians Receiving PCAs		107	94	86	86
2) Number of Physicians with One-Year PCA		6	1	1	1
3) Number of Physicians with Multi-Year PCA		101	93	85	85
4) Average Annual Physician Pay (without PCA payment)		$169,099	$172,520	$175,440	$184,300
5) Average Annual PCA Payment		$21,292	$21,996	$22,120	$23,237
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position				
	Category II Research Position	106	93	86	86
	Category III Occupational Health				
	Category IV-A Disability Evaluation				
	Category IV-B Health and Medical Admin.	1	1	0	0

7) If applicable, list and explain the necessity of any additional physician categories designated by your agency (for categories other than I through IV-B). Provide the number of PCA agreements per additional category for the PY, CY and BY.

N/A

8) Provide the maximum annual PCA amount paid to each category of physician in your agency and explain the reasoning for these amounts by category.

Maximum annual PCA amount for category II and IV-B vary based on grade level, amount of federal service and length of the PCA agreement. The monetary range is between $4,000 and $30,000. These flexible amounts are necessary to recruit and retain the caliber of physician needed to carry out the NIH mission which directly impacts the health of the nation.

9) Explain the recruitment and retention problem(s) for each category of physician in your agency (this should demonstrate that a current need continues to persist).(Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)

NIH strives to make progress recruiting and retaining qualified physicians to the Federal service. However, due to competition and more lucrative compensation in the private sector it continues to be challenging. NIH consistently has had a high turnover rate for physicians. NIH physicians require unique and specialized qualifications that make it difficult to fill vacancies.

10) Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior fiscal year. (Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)

In FY 2022, there were a total of 94 PCA recipients across NIH. In FY 2023 and beyond, as indicated by the decrease in recipients to-date relative to the prior year, the critical need continues to exist for highly qualified, specialized physicians to support the NIH mission. NIH still requires compensation flexibilities such as PCA to attract and retain qualified physicians.

11) Provide any additional information that may be useful in planning PCA staffing levels and amounts in your agency.

N/A

[1] FY 2023 data will be approved during the FY 2024 Budget cycle.

HISTORY OF OBLIGATIONS BY IC

(Dollars in Thousands)	FY 2014	FY 2015[1]	FY 2016[1]	FY 2017[1,6]	FY 2018[1,6,7]	FY 2019[1,6,8]	FY 2020[1,6,9]	FY 2021[1,6,10]	FY 2022[1,6,11]	FY 2023[1,6,12] Enacted	FY 2024[1,6,13] President's Budget
NCI	$4,932,368	$4,944,593	$5,206,169	$5,636,393	$5,948,569	$5,993,599	$6,418,988	$6,558,695	$6,901,989	$7,518,872	$7,820,159
NHLBI	$2,988,415	$2,995,546	$3,109,062	$3,209,843	$3,374,154	$3,482,237	$3,624,863	$3,653,569	$3,810,306	$3,985,158	$3,985,158
NIDCR	$397,833	$397,672	$412,788	$424,782	$446,656	$460,613	$477,644	$483,360	$501,183	$520,138	$520,138
NIDDK[2]	$1,884,377	$1,899,088	$1,963,738	$2,009,448	$1,989,700	$2,099,265	$2,220,977	$2,229,148	$2,326,434	$2,757,617	$2,553,098
NINDS	$1,588,899	$1,604,581	$1,692,830	$1,778,684	$1,949,067	$2,413,897	$2,443,099	$2,490,566	$2,595,418	$2,842,538	$2,825,418
NIAID	$4,401,185	$4,417,529	$4,749,884	$4,905,708	$5,262,398	$5,567,138	$5,880,084	$6,049,416	$6,322,105	$6,561,652	$6,561,652
NIGMS[3]	$2,366,429	$2,372,199	$2,508,868	$2,646,059	$2,780,954	$2,821,806	$2,937,142	$2,986,188	$3,092,310	$3,239,679	$3,239,679
NICHD	$1,283,314	$1,286,797	$1,338,280	$1,376,541	$1,449,613	$1,508,603	$1,556,841	$1,588,125	$1,681,161	$1,747,784	$1,747,784
NEI	$675,551	$676,726	$707,002	$731,203	$770,483	$793,767	$823,310	$832,967	$863,732	$896,136	$896,136
NIEHS[4]	$743,002	$745,533	$769,730	$789,860	$826,646	$850,793	$883,808	$893,521	$924,505	$996,842	$1,021,842
NIA	$1,171,656	$1,197,459	$1,596,005	$2,048,792	$2,571,438	$3,080,043	$3,545,814	$3,888,190	$4,222,568	$4,412,090	$4,412,090
NIAMS	$520,314	$521,480	$540,874	$556,568	$585,240	$602,907	$624,832	$632,353	$657,843	$687,639	$687,639
NIDCD	$404,237	$405,168	$422,311	$435,877	$458,876	$472,988	$490,687	$496,574	$514,876	$534,330	$534,330
NIMH	$1,419,632	$1,433,603	$1,516,325	$1,604,624	$1,754,423	$1,869,653	$2,044,852	$2,100,178	$2,214,181	$2,351,923	$2,541,653
NIDA	$1,017,957	$1,015,695	$1,048,971	$1,070,813	$1,161,149	$1,621,334	$1,457,683	$1,475,805	$1,596,069	$1,663,365	$1,663,365
NIAAA	$446,282	$447,152	$466,713	$482,449	$508,398	$525,282	$546,691	$553,201	$574,877	$596,616	$596,616
NINR	$140,553	$140,837	$145,701	$149,930	$157,633	$163,165	$172,342	$174,407	$180,831	$197,671	$197,671
NHGRI	$498,076	$498,648	$512,486	$528,316	$556,741	$575,361	$604,083	$614,131	$636,434	$660,510	$660,510
NIBIB	$326,989	$327,223	$342,997	$356,971	$376,700	$388,079	$404,616	$409,461	$424,559	$440,625	$440,625
NIMHD	$268,439	$270,480	$280,264	$287,640	$304,372	$313,195	$335,799	$389,453	$459,262	$525,138	$525,138
NCCIH	$124,368	$124,046	$129,760	$134,373	$141,667	$145,933	$151,871	$153,601	$159,277	$170,277	$170,277
NCATS	$633,571	$632,629	$684,366	$704,248	$754,080	$847,430	$832,856	$852,792	$882,240	$923,323	$923,323
FIC	$67,575	$67,576	$69,996	$71,813	$75,534	$77,894	$80,811	$83,752	$86,843	$95,130	$95,130
NLM[5]	$334,383	$336,653	$393,074	$406,250	$424,789	$441,645	$456,584	$460,083	$477,093	$495,314	$495,314
ORIP	$294,486	$294,662	$295,783	$279,130	$289,205	$288,096	$293,970	$299,884	$304,485	$309,393	$309,393
Common Fund	$531,146	$545,607	$675,628	$695,430	$600,707	$619,166	$639,111	$648,538	$670,001	$735,001	$735,001
OD - Other	$477,293	$573,328	$599,263	$714,058	$1,016,632	$1,185,155	$1,467,130	$1,560,407	$1,826,352	$2,068,260	$2,088,985
B&F	$88,880	$123,464	$79,883	$113,415	$106,434	$211,107	$108,709	$179,715	$376,452	$350,000	$350,000
ARPA-H	---	---	---	---	---	---	---	---	$43,981	$2,456,019	$2,500,000
Total, NIH Program Level	**$30,027,205**	**$30,295,974**	**$32,258,751**	**$34,149,217**	**$36,642,258**	**$39,420,151**	**$41,525,195**	**$42,738,079**	**$45,327,367**	**$50,739,040**	**$51,098,124**
Less funds allocated from different sources:											
Mandatory - Special type 1 Diabetes Research	-$139,200	-$150,000	-$150,000	-$139,650	-$26,292	-$73,923	-$105,893	-$103,778	-$120,259	-$454,519	-$250,000
PHS Program Evaluation	-$8,200	-$715,000	-$780,000	-$824,443	-$922,871	-$1,146,821	-$1,230,821	-$1,271,505	-$1,309,313	-$1,412,482	-$1,948,109
Total, NIH Discretionary Budget Authority	**$29,879,805**	**$29,430,974**	**$31,328,751**	**$33,185,124**	**$35,693,095**	**$38,199,407**	**$40,188,481**	**$41,362,796**	**$43,897,795**	**$48,872,039**	**$48,900,015**
Interior Budget Authority	-$77,345	-$77,349	-$77,252	-$77,337	-$77,342	-$78,988	-$80,993	-$81,488	$82,533	-$83,035	-$83,035
Total, NIH Labor/HHS Budget Authority	**$29,802,460**	**$29,353,625**	**$31,251,499**	**$33,107,787**	**$33,021,788**	**$38,120,419**	**$40,107,488**	**$41,281,308**	**$43,980,328**	**$48,789,004**	**$48,816,980**

[1] Excludes Ebola, Zika and other supplemental funding or transfers.

[2] Includes Special type 1 Diabetes Research mandatory account funding. Obligations for FY 2021 and prior years can include amounts from carryover.

[3] Includes Program Evaluation Financing resources of $715,000,000 in FY 2015, $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, $1,230,821,000 in FY 2020, and $1,271,505,000 in each year for FY 2021 through FY 2023.

[4] Includes Interior Appropriation allocation for Superfund Research activities.

[5] Includes PHS Program Evaluation financing of $8,200,000 for years before FY 2015.

[6] Includes funds under the 21st Century Cures Act.

[7] Includes obligations of $60,647,563 of 21st Century Cures carryover from FY 2017.

[8] Includes obligations of $429,883,740 of FY 2018 Opioids carryover in various ICs and $42,852,637 of 21st Century Cures carryover from FY 2017 and FY 2018 in various ICs and $415,197 of T1D carryover.

[9] Includes CURES carryover obligations of $230,278,992

[10] Includes obligations of $167,738,493 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2020, but carried over into FY 2021. Similarly, includes obligations of $83,955,593 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2020, but carried over into FY 2021. Obligations of carryover funding are distributed by mechanism.

[11] Includes obligations of $140,739,124 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2021, but carried over into FY 2022. Similarly, includes obligations of $87,348,076 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2021, but carried over into FY 2022.

[12] Includes obligations of $291,466,868 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2022, but carried over into FY 2023. Similarly, includes obligations of $313,069,191 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2022, but carried over into FY 2023, and obligations of $956,019,428 of FY 2022 ARPA-H funding carried over into FY 2023.

[13] Amounts represent estimated or requested budget authority as opposed to obligations displayed in historical years.

HISTORY OF OBLIGATIONS BY TOTAL MECHANISM

(Dollars in Thousands)[1]	FY 2014 Actual	FY 2015 Actual [4]	FY 2016 Actual [4]	FY 2017 Actual [4]	FY 2018 Actual [4,5]	FY 2019 Actual [4,6]	FY 2020 Actual [4,7]	FY 2021 Actual [4,8]	FY 2022 Actual [4,9]	FY 2023 Enacted [4,10]	FY 2024 President's Budget [4,11]
Research Project Grants	$16,168,246	$16,441,843	$17,839,691	$19,105,304	$20,756,893	$22,493,313	$23,744,187	$24,308,561	$25,400,428	$27,211,896	$27,089,942
Research Centers	$2,723,203	$2,663,064	$2,573,774	$2,536,308	$2,581,750	$2,680,161	$2,713,731	$2,761,258	$2,846,083	$2,926,695	$2,921,580
Other Research	$1,846,841	$1,802,719	$2,019,736	$2,181,261	$2,371,164	$2,698,036	$2,753,289	$2,894,236	$3,070,369	$3,373,062	$3,489,145
Subtotal, Research Grants	**$20,738,290**	**$20,907,625**	**$22,433,201**	**$23,822,873**	**$25,709,807**	**$27,871,510**	**$29,211,207**	**$29,964,055**	**$31,316,880**	**$33,511,653**	**$33,500,667**
Research Training	$738,429	$758,017	$803,869	$827,397	$855,844	$865,305	$907,010	$926,485	$967,125	$1,034,240	$1,050,644
R & D Contracts	$2,990,037	$2,826,971	$2,913,224	$3,046,759	$3,072,406	$3,124,750	$3,283,765	$3,363,105	$3,700,244	$3,877,568	$3,946,840
Intramural Research	$3,373,601	$3,409,362	$3,682,831	$3,780,181	$3,972,054	$4,179,250	$4,462,022	$4,583,901	$4,824,139	$5,023,065	$5,056,584
Res. Mgt. & Support	$1,527,131	$1,619,784	$1,653,230	$1,747,406	$1,813,738	$1,886,087	$1,974,360	$2,048,924	$2,159,662	$2,305,200	$2,491,369
Office of the Director[2]	$477,293	$573,328	$599,263	$701,864	$1,016,633	$1,185,155	$1,467,130	$1,560,407	$1,826,352	$2,068,260	$2,088,985
Subtotal	**$29,844,781**	**$30,095,088**	**$32,085,618**	**$33,928,465**	**$36,440,482**	**$39,112,057**	**$41,305,493**	**$42,446,877**	**$44,794,402**	**$47,819,986**	**$48,135,089**
Buildings & Facilities[3]	$96,880	$123,464	$95,883	$143,415	$124,434	$229,107	$138,709	$209,715	$406,452	$380,000	$380,000
Interior- Superfund	$77,345	$77,332	$77,252	$77,337	$77,342	$78,988	$80,993	$81,488	$82,533	$83,035	$83,035
ARPA-H	---	---	---	---	---	---	---	---	$43,981	$2,456,019	$2,500,000
Total	**$30,019,005**	**$30,295,884**	**$32,258,753**	**$34,149,217**	**$36,642,258**	**$39,420,151**	**$41,525,195**	**$42,738,079**	**$45,327,368**	**$50,739,040**	**$51,098,124**

[1] Obligations for actual years exclude lapse. Amounts for all years include Special Type 1 Diabetes. All Subtotal and Total numbers may not add due to rounding. FY 2017 through FY 2021 includes 21st Century Cures Act funding. All years exclude Ebola-related and supplemental funding.

[2] Excludes obligations for the Common Fund and the Office of Research Infrastructure Programs, which are distributed by mechanism.

[3] Includes B&F appropriation and monies allocated ($18,000,000 in FY 2018, $18,000,000 in FY 2019, $30,000,000 in FY 2020, and $30,000,000 in each of FY 2021 through FY2023) pursuant to appropriations acts provisions that funding may be used for facilities repairs and improvements at the NCI Federally funded Research and Development Center in Frederick, Maryland.

[4] Includes Program Evaluation Financing resources of $715,000,000 in FY 2015, $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, $1,230,821,000 in FY 2020, and $1,271,505,000 in each year for FY 2021 through FY 2023.

[5] Includes obligations of $60,647,563 of 21st Century Cures Act funding which was appropriated in FY 2017, but carried over into FY 2018.

[6] Includes obligations of $42,852,637 of 21st Century Cures Act funding which was appropriated in FY 2017 and FY 2018, but carried over into FY 2019. Similarly, includes $429,883,740 of Opioids funding and $415,917 of Type 1 Diabetes funding carried over from FY 2018.

[7] Includes obligations of $230,278,992 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2019, but carried over into FY 2020. Similarly, includes $200,200,850 of Type 1 Diabetes funding carried over from FY 2018 and FY 2019.

[8] Includes obligations of $167,738,493 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2020, but carried over into FY 2021. Similarly, includes obligations of $83,955,593 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2020, but carried over into FY 2021.

[9] Includes obligations of $140,739,124 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2021, but carried over into FY 2022. Similarly, includes obligations of $87,348,076 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2021, but carried over into FY 2022.

[10] Includes obligations of $291,466,868 of 21st Century Cures Act funding which was appropriated in FY 2017 through FY 2022, but carried over into FY 2023. Similarly, includes obligations of $313,069,191 for Special Type 1 Diabetes research program using available funding from FY 2018 through FY 2022, but carried over into FY 2023, and obligations of $956,019,428 of FY 2022 ARPA-H funding carried over into FY 2023.

[11] FY 2024 figures are based on requested budget authority.

STATISTICAL DATA: DIRECT AND INDIRECT COSTS AWARDED

(Dollars in Thousands)	Direct Cost Awarded	Indirect Cost Awarded	Percent of Total		Percent Change	
			Direct Cost Awarded	Indirect Cost Awarded	Direct Cost Awarded	Indirect Cost Awarded
FY 2012	$15,978,032	$6,182,900	72.1%	27.9%	0.8%	0.2%
FY 2013	$14,915,599	$5,755,617	72.2%	27.8%	-6.7%	-6.9%
FY 2014	$15,568,553	$5,908,275	72.5%	27.5%	4.4%	2.7%
FY 2015	$15,645,282	$6,020,843	72.2%	27.8%	0.5%	1.9%
FY 2016	$16,791,158	$6,445,133	72.3%	27.7%	7.3%	7.1%
FY 2017[1]	$17,799,515	$6,838,801	72.2%	27.8%	6.0%	6.1%
FY 2018[1]	$19,599,758	$7,481,452	72.4%	27.6%	10.1%	9.4%
FY 2019[1]	$20,544,931	$7,953,747	72.1%	27.9%	4.8%	6.3%
FY 2020[1]	$21,765,222	$8,406,459	72.2%	27.8%	5.9%	5.7%
FY 2021[1]	$22,363,606	$8,620,853	72.2%	27.8%	2.8%	2.6%
FY 2022 Final[1,a]	$23,352,941	$8,993,865	72.2%	27.8%	4.4%	4.3%
FY 2023 Enacted[1,a]	$24,591,138	$9,456,900	72.2%	27.8%	5.3%	5.2%
FY 2024 President's Budget[1,a]	$24,982,903	$9,568,408	72.3%	27.7%	1.6%	1.2%

Note: Data for fiscal years 2023 and later represent estimates and will change as actual data are received.

[1] Includes 21st Century Cures Act funding.

[2] Figures reflect BA carried over into later years.

RPGS – TOTAL NUMBER OF AWARDS AND FUNDING

(Dollars in Thousands)	FY 2014	FY 2015	FY 2016	FY 2017 Actual[1]	FY 2018 Actual[1]	FY 2019 Actual[1]	FY 2020 Actual[1]	FY 2021 Actual[1]	FY 2022 Final[1,a]	FY 2023 Enacted[1,a]	FY 2024 President's Budget[1,a]
No. of Awards:											
Competing	9,168	9,540	10,364	10,123	11,116	11,020	11,373	11,258	11,333	10,961	10,414
Noncompeting	23,504	23,261	23,528	24,638	25,780	27,624	28,366	28,492	29,423	30,768	32,055
Subtotal	32,672	32,801	33,892	34,761	36,896	38,644	39,739	39,750	40,756	41,729	42,469
SBIR/STTR	1,660	1,578	1,689	1,807	2,034	2,023	1,832	1,863	1,840	1,891	1,941
Total	**34,332**	**34,379**	**35,581**	**36,568**	**38,930**	**40,667**	**41,571**	**41,613**	**42,596**	**43,620**	**44,410**
Average Annual Cost:											
Competing RPGs	$489	$452	$484	$522	$527	$573	$559	$599	$588	$602	$581
Total RPGs[X]	474	479	502	523	546	552	571	583	594	613	608
Percent Change in Average Cost from Prior Year[Y]											
Competing RPGs	17.0%	-7.5%	7.2%	7.8%	1.0%	8.7%	-2.4%	7.2%	-1.8%	2.3%	-3.5%
Total RPGs[X]	6.7%	1.2%	4.8%	4.0%	4.4%	1.1%	3.5%	2.1%	2.0%	3.1%	-0.7%
Average Length of Award in Years	**3.5**	**3.5**	**3.6**	**3.6**	**3.6**	**3.6**	**3.6**	**3.6**	**3.6**	**3.6**	**3.6**

NOTE: Includes awards supported by the Common Fund program (for all years) and the Type 1 Diabetes mandatory account.

[X] Includes Noncompeting RPGs and Administrative Supplements. Excludes SBIR/STTR awards.

[Y] Based on average costs in whole dollars.

[1] Includes 21st Century Cures Act funding.

[a] Figures do not include any awards or funding related to ARPA-H.

RPGS – SUCCESS RATES

INSTITUTES & CENTERS[+,1,2]	FY 2015	FY 2016	FY 2017 Final[6]	FY 2018 Final[6]	FY 2019 Final[6]	FY 2020 Final[6]	FY 2021 Final[6]	FY 2022 Final[6,a]	FY 2023 Enacted[6,a]	FY 2024 President's Budget[6,a]
NCI	13.0%	12.0%	11.7%	11.3%	11.9%	12.9%	13.8%	15.4%	16.8%	16.7%
NHLBI	21.9%	24.2%	23.5%	25.1%	22.3%	22.2%	20.5%	21.3%	21.7%	20.8%
NIDCR	22.0%	19.9%	17.8%	22.2%	23.8%	21.7%	21.8%	21.0%	19.7%	16.4%
NIDDK	20.3%	20.1%	17.8%	21.6%	20.3%	24.4%	22.7%	22.1%	23.6%	20.5%
NINDS	20.5%	19.8%	17.7%	22.4%	20.4%	23.7%	20.2%	22.1%	18.6%	20.4%
NIAID	21.5%	23.8%	19.1%	22.9%	22.1%	23.9%	17.5%	17.3%	19.6%	18.6%
NIGMS	29.6%	29.6%	30.6%	29.2%	32.6%	32.3%	33.4%	35.8%	34.6%	26.4%
NICHD	11.5%	13.2%	16.1%	18.4%	19.5%	18.0%	18.4%	17.3%	18.0%	17.3%
NEI	21.4%	25.7%	24.9%	26.7%	28.4%	29.6%	24.8%	25.6%	22.1%	21.5%
NIEHS	14.7%	14.2%	15.0%	17.1%	14.8%	14.2%	14.4%	16.7%	17.6%	17.3%
NIA	17.7%	22.8%	26.6%	28.9%	29.2%	25.8%	24.2%	25.3%	17.3%	14.3%
NIAMS	16.7%	16.0%	17.0%	16.7%	17.1%	18.0%	17.6%	18.4%	13.8%	13.6%
NIDCD	24.9%	26.7%	24.4%	27.1%	25.2%	24.2%	24.0%	25.0%	25.3%	24.9%
NIMH	20.4%	22.9%	20.9%	22.2%	24.8%	22.5%	22.1%	24.3%	22.0%	28.7%
NIDA	19.6%	15.4%	19.7%	19.4%	17.5%	16.9%	14.7%	19.4%	14.8%	12.4%
NIAAA	16.4%	18.8%	22.0%	26.7%	20.9%	21.4%	17.1%	27.1%	28.9%	23.2%
NINR	8.0%	9.0%	8.9%	10.3%	9.3%	10.8%	12.6%	15.4%	18.0%	17.9%
NHGRI	18.8%	25.6%	23.9%	28.0%	19.2%	21.8%	24.7%	25.1%	20.7%	19.9%
NIBIB	12.0%	14.6%	13.0%	16.8%	18.3%	19.8%	17.2%	21.5%	19.5%	19.4%
NIMHD	13.7%	19.3%	21.5%	10.7%	7.5%	7.9%	11.2%	17.2%	15.5%	8.5%
NCCIH[3]	10.8%	13.9%	16.7%	20.3%	12.5%	11.6%	11.1%	14.8%	12.3%	11.6%
NCATS[4]	66.7%	27.7%	21.8%	36.4%	20.7%	25.2%	14.7%	20.4%	28.4%	17.2%
FIC	9.7%	29.5%	10.8%	19.5%	20.6%	19.7%	13.8%	20.9%	22.1%	11.0%
NLM	19.8%	13.0%	14.9%	17.7%	18.4%	13.4%	11.9%	15.3%	17.6%	13.8%
ORIP & SEPA[5]	21.5%	18.8%	16.5%	17.8%	34.2%	29.6%	25.9%	27.1%	37.5%	37.5%
Common Fund	12.1%	12.6%	11.8%	10.9%	11.0%	9.5%	8.8%	11.8%	14.9%	12.3%
NIH	18.3%	19.1%	18.7%	20.3%	20.1%	20.7%	19.1%	20.8%	19.9%	18.6%

[+] Success Rates identified in FY 2023 and beyond are estimates, and will change as applications are received and selected for funding.

[1] Application success rates represent the percentage of applications that are awarded during the fiscal year.

[2] Includes Special type 1 Diabetes Research program administered by NIDDK. Excludes NIEHS Superfund Research and OD Other awards.

[3] The National Center for Complementary and Alternative Medicine (NCCAM) was renamed in December 2014 to the National Center for Complementary and Integrative Health (NCCIH).

[4] The National Center for Advancing Translational Sciences (NCATS) was established concurrent with the dissolution of National Center for Research Resources (NCRR) effective FY 2012.

[5] The SEPA program transitioned to NIGMS in FY 2017 from the NIH Office of Research Infrastructure Programs (ORIP).

[6] Includes 21st Century Cures Act funding.

[a] Figures do not include any awards related to ARPA-H.

TOTAL R01 EQUIVALENT DATA FOR FIRST TIME AND ESTABLISHED INVESTIGATORS

R01 Equivalent Grants[1,2,3,4]	FY 2022 Final[5,a]	FY 2023 Enacted[5,a]	FY 2024 President's Budget[5,a]
Applications			
Received	36,199	36,745	37,737
Funded	**7,832**	**7,575**	**7,234**
Total Investigators			
Received	33,178	33,674	34,880
Funded	**9,828**	**9,641**	**9,329**
Established Investigators			
Received	20,493	20,644	21,348
Funded	**6,948**	**6,794**	**6,563**
First-time Investigators			
Received	12,685	13,030	13,532
Funded	**2,880**	**2,847**	**2,766**

[1] R01 Equivalent Grants form a subset of all RPG awards. In FY 2022 they comprised roughly 69% of Funded Applications, 72% of Funded Total Investigators, 76% of Funded Established Investigators and 60% of Funded First-time Applicants. The year-to-year variation of these figures is about 2%, plus or minus.

[2] The ratio of total and funded applicants to applications and the proportion of total and funded first-time applicants are based on linear extrapolation of five years of the latest actual data.

[3] Excludes applications and awards associated with reimbursable agreements and Superfund Research account.

[4] Estimates for received applications reflect consolidations of Institute/Center validated refinements to linear extrapolation of five years of latest actual data. Funded application figures reflect the annual estimate identified in the New/Competing RPG line of mechanism budget table.

[5] Includes 21st Century Cures Act funding.

[a] Figures do not include any awards related to ARPA-H.

COMPETING RPGS BY LENGTH OF AWARD

(Dollars in Thousands)	FY 2022 Final[1,a]		FY 2023 Enacted[1,a]		FY 2024 President's Budget[1,a]	
	No.	Amount	No.	Amount	No.	Amount
Competing RPGs:[x]						
One-Year Awards.....	1,500	$1,496,211	1,367	$1,460,665	1,299	$1,338,540
Two-Year Awards.....	2,240	$483,359	2,345	$539,845	2,228	$494,709
Three-Year Awards.....	526	$257,360	480	$270,557	456	$247,936
Four-Year Awards.....	1,823	$1,027,098	1,829	$1,057,574	1,738	$969,151
Five or More Year Awards.....	5,244	$3,404,911	4,940	$3,270,529	4,693	$2,997,083
Total Competing RPGs.....	11,333	$6,668,939	10,961	$6,599,170	10,414	$6,047,419

[x] The distribution of awards with durations of 1, 2, 3, 4 and 5+ years is based on historical data.

[1] Includes 21st Century Cures Act funding.

[a] Figures do not include any awards or funding related to ARPA-H.

NON-COMPETING COMMITMENTS

(Dollars in Thousands)	FY 2022 Final[4,5]	FY 2023 Enacted[4,5]	FY 2024 President's Budget[4,5]
Research Project Grants (RPGs)			
Noncompeting:			
Number	29,423	30,768	32,055
Amount	$17,056,649	$18,487,622	$19,393,431
Administrative Supp	$494,802	$476,969	$385,306
Competing:			
Number	11,333	10,961	10,414
Amount	$6,668,939	$6,599,170	$6,047,419
SBIR/STTR:			
Number	1,840	1,891	1,941
Noncompeting	951	725	806
Amount[1]	$1,202,743	$1,242,315	$1,263,786
Noncompeting	$621,515	$476,076	$524,896
Subtotal, RPGs:			
Number	42,596	43,620	44,410
Amount	$25,423,133	$26,806,076	$27,089,942
Research Centers:			
Number	1,230	1,280	1,302
Noncompeting	970	1,032	1,042
Amount	$2,846,455	$2,909,362	$2,921,580
Noncompeting	$2,245,896	$2,346,788	$2,338,272
Other Research:			
Number	8,082	8,384	8,457
Noncompeting	6,342	6,356	6,673
Amount	$3,110,215	$3,298,628	$3,489,145
Noncompeting	$2,440,655	$2,500,708	$2,753,217
Training:			
FTTPs	17,405	18,325	18,148
Noncompeting	13,249	13,619	14,347
Amount	$967,003	$1,033,972	$1,050,644
Noncompeting	$736,083	$768,443	$830,586
Total Extramural Research[2]	**$32,346,806**	**$34,048,038**	**$34,551,311**
Noncompeting Number/FTTPs	50,935	52,500	54,923
Competing Number/FTTPs	18,378	19,109	17,394
Noncompeting Amount	$23,595,600	$25,056,606	$26,225,708
Competing Amount	$8,751,206	$8,991,432	$8,325,603
Total Percent Change	**4.4%**	**5.3%**	**1.5%**
Total Discretionary Budget Authority[3]	**$45,036,540**	**$47,537,035**	**$48,348,124**
Percent Change	**5.6%**	**5.6%**	**1.7%**

[1] The 3.65% combined SBIR/STTR program threshold is achieved in FY 2022 and sustained in subsequent years.

[2] Includes both grants and FTTPs for Noncompeting and Competing figures.

[3] Includes Labor/HHS appropriations, the Interior Superfund Research account, 21st Century Cures Act funding, as well as Program Evaluation financing resources. Excludes ARPA-H and mandatory accounts such as Type 1 Diabetes.

[4] Includes 21st Century Cures Act funding.

[5] Figures do not include any awards or funding related to ARPA-H.

MF GENERAL STATEMENT

The NIH Management Fund (MF) was established on June 29, 1957, by Public Law 85-67. The MF was created to finance a variety of centralized support services and administrative activities that are required for the efficient and effective operation of all NIH programs and facilities. The services provided by the MF include a research hospital and outpatient clinic; receipt, review and referral of research and training grant applications, and general administrative support services. The MF is financed through offsetting collections from the NIH Institutes and Centers representing charges for services provided. Funds credited to the NIH Management Fund remain available for one fiscal year after the fiscal year in which they are deposited.

MF BUDGET AUTHORITY BY ACTIVITY

Budget Authority by Activity
(Dollars in Thousands)

Extramural Research	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023 Enacted	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Detail								
Clinical Center	1,815	$676,215	2,035	$700,750	2,035	$718,269	0	$17,519
Center for Scientific Review, SREA	451	$138,891	464	$142,563	510	$146,127	46	$3,564
Office of Research Services, and Administrative services, support	0	$7,639	0	$0	0	$0	0	$0
TOTAL	**2,266**	**$822,745**	**2,499**	**$843,313**	**2,545**	**$864,396**	**46**	**$21,083**

MF BUDGET AUTHORITY BY OBJECT CLASS

Budget Authority by Object Class [1]

(Dollars in Thousands)

		FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Total compensable workyears:				
	Full-time equivalent	2,499	2,545	46
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$214	$225	$11
	Average GM/GS grade	11.6	11.6	0.0
	Average GM/GS salary	$121	$127	$6
	Average salary, Commissioned Corps (42 U.S.C. 207)	$113	$118	$6
	Average salary of ungraded positions	$123	$129	$6
OBJECT CLASSES		**FY 2023 Enacted**	**FY 2024 President's Budget**	**FY 2024 +/- FY 2023**
	Personnel Compensation			
11.1	Full-Time Permanent	215,146	226,839	11,693
11.3	Other Than Full-Time Permanent	41,194	43,432	2,238
11.5	Other Personnel Compensation	27,199	28,677	1,478
11.7	Military Personnel	8,397	8,853	456
11.8	Special Personnel Services Payments	7,374	7,775	401
11.9	**Subtotal Personnel Compensation**	**299,309**	**315,577**	**16,268**
12.1	Civilian Personnel Benefits	99,344	104,301	4,957
12.2	Military Personnel Benefits	730	770	40
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**399,384**	**420,647**	**21,263**
21.0	Travel & Transportation of Persons	1,431	1,432	1
22.0	Transportation of Things	717	717	0
23.1	Rental Payments to GSA	48	48	0
23.2	Rental Payments to Others	274	274	0
23.3	Communications, Utilities & Misc. Charges	3,441	3,441	0
24.0	Printing & Reproduction	10	10	0
25.1	Consulting Services	22,631	22,631	0
25.2	Other Services	110,772	110,808	36
25.3	Purchase of Goods and Services from Government Accounts	76,125	76,154	29
25.4	Operation & Maintenance of Facilities	7,702	7,703	1
25.5	R&D Contracts	427	427	0
25.6	Medical Care	30,256	30,005	-251
25.7	Operation & Maintenance of Equipment	36,694	36,695	1
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**284,607**	**284,423**	**-184**
26.0	Supplies & Materials	125,379	125,380	0
31.0	Equipment	24,884	24,884	0
32.0	Land and Structures	3,135	3,135	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	0	0	0
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	7	7	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**443,933**	**443,751**	**-182**
	Total Budget Authority by Object Class	**843,313**	**864,396**	**21,083**

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

MF DETAIL OF POSITIONS

GRADE	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	$203,700	$213,600	$224,707
GM/GS-15	125	132	132
GM/GS-14	338	358	358
GM/GS-13	364	404	404
GS-12	515	581	581
GS-11	381	430	430
GS-10	33	37	37
GS-9	85	95	95
GS-8	67	72	72
GS-7	142	165	165
GS-6	53	56	56
GS-5	13	13	13
GS-4	5	6	6
GS-3	6	7	7
GS-2	3	3	3
GS-1	0	0	0
Subtotal	2,130	2,359	2,359
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	14	14	14
Senior Grade	11	11	11
Full Grade	9	9	9
Senior Assistant Grade	14	14	14
Assistant Grade	0	0	0
Subtotal	48	48	48
Ungraded	239	238	238
Total permanent positions	2,142	2,371	2,371
Total positions, end of year	2,418	2,646	2,646
Total full-time equivalent (FTE) employment, end of year	2,266	2,499	2,545
Average ES salary	203,700	213,600	224,707
Average GM/GS grade	11.6	11.6	11.6
Average GM/GS salary	115,359	120,666	126,940

SSF GENERAL STATEMENT

The NIH Service and Supply Fund (SSF) was established on July 3, 1945, under 42 U.S.C. 231. The SSF was created to finance a variety of centralized research support services and administrative activities that are required for the efficient and effective operation of all NIH programs and facilities. The SSF provides a single means for consolidating the financing and accounting of business-type operations, including the sales of services and commodities to customers. The services provided through the SSF include mainframe computing, enterprise IT software planning and development, facilities engineering, planning, and design, facility use and maintenance including leased buildings, printing, telecommunications, procurement, shipping and receiving, motor pool, research animals, fabrication and maintenance of scientific equipment, utilities and plant maintenance, finance and accounting operations, government-wide contracting for IT, biomedical engineering, security, consolidated human resources, collaborative computer science research and other administrative support services. The SSF is financed through offsetting collections from the NIH Institutes and Centers representing charges for goods and services provided.

SSF BUDGET AUTHORITY BY ACTIVITY

Budget Authority by Activity
(Dollars in Thousands)

Extramural Research	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023 Enacted	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Detail								
Research Support and Administrative, OD, CC-CIF, ORS	1,338	$1,926,989	1,409	$1,948,186	1,452	$1,969,616	43	$21,430
Office of Research Facilities, Development & Operations	726	$580,785	830	$587,177	830	$593,635	0	$6,459
Center for Information Technology	207	$465,917	247	$471,042	247	$476,223	0	$5,181
TOTAL	**2,271**	**$2,973,690**	**2,486**	**$3,006,404**	**2,529**	**$3,039,475**	**43**	**$33,070**

SSF BUDGET AUTHORITY BY OBJECT

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

		FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Total compensable workyears:				
	Full-time equivalent	2,486	2,529	43
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$209	$220	$11
	Average GM/GS grade	12.1	12.1	0
	Average GM/GS salary	$123	$130	$6
	Average salary, Commissioned Corps (42 U.S.C. 207)	$117	$123	$6
	Average salary of ungraded positions	$154	$162	$8
OBJECT CLASSES		**FY 2023 Enacted**	**FY 2024 President's Budget**	**FY 2024 +/- FY 2023**
	Personnel Compensation			
11.1	Full-Time Permanent	$252,870	$266,614	$13,744
11.3	Other Than Full-Time Permanent	$8,372	$8,827	$455
11.5	Other Personnel Compensation	$14,871	$15,680	$808
11.7	Military Personnel	$4,148	$4,374	$225
11.8	Special Personnel Services Payments	$149	$157	$8
11.9	**Subtotal Personnel Compensation**	**$280,411**	**$295,651**	**$15,240**
12.1	Civilian Personnel Benefits	$104,757	$109,983	$5,226
12.2	Military Personnel Benefits	$6	$6	$0
13.0	Benefits to Former Personnel	$0	$0	$0
	Subtotal Pay Costs	**$385,173**	**$405,640**	**$20,467**
21.0	Travel & Transportation of Persons	$1,310	$1,325	$14
22.0	Transportation of Things	$1,678	$1,696	$18
23.1	Rental Payments to GSA	$71,994	$72,786	$792
23.2	Rental Payments to Others	$64,683	$65,395	$712
23.3	Communications, Utilities & Misc. Charges	$113,645	$114,895	$1,250
24.0	Printing & Reproduction	$3	$3	$0
25.1	Consulting Services	$91,580	$92,088	$507
25.2	Other Services	$1,416,794	$1,420,929	$4,135
25.3	Purchase of Goods and Services from Government Accounts	$370,336	$372,410	$2,074
25.4	Operation & Maintenance of Facilities	$142,469	$144,036	$1,567
25.5	R&D Contracts	$720	$728	$8
25.6	Medical Care	$4,365	$4,414	$48
25.7	Operation & Maintenance of Equipment	$216,789	$217,943	$1,155
25.8	Subsistence & Support of Persons	$0	$0	$0
25.0	**Subtotal Other Contractual Services**	**$2,243,054**	**$2,252,547**	**$9,494**
26.0	Supplies & Materials	$76,316	$76,355	$39
31.0	Equipment	$34,671	$34,802	$131
32.0	Land and Structures	$13,822	$13,974	$152
33.0	Investments & Loans	$0	$0	$0
41.0	Grants, Subsidies & Contributions	$0	$0	$0
42.0	Insurance Claims & Indemnities	$0	$0	$0
43.0	Interest & Dividends	$56	$57	$1
44.0	Refunds	$0	$0	$0
	Subtotal Non-Pay Costs	**$2,621,231**	**$2,633,835**	**$12,604**
	Total Budget Authority by Object Class	**$3,006,404**	**$3,039,475**	**$33,070**

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

SSF DETAIL OF POSITIONS

GRADE	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Total, ES Positions	9	9	9
Total, ES Salary	$1,798,584	$1,882,948	$1,982,497
GM/GS-15	112	121	123
GM/GS-14	348	375	381
GM/GS-13	730	786	798
GS-12	350	377	391
GS-11	108	118	124
GS-10	11	11	11
GS-9	102	109	111
GS-8	50	54	54
GS-7	93	99	99
GS-6	10	11	11
GS-5	6	6	6
GS-4	10	10	10
GS-3	13	14	14
GS-2	5	5	5
GS-1	9	10	10
Subtotal	1,957	2,106	2,148
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	6	7	7
Senior Grade	3	3	3
Full Grade	11	11	11
Senior Assistant Grade	3	3	3
Assistant Grade	0	0	0
Subtotal	23	24	24
Ungraded	311	349	349
Total permanent positions	2,239	2,343	2,386
Total positions, end of year	2,300	2,488	2,530
Total full-time equivalent (FTE) employment, end of year	2,271	2,486	2,529
Average ES salary	199,843	209,216	220,277
Average GM/GS grade	12.1	12.1	12.1
Average GM/GS salary	117,603	123,116	129,581

IDEA DIGITAL MODERNIZATION

Modernization of the Public-Facing Digital Services – 21st Century Integrated Digital Experience Act

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are working to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied, they move on and the opportunity for impact is lost.

Modernization Efforts

In FY 2019, HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. In FY 2020, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- continuing to develop estimated costs and impact measures for achieving IDEA.

Over the next four years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

CYBERSECURITY

(Dollars in millions)

Cyber Category	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Cyber Human Capital				--
Sector Risk Management Agency (SRMA)				--
Securing Infrastructure Investments				--
Technology Ecosystems				--
Zero Trust Implementation				--
Other NIST CSF Capabilities	224.170	266.980	271.230	+4.250
Detect	25.000	42.000	42.000	--
Identity	64.000	77.000	79.000	+2.000
Protect	98.170	102.000	105.230	+3.230
Recover	10.000	17.980	17.000	-0.980
Respond	27.000	28.000	28.000	--
Total Cyber Request	**224.170**	**266.980**	**271.230**	**+4.250**

LEGISLATIVE PROPOSALS

Discretionary Legislative Proposals

Expanding the Hiring Authorities for NIH Undergraduate Scholarship Program.
In an effort to improve equity in STEM (science, technology, engineering, and math) education, the National Institutes of Health (NIH) Undergraduate Scholarship Program (UGSP) offers competitive college scholarships to students from disadvantaged backgrounds. The program offers college scholarships, up to $20,000 annually, in return for two payback obligations in the form of service to NIH under 42 CFR § 68b.7. The proposal would allow for expanding the hiring authorities that may be used to appoint awardees in the Undergraduate Scholarship Program (UGSP), allowing the use of the more appropriate Intramural Research Training Award hiring authority to appoint all scholarship awardees during the summer payback and some award recipients during the full-year payback obligation. This would allow awardees to receive benefits and support provided to other NIH public health interns and trainees, and would streamline administration of the program compared to appointing awardees using the time-consuming Title 42 employee appointment authority.

Permit the Mailing of Electronic Nicotine Delivery Systems Through the United States Postal Service for Certain Research and Public Health Purposes.
The Prevent All Cigarette Trafficking Act of 2009 (PACT Act), Public Law 111–154, codified in 18 U.S.C. 1716E, imposes certain restrictions on the mailing of cigarettes and smokeless tobacco. Title VI of Division FF of the Consolidated Appropriations Act of 2021 instructed the U.S Postal Service (USPS) to apply the same restrictions to the mailing of electronic nicotine delivery systems (ENDS). The proposal would allow the mailing of ENDS for the purposes of conducting public health research, investigations, and surveillance. This would remove restrictions that are creating serious obstacles to the ability of NIH-funded researchers to obtain consistent ENDS products and to conduct research on the factors that contribute to ENDS use and addiction, and the potential long-term health consequences of ENDS.

Mandatory Legislative Proposals

Reauthorization of the Special Statutory Funding Program for Type 1 Diabetes Research.
Codified in Section 330B of the PHS Act, this Program began in FY 1998 with a funding level of $30 million per year over 5 years. In December 2000, the Program was renewed to increase the FY 2001 and 2002 levels to $100 million and to extend the FY 2003 level at $100 million of mandatory funds. In December 2002, the Program was extended and increased to $150 million per year for FY 2004-2008. The Program has subsequently been extended multiple times at this annual level of $150 million. Most recently, the Program was extended at a level of $150 million per year for FY 2021-2023.[96] No funding will be provided after September 30, 2023, without a reauthorization. The proposal would reauthorize the NIH Special Diabetes Program for Type 1 Diabetes Research at an annual amount of $250 million in FY 2024, $260 million in FY

[96] The final FY 2023 funding level of $141.450 million for Type 1 Diabetes reflects the 5.7 percent reduction for Budget Control Act sequestration.

2025, and $270 million in FY 2026. The three-year reauthorization would facilitate planning of long-term research projects, and the reauthorized funding level would restore the lost purchasing power of the program since it was last increased to the level of $150 million in FY 2004.

Provide Outyear Funding and Enhanced Operating Authorities to the National Cancer Institute to Conduct Initiatives to Deliver Cancer Moonshot Goals.
In February 2022, President Biden announced a reignition of the Cancer Moonshot, highlighting new goals: to reduce the cancer death rate by half within 25 years to improve the lives of people with cancer and cancer survivors, and to reduce cancer health disparities. The legislative proposal extends the 21st Century Cures Act authorization through FY 2026 and would provide $1.448 billion of mandatory funding in each of FY 2025 and FY 2026 to advance Cancer Moonshot priorities, including doubling cancer clinical trial accruals and establishing a comprehensive cancer data ecosystem to accelerate the pace of cancer discovery and speed the introduction of precision oncology into clinical practice.[97] The proposal would also grant NCI three key operating authorities – Other Transactions Authority, Management and Operating Authority, and Strategic Partnership Authority – to support these Cancer Moonshot efforts.

Other Transaction (OT) Authority for Cancer Moonshot activities would enable NCI to scale up clinical trials and other National Cancer program activities to deliver Cancer Moonshot goals. Grants and contracts would remain the norm for many NCI awards, but OT Authority would enable accelerated progress toward cutting cancer deaths in half. OT Authority would permit NCI to take a more active, substantive role in managing the science of trials and would allow NCI to bring non-traditional partners, companies, and individuals into NCI's expanded and re-engineered clinical trial enterprise. This language would provide authorities similar to those available to the *All of Us* program under the 21st Century Cures Act.

Management and Operating (M&O) Authority would grant the NCI Frederick National Laboratory for Cancer (FNLCR) access to a valuable authority that other U.S. national laboratories enjoy, but FNLCR currently lacks. Unlike many of the other existing Federally Funded Research and Development Centers (FFRDCs) at national labs, the NCI FFRDC only has access to basic, limited FFRDC authorities under current law. M&O contracting, as defined by Federal Acquisition Regulations (FAR) subpart 17.6, would be especially beneficial to deliver rapid, creative solutions required for Cancer Moonshot success.

Strategic Partnership Authority would give FNLCR the flexibility to conduct research, development, commercialization, and training activities with or on behalf of other public or private research labs, allowing the labs to access the unique FNLCR facilities, services, and technical expertise to advance cancer science and Moonshot priorities. Another advantage of Strategic Partnerships is the possibility of establishing more flexible terms for intellectual property and licensing rights. This authority would include allowing NCI to accept, retain, and use funds and tangible and intangible property provided by others to support such activities. The authority also allows any funds received to support such activities to remain available until expended.

[97] For more information on the reignited Cancer Moonshot, see the NCI FY 2024 Congressional Justification.

CROSS-CUTTING NIH INITIATIVES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Cross Cutting Initiatives

FY 2024 Budget Table of Contents Page No.

INTRODUCTION

The National Institutes of Health (NIH), the Nation's premiere biomedical research agency, is tasked with guiding United States scientific research and development in an ever-changing world. The pace of research and development is continuing to move fast, and the coming years are certain to offer both new scientific opportunities and pose continued serious challenges for human health. As ever, NIH constantly strives to not only meet the current and evolving biomedical needs, but to set the standard for high caliber research and ethical conduct of science.

NIH seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. To achieve its mission, NIH invests in research programs designed to explore the causes, prevention, and treatments of human diseases and disorders; processes in healthy development and aging; and methods for collecting and disseminating data and health information. In addition, NIH Institutes, Centers, and Offices (ICOs) leverage existing strengths and resources by collaborating in innovative, creative, and multidisciplinary ways to answer complex and crucial questions about human health and disease.

NIH is made up of 27 Institutes and Centers (ICs), each with a specific research agenda and budget, often focusing on particular diseases or body systems. NIH ICs came together to address emerging scientific and clinical questions by contributing to major NIH-wide initiatives in areas such as health disparities and pain research, and by contributing to capacity building. This allows NIH ICs with comparatively smaller budgets (less than $1 billion) to have a much larger contribution to biomedical research than one might expect from the size of their budgets alone. Building strong research collaborations and partnerships across ICs requires both a diverse scientific workforce and recruitment of diverse research participants to ensure thoughtful methodology can capture the wide variety of human health needs. NIH-wide efforts continue to focus on developing and testing interventions to reduce health disparities, identifying key gaps in science related to health disparities, and promoting targeted research on appropriately tailored public health, clinical, and community preventive services in diverse settings and contexts. For example, the NIH UNITE Initiative, comprised of representatives from across all 27 NIH ICs, was established in 2021 with the goal of identifying and addressing structural racism within the NIH community and the greater biomedical research community.

To tackle some of the most complex questions facing biomedical science currently, NIH leverages crosscutting, multi-ICO initiatives and research programs which bring together diverse experts and leaders from across this and other agencies. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership involves many ICOs as well as sister agencies in the United States Department of Health and Human Services (HHS) to develop a coordinated research strategy for prioritizing and speeding development of the most promising COVID-19 treatments and vaccines. The NIH Climate Change and Health Initiative also includes multiple ICOs working together toward reducing health threats from climate change across the lifespan to build health resilience in individuals, communities, and nations around the world. A bedrock of cross-cutting, multi-ICO research is exemplified by the NIH Clinical Center, America's research hospital, located on the NIH campus in Bethesda, Maryland. The Clinical Center has supported multidisciplined, ethical, and efficient clinical research since

1953 to translate laboratory discoveries into state-of-the-art diagnostic, preventive, and therapeutic interventions to improve the nation's health.

Multifaceted questions about human health and disease are best served by inter-Institute, interdisciplinary, collaborative efforts that fully capture the complexities of the research need. For example, the NIH Common Fund Molecular Transducers of Physical Activity Consortium (MoTrPAC) brings together a multidisciplinary team to uncover, at the molecular level, how exercise improves and maintains the health of the body's tissues and organs. Tracking the impact of exercise on biological molecules through time will help MoTrPAC researchers create a map of molecular changes in the body. The Office of Research on Women's Health (ORWH) is another example of how interdisciplinary collaborations can advance research for the health of women and develop evidence-based care and personalized medicine for both women and men by understanding sex and gender differences in many disease conditions. Another important NIH-wide effort that applies expertise and resources from multiple NIH ICOs has been the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project, that investigates conditions affecting individuals with Down syndrome and the general population, such as Alzheimer's disease/dementia, autism, cataracts, celiac disease, congenital heart disease and diabetes.

During FY 2024, NIH will continue to facilitate partnerships across ICOs to leverage infrastructure and synergize scientific expertise to effectively turn scientific discovery into improved human health and disease prevention. Building partnerships and leveraging existing relationships are critical to supporting and facilitating scientific and clinical research to prevent illness and disease. NIH will learn from its most recent advances and build on these collaborations going forward. By responding to urgent and evolving health needs, addressing health disparities, building upon previous discoveries, and embracing diversity, equity, and inclusion, NIH will remain a leader in biomedical research and development well beyond FY 2024 and continue to be the steward of medical and behavioral research for the Nation.

ACCELERATING COVID-19 THERAPEUTIC INTERVENTIONS AND VACCINES (ACTIV)

Program Overview

While the traditional model of drug discovery and approval takes years to complete, the rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) globally in early 2020 required immediate action by the U.S. government biomedical research agencies to accelerate development of coronavirus disease 2019 (COVID-19) vaccines, therapeutics, and diagnostics. Responding to this urgent and unprecedented need, in April 2020, NIH established the public–private partnership Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)[98] to harness the collective scientific power of both public and private sectors and develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. ACTIV leverages the scientific innovation, knowledge, and biomedical resources of both the U.S. government and the private sector to mitigate COVID-19 morbidity and mortality and to hasten an end to the pandemic.

The ACTIV partnership has enabled the rapid and open exchange of ideas and information among government participants, industry members, and investigators. Coordinated by the Foundation for the National Institutes of Health (FNIH), NIH is joined by its sibling agencies in the Department of Health and Human Services (HHS), including the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA); other government agencies including the Department of Defense (DoD), and Department of Veterans Affairs (VA); the HHS Coordination Operations and Response Element (and formerly Operation Warp Speed); the European Medicines Agency (EMA); and representatives from academic, non-profit and philanthropic organizations, and numerous biopharmaceutical companies.

As a highly collaborative venture, ACTIV governance includes an NIH-led Leadership Group, an Executive Committee, and five working groups. The Leadership Group, comprising representatives from each organization involved in ACTIV, regularly reviews ACTIV's progress. The Executive Committee includes scientific executives representing both U.S. government agencies and industry, and oversees ACTIV's activities and operations. Leaders from across NIH, including from the National Center for Advancing Translational Sciences (NCATS), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), and the Office of the Director (OD), actively participate in the Leadership Group and Executive Committee, as well as collaborate in the five working groups.

The ACTIV working groups are pursuing five fast-track focus areas, with each working group led by senior scientists representing relevant sector partners:

- The Preclinical Working Group focused on development of a collaborative, streamlined forum to identify preclinical treatments[99, 100]

[98] nih.gov/research-training/medical-research-initiatives/activ
[99] nih.gov/research-training/medical-research-initiatives/activ/preclinical-working-group
[100] The Preclinical Working Groups completed its charge as of September 2021

- The Clinical Trial Capacity Working Group focused on improvement of clinical trial capacity and effectiveness[101, 102]
- The Clinical Therapeutics Working Group focused on acceleration of clinical testing of the most promising therapeutics[103]
- The Vaccines Working Group focused on acceleration of the evaluation of vaccine candidates to enable rapid authorization or approval[104]
- The ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) Working Group focused on tracking of emerging SARS-CoV-2 variants and coordination of open data and reagent sharing[105]

ACTIV ACCOMPLISHMENTS

The ACTIV partnership has been successful in accelerating the development of COVID-19 vaccines, therapeutics, and diagnostics, generating significant findings and results that have informed the care of patients with COVID-19 in the United States and worldwide. Importantly, the ACTIV program has advanced the U.S. government and global preparedness for future emerging infectious disease research response in keeping with the U.S. Government National Security Strategy.

Supporting Preclinical Testing of COVID-19 Therapeutics

Shortly after the start of the pandemic, the ACTIV partnership pulled together leaders from across the government and other sectors to swiftly tackle the need for COVID-specific therapeutics and vaccines. Led by the Preclinical Working Group, ACTIV worked to accelerate preclinical testing of candidate therapies by creating a prioritization framework that facilitated rapid review of potential therapeutic candidates to enter into COVID-19 clinical trials for clinical investigation. NCATS, NIAID, and OD's Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) worked closely with other ACTIV members on triaging and prioritizing preclinical resources. Additionally, the ACTIV Preclinical Working Group standardized and shared preclinical evaluation resources and methods, including a master inventory for preclinical testing resources, development of a centralized process and repository for harmonizing and sharing methods and evaluation animal models,[106] creation of publicly available databases of preclinical studies[107] and COVID-19 related animal studies,[108] and creation of a virtual testing network for triaged drug candidates.

[101] nih.gov/research-training/medical-research-initiatives/activ/clinical-trial-capacity-working-group
[102] The Clinical Trial Capacity Working Group completed its charge as of July 2020.
[103]nih.gov/research-training/medical-research-initiatives/activ/therapeutics-clinical-working-group
[104]nih.gov/research-training/medical-research-initiatives/activ/vaccines-working-group
[105] nih.gov/research-training/medical-research-initiatives/activ/trace-working-group
[106]Hewitt JA, et al. ACTIVating Resources for the COVID-19 Pandemic: In Vivo Models for Vaccines and Therapeutics. Cell Host Microbe. 2020 Nov 11;28(5):646-659. doi: 10.1016/j.chom.2020.09.016. Epub 2020 Oct 1. PMID: 33152279; PMCID: PMC7528903.
[107] opendata.ncats.nih.gov/covid19/databrowser
[108] opendata.ncats.nih.gov/covid19/animal

Conducting Clinical Trials for COVID-19 Vaccines and Therapeutics

In order to expedite clinical trials for testing of COVID-19 vaccines and therapeutics, ACTIV leveraged the existing infrastructure of both NIH and non-NIH clinical trial networks. To support these efforts, the ACTIV Clinical Trial Capacity Working Group developed an inventory of clinical trial capacity to inform implementation of ACTIV trials, including existing NIH trial networks and contract research organizations (CROs) that could be rapidly deployed to test COVID therapeutics.

To support vaccine efforts, the ACTIV Vaccines Working Group accelerated the evaluation of COVID-19 vaccine candidates by supporting harmonized clinical efficacy trials and a parallel effort to generate biomarkers and other evidence for more rapid approval and authorization. They advised on the protocol designs and endpoints to ensure a harmonized approach across multiple vaccine efficacy trials. Several SARS-CoV-2 vaccine trials used harmonized protocols informed by ACTIV.[109]

Through the Clinical Therapeutics Working Group, ACTIV has developed a process for evaluating potential therapeutic agents by reviewing publicly available data, submissions from investigators, and information gathered from an online survey and then moving prioritized agents into clinical trials. ACTIV has been able to rapidly deploy potential therapeutics into clinical trials by leveraging existing NIH networks supported by various Institute and Centers (ICs) including NIAID, NCI, National Institute of Neurological Disorders and Stroke (NINDS), NHLBI, and NCATS, allowing for ACTIV agents to be studied in more than 620 trial sites across the United States and internationally. Using this process, ACTIV has evaluated over 800 therapeutic agents and prioritized 33 for testing in ACTIV clinical trials.[110]

ACTIV clinical trials are examining the effectiveness of multiple therapeutic classes aimed at COVID-19 patients with varying disease severity. By developing and implementing multiple master protocols, which allow coordinated, efficient, and adaptive evaluation of potential therapeutic agents across multiple study sites, ACTIV has been able to nimbly test drug and biological candidates as they became available and to swiftly weed out those that do not demonstrate effectiveness. ACTIV includes six master protocol-driven adaptive clinical trials:

- The ACTIV-1 master protocol was overseen by NCATS and tested promising immune modulator compounds, a class of drugs that helps minimize the deleterious effects of an overactive immune response to SARS-CoV-2 infections, in hospitalized patients with moderate to severe COVID-19 disease.[111]
- Led by NIAID, the ACTIV-2[112] and ACTIV-3[113] master protocols examine monoclonal antibody therapies and other therapeutics in two patient populations, with ACTIV-2

[109] nih.gov/research-training/medical-research-initiatives/activ/sars-cov-2-vaccine-clinical-trials-using-activ-informed-harmonized-protocols
[110] nih.gov/activ/nih-funded-activ/activ-associated-clinical-trials
[111] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ1
[112]nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ2
[113] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ3

focusing on non-hospitalized adults and ACTIV-3 on hospitalized patients, including those in critical care.

- ACTIV-4, which is led by NHLBI, evaluates the safety and effectiveness of several interventions aimed at preventing or treating the blood clots, vascular damage, and host-tissue injury caused by SARS-CoV-2. These intervention range from blood thinners, such as antithrombotics, anticoagulants, and antiplatelets, to vascular/tissue-protective agents, in hospitalized, non-hospitalized, and convalescent participants.[114]
- ACTIV-5 is led by NIAID and is conducting a series of Phase II trials to look at whether certain approved therapies or investigational products in late-stage clinical development show promise against COVID-19.[115]
- The NCATS-led ACTIV-6 trial focuses on using repurposed drugs in outpatient settings to see if therapeutics that have been previously approved by the FDA for other diseases are also effective in treating COVID-19.[116]

Additionally, several NIH-funded trials are testing ACTIV-prioritized agents using protocols informed or endorsed by the ACTIV partnership.[117]

The ACTIV trials have had significant impact on clinical treatment of COVID-19 patients. For example, initial results from ACTIV-4 on heparin and other anticoagulants have already changed clinical practice. Results from ACTIV-4 showed that heparin improved outcomes in hospitalized moderately ill patients with COVID-19 by increasing the probability of survival to hospital discharge and reducing the need for cardiovascular or respiratory organ support.[118] However, ACTIV-4 showed this treatment is not effective for critically ill patients.[119, 21] ACTIV-1 has shown that the immune modulator drugs infliximab and abatacept both substantially improve clinical status and reduce deaths in hospitalized patients, though they do not substantially shorten time to recovery.[120] Additionally, ACTIV-2 and ACTIV-3 studies have supported the use of monoclonal antibodies in the treatment of COVID-19, with data from ACTIV-2 used to support an application for Emergency Use Authorization (EUA) for a monoclonal antibody combination from Brii Bio (BRII-196/BRII-198).[121] Three products tested in ACTIV trials also received EUAs based on separate, industry-supported trials: the monoclonal antibodies sotrovimab,[122] bamlanivimab,[123] and AZD7442/ Evusheld.[124] Though some of these EUAs have since been

[114] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ4
[115] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ5
[116] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ6
[117] nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#ACTIV-Associated
[118] ATTACC Investigators et al. Therapeutic Anticoagulation with Heparin in Noncritically Ill Patients with Covid-19. N Engl J Med. 2021 Aug 26;385(9):790-802. doi: 10.1056/NEJMoa2105911. Epub 2021 Aug 4. PMID: 34351721; PMCID: PMC8362594.
[119] www.nih.gov/news-events/news-releases/nih-activ-trial-blood-thinners-pauses-enrollment-critically-ill-covid-19-patients
[120] nih.gov/news-events/news-releases/immune-modulator-drugs-improved-survival-people-hospitalized-covid-19
[121] briibio.com/news-detail.php?id=370
[122] fda.gov/media/149534/download
[123] fda.gov/media/145802/download
[124] fda.gov/media/154701/download

revised due to changes in effectiveness in more recent SARS-CoV-2 variants,[125, 126] they have served as important clinical tools at varying stages throughout the pandemic.

Equally as important, ACTIV also demonstrated which therapeutics do not have efficacy against SARS-CoV-2, thus informing better clinical practice. For example, ACTIV-6 found that fluticasone furoate has no clinical benefit for patients with mild to moderate COVID-19 symptoms.[127] ACTIV-6 is also examining the use of ivermectin for patients with mild to moderate COVID-19 disease and showed ivermectin at the lower of two ivermectin doses being tested in the trial did not lower incidence of hospitalization or death among COVID-19 patients with mild to moderate disease.[128] Results from testing of a higher dose of ivermectin are not yet available. Initial data about three of the monoclonal antibody products tested in ACTIV-3 (Lilly, Brii Bio, and GSK-Vir products) did not support further testing.[129, 130, 131] The results of ACTIV trials identified new treatment strategies and how these should be applied to specific sets of patients along the spectrum of SARS-CoV-2 infection. Furthermore, these results are critically important to avoid applying ineffective and risky treatments to certain categories of COVID-19 patients and helped focus further clinical trial efforts on other possibilities.

Tracking the Impact of Emerging SARS-CoV-2 Variants on Vaccines and Therapeutics

To ensure patients receive effective vaccines and therapeutics, tracking the evolution of the SARS-CoV-2 virus and its impact on treatments is a critical need. ACTIV's TRACE Working Group is tackling this challenge. ACTIV partners have developed processes and infrastructure for monitoring and testing emerging SARS-CoV-2 variants, and for gathering and publicly sharing variant sequencing and phenotypic data. TRACE is following a multi-step approach to variant monitoring and data sharing: to monitor global emergence and circulation of SARS-CoV-2 mutations; characterize prioritized mutants *in vitro* through critical-path assays; characterize prioritized mutants *in vivo* through critical-path assays; and rapidly share activity data with ACTIV and scientific community.

In collaboration with NCATS, NIAID, and the National Center for Biotechnology Information (NCBI) in the National Library of Medicine (NLM), TRACE is improving the analysis pipeline for COVID-19 variants. Along with a weekly report that summarizes shifting trends in emerging variants based on sequence data deposition to GenBank/SRA[132], TRACE provides publicly available information on viral variant phenotypic characteristics and overviews of preclinical

[125].fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization
[126] fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab
[127] activ6study.org/wp-content/uploads/2022/07/ACTIV-6_Lay_Summary-Fluticasone_30JUNE20221_508.pdf
[128] Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)-6 Study Group, Naggie S. Ivermectin for Treatment of Mild-to-Moderate COVID-19 in the Outpatient Setting: A Decentralized, Placebo-controlled, Randomized, Platform Clinical Trial. medRxiv [Preprint]. 2022 Aug 11:2022.06.10.22276252. doi: 10.1101/2022.06.10.22276252. PMID: 35982669; PMCID: PMC9387156.
[129] nih.gov/news-events/news-releases/nih-sponsored-activ-3-clinical-trial-closes-enrollment-into-two-sub-studies
[130] niaid.nih.gov/news-events/statement-nih-sponsored-activ-3-trial-closes-ly-cov555-sub-study
[131] nih.gov/activ/nih-funded-activ/activ-associated-clinical-trials
[132] ftp.ncbi.nlm.nih.gov/pub/ACTIV-TRACE/

assays used to test them through the Variant Therapeutic Data Summary[133] within the NCATS OpenData Portal. These are valuable resources for tracking the changing COVID-19 landscape.

Next Steps/Goals

As the pandemic evolves, so does ACTIV. As new SARS-CoV-2 variants emerge, the TRACE Working Group continues to monitor them and examine their sensitivity to extant COVID therapeutics. The ACTIV Vaccines Working Group determines the implications of the changing variant landscape for current and second-generation vaccination strategies. In parallel, ACTIV will complete its ongoing clinical trials of COVID therapeutics, which include continued tracking of participant outcomes. Current inpatient activities will be transitioned as appropriate to ACTIV's new Strategies and Treatments for Respiratory Infectious Viral Emergencies (STRIVE) Platform. STRIVE will evaluate therapeutic agents and combinations of therapeutics in a strategic manner across disease severity, from those with mild to severe COVID symptoms.

ACTIV is a demonstration of what a team of dedicated experts from across sectors can accomplish and serves as a model for future partnerships. The lessons learned from ACTIV will continue to inform future COVID-19 and other viral disease research and pandemic preparedness.

[133] opendata.ncats.nih.gov/variant/summary

INCLUDE (INVESTIGATION OF CO-OCCURRING CONDITIONS ACROSS THE LIFESPAN TO UNDERSTAND DOWN SYNDROME) PROJECT

Program Overview

In FY 2018, NIH launched the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project[134] in support of a Congressional directive to increase participation of people with Down syndrome (DS) and their families in clinical research, expand knowledge about DS and its links to other health conditions, and improve the health of individuals with DS.

DS is the most common genetic cause of intellectual disability, the most common autosomal trisomy, and one of the most visible and universally recognized genetic syndromes. Each year there are approximately 6,000 babies born in the United States with DS. Within the past 25 years, the average lifespan for a person with DS has doubled from 30 to 60 years, though significant disparities persist among racial and ethnic minority groups. Despite this increase, individuals with DS and their families face serious and changing health challenges. About 50 percent of all babies born with DS are also born with congenital heart disease, and estimates suggest that 50 percent or more of adults with DS will develop dementia due to Alzheimer's disease (AD). Additional common co-occurring conditions in individuals with DS include intellectual disability, leukemia, sleep apnea, autism, immune disorders, celiac disease and diabetes, and problems with hearing and vision.

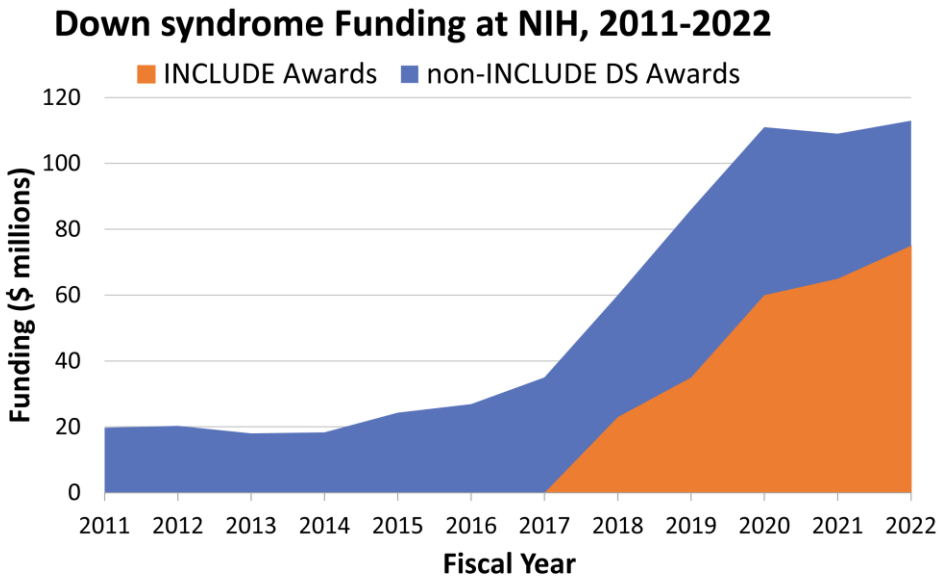


FIGURE 1 DOWN SYNDROME FUNDING AT NIH, FISCAL YEARS 2011-2022. NOTE THAT NON-INCLUDE DS AWARD FUNDING FOR FY 2022 REFLECTS THE PRELIMINARY ACTUAL LEVEL.

[134] nih.gov/include-project

INCLUDE builds on NIH's creation of the public-private Down Syndrome Consortium[135] formed in 2011 as outlined in *Down Syndrome Directions: The NIH Research Plan on Down Syndrome*.[136] INCLUDE has increased its support each year, from $23 million in FY 2018 to $35 million in FY 2019 to $61 million in FY 2020 and to $65 million in FY 2021. In FY 2022, INCLUDE committed $75 million in 67 new awards across 12 NIH Institutes and Centers (ICs), including 5 new clinical trials.[137]

INCLUDE aims to understand critical health and quality of life needs for individuals with DS across the lifespan with two goals: (1) to yield scientific discoveries that will improve the health, well-being, and neurodevelopment of individuals with DS and (2) to inform scientific thinking about common conditions they share with individuals who do not have DS. In addition, INCLUDE aims to increase the number and diversity of participants and investigators involved in DS-related research. INCLUDE pursues these goals through three major scientific components:

1. Conduct targeted, high-risk, high-reward basic science studies on chromosome 21. Research has elucidated the roles of individual genes in the DS critical region on chromosome 21 and has provided insights about their roles in cognition and neurodegeneration. INCLUDE funds basic science investigations of promising new cellular, organoid, and animal models with the goal of understanding mechanisms underlying many of the clinical manifestations of DS.

2. Assemble a large study population of individuals with DS. A large cohort of individuals with DS is essential to follow individuals' development over time and perform deep phenotyping, genomic and biomarker analyses, and natural history studies. Enrolling a cross-sectional cohort of individuals with DS at different ages across the lifespan captures the broadest array of phenotypes and ages of onset for the co-existing conditions, as well as the critical windows for interventions.

3. Conduct clinical trials research inclusive of individuals with DS. Despite the relative frequency of DS in the population, very few clinical trials have focused solely on people with DS. INCLUDE funding opportunities offer a compelling route for investigators to conduct such trials and for investigators new to DS to bring their prior trial experience to bear. In conducting these trials, INCLUDE is demonstrating that such research can be conducted safely in individuals with DS, which should lead to inclusion of this population more broadly in clinical research.

Selected Achievements

The Alzheimer's Biomarkers Consortium - Down Syndrome[138] (ABC-DS), a longitudinal study funded by INCLUDE, the National Institute on Aging (NIA), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), follows a cohort of adults with DS over time to identify early biomarkers that may herald the onset of AD. ABC-DS has

[135] downsyndrome.nih.gov
[136] nichd.nih.gov/publications/product/441
[137] Figures incorporate INCLUDE funding in the NIH Office of the Director as well as contributions from NIH ICs.
[138] nia.nih.gov/research/abc-ds

enrolled more than 400 adults with DS, plus sibling controls. Early results have identified neuroimaging and blood-based biomarkers that distinguish between cognitive stability and AD in aging adults with DS.[139] Investigators hope that these biomarkers can be useful to inform clinical trials and improve the quality of life for people with DS and for the general population.

Launched in FY 2020, the INCLUDE Data Coordinating Center[140] (DCC) has created a cloud-based, open digital platform to easily access and share DS data resources to accelerate research. The INCLUDE Data Hub brings information and resources from many sources together in one place. With these tools, scientists and community members can work together more easily and quickly and combine their data to learn about health conditions that impact people with DS. The DCC also advances community access to research by working closely with DS-Connect®: The Down Syndrome Registry,[141] which is a resource where people with DS and their families can connect with researchers, health care providers, and study opportunities.

INCLUDE-funded investigators are making strides in both our basic science and clinical understanding of DS. At the basic science level, projects include generating and characterizing rodent models of DS and using cellular models to study heart and brain development. On the clinical side, one study developed a language test to better evaluate possible language interventions for individuals with DS.[142] Another established the need for precise diagnostic tools for attention deficit hyperactivity disorder (ADHD) in children with DS,[143] and additional work suggests that children with co-occurring DS and ADHD may be more sensitive to certain medications than other children. Ongoing projects include developing better diagnostic tools and novel therapeutic interventions for obstructive sleep apnea syndrome in children with DS. Clinical trials are studying specific treatments for some of these conditions, including ADHD, sleep apnea, and prevention of AD.

Diversity, Equity, Inclusion, and Accessibility (DEIA)

NIH is interested in expanding and diversifying both research participants and the DS research workforce. NIH recognizes that there are health disparities among individuals with DS. New INCLUDE funding opportunity announcements require that projects that are enrolling individuals with DS include a Recruitment Plan to Enhance Diversity, and several INCLUDE funding opportunities have direct diversity, equity, inclusion, and accessibility (DEIA) emphases, including:

- R25 awards for creative and innovative short courses to train the next generation of DS researchers in state-of-the-art clinical research skills[144]
- R15 awards supporting trainees pursuing small-scale basic and translational DS-specific research projects at institutions that do not receive substantial funding from the NIH[145]
- R21 Community-Based Participatory Research (CBPR) initiative focused on reducing health disparities to address diverse representation in research on DS[146]

[139] pubmed.ncbi.nlm.nih.gov/33337378/
[140] includedcc.org
[141] dsconnect.nih.gov
[142] pubmed.ncbi.nlm.nih.gov/33827417/
[143] pubmed.ncbi.nlm.nih.gov/34939724/
[144] grants.nih.gov/grants/guide/pa-files/PAR-22-195.html
[145] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-136.html
[146] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-142.html

INCLUDE also commits significant support to community outreach and engagement to support DEIA efforts through websites, workshops, seminars, conferences, and resources. Among these efforts, in July 2022, the DCC hosted the Data Science for Diverse Scholars in Down Syndrome Research (DS3), an in-person, immersive summer course for graduate students and early-stage postdoctoral fellows from underrepresented groups to provide bioinformatics training and promote their career advancement. In September 2022, INCLUDE held a two-day "Building a Diverse Community for Down Syndrome Research" Workshop, bringing together more than 200 self-advocates, family members, scientists, healthcare and service providers, government and agency partners, and experts in diversity and inclusion to discuss expanding representation among both the DS research community and the DS scientific workforce.

Collaboration Within and Beyond NIH

Appropriate to the multi-organ system involvement of DS and its co-occurring conditions, and in a truly NIH-wide effort, INCLUDE has assembled a team across NIH, leveraging the expertise and resources of at least 20 ICs. INCLUDE is co-chaired by Dr. Tara Schwetz, NIH Acting Principal Deputy Director, Office of the Director (OD), Dr. Diana Bianchi, Director, NICHD, and Dr. Gary Gibbons, Director, National Heart, Lung, and Blood Institute (NHLBI). Other institutes with significant involvement on the INCLUDE Steering Committee include NIA, the National Cancer Institute (NCI), National Human Genome Research Institute (NHGRI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of General Medical Sciences (NIGMS), and National Institute of Neurological Disorders and Stroke (NINDS). The Steering Committee is complemented by the participation of at least 11 additional ICs across the NIH-wide Down Syndrome Working Group, and program working groups on data coordination and each scientific component. Together, these groups drive the development of funding opportunities, outreach activities, resources, and awareness of emerging needs in the DS research community.

Integral to the program's goals, collaboration by INCLUDE extends beyond NIH to DS organizations and communities throughout the U.S. The team actively participates in DS-related events and conferences, works closely with major DS organizations through the DS Consortium, and conducts outreach to DS parent organizations and DS clinics. INCLUDE strives to be a true partner to research and participant communities both within NIH and beyond; for example, the September diversity workshop was developed in response to listening sessions for families and researchers held by INCLUDE earlier in FY 2022.

Next Steps / Goals

To reflect the progress made to date and integrate DS efforts across NIH, the agency has developed the 2022 NIH INCLUDE Down Syndrome Research Plan. The plan incorporates input from the DS community, addresses the need for greater diversity among DS research participants, and proposes a roadmap to further expand understanding of health disparities among individuals with DS. It also describes training opportunities to increase the pipeline of new and early-stage investigators conducting DS research.

As part of this roadmap, INCLUDE has developed a communications and outreach plan to further engage communities and investigators and expand the DS-Connect registry, with goals to

increase the number of research teams and trainees engaged in DS research; increase the representation, diversity, and number of participants in DS research; and share results of DS research broadly with the entire DS community.

INCLUDE plans to expand its efforts to create a large cohort of individuals with DS, including those from diverse communities across the lifespan. Accompanying this cohort-building, INCLUDE plans to establish one or more biorepositories that will bank cells, plasma, serum, cerebrospinal fluid, and brain and other tissues to accelerate research into co-occurring conditions. Biorepository data will be integrated with the DCC, as feasible, thereby facilitating rapid, broad data sharing, integration, and analysis. Additionally, to expand research infrastructure, participant diversity, and the investigator pool, INCLUDE will establish or augment collaborations among clinical studies and research networks that conduct research related to DS and its co-occurring conditions.

INCLUDE's investments in high-risk basic science, cohort-building, clinical trial representation, scientific infrastructure, and community engagement are breaking new ground to improve the health and quality of life of individuals with DS and all individuals who are impacted by the condition.

MOLECULAR TRANSDUCERS OF PHYSICAL ACTIVITY IN HUMANS CONSORTIUM (MOTRPAC)

Program Overview

We know that physical activity promotes health in a variety of ways and benefits many different organs of the body. However, very little is known about the specific biological molecules that confer the benefits of physical activity. Additionally, although it is likely that individual differences play a role in response to physical activity, researchers and clinicians do not understand these differences and therefore cannot develop personalized exercise recommendations. The NIH Common Fund is in a unique position to bring together scientists from diverse fields, such as exercise physiology, genetics, biochemistry, and computational biology, to shed light on how physical activity benefits health and how individuals differ in their response to exercise.

The Common Fund's Molecular Transducers of Physical Activity in Humans Consortium (MoTrPAC)[147] aims to uncover, at the molecular level, how exercise improves and maintains the health of the body's tissues and organs. Through a 10-year, $261 million investment, MoTrPAC will transform our understanding of the health benefits of physical activity by measuring the molecular and physiological changes that occur following endurance and resistance training in hundreds of adults and children so that individual variability in response can be assessed. Tracking the impact of exercise on biological molecules through time will help MoTrPAC researchers create a map of molecular changes in the body. In parallel, extensive preclinical studies in rats are allowing many additional tissue types to be explored, substantially increasing the impact of the program. Researchers will use the molecular map produced by MoTrPAC to better understand how exercise affects diverse people of different ages, sexes, body compositions, and fitness levels. In the future, the map also may enable clinicians to make more tailored recommendations to patients when using exercise as an intervention to improve health.

MoTrPAC – An NIH-wide Collaboration

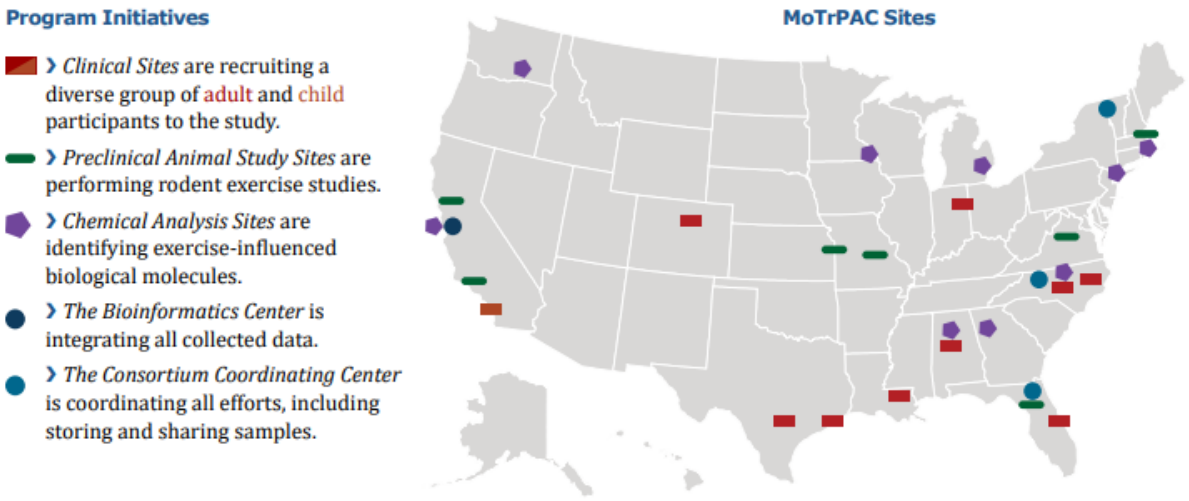
As a Common Fund program, MoTrPAC is managed as a collaboration between the Office of Strategic Coordination (OSC), in the Office of the Director (OD), and many NIH Institutes, Centers, and Offices (ICOs) that have an interest in research on physical activity. MoTrPAC is managed by a cross-NIH Working Group led by OSC, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute on Aging (NIA), and the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK), with representatives from an additional 11 ICOs across NIH.

Current Status of MoTrPAC

MoTrPAC is the largest study of its kind. To undertake this unprecedented study, MoTrPAC supports several coordinated initiatives: 1) adult and pediatric physical activity studies; 2) complementary animal model physical activity studies analyzing both endurance/aerobic exercise and resistance/weight lifting exercise; 3) analysis of biological samples to identify exercise-influenced biological molecules; 4) integration and dissemination of data; and 5) study coordination, including storing and sharing biological samples. The seven Clinical Sites are

[147] commonfund.nih.gov/MolecularTransducers

recruiting a diverse group of adults spanning a wide range of ages (six sites), as well as pediatric participants (one site).



MoTrPAC Adult Studies

Adult exercise studies are asking "What is the molecular profile of adults who exercise regularly?" and "What is the molecular profile of sedentary adults before and after exercise training?" To answer these questions, blood, muscle, and adipose tissue samples are collected from sedentary and highly active adult volunteers performing resistance or aerobic endurance exercises. To investigate the molecular effects of starting a new exercise regimen, sedentary individuals are evaluated before and after 12 weeks of supervised training.

MoTrPAC Pediatric Studies

Pediatric exercise studies are investigating the molecular profiles of children who currently engage in low or high levels of physical activity. In this study, blood samples are collected from sedentary and highly active pediatric volunteers performing aerobic exercises. This study will help identify the molecular differences between children who are highly physically active and those who are not and, in combination with the data generated by MoTrPAC adult studies, will also reveal differences in the response to physical activity between children and adults.

MoTrPAC Preclinical (Animal) Studies

Parallel studies in animals will allow analysis of additional tissue types beyond what is available from humans. These studies are investigating molecular profiles before and after a single bout of endurance exercise and molecular profiles before and after endurance training, in both young (6 months) and old (18 months) rats. Animal studies allow collection and analysis of a wide variety of tissue samples, with sources including adipose tissue, adrenal glands, aorta, bone, colon, several parts of the brain, gonads, heart, kidney, liver, lung, small intestine, and spleen. Additionally, a resistance training protocol has now been developed for the animal studies and could be used in future studies.

Recent Accomplishments of MoTrPAC

While human exercise studies are underway, preliminary results from the animal studies have begun to emerge. In an analysis of animals undergoing 8 weeks of endurance training, researchers identified over 35,000 molecular changes in response to exercise. These changes cluster into networks and pathways that influence a variety of biological functions, such as metabolism, inflammation, and nutrient absorption. Interestingly, approximately half of these clusters have different trajectories in males and females, and many show tissue-specific variation. For example, although both male and female animals demonstrate cardiovascular improvements after exercise training, only males demonstrated reduced whole-body fat content (adiposity), fat cell (adipocyte) size, and abundance of a type of fat found in the blood (triglycerides). Novel findings from the animal studies suggest additional effects of exercise on different organs, including the discovery that exercise increases anti-inflammatory proteins in the kidney and elicits production of bile acid and cholesterol in the liver that could impact digestive health.

Next Steps and Goals

MoTrPAC is continuing to support human and animal physical activity studies and the associated molecular analysis of samples. Although the COVID-19 pandemic paused human studies, all clinical sites have resumed recruitment under enhanced safety protocols, and human samples from pre-COVID-19 cohorts are now undergoing analysis. MoTrPAC will deliver a data-rich map of molecular changes in response to exercise across a variety of tissues by the end of the program in FY 2026. This resource, which will be openly shared with the broad biomedical research community, is expected to stimulate investigator-initiated research that will continue long beyond the lifetime of the MoTrPAC program. By delivering the largest and most detailed data set of its kind, MoTrPAC will provide a key foundational resource to generate new insights into the functional effects of molecules influenced by physical activity, individual differences in the response to exercise, and how tailored exercise recommendations can improve health for all people.

NIH CLIMATE CHANGE AND HEALTH (CCH) INITIATIVE

Program Overview

Climate change elevates threats to human health across a wide range of illnesses, including respiratory diseases, cancers, cardiovascular diseases, mental illnesses and neuropsychiatric disorders, reproductive outcomes, and atypical development. Climate change alters environmental and social stressors that affect well-being, thereby increasing the risk of foodborne diseases and malnutrition, vector-borne and zoonotic diseases, waterborne diseases, and extreme temperature- and weather-related morbidities and mortality. Of particular concern is the disproportionate impact of climate change on communities already experiencing social and environmental inequalities where they live, work, learn, and play, both in the United States and globally. Certain populations are also disproportionately at risk of climate change effects, including children, older adults, pregnant women, persons with disabilities, persons experiencing homelessness, those with mental illness, and others. In the global community, these same populations, as well as all those living in extreme poverty with limited access to health and economic services, experience a higher risk of climate change consequences for health.

Leaders at NIH recognize the urgent need for a concerted, collective effort across NIH Institutes, Centers, and Offices (ICOs) to advance understanding of impacts of climate change on health, identify health co-benefits of reducing exposures to direct and downstream climate events, and provide opportunities to develop and test interventions that can increase the long-term resilience of communities to the effects of climate change. NIH funding support for climate change and health research has historically been concentrated in a few Institutes. However, more than half of the ICOs have funded at least one or more—in several cases, significantly more—relevant projects. The level of funding has increased in the last few years and received a significant boost this year with $40.0 million in new funding provided for climate change and health research in FY 2023 appropriations.

Funding level alone, however, belies the full NIH contribution to the evolution of the understanding of climate change and health. For decades NIH has provided leadership on the issue of impacts of climate change on health through engagement of its scientists at national and global levels, beginning with the first Intergovernmental Panel on Climate Change (IPCC). In 2010, NIH co-led with the Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), and National Oceanic and Atmospheric Administration the creation of the first federal climate change and health research needs assessment, titled "A Human Health Perspective on Climate Change."[148] Over more than a decade of engagement with the U.S. Global Climate Change Research Program, NIH has contributed strong leadership to influential outcomes including the Interagency Crosscutting Group on Human Health and health-focused chapters of multiple National Climate Assessments.

[148] Portier CJ, Thigpen Tart K, Carter SR, Dilworth CH, Grambsch AE, Gohlke J, Hess J, Howard SN, Luber G, Lutz JT, Maslak T, Prudent N, Radtke M, Rosenthal JP, Rowles T, Sandifer PA, Scheraga J, Schramm PJ, Strickman D, Trtanj JM, Whung P-Y. 2010. A Human Health Perspective On Climate Change: A Report Outlining the Research Needs on the Human Health Effects of Climate Change. Research Triangle Park, NC:Environmental Health Perspectives/National Institute of Environmental Health Sciences. doi:10.1289/ehp.1002272 Available: www.niehs.nih.gov/climatereport

In 2021, in response to President Biden's Executive Order 14008: Tackling the Climate Crisis at Home and Abroad, NIH committed to developing an NIH-wide Climate Change and Health (CCH) Initiative to grow the NIH research portfolio and investigator community to address these urgent issues.[149] An Executive Committee comprised of directors from seven NIH Institutes and Centers (ICs) was established to lead the Initiative. These ICs include:

- the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD);
- Fogarty International Center (FIC);
- National Heart, Lung, and Blood Institute (NHLBI);
- National Institute of Environmental Health Sciences (NIEHS);
- National Institute of Mental Health (NIMH);
- National Institute on Minority Health and Health Disparities (NIMHD); and
- the National Institute of Nursing Research (NINR).

Staff of the National Institute of Allergy and Infectious Diseases (NIAID), National Cancer Institute (NCI), and National Institute of Aging (NIA) also joined the Initiative through its Steering Committee and Planning and Implementation Team (PIT), which help to guide and execute the Initiative's Strategic Framework. An NIH Climate Change and Health Working Group comprises more than 140 NIH scientific and programmatic staff across 24 ICOs and meets regularly to exchange information on climate change and health topics, host presentations from CCH partners to increase awareness of the field, and provide input on opportunities for member engagement in the Initiative's work plan.

Goals and Objectives

Members of the CCH Initiative have worked steadily since its establishment to create an infrastructure for the program and begin to implement projects and proposals in support of its goals. The NIH CCH Initiative Strategic Framework[150] was developed with input from a range of stakeholders, including the larger scientific community, clinicians, advocates, and policymakers. It was published in February 2022.

This Strategic Framework outlines the goals of the Initiative, which are to reduce health threats across the lifespan and build health resilience among individuals, communities, and nations around the world, especially among those at highest risk of adverse health impacts. The framework's four core elements are depicted in Figure 1, and include: health effects research, health equity, intervention science, and training and capacity building. Objectives described in the framework are to:

- **Identify risks and optimize benefits** to the health of individuals, communities, and populations from climate related factors and actions to mitigate or adapt to climate change.

[149] Woychik RP, Bianchi DW, Gibbons GH, Glass RI, Gordon JA, Pérez-Stable EJ, Zenk SN. The NIH Climate Change and Health Initiative and Strategic Framework: addressing the threat of climate change to health. Lancet. 2022 Nov 26;400(10366):1831-1833. doi: 10.1016/S0140-6736(22)02163-8. Epub 2022 Nov 4. PMID: 36343650.
[150] National Institutes of Health. NIH Climate Change and Health Strategic Framework. Research Triangle Park, NC: National Institutes of Health; 2022 Feb. 11 p.

- Develop the necessary **research infrastructure and workforce** to enable the generation of timely and relevant knowledge, drawing from the full spectrum of biomedical disciplines.
- **Leverage partnerships** with other scientific and social disciplines and organizations to achieve the most impactful results.
- **Innovate** across the research translation continuum to ensure findings are credible, accessible, and actionable for achieving these goals.

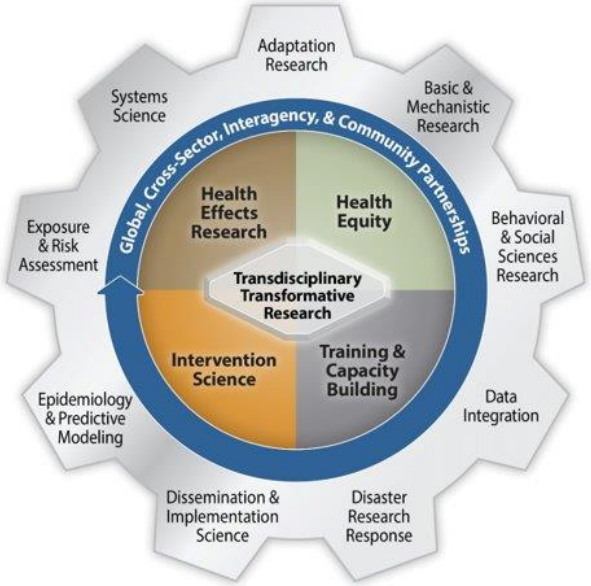


FIGURE 1. NIH CLIMATE CHANGE AND HEALTH STRATEGIC FRAMEWORK

The NIH CCH Executive Committee and Working Group have led the development of new funding opportunities within existing budgets, including:

- **Alliance for Community Engagement-Climate and Health**[151] (ACE-CH). The ACE-CH seeks to empower communities across the United States to participate in community-engaged research, assist to understand factors that contribute to health inequities related to climate change, and develop solutions through health equity. The ACE-CH will collaborate with an NIH-funded Research Coordinating Center (RCC) being established in parallel to manage and support current and future climate change and health research and capacity building efforts. Together, they will help to support the development of an NIH-wide Climate and Health Community of Practice. NHLBI will take the lead for administering the ACE-CH, which has been developed with input and funding support from across NIH.
- **NIH-wide Notices of Special Interest (NOSIs)** (NOT-ES-22-006, NOT-ES-22-009, NOT-ES-22-010) were released in 2022 to encourage investigator-initiated research related to the scientific domains outlined in the strategic framework. ICOs across NIH are participating in these announcements.

[151] Research Opportunity Announcement - Alliance for Community Engagement (nih.gov)

- **Climate Change and Health Research Coordinating Center**[152] (RFA-ES-22-003). The Research Coordinating Center (RCC) will support the progress of the NIH CCH Community of Practice by creating opportunities for networking and collaborations among NIH-supported CCH scientists. Working groups led by the RCC will explore contemporary themes in CCH in in-depth, meaningful ways to support future directions of the program.

Highlights of NIH-supported CCH Research Projects

Highlights of ongoing research are below. In addition, NIH grantees have published 43 climate and health related manuscripts since April 2022.

- *Training in Interventions to Improve Outcomes in Chronic Conditions* **(NINR)**: This research addresses farmworkers' vulnerability to heat hazards and provides evidence-based tools and interventions to maintain worker safety during extreme conditions.
- *Effects of Agricultural Expansion and Intensification on Infections, 2015-2021* **(FIC)**: This research demonstrated that temperature increases from climate change will increase the risk of schistosomiasis (river blindness) in parts of the world. These findings can help inform and improve control measures used to reduce the spread of the disease.
- *Assessing and Addressing Heat-Health Vulnerability in Ahmedabad, India, 2015-2017* **(FIC)**: Investigators learned that despite substantial risks to heat-related illnesses, health workers did not routinely consider heat effects when making diagnoses. Health workers may have attributed symptoms of heat stroke — such as high fever and altered mental state — to malaria, which is common in the area. Training sessions were held to sensitize health professionals to the signs of heat-related illnesses and best practices for treatment.
- *Research on health risks and resilience in Puerto Rico and the U.S. Virgin Islands after the 2019 Hurricanes Irma and Maria* **(NIMHD)**: This time-sensitive research looked at how the events impacted social determinants of health in communities with health disparities for several diseases. Additionally, over the past 10 years, NIEHS's grant program has funded rapid response research across the United States on climate-related disasters including hurricanes, wildfires, and floods.
- *Wildfire Smoke* (**NIMHD, NIEHS)**: In Northern Arizona, researchers are incorporating community input while developing a methodology for exploring health inequities tied to wildfire smoke in Native American populations. (**NIMHD**) Scientists in California are studying adverse impacts of wildfire smoke on pregnant women and their children (**NIEHS**), as well as characterizing the chemical composition of air pollution from wildfires in rural and urban settings (**NIEHS**).
- *Pediatric Health and Extreme Weather - Health Effects of Ambient Temperature* **(NIEHS)**: Children's vulnerability to heat effects varies by age in ways that are important for public health messaging. Other heat outcomes, such as injury, are an important gap in existing research, which may be missing the bulk of heat-health burden for children.
- *Investigation of Neighborhood Greenspace as Protection Against Development of Childhood Asthma* **(NIEHS)**: Exposure to vegetated land cover, or "greenspace," particularly in early life, may prevent development of asthma. This study will look at

[152] RFA-ES-22-003: Research Coordinating Center to Support Climate Change and Health Community of Practice (U24 Clinical Trial Not Allowed) (nih.gov)

neighborhood greenspace and asthma incidence in a longitudinal cohort of over 170,000 children living in the Philadelphia metropolitan region.

- *Influence of Temperature on Malaria Transmission and Prospective Vector Control* **(NIAID)**: Knowing that not all malaria-transmitting Anopheles species feed at night and that night-feeding Anopheles can shift their feeding behavior in response to bed nets, the results show differences in vector competence resulting from biting time with implications for malaria transmission. Shifts towards morning feeding might have little impact as these mosquitoes may have limited capacity to transmit malaria. However, mosquitoes feeding in the early evening could improve vector efficiency.

Partnerships

The NIH CCH Initiative has worked to develop partnerships across federal agencies, non-profits, and academic organizations. Examples of federal partners include HHS (Office of Climate Change and Health Equity Office, Office of the Assistant Secretary for Policy and Evaluation [ASPE], Administration for Strategic Preparedness and Response, Administration for Health Research and Quality [AHRQ], Centers for Disease Control and Prevention, and other operating divisions), National Oceanic and Atmospheric Administration, National Aeronautics and Space Administration, National Science Foundation, and U.S. Global Change Research Program. In a newly funded collaborative project, NIH staff from three ICOs will work with AHRQ and ASPE to develop data integration resources, tools, and systems to support patient and population-based climate change and human health research, specifically around a use case related to wildfires.

Next Steps

The CCH Initiative will expand outreach and engagement at global and domestic conferences to increase awareness of funding and partnership opportunities and build the NIH climate change and health community of practice. Other efforts will target the development of government, academic, and healthcare partnerships with key organizations including the International Society of Environmental Epidemiologists, the American Public Health Association, the American Geophysical Union, the Wellcome Trust, and the Rockefeller Foundation.

MAJOR CONTRIBUTIONS FROM INSTITUTES AND CENTERS WITH BUDGETS LESS THAN $1 BILLION

Program Overview

All 27 NIH Institutes and Centers (ICs) support research or other activities to achieve the overall NIH mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The breadth and diversity of IC missions enables all ICs to make very significant contributions to improving human health. This section highlights some of the efforts of NIH ICs with budgets under $1 billion, such as in the areas of chronic pain, whole person health, new innovations, research to benefit everyone, biomedical research stewardship, and capacity building and infrastructure. The ICs included in this section are:

- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Complementary and Integrative Health (NCCIH)
- National Eye Institute (NEI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Alcohol Effects and Alcohol-Associated Disorders (NIAAA)[153]
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Instiute on Deafness and Other Communication Disorders (NIDCD)
- National Instute of Dental and Craniofacial Research (NIDCR)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Institute of Nursing Research (NINR)
- National Library of Medicine (NLM)

Chronic Pain

Nearly 20 percent of United States adults report having pain every day for the previous 3 months. Chonic pain permeates every aspect of a person's life making it difficult to complete day-to-day tasks. Individuals with severe pain have worse health, use more health care, and have more disability than individuals with less severe or no pain. While the National Institute on Neurological Disorders and Stroke (NINDS) has a lead role in supporting research to address chronic pain, many other NIH ICs play a critical role in developing approaches to treating pain.

The NIH Pain Reseach Center and Pain Management Collaboratory

NCCIH supports several initiatives to address chronic pain. The NCCIH-led Intramural Research Program Pain Research Center, located within the NIH Clinical Center in Bethesda, MD, is a multidisciplinary, trans-NIH initiative that is working to identify specific pain mechanims, determine the efficacy of non-opioid treatments, and predict individal patient response to therapies and outcomes. The overarching mission of the Pain Research Center is to better understand diverse pain states in order to recommend personalized therapies to better

[153] The FY 2024 Budget proposes that the National Institute on Alcohol Abuse and Alcoholism be renamed the "National Institute on Alcohol Effects and Alcohol-Associated Disorders."

manage or prevent the development of chronic pain and opioid abuse.[154] NCCIH also supports the Pain Management Collaboratory (PMC), a joint effort between the Department of Defense, Department of Veterans Affairs (VA), and NIH (led by NCCIH). It is composed of 11 large-scale, multi-site, pragmatic clinical trials that are studying nonpharmacological approaches for the management of pain and common co-occurring conditions in Military and Veterans healthcare systems and are supported by a central Coordinating Center.[155] These studies involve 42 Military Health Service and VA facilities with over 8,200 participants enrolled. The PMC mission to improve the capacity, tools, and skills available to health care providers to provide timely, equitable and cost-effective integrated, patient-centered, multimodal and interdisciplinary pain care that incorporates evidence-based nonpharmacological approaches to pain management while reducing the reliance on opioid and other potentially harmful medications and invasive procedures.

Osteoarthritis Research

A study supported by NIBIB and NIAMS aims to address osteoarthritis, a challenging problem in aging adults that causes pain and discomfort. As people age, cartilage deteriorates; however, regenerating native cartilage has proven to be difficult, and surgical treatment options can be costly, time-consuming, and unreliable. Researchers have developed a small, biodegradable film with piezoelectric properties that stimulates new cartilage growth. Piezoelectric materials generate electrical signals from pressure or vibrations to the material. The film was evaluated in an osteoarthritis model by implanting the film in rabbits at sites of damaged knee joints.[156] Rabbits that were treated with the piezoelectric film and exercised developed a new layer of cartilage that looked like native tissue which was not seen in untreated rabbits or those that were treated but did not exercise. This biomaterial is easy to scale and manufacture and next steps will be to test in larger animal models and humans.

The Osteoarthritis Initiative is a multicenter, longitudinal, prospective observational study to follow people who either have or are at risk for developing knee osteoarthritis, currently in its 14th year of follow up. This Initiative is a public-private partnership between NIH and private industry that seeks to develop a public-domain research resource to facilitate the scientific evaluation of biomarkers for osteoarthritis as potential surrogate endpoints for disease onset and progression.[157] Within NIH, this effort is led by NIAMS with additional support from NCCIH, NIMHD, NIDCR, and NIBIB, among others. This groundbreaking study is advancing our understanding of how modifiable and non-modifiable risk factors are linked to development and worsening of knee osteoarthritis. Such findings may, in turn, lead to improved strategies for prevention of disease and identification of novel treatment targets, which could result in prevention of later-life disability in individuals with knee osteoarthritis.

Alcohol Use Disorder and Chronic Pain

There is a complex relationship between alcohol misuse and pain. While drinking can help relieve pain in the short term, over time, heavy drinking may cause or exacerbate chronic pain. Withdrawal from alcohol is associated with increased pain and may motivate individuals to drink

[154] www.nccih.nih.gov/research/nih-pain-research-center
[155] painmanagementcollaboratory.org/
[156] pubmed.ncbi.nlm.nih.gov/35020409/
[157] www.niams.nih.gov/grants-funding/funded-research/osteoarthritis-initiative

for pain relief. Heavy drinking to relieve pain can thus drive the development of alcohol use disorder (AUD), and conversely, AUD-related changes in how the brain processes pain may drive the development of chronic pain conditions. NIAAA-funded research is focused on enhancing our understanding of the complex relationship between alcohol and pain, including the interactions between alcohol and opioids in the development and perpetuation of chronic pain.[158]

Orofacial Pain

Orofacial pain affects 5 to 12 percent of the population and can have long-reaching effects on the afflicted individual. NIDCR has a robust portfolio in understanding and treating orofacial pain. The Neuroscience of Orofacial Pain and Temporomandibular Disorders Program within NIDCR supports basic, translational, and clinical research on orofacial pain and neuropathies, temporomandibular joint and muscle disorders (TMJD), development of biomarkers for diagnositics and prognostics, and development of therapeutics. Addressing orofacial pain remains a top priority for the Institute. The NIDCR Strategic Plan (2021-2026), "Science: Advancing Oral Health for All," includes an objective to stimulate and sustain collaborative alliances across the research spectrum to prevent, modulate, and treat dental pain and orofacial neuropathies.[159]

NIH HEAL Initiative®

Many NIH ICs, including NIAMS and NCCIH (each received an additional $5 million in the FY 2023 appropriations omnibus), NIDCR, NIAAA, NCATS, and NINR, support the Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®. A major component of the HEAL Initiative® is enhancing pain management including understanding the biological underpinning of chronic pain, developing and advancing non-addictive treatments for pain, and establishing best practices for managing acute and chronic pain. One program supported by the HEAL Initiative® is the Back Pain Consortium Research Program (BACPAC). BACPAC, managed by NIAMS, is a translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain. It is examining biomedical mechanisms within a biopsychosocial context by using interdisciplinary methods and exploring innovative technologies.[160] A new program on myofascial pain led by NCCIH aims to develop new technologies to quantify abnormalities of myofascial tissues that likely underlie a wide variety of common musculoskeletal pain conditions including back, neck and shoulder pain, as well as temporomandibular pain and headache.[161]

Whole Person Health

Whole person health involves looking at the whole person—not just separate organs or body systems—and considering multiple factors that promote either health or disease. It means helping and empowering individuals, families, communities, and populations to improve their health in multiple interconnected biological, behavioral, social, and environmental areas. Instead of treating a specific disease, whole person health focuses on restoring health, promoting

[158] niaaa.scienceblog.com/231/the-complex-relationship-between-alcohol-and-pain/
[159] www.nidcr.nih.gov/sites/default/files/2022-01/NIDCR-Strategic-Plan-2021-2026.pdf
[160] heal.nih.gov/research/clinical-research/back-pain
[161] www.nccih.nih.gov/about/offices/od/director/past-messages/entering-a-new-chapter-in-understanding-myofascial-pain

resilience, and preventing diseases across a lifespan.[162] In September 2021, NCCIH held a workshop titled "Methodological Approaches for Whole Person Research Workshop." The goal of the workshop was to discuss examples of research and explore methodologies potentially appropriate for whole person research. Other ICs collaborating on the workshop include, but are not limited to, NIMHD, NINR, NIBIB, NIEHS, NIDCR, and FIC. Further exemplifying the significance of whole person health, NCCIH's strategic plan for fiscal years 2021-2025[163] expanded the definition of integrative health to include whole person health, and NCCIH has indicated research on whole person health is a top priority during this time. Recognizing a greater understanding of whole person health can influence research programs across the agency, other ICs, such as NIAMS, are also committed to the issue.

The environment and environmental exposures have a strong influence on whole person health. Measuring the totality of exposures a person experiences from conception to death along with the associated biological response is referred to as the exposome, a concept that has become increasingly important for discovering environmental causes of disease. One major initiative related to this topic is "Accelerating Precision Environmental Health: Demonstrating the Value of the Exposome." This initiative is led by NIEHS with support from NIAMS, NINR, NIMHD, and NHGRI, among other ICs and HHS operating divisions. This effort involves expanding and catalyzing the emerging exposomics scientific community to work collaboratively to discover, determine, and design the best ways to operationalize exposomics toward the goal of precision environmental health. NIEHS is working across NIH and multiple scientific disciplines to investigate, identify, and foster key aspects of this critical work, including:

- Tools, Technologies, and Methodologies (measuring the exposome);
- Biological Responses and Impact on Health and Disease, (integrating multi-omics with biomarkers of exposure, response, effect, susceptibility, vulnerability, and resilience);
- Future of Clinical & Prevention Trials, Cohorts and Epidemiology (designing studies, refining methodology, determining statistical power and pooling samples);
- Social and Societal Impacts (integrating social determinants of health, diversity, health disparities, privacy, etc.); and
- Data Infrastructure and Data Analytics (sharing data and harmonizing it; analyzing, interpreting, visualizing, and modeling data).

New Innovations

Remaining at the forefront of scientific discovery is paramount for advancing human health. Most NIH ICs are investing in developing novel technologies that have the potential to change how human diseases are diagnosed or treated. This section highlights programs and initiatives to advance research on artificial intelligence (AI) and machine learning (ML), genetics and genomics, neuroscience, and mobile health.

Artificial Intelligence and Machine Learning

AI and ML have the potential to transform research and clinical care. Multiple ICs, including but not limited to NLM, NEI, NHGRI, NCCIH, NCATS, and NIBIB, are actively involved in supporting AI research through the NIH Common Fund's Bridge2AI program.[164] The goal of

[162] www.nccih.nih.gov/health/whole-person-health-what-you-need-to-know
[163] www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025
[164] commonfund.nih.gov/bridge2ai

the program is to tap the potential of AI for revolutionizing biomedical discovery, increasing our understanding of human health, and improving the practice of medicine. The program is assembling team members from diverse disciplines and backgrounds to generate tools, resources, and richly detailed data that are responsive to AI approaches. At the same time, the program will ensure its tools and data do not perpetuate inequities or ethical problems that may occur during data collection and analysis. Through extensive collaboration across projects, Bridge2AI researchers will create guidance and standards for the development of ethically sourced, state-of-the-art, AI-ready data sets that have the potential to help solve some of the most pressing challenges in human health — such as uncovering how genetic, behavioral, and environmental factors influence a person's physical condition throughout their life.

The AI/ML field currently lacks diversity in its researchers and in data, including electronic health record (EHR) data. These gaps pose a risk of creating and continuing harmful biases in how AI/ML is used, how algorithms are developed and trained, and how findings are interpreted. Critically, these gaps can lead to continued health disparities and inequities for underrepresented communities. Underrepresented communities have untapped potential to contribute new expertise, data, recruitment strategies, and cutting-edge science to the AI/ML field. To close the gaps in the field and to better engage underrepresented communities, NIH has launched the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program.[165] Several NIH ICs, including NIMHD and NEI, provide funding for or otherwise participate in the AIM-AHEAD program. This program seeks to increase the participation and representation of the researchers and communities that are currently underrepresented in AI/ML modeling and applications through mutually beneficial partnerships.

The NIH Common Fund's Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) program supports data science-related research, including AI and ML. This initiative is led by FIC, NIBIB, NLM, and NIMH with the involvement of many other ICs interested in leveraging these tools to address some of Africa's most pressing public health problems through a robust ecosystem of new partners from academic, government, and private sectors.

In addition, NIH investigators and extramurally-funded researchers are advancing development and use of AI/ML methods and approaches for discovery and health. For example, NLM investigators have collaborated with the National Institute of Allergy and Infectious Diseases (NIAID), the National Heart, Lung, and Blood Institute (NHLBI), and the National Cancer Institute (NCI) to develop AI algorithms that analyze imaging and non-imaging data in support of HIV, tuberculosis, and sickle cell disease screening; and are designing a novel pipeline for automated localization of possible lesions in dynamic cervical imaging to support cancer research. NLM-funded extramural researchers have applied artificial intelligence and machine learning to predict treatment effectiveness and inform personalized medicine approaches and have developed new AI methods for image and biomedical data analysis.

[165] datascience.nih.gov/artificial-intelligence/aim-ahead

Genetics and Genomics

Understanding the human genome and learning how it can be manipulated is a promising approach for treating a number of diseases and conditions. This section highlights efforts being undertaken by several ICs to better understanding human genomics and to test potential approaches to advance gene therapies and to utilize the power of genomics to improve human health.

New technologies – including the use of viruses to deliver genes to cells that need properly functioning genes – are making gene therapy an increasingly attractive treatment option for individuals with rare genetic diseases. Yet, thousands of these disorders are so rare that companies might be reluctant or unable to invest the years of research and the millions of dollars needed to develop, test, and bring a gene therapy for a very rare disease to market. To address the unmet need for more efficient gene therapy clinical development, NCATS, leading a partnership with NHGRI, NINDS, and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), launched the Platform Vector Gene Therapy (PaVe-GT) pilot project in February 2019.[166] The goal of this project is to test the impact of using the same gene delivery system and manufacturing methods in multiple rare disease gene therapy clinical trials. A related example in collaboration with the Foundation for NIH, NCATS, NHGRI, NICHD, NEI, NIDCD, NIDCR, and NIAMS, is the Accelerating Medicines Partnership's Bespoke Gene Therapy Consortium.[167]

The Clinical Genome (ClinGen) Resource, which is primarily funded by NHGRI, is an effort dedicated to building an authoritative central resource that defines the clinical relevance of genes and variants for use in precision medicine and research.[168] The key goals of the program are aggregating and sharing relevant data about genes; curating a public resource of clinically-relevant genes and variants through the ongoing evolution of data standards; broadly disseminating tools, standards, and expert assertions; and continually evaluating and improving ClinGen resources.

Other NIH genetic data resources, such as the Gene Expression Omnibus (GEO),[169] an open-access repository managed by NLM, support sharing of research outputs for use in subsequent studies. GEO stores gene expression and epigenetic data that describe how different biological conditions or environment can impact biological processes. GEO datasets represent a rich data source which may be further analyzed, mined, and aggregated by interested parties. Researchers use GEO data to extract meaningful information and make new discoveries that accelerate biological and health sciences.

Neuroscience

To develop technologies that treat nervous system disorders, NIBIB has partnered with the NIH Blueprint for Neuroscience consortium of institutes to launch the Blueprint MedTech program. This program is designed to overcome barriers to the commercialization of groundbreaking neurotherapuetic devices. The program will provide support to develop and de-risk technologies

[166] ncats.nih.gov/expertise/pave-gt-pilot-project
[167] fnih.org/our-programs/AMP/BGTC
[168] clinicalgenome.org/about/
[169] www.ncbi.nlm.nih.gov/geo/

to the point where additional investments are warranted from industry partners, investors, and government. One-year pilot project awards of $100,000 each, along with technical support, have been made. One project is developing a novel method to optimize neurostimulation therapy for treatment of people with mental disorders, including severe depression and anxiety. The system will allow clinicians to select parameters for deep brain stimulation that target specific brain circuits identified as areas of dysfunction and restore patterns of neural activity that are necessary for healthy cognitive function and control.

Mobile Health in LMICs

On behalf of NIH, FIC has coordinated the Mobile Health (mHealth): Technology and Outcomes in Low- and Middle-Income Countries program since 2014.[170] In total, 10 NIH ICOs participate in the program including NEI, NIBIB, NIDCD, NIEHS, and FIC. The purpose of the program is to encourage exploratory/developmental research applications that study the development, validation, feasibility, and effectiveness of innovative mHealth interventions or tools specifically suited for low- and middle-income countries (LMICs) that utilize new or emerging technology, platforms, systems, or analytics. The overall goal of the program is to catalyze innovation through multidisciplinary research that addresses global health problems, develop an evidence base for the use of mHealth technology to improve clinical and public health outcomes, and strengthen mHealth research capacity in LMICs.

Research to Benefit Everyone

The entirety of NIH is committed to a scientific enterprise in which everyone can benefit, and everyone can participate. This section highlights just a few of NIH's efforts to minimize health disparities, research on social determinants of health, and efforts to diagnose and treat rare diseases.

Health Disparities

NIMHD is co-leading two NIH-wide research initiatives related to COVID-19. The RADx® Underserved Populations (RADx-UP) initiative supports a consortium of more than 137 research projects to examine testing as an intervention to mitigate disparities in COVID-19 morbidity and mortality for individuals from populations and communities disproportionately affected by the pandemic. The RADx-UP initiative includes participation from 16 ICs along with the NIH Office of the Director. This initiative resulted in a recent peer-reviewed special issue of the *American Journal of Public Health* highlighting interventions to promote testing for SARS-CoV-2 and studies on the social, behavioral, and ethical issues of the pandemic in underserved populations.[171] The publication will inform and prioritize key strategies for future public health responses among communities experiencing health disparities. NIMHD has awarded 33 RADx-UP grants that will enable a targeted public health response to COVID-19 through a variety of testing methods among specific populations, areas, and settings. The results will support evidence-based approaches to address disparities in COVID-19 diagnostic testing uptake and effectiveness among populations disproportionately affected by COVID-19. In addition, NIMHD houses and manages the RADx-UP coordination and data collection center, a

[170] www.fic.nih.gov/Programs/Pages/mhealth.aspx
[171] pubmed.ncbi.nlm.nih.gov/36265091/; pubmed.ncbi.nlm.nih.gov/36265090/; pubmed.ncbi.nlm.nih.gov/36194852/

centralized hub that provides organizational and analytical infrastructure and expertise, facilitates data integration and analysis, and coordinates across RADx-UP projects.[172]

NIMHD and NHLBI co-lead the Community Engagement Alliance Against COVID-19 Disparities (CEAL) initiative. The initiative promotes diversity and inclusion in COVID-19 prevention, vaccine, and therapeutic trials and conducts urgent community-engaged research and outreach focused on COVID-19 awareness and education. The CEAL teams have been actively working in regions around the United States and its territories to build trusting relationships and share science-based information with the communities most impacted by the COVID-19 pandemic. CEAL partners have developed educational tools, factual materials, and resources in different languages such as Spanish, Chinese, and Korean to broaden CEAL's reach into the affected communities. The CEAL initiative is addressing misinformation and has recently released a guide for healthcare professionals on adapting fact-based information to the needs of communities.[173] To further its work, the CEAL initiative started a new network for community-engaged primary care research that will: 1) support research on awareness, education, and mistrust around COVID-19, as well as testing and vaccine acceptance; and 2) promote inclusive participation of underserved racial and ethnic minority and rural populations in clinical research.[174]

NINR is committed to supporting research that optimizes health and advances health equity. In fact, 34 percent of its budget in FY 2021 and FY 2022 funded research that aims to eliminate health disparities. Focused on identifying solutions, NINR is leading a bold initiative to reduce disparities in severe maternal morbidity and mortality. The Advancing Integrated Models of Care (AIM)[175] to Improve Maternal Health Outcomes among Women Who Experience Persistent Disparities initiative supports intervention research to develop, implement, and evaluate integrated models of supportive care that address structural inequities to prevent adverse maternal health outcomes.

Finally, NIAMS convened a 2-day workshop on health disparities in osteoarthritis in July 2022. The workshop was co-sponsored by NIMHD and the National Institute on Aging. The workshop brought together osteoarthritis investigators with others who have health disparities research expertise to exchange ideas regarding how and why disparities in osteoarthritis treatment outcomes and access to care exist and how they can be addressed. Panelists and speakers highlighted mechanisms through which integration of behavioral and biomedical science can lead to better health in osteoarthritis. Participants were also invited to attend breakout sessions to exchange ideas on how to address and improves issues related to health disparities in osteoarthritis.

Social Determinants of Health

Social determinants of health are the conditions in which people are born, live, learn, work, play, and age that affect health and quality of life for individuals and populations. Social determinants of health include community conditions (e.g., job opportunities, school quality, transportation

[172] nimhd.nih.gov/programs/extramural/investigator-initiated-research/emergency-awards-RADx-UP.html
[173] covid19community.nih.gov/community-engagement-teams/ceal-teams-resources
[174] covid19community.nih.gov/Network-for-Community-Engaged-Primary-Care-Research
[175] grants.nih.gov/grants/guide/rfa-files/RFA-NR-22-002.html

systems, social cohesion, and green space) and individual and family social and economic circumstances (e.g., income, educational attainment, social isolation, traumatic experiences, nutrition security, and housing) that can have positive or negative influences on health. As co-chair of a new NIH-wide social determinants of health research coordinating committee, NINR, along with NIMHD and the Office of Behavioral and Social Sciences Research, is leading an exciting initiative to accelerate this area of research across NIH – across diseases and conditions, populations, and the life course. The committee has been joined by 15 other NIH Institutes, Centers, and Offices.

NIMHD led the development of the PhenX Toolkit Social Determinants of Health Assessments Collection which enables researchers to develop, disseminate, and use standard data collection measures.[176,177] The SDOH Collection features a Core collection of 16 measurement protocols designed to create common data elements for cross-study analyses that compare or combine data from different studies that includes elements such as race or ethnicity, age, and gender identity. The Specialty collection has two components. An individual SDOH collection of 22 measurement protocols for researchers collecting information for individuals or their family through elements such as affordability of accessing dental care or prescriptions, discrimination in health care, and housing instability due to affordability. The structural SDOH collection includes 15 measurement protocols at the structural or community level of the socioecological framework with elements such as: minimum wage, neighborhood walking and biking environment, and physical activity-neighborhood environment.

Rare Diseases

While rare diseases are individually rare, collectively they affect about 30 million people in the United States. NCATS is committed to using research to address significant economic burden[178] and the public health crisis presented by rare diseases. Speeding development of treatments for patients requires innovation in science and technology and engaging patients and their support organizations as essential partners. Toward that goal, NCATS supports several programs on research to treat or prevent rare diseases. The Rare Diseases Clinical Research Network (RDCRN) program, involving NCATS and several other ICs, is designed to advance medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment and data sharing.[179] Through the RDCRN Consortia, physician scientists and their multidisciplinary teams work together with patient advocacy groups to study more than 200 rare diseases at sites across the nation. The NCATS Division of Preclinical Innovation's Therapeutics for Rare and Neglected Diseases (TRND) program supports preclinical development of therapeutic candidates intended to treat rare or neglected disorders, with the goal of enabling an Investigational New Drug (IND) application.[180] In addition to these innovative research programs, NCATS also provides resources to people with rare diseases[181] and hosts an

[176] www.nimhd.nih.gov/resources/phenx/
[177] www.phenxtoolkit.org/collections/view/6
[178] ncats.nih.gov/news/releases/2021/nih-study-suggests-people-with-rare-diseases-face-significantly-higher-health-care-costs
[179] ncats.nih.gov/rdcrn
[180] ncats.nih.gov/trnd
[181] ncats.nih.gov/engagement

annual Rare Disease Day to raise awareness about rare diseases, the people they affect, and NIH collaborations that address scientific questions and advance research for new treatments.[182]

Biomedical Research Stewardship

NIH is committed to funding the highest priority biomedical research while also maintaining stewardship of taxpayer investments. ICs such as NHGRI, NLM, NIDCR, NCCIH, and NINR are making great strides in ensuring that research is conducted in a way that continually improves agency operations and research programs.

Ethical, Legal, and Societal Implications Research Program

The NHGRI Ethical, Legal, and Societal Implications (ELSI) Research Program fosters basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities.[183] Since its creation in 1990, the ELSI Research Program has supported a large body of research on a wide range of topics. ELSI research addresses the new and sometimes unexpected ways that genomics interacts with many aspects of daily life, from how healthcare is designed and delivered to the ways individuals, families and communities understand such basic concepts as belonging and what it means to be human. Of particular interest are studies that explore these issues with and within communities that have been underrepresented and/or underserved in biomedical research and healthcare. The ELSI Research Program is often at the forefront of newly arising issues such as the appropriate use and implementation of genomics in diverse communities or the ELSI concerns of citizen science. The information gained from this program can be used to inform research and policy across the agency.

Development of Common Data Elements

NIH continues to develop novel approaches to enhance the scientific rigor of the research it funds. NLM is providing leadership and coordination in a trans-NIH effort to improve research rigor through the use of common data elements (CDEs) across NIH-funded research. NLM is also making CDEs findable through NIH's Common Data Elements (CDE) Repository, a freely available source of standard, structured, machine-readable definitions of data elements, standard variables, and measures used in NIH-funded clinical research.[184]

The National Dental Practice-Based Research Network

NIDCR supports clinical studies conducted in a practice-based research setting. The National Dental Practice-Based Research Network (PBRN) is a nationally coordinated program committed to advancing knowledge of dental practice and ways to improve it.[185] Essentially, it is research done in the "real world" of daily clinical practice. The goals of the National Dental PBRN are to support national oral health research studies in dental practices on topics of importance to practitioners and their patients, to provide evidence useful in daily patient care, and to facilitate the translation of research findings into clinical practice. This real-world evidence can inform NIH-funded research as well as improve clinical practice.

[182] ncats.nih.gov/news/events/rdd
[183] www.genome.gov/Funded-Programs-Projects/ELSI-Research-Program-ethical-legal-social-implications
[184] cde.nlm.nih.gov/home
[185] www.nidcr.nih.gov/grants-funding/grant-programs/clinical-practice-based-research-program/more

Community Partnerships to Advance Science for Society

NINR and the Common Fund are partners in the newly launched "Community Partnerships to Advance Science for Society (ComPASS) Program."[186] The goals of ComPASS are to:

- Develop, share, and evaluate community-driven structural health equity interventions that leverage partnerships across multiple sectors to reduce health disparities.
- Develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies.

The program will enable communities and researchers to work collaboratively as equal partners in all phases of the research process to enhance the quality of interventions and to advance health disparities research.

Capacity Building and Research Infrastructure

Investing in capacity building and research infrastructure helps to ensure that NIH, and its funded institutions, are prepared to address pressing issues. A few examples of those efforts are highlighted here.

Capacity Building in LMICs

FIC leads the Global Brain Disorders Research program in partnership with NIEHS, NEI, and NIDCD, among others, to support research and capacity building on brain and nervous system disorders relevant to LMICs.[187] Since its start in 2002, the program has supported innovative collaborations that contribute to the long-term goals of building and strengthening sustainable neuro-health research capacity in LMICs to address brain, nervous system and neuromuscular development, function and impairment throughout life and to lead to diagnostics, treatments, prevention and implementation strategies. The program also supports the development of research networks and aims to inform evidence-based policy beyond specific research projects.

FIC also leads the Chronic, Noncommunicable Diseases and Disorders Across the Lifespan International Research Training (NCD-Lifespan) program in partnership with NIA, NIAAA, NIDCR, and NCCIH, among others.[188] Since 2011, the program has helped strengthen research capacity in institutions in LMICs by supporting the training of in-country experts to conduct research on chronic, noncommunicable diseases and disorders. The ultimate goal of this program is to help countries implement evidence-based interventions for conditions such as mental health disorders, cardiovascular disease, diabetes, and many more.

Through both programs, FIC leverages its expertise in global health and research coordination to enhance the infrastructure in LMICs, which can have significant impacts in the health and quality of life in these regions.

SARS-CoV-2 Variant Tracking

NLM, in collaboration with NCATS, NIAID, and NHLBI as well as other U.S. government agencies, continued to participate in the ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) project to develop processes and infrastructure to evaluate submitted SARS-CoV-2 sequence data using standardized methods to identify variants and mutations and to publicly

[186] commonfund.nih.gov/compass
[187] www.fic.nih.gov/Programs/Pages/brain-disorders.aspx
[188] www.fic.nih.gov/Programs/Pages/chronic-lifespan.aspx

disseminate analysis results.[189] In FY 2022, NLM refined data processing and analysis methods to support tracking frequency of SARS-CoV-2 sequence mutations and variants and to predict their impact on vaccine and biologic interventions. As part of this effort, NLM also provided results of this standardized analysis in a lightweight variant report format available through a cloud-based open data platform, through an extensive table that supports findability of individual samples and large-scale analysis across the entire dataset, and through a website interface.

Conclusion

The work highlighted in this section demonstrates that important impacts, resources, and scientific advances to benefit researchers and human health come from across NIH including Institutes and Centers with budgets under $1 billion. More information on the important work and priorities of all ICs is available in their sections of the Congressional Justification.

[189] www.ncbi.nlm.nih.gov/activ

UNITE INITIATIVE

Program Overview

NIH launched the UNITE Initiative[190] at a special meeting of the Advisory Committee to the Director (ACD)[191] on February 26, 2021, with the goal of identifying and addressing structural racism within the NIH community and the greater research community. UNITE is an NIH-wide, collaborative effort comprised of five workstreams—U, N, I, T, and E— with distinct but coordinated objectives to tackle the problem of racial and ethnic equity in science while developing data-driven methods to promote diversity, equity, and inclusion across the biomedical and behavioral enterprise. To thoroughly address structural racism that may exist within the enterprise, UNITE works across three domains of the enterprise—Health Disparities and Minority Health Research (HD/MH), internal NIH workforce, and external biomedical and behavioral research workforce (Fig. 1). Data gathering and analysis are central to all activities, and therefore evidence drives the work of UNITE.

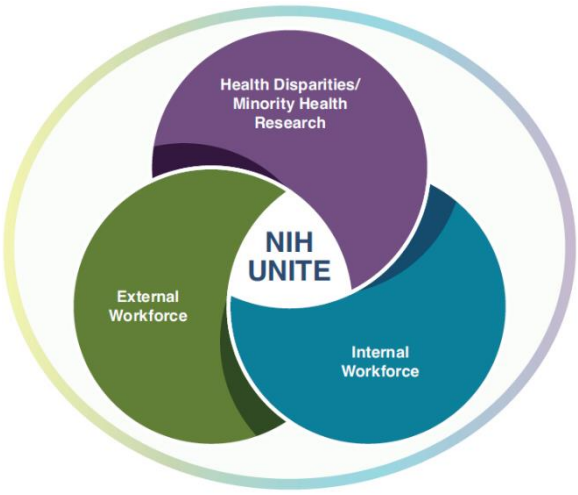


Fig. 1. UNITE's Role Intersecting HD/MH and Internal/External Workforces. In order to address entrenched issues of structural systematic racism in the scientific enterprise, UNITE works across three intersecting domains that are typically singularly focused on by other NIH DEIA-related entities. This design enables greater transparency, accountability, and communications across the NIH and the biomedical research community.

Since its launch, UNITE has endeavored to identify and address challenges associated with addressing racial and ethnic equity in science. Consequently, four focus areas have emerged as priorities for UNITE actions. Accomplishments associated with each focus area below were the result of ideas brought forth by UNITE workstreams and implemented by Institutes, Centers, and Offices (ICOs). By addressing these priority areas, UNITE is working to ensure health for all, build and inspire the next generation of scientists, support the development of targeted preventions and cures, and overall promote the public good.

Focus Area 1: Elevating Health Disparities and Minority Health Research

Fundamental to the NIH's role as the "Federal focal point for health research" and the "steward of medical and behavioral research for the Nation"[192] is the agency's ability to conduct research pertaining to HD/MH. Led by the National Institute of Minority Health and Health Disparities (NIMHD), UNITE works to bolster this role by recommending multiple efforts to encourage prioritization of HD/MH research across the NIH. For example, in FY 2021 NIH launched the Common Fund Transformative Research to Address Health Disparities and Advance Health

[190] www.nih.gov/ending-structural-racism/unite
[191] acd.od.nih.gov/meetings.html
[192] www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih

Equity Initiative.[193] This initiative has dedicated approximately $58 million over 5 years to support research projects to prevent, reduce, or eliminate HDs, advance health equity (HE), and expand HD research, including at minority-serving institutions (MSIs). Eleven grants have been issued, five of which were awarded to MSIs.

Based on UNITE recommendations to enhance research on interventions for HDs, in 2022, the Common Fund's Community Partnerships to Advance Science for Society (ComPASS) Program[194] was established and approved for a 10-year research investment of approximately $400 million. ComPASS is led by NIMHD, the National Institute on Mental Health (NIMH), the National Institute of Nursing Research (NINR), the Office of Research on Women's Health (ORWH), and the Tribal Health Research Office (THRO). The initiative aims to catalyze, develop, and assess community-led HE structural interventions to advance health equity that leverage partnerships across multiple sectors to reduce health disparities, and develop a new HE research model for community-led, multisectoral structural intervention research across NIH and other federal agencies. As of October 2022, NIH has released two funding opportunity announcements (FOAs) (OTA-22-007 and RFA-RM-23-001)[195,196] associated with the ComPASS program.

Focus Area 2: Funding Extramural Research to Enhance Diversity and Inclusion of Underrepresented Groups (URGs)

Scientific innovation and progress are driven by a workforce that is diverse, inclusive, and equitable. Based on recommendations from UNITE, NIH has implemented several strategies to reduce disparities and enhance diversity, equity, and inclusion (DEI) throughout the external workforce:

Enhance and maintain cultures of inclusive excellence in the biomedical research community: In FY 2021 the Common Fund set aside up to $241 million over 9 years to launch the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program.[197] FIRST supports extramural institutions in building a self-reinforcing community of scientists through recruitment of early-career faculty committed to inclusive excellence.

Support educational opportunities that complement or enhance workforce training: As of FY 2022 17 NIH ICOs signed on to expand the Science Education Partnership Awards (SEPA) program[198] to provide opportunities for students from underserved communities to consider careers in basic or clinical research, give teachers professional development in science content creation, and improve community health literacy.

Encourage institutional cultural change at extramural institutions: Through the efforts of UNITE, NIH is establishing a Diversity, Equity, Inclusion, and Accessibility (DEIA) Prize Competition.[199] The goals of this prize are to 1) recognize institutions of higher education that

[193] www.commonfund.nih.gov/healthdisparitiestransformation
[194] commonfund.nih.gov/compass
[195] commonfund.nih.gov/sites/default/files/OTA-22-007.pdf
[196] grants.nih.gov/grants/guide/rfa-files/RFA-RM-23-001.html
[197] commonfund.nih.gov/first
[198] nihsepa.org/
[199] diversity.nih.gov/blog/2022-05-03-requesting-your-input-development-deia-prize-competition

have implemented successful, innovative interventions for enhancing faculty and student DEIA and 2) identify and highlight evidence-based best practices proven to create more inclusive environments for students and faculty. This effort is expected to launch in FY 2023.

Support Extramural DEIA Efforts and Enhance MSI Capacity: In FY 2023 NIH anticipates releasing FOAs based on four concepts approved by the National Institute of General Medical Sciences (NIGMS) and NIMHD Councils for funding in FY 2024. These FOAs will provide institutions support for 1) assessment of institutional climate and achieving DEIA culture change, 2) principal investigators (PIs) who have demonstrated excellence in promoting DEIA in biomedical research to continue their research program and DEIA efforts, 3) low-resource MSIs to increase capacity through instrumentation grants, and 4) MSIs to assess and develop research and training capacity.

Focus Area 3: Creating & Sustaining an Equitable NIH Workplace & Organizational Culture

NIH's mission to solve many of the world's health and well-being challenges relies on the contributions of thousands of diverse staff and researchers internal to NIH. UNITE works to promote equity in the internal NIH workforce through role-modeling the expectations of the external biomedical ecosystem and bolstering NIH's culture of inclusive excellence. To recognize the contributions of all NIH staff and engender a spirit of inclusion across NIH, UNITE launched The Power of an Inclusive Workplace Recognition Project (Fig. 2).[200] Spearheaded by Dr. Sadhana Jackson[201] a National Institute of Neurological Disorders and Stroke (NINDS) and National Cancer Institute (NCI) tenure-track scientist, NIH Distinguished Scholar[202] and T Committee Co-Chair, the initiative endeavored to diversify the portraiture within NIH buildings and digital spaces to recognize the contributions of all NIH staff and acknowledge the rich diversity of our NIH workforce.

Fig. 2. The Power of an Inclusive Workplace Recognition Imagery. The artwork in shared or public spaces encodes an institution's values and sends messages to its members about belonging. Unveiled in November 2021, the Power of an Inclusive Workplace Recognition Project includes portraits, murals, and inspirational quotes, that celebrate NIH staff from various career paths and identities. The Recognition Project is designed to increase feelings of belonging and inclusion across the NIH.

Across NIH, each ICO and the Office of the Director (OD) developed and began implementing racial and ethnic equity plans (REEPs) in April and June of 2022, respectively. ICs applied a

[200] www.nih.gov/ending-structural-racism/power-inclusive-workplace-recognition-project
[201] www.statnews.com/2022/04/11/the-power-of-inclusion-overturning-the-white-wall-standard/
[202] diversity.nih.gov/programs-partnerships/dsp

racial and ethnic equity lens to each IC's workforce, structure, and systems, to identify and address any racial or ethnic disparities that may exist in the IC's workforce, and enhance racial and ethnic equity and diversity. As REEP implementation continues, UNITE anticipates that each IC may modify IC-specific policies and procedures based on what is learned during this process, and that any changes will benefit all NIH employees.

Focus Area 4: Improving Accuracy and Transparency of Racial and Ethnic Equity Data
The NIH is committed to standing against structural racism in biomedical and behavioral research[203] by identifying and correcting scientific policies and practices that may have helped to perpetuate structural racism. Foundational to these efforts is strengthening the accuracy and transparency of racial and ethnic equity data. Since its launch UNITE has continuously gathered data to inform its activities. UNITE developed a request for information (RFI)[204] for public comments and suggestions to advance racial equity, diversity, and inclusion within the biomedical research workforce, and expand research to eliminate or lessen HDs. UNITE utilized emerging themes from the RFI to inform planning and activities.

Another facet of data gathering was a series of 14 listening sessions with external stakeholders,[205] e.g., Minority-Serving Colleges and Universities, Faith-based Organizations and Houses of Worship, Health Centers and Systems, etc. Topics of interest included but were not limited to changing culture to promote equity, inclusivity, and justice; improving policies, transparency, and oversight; and ensuring fairness in review and funding deliberations (Fig. 3).

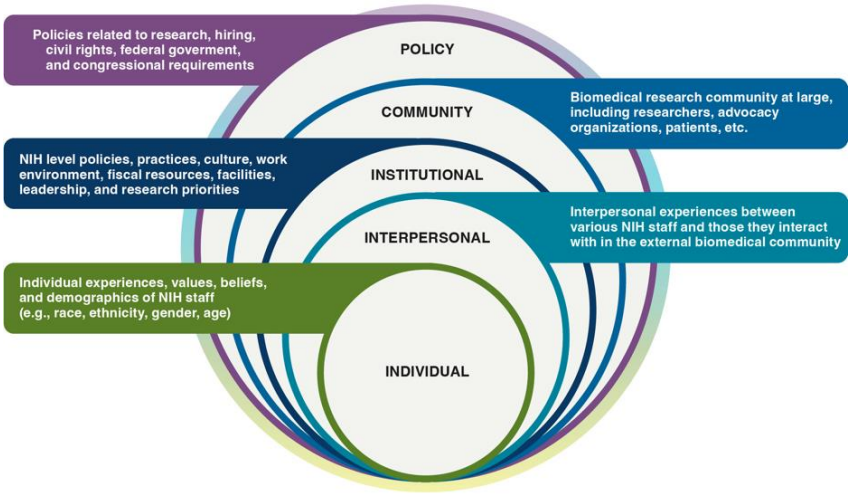


Fig. 3. Socioecological model approach to external listening sessions. The UNITE U Committee drew on the social-ecological model to inform its approach to the extramural listening sessions. The model accounts for factors at the individual, interpersonal, institutional, community, and policy levels, and considers the interplay between the levels. The overlapping nature of these levels emphasizes the need to act across multiple levels at the same time in order to have a sustained and broad impact.

Like the RFI, insights from these sessions provided valuable information on the full range of issues and challenges facing diverse talent that informed the development of UNITE priorities.

To improve transparency and accountability with the public UNITE launched the UNITE Data Dashboard[206] to provide information on aggregated, public-facing facts and figures regarding diversity, equity, and inclusion-related data and analyses from the NIH. UNITE efforts made

[203] www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-stands-against-structural-racism-biomedical-research
[204] grants.nih.gov/grants/guide/notice-files/NOT-OD-21-066.html
[205] www.nih.gov/ending-structural-racism/unite-events
[206] www.nih.gov/ending-structural-racism/data-dashboard

data more accessible for the NIH intramural researcher demographics, the NIH-funded extramural workforce, and NIH health disparities research funding.

NIH Cross-Cutting Collaboration

UNITE is spearheaded by the Immediate Office of the Director and co-chaired by the Chief Officer for Scientific Workforce Diversity, the Deputy Director of Management, and the Acting Principal Deputy Director. As of FY 2023 an IC Director is joining as a co-chair of UNITE. The five workstreams of UNITE have more than 80 members from across the NIH workforce with representation from each of NIH's 27 Institutes and Centers and the Office of the Director and across all staff levels. Members of UNITE work collaboratively to recommend and support the implementation of actions at appropriate ICOs and throughout NIH.

UNITE works in collaboration with several NIH key stakeholders including the Office of Equity, Diversity, and Inclusion, the Chief Officer for Scientific Workforce Diversity Office, the Office of Human Resources, the Civil Program, the Office of Communications and Public Liaison, the Division of Program Coordination, Planning, and Strategic Initiatives, and others. Additionally, UNITE goals and charges are aligned with fundamental tenets of the NIH-Wide Strategic Plan for 2021–2025,[207] the NIH Minority Health and Health Disparities Strategic Plan 2021–2025,[208] and the NIH-Wide DEIA Strategic Plan for 2022–2026, released in December of 2022. The UNITE Initiative reports to the NIH Steering Committee and reports out to the NIH Advisory Committee to the Director (ACD).

The collaborative structure described here allows UNITE to receive input from across NIH, at all levels, and supports the generation of proposals and concepts that receive NIH-wide support.

Next Steps/Goals

While NIH understands that achieving racial and ethnic equity in the biomedical and behavioral research enterprise will take time, the agency believes doing so will propel its work in biomedical and behavioral research and discovery. Recommendations put forward by UNITE for next steps within the four focus areas include but are not limited to:

Focus Area 1: Elevating Health Disparities and Minority Health Research
Develop additional FOAs that focus on IC-specific diseases or topic areas in health disparities and minority health research

Focus Area 2: Funding Extramural Research to Enhance Diversity and Inclusion of Underrepresented Groups
Expand Sponsored Program Administration (SPAD) services and activities

Focus Area 3: Creating & Sustaining an Equitable NIH Workplace & Organizational Culture
Support ICOs in implementing and proposing action steps for REEPs

Focus Area 4: Improving Accuracy and Transparency of Racial and Ethnic Equity Data
Continue listening and learning from internal and external stakeholders

[207] www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf
[208] www.nimhd.nih.gov/docs/nimhd-strategic-plan-2021-2025.pdf

WOMEN'S HEALTH

Program Overview

Improving the health of women benefits all members of our society. Support for research on the health of women has produced significant returns on investment. The 2019–2023 Trans-NIH Strategic Plan for Women's Health Research sets an ambitious vision for a world in which the biomedical research enterprise thoroughly integrates sex and gender influences; every woman receives evidence-based disease treatment and prevention tailored to her own needs, circumstances, and goals; and all women in scientific careers reach their full potential.[209] The NIH Office of Research on Women's Health (ORWH) is well positioned to drive progress in each of these areas as part of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the NIH Office of the Director. ORWH coordinates and collaborates with all NIH Institutes, Centers, and Offices (ICOs) to set the NIH agenda for research on the health of women, address critical gaps in knowledge about the health of women across the lifespan by stimulating interdisciplinary and innovative research approaches, and launch the careers of promising women's health researchers. These programs set the stage for improved health for women and their families and career opportunities and advancement for a diverse biomedical workforce.

NIH Collaborations

NIH ICOs support research relevant to the health of women, from the laboratory to the clinic, generating new knowledge to inform better treatment of diseases unique to women as well as diseases that may affect women differently. For example, in response to a FY 2021 Congressional request, ORWH and the NIH Advisory Committee on Research on Women's Health (ACRWH) co-hosted "Advancing NIH Research on the Health of Women: A 2021 Conference."[210] Subsequently, the ACRWH outlined opportunities for future NIH research related to maternal morbidity and mortality (MMM), rising rates of chronic debilitating conditions in women (CDCW) and stagnant cervical cancer survival, emphasizing the importance of an intentional approach and enhanced efforts on female-specific conditions and diseases as well as strategic clinical research relevant to the health needs of women.[211]

Maternal Health and Health Disparities

In the United States, there is a growing MMM crisis and thousands of women experience severe maternal morbidity (SMM), which are unexpected outcomes of labor and delivery that result in significant short- or long-term health consequences. This crisis disproportionately affects African American and American Indian/Alaska Native, women who are two to three times more likely to die from pregnancy-related causes compared with non-Hispanic White women; they also have a higher incidence of SMM compared to non-Hispanic White women.[212] [213] NIH is committed to advancing research in this space to lower poor pregnancy-related and -associated

[209] orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research
[210] orwh.od.nih.gov/research/2021-womens-health-research-conference
[211] orwh.od.nih.gov/sites/orwh/files/docs/ORWH-WHC-Report-508C.pdf
[212] cdc.gov/reproductivehealth/maternal-mortality/disparities-pregnancy-related-deaths/infographic.html
[213] Gray KE, Wallace ER, Nelson KR, Reed SD, Schiff MA. Population-based study of risk factors for severe maternal morbidity. Paediatr Perinat Epidemiol. 2012 Nov;26(6):506-14. doi: 10.1111/ppe.12011. PMID: 23061686; PMCID: PMC3498497.

outcomes and to reduce maternal health disparities. Among the activities that NIH has recently led are the following:

Implementing a Maternal Health and PRegnancy Outcomes Vision for Everyone (IMPROVE)
IMPROVE is an NIH-wide effort coordinated by the NIH Coordinating Committee for Maternal Morbidity and Mortality, which is co-led by *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), ORWH, and the National Institute of Nursing Research (NINR) with participation from 30 other NIH ICOs.[214] IMPROVE seeks to address the leading causes of maternal mortality and morbidity in the United States – cardiovascular disease, infection, and immunity – as well as other health conditions and social factors, such as mental health and substance use. The initiative addresses structural and health system factors and community engagement in implementation of interventions for pregnancy-related complications particularly for populations experiencing health disparities. Recent projects supported with IMPROVE funding include one that will examine the impact of structural racism and discrimination on perinatal mental health during the COVID-19 pandemic.[215]

Understudied, Underrepresented, and Underreported (U3) Populations Interdisciplinary Research Administrative Supplement
The U3 framework was developed by ORWH to address persistent disparities in women's health and healthcare, support research to address this gap, and highlight how intersectional experiences and social determinants of health interact to contribute to different health outcomes.[216] Investigators who have been awarded a grant from one of the 21 participating NIH ICOs can apply for a U3 supplement to their grant. The U3 Supplement Program provides support for scientists from different disciplines who are conducting preclinical, clinical, behavioral, or translational research addressing health disparities among women from one or more NIH-designated health disparity populations. Supplements focus on many aspects of maternal health, including the role of inflammation and possible biomarkers for risk of gestational diabetes among Native Hawaiian and other Pacific Islander women.[217]

Women's Health Research in Institutional Development Award (IDeA) States
The IDeA program builds research capacity in states with historically low levels of NIH funding.[218] ORWH and the National Institute of General Medical Sciences (NIGMS) expanded research on women's health and health disparities, including maternal and infant morbidity and mortality,[219] through supplemental funding and a new Women's Health Research Center of Biomedical Research Excellence (COBRE) to strengthen research infrastructure and investigator competitiveness.[220] [221] One recent publication supported by the administrative supplements for women's health research in IDeA states reported the development of a novel, noninvasive

[214] nichd.nih.gov/research/supported/IMPROVE
[215] reporter.nih.gov/search/q4mKX5AkrEKHRnaHQzjwtQ/project-details/10392594
[216] orwh.od.nih.gov/womens-health-research/interdisciplinary-research/u3-interdisciplinary-research/orwh-u3
[217] reporter.nih.gov/project-details/10387025
[218] nigms.nih.gov/capacity-building/division-for-research-capacity-building/institutional-development-award-(idea)
[219] nigms.nih.gov/News/results/Pages/20201009.aspx
[220] grants.nih.gov/grants/guide/notice-files/NOT-GM-21-018.html
[221] grants.nih.gov/grants/guide/notice-files/NOT-GM-21-056.html

diagnostic and predictive assay for preeclampsia, a high blood pressure disorder that can occur during pregnancy which is a leading cause of maternal and fetal morbidity.[222]

Chronic Debilitating Conditions and Women's Health Across the Lifespan

Pregnancy complications like gestational diabetes and preeclampsia are associated with increased risk of Type 2 diabetes and hypertension, that can last a lifetime.[223] Chronic debilitating conditions such as these pose a significant burden on the health and quality of life of women. These conditions include diseases and disorders that occur across the lifespan, many of which predominantly affect women, including: cardiovascular disease, arthritis, depression, dementia, and osteoporosis. Lower socioeconomic status and education are risk factors for multimorbidity, particularly for underrepresented populations. NIH supports several collaborative efforts employing a life course approach to address chronic debilitating conditions in women of all ages, including the following:

Accelerating Medicines Partnership (AMP®)

The AMP Autoimmune and Immune-mediated Diseases (AMP-AIM) public-private partnership seeks to better understand cellular and molecular interactions that lead to inflammation and autoimmune diseases, frequently seen in women, and develop new research tools in rheumatoid arthritis, systemic lupus erythematous, psoriasis/psoriatic arthritis, and Sjögren's disease.[224]

Study of Women's Health Across the Nation (SWAN)

SWAN is a multi-site longitudinal, epidemiologic study on physical, biological, psychological, and social mid-life changes women experience.[225] It includes diverse participants from a variety of racial and ethnic groups (Black, Chinese, Hispanic, Japanese, and White) at designated research centers. SWAN has generated new knowledge informing midlife women's health care for example, weight gain and menopause symptom management, as well as heart disease and osteoporosis risk. SWAN, co-sponsored by ORWH and several ICs, began in 1994 and has enrolled 3,302 participants providing critical insights into important differences among diverse populations of women.

Funding Opportunities for Basic, Clinical and Behavioral Research on Sex & Gender Influences in CDCW

ORWH leads several funding opportunities in collaboration with NIH ICOs to advance biomedical research on sex and gender influences on health and disease, including CDCW to inform and improve the health of women across the lifespan. The Specialized Centers of Research Excellence in Sex Differences is an innovative interdisciplinary research and training program that supports groundbreaking research integrating basic, clinical, and behavioral research approaches focused on major medical conditions, including chronic debilitating conditions affecting women such as HIV, kidney disease, and irritable bowel syndrome.[226] The

[222] Cheng S, Banerjee S, Daiello LA, Nakashima A, Jash S, Huang Z, Drake JD, Ernerudh J, Berg G, Padbury J, Saito S, Ott BR, Sharma S. Novel blood test for early biomarkers of preeclampsia and Alzheimer's disease. Sci Rep. 2021 Aug 5;11(1):15934. doi: 10.1038/s41598-021-95611-5. PMID: 34354200; PMCID: PMC8342418.
[223] nhlbi.nih.gov/news/2022/hypertensive-pregnancy-disorders-linked-future-cardiac-events
[224] niams.nih.gov/grants-funding/niams-supported-research-programs/accelerating-medicines-partnership-amp
[225] swanstudy.org/
[226] orwh.od.nih.gov/womens-health-research/interdisciplinary-research/specialized-centers-of-research-excellence-on-sex-differences-u54-clinical-trial-optional

Intersection of Sex and Gender Influences on Health and Disease R01 is an initiative that targets gaps in knowledge regarding the influence and intersection of sex and gender on disease, including CDCW such as asthma and substance use disorder, to improve our understanding of factors and mechanisms underlying sex differences in health.[227] The Research on Sex/Gender Influences is an NIH-wide administrative supplement program that catalyzes new insights by accelerating consideration of sex as a biological variable and gender as a social construct across a wide array of scientific disciplines and throughout the research spectrum from the laboratory to the clinic. [228] Over the last ten years, ORWH/NIH has supported over 1,400 investigators from 19 NIH ICOs for a total investment of more than $42 million under the umbrella of this program.

Women's Health Research and Career Development Programs

The fourth goal of the FY 2019-2023 Trans-NIH Strategic Plan for Women's Health Research, *Promote Training and Careers*, focuses on attracting, retaining, and advancing women in biomedical science careers; building interdisciplinary research careers in women's health; and training scientists and health professionals on sex and gender influences in health and disease. Many NIH-wide collaborative activities support a diverse and robust workforce to accelerate the translation of research findings into improved health care for women.

Programs to Promote Careers in Women's Health Research

The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program was established by ORWH and collaborating NIH ICOs in 2000, and since its inception has supported more than 750 BIRCWH Scholars who are junior faculty matched with several research mentors.[229] Most of the Scholars achieve productive careers in women's health research, successfully compete for at least one NIH research grant and generate impactful publications. The ORWH funding level for FY 2022 included $4 million for the BIRCWH program to support additional fellows at existing sites to increase the diversity of the scholars and research areas. The Women's Reproductive Health Research (WRHR) Program was established in 1998 by NICHD, with support from ORWH. The focus of this institutional career development program is to create a cohort of clinically trained junior obstetrics/gynecologic investigators representing several subspecialities and emerging areas with expertise in women's reproductive health research at academic settings across the United States.[230]

Career Development Opportunities to Advance Women in Biomedical Research

The Research Supplements to Promote Re-Entry and Re-integration into Health-Related Research Careers program provides mentored research training experience for scientists to re-enter or re-integrate into an active research career after an interruption due to family responsibilities or having been adversely affected by unsafe (e.g., sexual harassment) or discriminatory environments.[231] Between FY 2012-2021, 80 percent of the applicants were women and the most cited reason for hiatus was childrearing. The Continuity Supplements program for NIH-mentored career development and research program grant awardees aims to

[227] grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-028.html
[228] orwh.od.nih.gov/research/funded-research-and-programs/administrative-supplements
[229] orwh.od.nih.gov/career-development-education/building-interdisciplinary-research-careers-in-womens-health-bircwh
[230] nichd.nih.gov/research/supported/wrhr
[231] orwh.od.nih.gov/career-development-education/research-supplements-promote-reentry-and-reintegration-health-related

retain investigators facing critical life events such as childbirth, adoption, or primary caregiving responsibility for an ailing immediate family member as they transition to the first renewal of their first independent research project grant award or transitioning from career development grants to R01s.[232] [233] In the first 2 years, the success rate for both programs was around 65 percent and a majority of the awardees have been women. The most frequently cited critical life event was childbirth, and the funds were used to hire additional personnel to continue the research. The Advancing Gender Inclusive Excellence (AGIE) initiative seeks to investigate institutional strategies enabling, and barriers preventing, women to attain leadership positions in Science, Technology, Engineering, Mathematics, and Medicine (STEMM) research, leading to expanded dissemination to additional institutions so more women can benefit from these opportunities.[234] The NIH Prize for Enhancing Faculty Gender Diversity recognized organizations achieving sustained improvements and ORWH shared success strategies for broad application.[235]

NIH Working Groups Supporting Career Development

The ORWH and NIH Directors co-chair the Working Group on Women in Biomedical Careers which has membership from multiple NIH ICOs and develops innovative strategies and actions to promote sustained advancement of women in biomedical and research careers, within NIH and throughout the extramural community.[236] Initiatives advanced by the Working Group include the NIH Prize for Enhancing Faculty Gender Diversity, and the Continuity Supplements.[237] The Women of Color Research Network was created to provide women of color and supporters of their advancement in the biomedical sciences with information about NIH grants process, career development, and a forum for sharing information.[238]

ORWH-NIAMS Team Science Leadership Scholars Program (LSP)

The LSP, led by ORWH and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and embedded within the AMP-AIM program, was launched in 2022 to train research scholars to lead interdisciplinary, cross-sectoral collaborative projects.[239] The LSP is a joint initiative that aligns NIAMS' goal of supporting team science and collaboration with the ORWH vision of preparing leaders in women's health research.

Future Directions

ORWH leads the development of an NIH-wide strategic plan for research on the health of women that serves as a guide for future NIH efforts to improve the health of all women throughout their lifespan and promote advancement of women in STEMM. Development of the next iteration of the plan, the FY 2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women, is currently underway. As in past years, the strategic planning process will be a collaborative effort, with involvement from members of the NIH Coordinating Committee for

[232] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-054.html
[233] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-055.html
[234] grants.nih.gov/grants/guide/rfa-files/rfa-od-21-010.html
[235] orwh.od.nih.gov/career-development-education/prize-competition
[236] orwh.od.nih.gov/career-development-education/nih-working-group-on-women-in-biomedical-careers
[237] orwh.od.nih.gov/career-development-education/prize-competition
[238] womeninscience.nih.gov/women-science/women-color-research-network-wocrn
[239] niams.nih.gov/about/about-the-director/letter/new-pilot-program-will-mentor-leaders-and-advance-womens-health

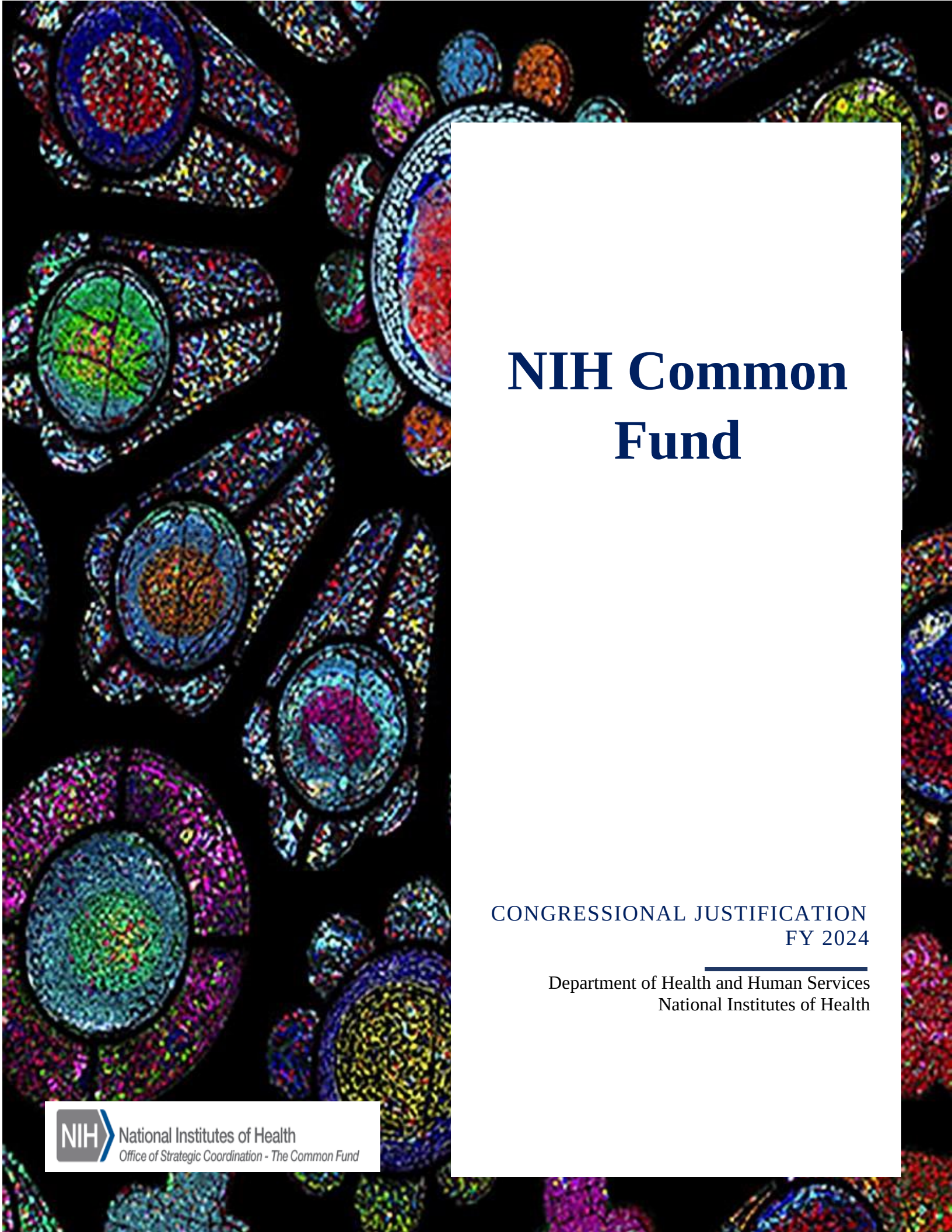
Research on Women's Health (CCRWH); the NIH Advisory Committee for Research on Women's Health (ACRWH); staff from NIH ICOs; other federal partners; and input from the public.

In FY 2023 NIH will implement several activities to advance maternal health research, such as the IMPROVE initiative Maternal Health Research Centers of Excellence, a national network of research centers prioritizing community partnerships in maternity care deserts and underserved populations.[240] Additionally, the Implementation Science to Advance Maternal Health and Maternal Health Equity initiative aims to disseminate and implement evidence-based findings with emphasis on strategies for populations with health disparities.[241] The IMPROVE – Community Implementation Project will establish community-engaged implementation science projects for evidence-based interventions in disproportionately impacted populations.[242] The Connecting the Community for Maternal Health Challenge will build a research infrastructure that helps address structural barriers for community and advocacy organizations conducting maternal health research.[243] Lastly, the NIH Rapid Acceleration of Diagnostics (RADx®) Tech for Maternal Health Challenge aims to innovate point-of-care and home-based diagnostics that can predict and/or diagnose risk of MMM for postpartum individuals.[244]

NIH is strongly committed in engaging stakeholders to address, prevent, and treat CDCW. As such, ORWH has recently engaged the National Academies of Sciences, Engineering, and Medicine (NASEM) to generate a framework for consideration of CDCW and describe current gaps in evidence. To ensure that NIH is fully supporting scientists who have caregiving responsibilities, NASEM has also been contracted to conduct a comprehensive study to explore promising and innovative policies and practices for supporting caregivers working in STEMM. Additionally, ORWH and NIH partners provide online interprofessional health educational resources and have launched a new research education program, Galvanizing Health Equity Through Novel and Diverse Educational Resources (GENDER) R25 to meet the need for sex- and gender-specific training in science, medicine, and allied health professions by supporting the development of courses, curricula, and methods for the extramural community.[245]

Together with the NIH community, federal partners and additional stakeholders, NIH strives to advance research for the health of women, ensure women are appropriately represented in biomedical studies, and support advancement of women in biomedical careers.

[240] grants.nih.gov/grants/guide/rfa-files/RFA-HD-23-035.html
[241] grants.nih.gov/grants/guide/notice-files/NOT-OD-22-125.html
[242] nhlbi.nih.gov/sites/default/files/media/docs/IMPROVE-CIP_ROA_FINAL_508C.pdf
[243] nichd.nih.gov/research/supported/challenges/community-maternal-health
[244] grants.nih.gov/grants/guide/notice-files/NOT-HD-22-035.html
[245] grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-015.html



NIH Common Fund

CONGRESSIONAL JUSTIFICATION
FY 2024

Department of Health and Human Services
National Institutes of Health

NIH National Institutes of Health
Office of Strategic Coordination - The Common Fund

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH Common Fund

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Cover image: "Cathedral of Science" - image of cell-cell interactions in a human lymph node. Researchers in the Common Fund's Human BioMolecular Atlas Program (HuBMAP), along with collaborators, published a primer on how to use multiplexed antibody-based imaging to create complex, information-rich visualizations like this one. Image courtesy of Andrea Radtke, NIAID.

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DIRECTOR'S OVERVIEW

Director's Overview

Douglas Sheeley, Sc.D., Acting Director, Office of Strategic Coordination

The NIH Common Fund (CF) is a unique and exciting component of the NIH, specifically designed to address challenges and opportunities that are of high priority for the NIH as a whole.[246] We support research in areas of emerging scientific opportunities, public health challenges, and knowledge gaps that deserve special emphasis; that would benefit from strategic coordination and planning across NIH Institutes and Centers (ICs); and are designed to achieve specific, high-impact goals and milestones within a 5- to 10-year timeframe. Many Common Fund programs are designed to produce specific deliverables, such as data sets, tools, technologies, or fundamental scientific paradigms. We intend for these deliverables to spur subsequent scientific advances that would not be possible without our strategic investment. Common Fund programs provide a venue for NIH to respond to critical needs and scientific opportunities using a cross-agency approach, complementing IC-specific programs and activities. The Common Fund is managed by the Office of Strategic Coordination (OSC) in the NIH Office of the Director.

Team-based approaches and interdisciplinary science are integral to the science and management of the Common Fund. Most Common Fund programs involve a consortium of researchers working together across disciplines to achieve a shared, ambitious goal. Researchers within a consortium share data, ideas, and resources to accelerate program-wide progress. For example, the Stimulating Peripheral Activity to Relieve Conditions (SPARC) program brings together experts in neuroscience, biomedical engineering, electrophysiology, data science, anatomy, and clinical research to accelerate the development of therapeutic devices that modulate nerve activity for improved health.[247] Common Fund programs may also leverage additional partnerships, as appropriate, to support the goals of the program. The Community Partnerships to Advance Science for Society (ComPASS) program is establishing new models for community-led research, in which communities and researchers work collaboratively as equal partners to develop, share, and evaluate health equity structural interventions to reduce health disparities. [248]

Management of Common Fund programs also leverages a team-based approach. Each Common Fund program is managed as a partnership between OSC and NIH Institutes, Centers, and Offices (ICOs). This partnership ensures that the resources developed through Common Fund

[246] commonfund.nih.gov/
[247] commonfund.nih.gov/sparc
[248] commonfund.nih.gov/compass

programs will enable ICO-supported research across a wide range of scientific disciplines, populations, life stages, and diseases or conditions. ICOs are involved in all stages of the Common Fund program lifecycle, from program planning to implementation to transition. In FY 2022, 24 NIH ICOs co-led Common Fund programs.

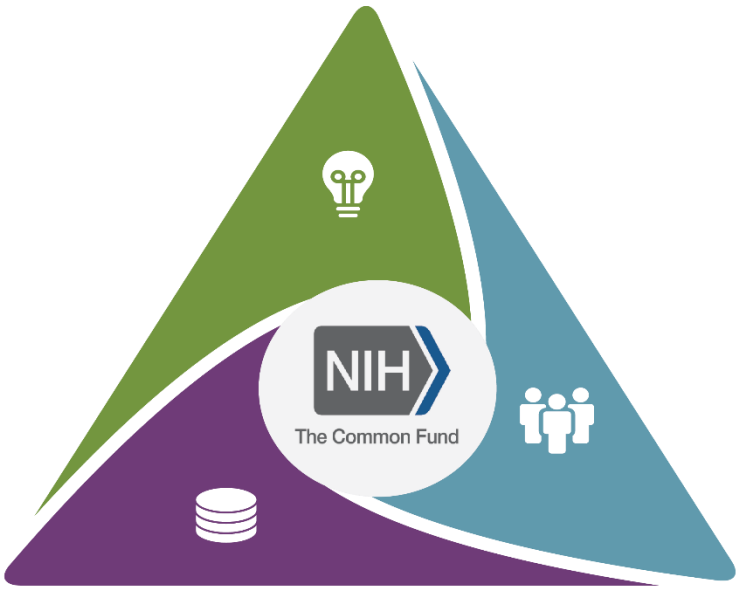
Common Fund programs are broad-reaching and span the entire NIH mission. As a general framework, however, they can be grouped into three categories: Transformational Science and Discovery, Catalytic Data Resources, and Re-engineering the Research Enterprise.

Transformational Science and Discovery
These Common Fund programs are designed to establish new scientific principles, models, and research resources to transform scientific knowledge and paths to discovery. For example, the 4D Nucleome program is establishing a fundamental understanding of how the spatial arrangement of DNA in the cell influences health and disease over time.[249]

Catalytic Data Resources
Several Common Fund programs are designed to manage and develop data for scientific discoveries by accelerating research through data resources. Also included in this category are efforts to enhance the utility of Common Fund data sets. The Bridge to Artificial Intelligence (Bridge2AI) program is generating flagship data sets and best practices for the collection and preparation of data sets amenable to AI and machine learning approaches to address biomedical and behavioral grand challenges.[250]

Re-engineering the Research Enterprise
Common Fund also supports programs that are designed to transform how biomedical and behavioral research is

The goals of Common Fund programs align with three general categories



Transformational Science and Discovery
These programs are designed to establish new scientific principles, models, and research resources to transform scientific knowledge and paths to discovery.

Catalytic Data Resources
These programs are designed to manage and develop data for scientific discoveries by accelerating research through data resources.

Re-Engineering the Research Enterprise
These programs are designed to transform how we do biomedical and behavioral research, how we make the biomedical workforce as robust as possible to ensure new perspectives and ideas contribute to discovery, how we transition that research into prevention and therapies, and how those successful prevention and therapies can be shared broadly.

[249] commonfund.nih.gov/4Dnucleome
[250] commonfund.nih.gov/bridge2ai

conducted, how research results are translated into new treatments and preventive strategies, and how to make the biomedical workforce as robust as possible. For example, the Somatic Cell Genome Editing (SCGE) program is developing a translational pipeline for somatic cell genome editing therapies through improved, Investigational New Device (IND)–enabling technologies.[251]

Science for Everyone by Everyone

The Common Fund supports science for everyone by everyone – through programs that strengthen the biomedical workforce, engage diverse participants in research studies, address research opportunities to support health throughout the lifespan, and develop targeted prevention strategies, treatments, and cures. Diversity, equity, inclusion, and accessibility (DEIA) are critical considerations in all our efforts related to the workforce we support, the science we conduct, and the populations and communities we serve. The importance of DEIA is also highlighted by two programs that directly address major impediments to achieving health equity for all. The Transformative Research to Address Health Disparities and Advance Health Equity program is supporting innovative research projects to develop, implement, or disseminate effective interventions to advance health equity.[252] The ComPASS program is addressing the persistent challenge of health disparities by developing, sharing, and evaluating community-led structural interventions to change the social, physical, or economic environments that shape health behaviors and outcomes and contribute to health disparities.

Strengthening the Biomedical Workforce

Strengthening the biomedical workforce is an explicit goal of several Common Fund programs, which support efforts to ensure that the biomedical research workforce benefits from the full range of scientific talent. For example, the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program aims to establish a more inclusive and diverse biomedical research workforce through support of cluster hiring and institutional culture change efforts, providing evidence-backed strategies for diversifying the biomedical research workforce.[253] The Common Fund Data Ecosystem (CFDE), an infrastructure investment that aims to enhance the use of Common Fund data resources, will support multiple training and outreach efforts to develop a diverse user base for Common Fund data, equipping researchers from all backgrounds with in-demand skills for cloud computing and data analysis.[254]

Other Common Fund programs, such as the New Innovator and Early Independence Awards, specifically target early-career investigators with bold ideas to enable new perspectives and ideas to contribute to scientific discovery.[255,256] These awards do not require substantial preliminary data, thus removing a major roadblock for scientists who are in the beginning stages of establishing research independence. We are making robust efforts to enhance the diversity of New Innovator and Early Independence Awardees through targeted outreach and technical assistance.

[251] commonfund.nih.gov/editing
[252] commonfund.nih.gov/healthdisparitiestransformation
[253] commonfund.nih.gov/first
[254] commonfund.nih.gov/dataecosystem
[255] commonfund.nih.gov/newinnovator
[256] commonfund.nih.gov/earlyindependence

Engaging Diverse Research Participants

Diverse representation in research studies is required to generate knowledge, treatments, and prevention strategies that benefit all segments of the population. Several Common Fund programs conduct clinical research that engages research participants from diverse backgrounds, including Molecular Transducers of Physical Activity in Humans Consortium (MoTrPAC), Nutrition for Precision Health (NPH), and Acute to Chronic Pain Signatures (A2CPS).[257,258,259] Other Common Fund programs build foundational resources that enable studies of a variety of cellular and tissue characteristics, using human samples from diverse donors. These include a platform to map spatial organization of healthy cells in the human body from the Human BioMolecular Atlas Program (HuBMAP), atlases of senescent (no longer dividing) cells through the Cellular Senescence Network (SenNet), and systematic documentation of genomic variation across tissues in the Somatic Mosaicism across Human Tissues (SMaHT) program.[260,261,262]

Supporting Health throughout the Lifespan

Many Common Fund programs build foundational resources or discover new knowledge about basic biological processes that are relevant to all stages of development and throughout the lifespan. Additionally, some programs focus on study populations that represent specific life stages. The Gabriella Miller Kids First Pediatric Research program leverages data from pediatric patients and their families to uncover new insights into the biology of childhood cancer and structural birth defects, including discovery of shared genetic pathways between these conditions.[263] SenNet is exploring the biology of senescent cells, which accumulate as we age and play important roles in health, disease, and aging. MoTrPAC includes physical activity studies in children, adults, and older adults, exploring how exercise benefits our health throughout the lifespan.

Developing Targeted Preventions and Cures

As biomedical research moves away from a "one size fits all" approach to prevention and cures, several Common Fund programs are on the forefront of developing foundational data and tools to enable precision health approaches and develop more targeted prevention strategies and therapies. MoTrPAC is uncovering the molecules that change in response to physical activity for people of different ages, sexes, body compositions, and fitness levels. In the future, this information may enable clinicians to make more specific exercise recommendations to patients based on their unique characteristics. Similarly, NPH aims to develop algorithms that predict individual responses to nutrition and dietary patterns by examining the interactions between diet, genes, proteins, microbiome, metabolism, and other individual factors. The Illuminating the Druggable Genome (IDG) program is expanding our understanding of potentially druggable protein targets that are currently understudied, in the

[257] commonfund.nih.gov/MolecularTransducers
[258] commonfund.nih.gov/nutritionforprecisionhealth
[259] commonfund.nih.gov/pain
[260] commonfund.nih.gov/HuBMAP
[261] commonfund.nih.gov/senescence
[262] commonfund.nih.gov/smaht/
[263] commonfund.nih.gov/KidsFirst

hopes that these proteins may lead to new drug targets that are more specific and may lead to fewer side effects.[264]

The Common Fund fulfills a unique role at NIH, supporting research that is often broad-reaching across scientific disciplines and provides catalytic data, tools, and resources with the potential to advance many different research areas. This focus on broadly relevant scientific research areas and resources meant that the Common Fund was well-poised to rapidly respond to the COVID-19 pandemic, supporting both new COVID-19-related research projects, as well as existing studies that could appropriately add COVID-19-related research while still maintaining focus on the original project goals. Common Fund programs are carefully planned to address major challenges and opportunities across biomedical research. Therefore, although several Common Fund activities were rapidly launched to address critical health needs related to the COVID-19 pandemic, continued investment in Common Fund programs to provide foundational support for the biomedical research enterprise remains crucially important. These activities are essential to continue even in times of major upheavals in and rapid change of research priorities, helping to ensure the biomedical research community is well-poised to respond nimbly to new and unpredictable issues that emerge in the future.

Since Common Fund programs are designed with clearly defined goals and milestones, it is critically important to rigorously monitor ongoing progress to ensure programs are on track, and to adjust if needed. Additionally, as Common Fund programs are intended to produce valuable resources and knowledge to spur subsequent research advances, it is also important to assess the impact of each program and its deliverables on the broad biomedical research landscape. We thoroughly evaluate Common Fund programs during their lifetime, and outcomes are assessed as programs end. Continuous, ongoing evaluation during program implementation allows flexibility to modify program management and/or budgets in response to rapidly evolving scientific landscapes, technical challenges, or other unforeseen challenges or opportunities. New challenges and opportunities will be addressed in FY 2024 from funds made available as programs end, move to other sources of support, or require decreased support as indicated by evaluative data.

[264] commonfund.nih.gov/IDG

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The Common Fund

Bold science, catalyzing discoveries

The NIH Common Fund provides a dedicated source of support for scientific programs that are high-priority for NIH as a whole

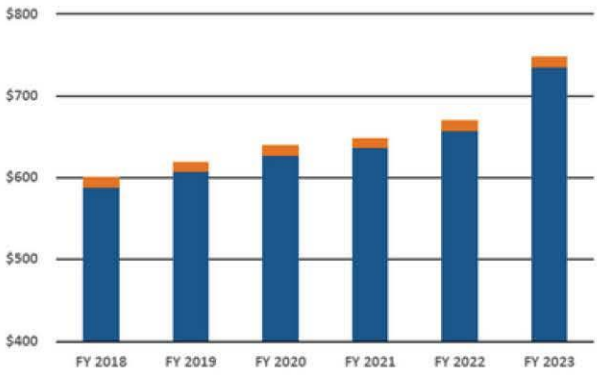
SUPPORTING multi-disciplinary research efforts

INVESTING in time-limited, goal-driven programs

ACCELERATING emerging science

REMOVING research roadblocks

FUNDING HISTORY



The FY 2024 President's Budget request is $735.0 million.

Blue = Common Fund base appropriation
Orange = Gabriella Miller Kids First Pediatric Research

FACTS AND FIGURES

23 Scientific Programs in FY 2022

529 Principal Investigators (PIs)*

- **183** High-Risk, High-Reward (HRHR) PIs*
- **102** Early-Career HRHR PIs*

136 Competing Research Project Grants*

24 NIH Institutes, Centers, and Offices Co-Leading Programs in FY 2022

**yearly averages FY 2018 – FY 2022*

THE OFFICE OF STRATEGIC COORDINATION LEADERSHIP

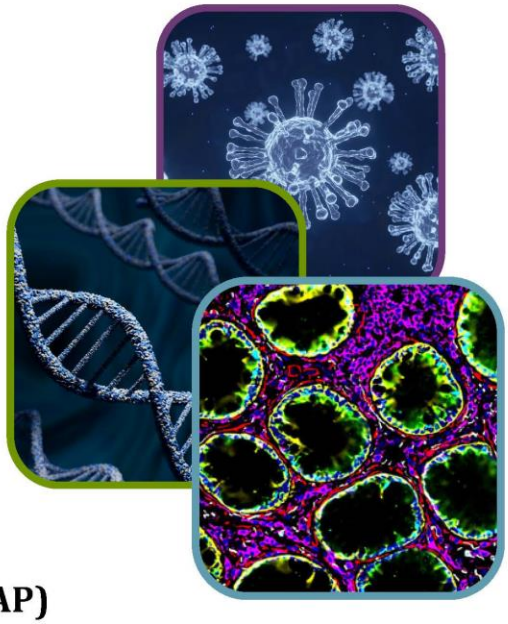
Douglas Sheeley, Sc.D.

Dr. Sheeley became the Deputy Director of the Office of Strategic Coordination (OSC) in 2022 and the Acting Director of OSC in 2023.

SELECTED RESEARCH ACCOMPLISHMENTS

COVID-19 Research

Common Fund awards have advanced innovative research on SARS-CoV-2 and COVID-19, uncovering genes that may influence risk, developing ultrasonic imaging for SARS-CoV-2-infected lungs, identifying disrupted gene regulation as a cause of COVID-related loss of smell, and developing technology for faster and more accurate detection of virus.



Somatic Cell Genome Editing (SCGE)

SCGE is advancing genome editing therapies, so that safe and effective therapies can reach patients sooner. SCGE has developed new methods for tissue-specific gene delivery, generated improved genome editors, and optimized detection of unintended effects of genome editing. These resources are leading to advances in genome editing to treat conditions such as sickle cell disease, progeria, and deafness.

Human BioMolecular Atlas Program (HuBMAP)

HuBMAP is developing widely available resources to enable mapping of the human body at the single cell level. Groundbreaking HuBMAP resources include a 3D reference atlas connecting anatomy, structure, cell types, and biomarkers; methods to identify different forms of proteins within tissues; and visualization tools for complex imaging data.

SELECTED CURRENT ACTIVITIES

Cellular Senescence Network (SenNet)

SenNet is transforming our understanding of senescent (no longer dividing) cells by generating complementary human and mouse atlases of senescent cells and developing critically needed technologies.

Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

FIRST is testing new approaches to fostering inclusive and diverse research environments through faculty cohort hiring, professional development and retention, and institutional culture change.

Somatic Mosaicism across Human Tissues (SMaHT)

SMaHT is analyzing genomic mosaicism (variation) in a variety of human tissues, leading to new understanding of how mosaicism influences health and disease.

PLANNING FOR THE FUTURE

Several topics are in development for potential program launch in FY 2024.

Advancing Health Communication Science and Practice

To investigate, develop, test, and disseminate new approaches for effective and equitable health communication

Human Virome Program

To characterize the enormous number of viruses that healthy humans harbor and determine their impact on immune function and human health

Advancing Non-Animal Approaches

To foster development of sophisticated non-animal approaches, including cell-based methods, computer modeling, and human tissue sampling

MAJOR CHANGES IN THE PRESIDENT'S BUDGET REQUEST

Major Changes in the Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note there may be overlap between budget mechanisms and activity detail, and these highlights will not sum to the total for the FY 2024 President's Budget request for the Common Fund, which is equal to the FY 2023 Enacted level, for a total of $735.0 million.

Research Project Grants (+$22.4 million; total $357.4 million): The Common Fund expects to support a total of 427 Research Project Grant (RPG) awards in FY 2024, up from 402 in FY 2023. Estimated awards for FY 2024 include 266 Noncompeting RPGs and 161 Competing RPGs.

Research Centers (-$19.5 million; total $165.0 million): The Common Fund expects to support a total of 82 Research Centers in FY 2024, down from 95 in FY 2023. This change reflects the planned completion of awards supporting Clinical Research Centers within the Enhancing the Diversity of the NIH-Funded Workforce program.

Other Research (-$3.0 million; total $168.9 million): The Common Fund expects to support a total of 106 Other Research awards in FY 2024, a decrease of 2 awards from 108 in FY 2023. Within this category, the Common Fund supports Other Transaction (OT) awards in several programs, including Stimulating Peripheral Activity to Relieve Conditions (SPARC), Human BioMolecular Atlas Project (HuBMAP), Bridge to Artificial Intelligence, and the Common Fund Data Ecosystem (CFDE).

Research Training (-$4.3 million; total $0.6 million): The Common Fund expects to support a total of 7 full time training positions (FTTPs) as new Research Training Individual Awards within the CFDE. The decrease in support for Research Training reflects the planned completion of Research Training Institutional Awards within the Enhancing the Diversity of the NIH-Funded Workforce program.

BUDGET MECHANISM TABLE

(Dollars in Thousands)	FY 2022 Final	FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023 Enacted	
	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:							
Noncompeting	$194,172	207	$155,618	266	$209,923	59	$54,305
Administrative Supplements	20,214	*(13)*	7,484	*(10)*	5,675	*(-3)*	-1,809
Competing:							
Renewal	1,082	0	0	0	0	0	0
New	105,381	195	171,846	161	141,799	-34	-30,047
Supplements	0	0	0	0	0	0	0
Subtotal, Competing	$106,463	195	$171,846	161	$141,799	-34	-$30,047
Subtotal, RPGs	$320,849	402	$334,948	427	$357,397	25	$22,449
SBIR/STTR	0	0	0	0	0	0	0
Research Project Grants	$320,849	402	$334,948	427	$357,397	25	$22,449
Research Centers:							
Specialized/Comprehensive	$112,190	80	$154,432	79	$152,494	-1	-$1,938
Clinical Research	13,789	11	15,576	0	0	-11	-15,576
Biotechnology	8,429	2	10,000	3	12,500	1	2,500
Comparative Medicine	9,218	2	4,500	0	0	-2	-4,500
Research Centers in Minority Institutions	0	0	0	0	0	0	0
Research Centers	$143,626	95	$184,508	82	$164,994	-13	-$19,514
Other Research:							
Research Careers	$0	0	$0	0	$0	0	$0
Cancer Education	0	0	0	0	0	0	0
Cooperative Clinical Research	5,581	16	14,462	16	14,995	0	533
Biomedical Research Support	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0
Other	146,756	92	157,500	90	153,945	-2	-3,555
Other Research	$152,337	108	$171,962	106	$168,940	-2	-$3,022
Total Research Grants	$616,813	605	$691,418	615	$691,331	10	-$87
Ruth L Kirchstein Training Awards:		FTTPs		FTTPs		FTTPs	
Individual Awards	$0	0	$0	7	$600	7	$600
Institutional Awards	7,326	304	4,857	0	0	-304	-4,857
Total Research Training	$7,326	304	$4,857	7	$600	-297	-$4,257
Research & Develop. Contracts	$8,304	2	$8,011	2	$9,008	0	$997
(SBIR/STTR) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Intramural Research	8,003	0	690	0	383	0	-307
Res. Management & Support	29,555	0	30,025	0	33,679	0	3,654
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Construction	0		0		0		0
Buildings and Facilities	0		0		0		0
Total, Common Fund	$670,001	605	$735,001	615	$735,001	10	$0

[1] All items in italics and brackets are non-add entries.

BUDGET BY INITIATIVE

Common Fund Program (Dollars in Thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
4D Nucleome	28,673	28,394	28,378
Acute to Chronic Pain Signatures	18,600	783	3,338
Bridge to Artificial Intelligence (Bridge2AI)	30,506	35,406	32,398
Cellular Senescence Network (SenNET)	39,908	41,850	43,850
Common Fund Data Ecosystem	0	9,900	21,000
Community Partnerships to Advance Science for Society (ComPASS) Program	0	23,401	27,082
Enhancing the Diversity of the NIH-Funded Workforce	44,237	39,478	0
Extracellular RNA Communication	11,236	315	0
Faculty Institutional Recruitment for Sustainable Transformation (FIRST)	30,803	52,886	72,688
Gabriella Miller Kids First Pediatric Research	13,053	13,080	12,983
Global Health	823	85	0
Glycoscience	472	0	0
Harnessing Data Science for Health Discovery and Innovation in Africa (DSI-Africa)	12,455	16,418	16,418
Health Care Systems Research Collaboratory	225	0	0
High-Risk Research	187,175	171,995	198,958
NIH Director's Pioneer Award	*45,814*	*44,633*	*42,469*
NIH Director's New Innovator Award Program	*73,745*	*58,963*	*87,320*
Transformative Research Award	*44,308*	*44,473*	*44,329*
NIH Director's Early Independence Award Program	*23,309*	*23,926*	*24,840*
Human BioMolecular Atlas Project (HuBMAP)	36,452	44,636	34,586
Illuminating the Druggable Genome	13,394	7,900	390
Metabolomics	106	0	0
Molecular Transducers of Physical Activity	36,418	20,514	21,231
Nutrition for Precision Health	20,323	40,838	39,324
Somatic Cell Genome Editing	46,199	46,960	51,754
Somatic Mosaicism across Human Tissues (SMaHT)	0	22,906	25,913
S.P.A.R.C. - Stimulating Peripheral Activity to Relieve Conditions	35,865	31,741	39,277
Transformative High Resolution Cryo-Electron Microscopy (CryoEM)	19,883	25,508	4,255
Transformative Research to Address Health Disparities	19	19,887	17,010
Undiagnosed Diseases Network	17,697	11,547	0
Strategic Planning, Evaluation, and Infrastructure	25,481	28,575	16,400
Subtotal Common Fund	670,001	735,001	707,231
New Initiatives in Common Fund	0	0	27,770
Total Common Fund	670,001	735,001	735,001

JUSTIFICATION OF BUDGET REQUEST

NIH Common Fund

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

Budget Authority (BA):

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
BA	$670,001,000	$735,001,000	$735,001,000	0
FTE	0	0	0	0

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

Overall Budget Policy. The FY 2024 President's Budget request for the Common Fund is $735.0 million, equal to the FY 2023 Enacted level. This level of funding will support high priority activities within existing programs and support the launch of several new programs, as described below.

Program Descriptions

The Common Fund supports over 20 programs, most of which consist of a series of integrated initiatives that collectively address a set of goals that can be achieved within 5 to 10 years. Planned activities and budgets for Common Fund programs are strategically developed, with clear milestones defined throughout the lifetime of the program to enable measurement of progress towards pre-defined goals. Therefore, Common Fund programs often undergo planned budget shifts driven by the needs and activities for each program.

Several Common Fund programs will receive their last year of support in FY 2023; funds are therefore not requested in FY 2024 for these programs. These include Enhancing the Diversity of the NIH-Funded Workforce, Extracellular RNA Communication, Global Health, and the Undiagnosed Diseases Network.[265,266,267,268,269] Information on these programs and their accomplishments can be found on the program websites.

[265] commonfund.nih.gov/diversity
[266] commonfund.nih.gov/exrna
[267] commonfund.nih.gov/globalhealth
[268] commonfund.nih.gov/Diseases
[269] CF provided partial funding for the Undiagnosed Diseases Network in FY 2023 as part of the program's transition to full support from other components of NIH beginning in FY 2024.

Highlighted below are programs that exemplify the high priority science to be supported in FY 2024, and/or which are undergoing significant programmatic changes in FY 2024.

Acute to Chronic Pain Signatures (A2CPS)

A2CPS aims to improve understanding of the transition from acute to chronic pain following injury. Currently, this transition is poorly understood, and therefore prevention or treatment is difficult. A2CPS is addressing this challenge by developing an objective set of biomarkers (a "signature") to predict susceptibility of transitioning from acute to chronic pain. The high prevalence of chronic pain has contributed to the current opioid epidemic, and a signature to predict susceptibility to transition from acute to chronic pain could help accelerate therapy development and ultimately guide pain prevention strategies. A2CPS enhances the objectives of the NIH Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®, an agency-wide effort to speed scientific solutions to end the opioid public health crisis.[270] A2CPS will benefit the HEAL research priority to enhance pain management. Increased funds requested in FY 2024 reflect expanded support for data generation centers and the data integration and resource center, following the planned completion of clinical studies in FY 2023.

Community Partnerships to Advance Science for Society (ComPASS)

Launched in FY 2023, the ComPASS program aims to accelerate the science on health disparities and advance health equity research. This program addresses the critical need to address the complex nature of health disparities through structural interventions, efforts that aim to change the social, physical, economic, and/or political environments that may shape or constrain health behaviors and outcomes. The goals of ComPASS are to: 1) develop, share, and evaluate community-driven structural health equity interventions that leverage partnerships across multiple sectors to reduce health disparities, and 2) develop a new health equity research model for community-led, multisectoral structural intervention research across NIH and other federal agencies. Funds requested in FY 2024 will support the scale-up of this program as it supports research on health equity structural interventions and coordinates across program activities.

Budget Policy. The FY 2024 President's Budget request is $3.3 million, an increase of $2.6 million or 326.2 percent compared with the FY 2023 Enacted level. This increase will support additional data generation, data integration, and resource development activities.

Cellular Senescence Network (SenNet)

As we age, tissues throughout the body accumulate small numbers of specialized cells that no longer divide, called senescent cells. There are many unanswered questions about how, when, why, and where senescent cells form and what impact they have on human health and disease. However, their rarity and diversity make them difficult to study. The SenNet program aims to comprehensively identify and characterize the differences in senescent cells across the body, across various states of human health, and across the lifespan. SenNet will provide critically needed resources, including atlases of senescent cells in various tissues from humans and animals, as well as novel tools and technologies to identify and characterize these rare cells. Funds requested in FY 2024 will support tissue mapping centers, technology development and application, and a data coordination and organization center.

[270] NIH HEAL Initiative and Helping to End Addiction Long-term are registered service marks of the U.S. Department of Health and Human Services.

Budget Policy. The FY 2024 President's Budget request is $43.9 million, an increase of $2.0 million or 4.8 percent compared with the FY 2023 Enacted level. This level of support will allow for continued funding for tissue mapping, technology development and application, and data coordination and integration.

Common Fund Data Ecosystem (CFDE)

As data-intensive strategies are increasingly undertaken to achieve the goals of Common Fund programs, infrastructure to address challenges facing all data management centers has become necessary. This infrastructure, referred to as the Common Fund Data Ecosystem (CFDE), is enabling researchers to query across and use multiple Common Fund data sets, providing training for users to operate on the data in a cloud environment, and ensuring that Common Fund data continue to be available after individual programs are completed. The CFDE will amplify the impact of many Common Fund programs by enabling researchers to interrogate multiple disparate data sets, and thereby make new kinds of scientific discoveries that were not possible before. Prior to FY 2023, support for the CFDE was included within the Strategic Planning, Evaluation, and Infrastructure budget line. With the launch of a new stage in FY 2023, support for the new CFDE activities appears as a stand-alone line in the budget by initiative table. Ongoing FY 2023 activities from the first stage remain within the Strategic Planning, Evaluation, and Infrastructure item.

Budget Policy. The FY 2024 President's Budget request is $21.0 million, a decrease of $1.2 million or 5.2 percent compared with the FY 2023 Enacted level (consisting of total support from the FY 2023 CFDE budget line as well as the FY 2023 amount for CFDE within Strategic Planning, Evaluation, and Infrastructure). The new stage of CFDE will continue to engage with many Common Fund data generating programs and coordinate across the entire data ecosystem, enhancing the findability and accessibility of data and increasing emphasis on training and outreach to develop a diverse user base for Common Fund data resources.

Faculty Institutional Recruitment for Sustainable Transformation (FIRST)

The FIRST program aims to establish a more inclusive and diverse biomedical research workforce through support of cluster hiring and institutional culture change efforts. Based on early results from other cohort-based recruitment programs, FIRST will establish a faculty cohort model for hiring, mentoring, and professional development; integrated, institution-wide approaches to address bias, faculty equity, mentoring, and work/life issues; and a coordination and evaluation center to conduct independent evaluations of program impacts. Through widespread dissemination of evidence-based approaches, FIRST will provide approaches and tools to enable many more research institutions to develop cultures of inclusive excellence. The NIH expects its efforts to lead to the recruitment of talented researchers from all groups, to improve the quality of the training environment, to balance and broaden the perspective in setting research priorities, and to positively impact scientific discovery. Increased funds requested in FY 2024 will support hiring the third and final faculty cohort, while continuing to support the first two faculty cohorts and program-wide coordination and evaluation efforts.

Budget Policy. The FY 2024 President's Budget request is $72.7 million, an increase of $19.8 million or 37.4 percent compared with the FY 2023 Enacted level. This increase will

support hiring the third and final faculty cohort and ongoing efforts to establish and maintain cultures of inclusive excellence at all awardee institutions, as well as program-wide coordination and evaluation activities.

Gabriella Miller Kids First Pediatric Research (Kids First)

The Kids First program aims to generate new insights into childhood cancer and birth defects through development of a widely accessible data resource containing high-quality genetic and clinical data from pediatric patient cohorts, along with associated computational tools to facilitate data analysis. There is considerable evidence for undiscovered connections between childhood cancer and structural birth defects, and therefore examining these data sets together will facilitate new discoveries and novel ways of thinking about these conditions. Kids First has developed one of the largest pediatric data resources of its kind, with over 63 conditions represented and including 55,000 genomes from 22,000 participants. This data resource has enabled new biological insights into genetic causes of conditions such as childhood neuroblastoma, congenital heart defects, disorders of sex development, Ewing sarcoma, orofacial cleft, and syndromic cranial dysinnervation. Researchers have also used the data resource to study a novel drug treatment for pediatric diffuse midline gliomas. Funds requested in FY 2024 will be used to support pediatric research, consistent with the Gabriella Miller Kids First Research Act, and remain constant at the statutory level set by this legislation for FY 2023. These funds will be used to continue support for the Kids First Data Resource, genetic sequencing of patient cohorts, and research projects to demonstrate the value of Kids First data.

Budget Policy. The FY 2024 President's Budget request is $13.0 million, a decrease of $0.1 million or 0.8 percent compared with the FY 2023 Enacted level. Programmatic funding remains constant at the $12.6 million statutory level and will be used to conduct pediatric research. The remainder of the funds are requested in the regular Common Fund appropriation to support research management activities.

High-Risk, High-Reward Research (HRHR)

The HRHR program supports exceptionally creative scientists proposing innovative and transformative research in any scientific area within the NIH mission through four complementary initiatives: Pioneer Award, New Innovator Award, Transformative Research Award, and Early Independence Award.[271] These awards are intended to support transformative science that is inherently difficult and risky, but necessary to accelerate the pace of scientific discovery and advance human health. To improve financial stewardship, starting in FY 2021, the New Innovator awards provide support for years one through three of the projects in the first fiscal year and years four and five in the fourth fiscal year; thus, this change in funding approach resulted in a temporary decline in funding levels for FYs 2021 – 2023. The increased funding request for FY 2024 results from this being the first year that will include non-competing commitments generated by the FY 2021 cohort of awards. Funds requested in FY 2024 will be used to support additional innovative projects with the potential for extraordinary impact.

Budget Policy. The FY 2024 President's Budget request is $199.0 million, an increase of $27.0 million or 15.7 percent compared with the FY 2023 Enacted level. This increase includes

[271] commonfund.nih.gov/highrisk

Molecular Transducers of Physical Activity in Humans

Physical activity has been demonstrated to contribute to health in a wide variety of ways, and lack of physical activity is at the root of many common chronic health problems. However, we have a limited understanding of the molecular mechanisms that underlie how physical activity provides health benefits. A better understanding of the molecules that underlie the benefits of physical activity could lead to the development of improved, personalized exercise recommendations, as well as therapies for individuals who are unable to exercise due to illness or disability. The Molecular Transducers of Physical Activity in Humans Consortium (MoTrPAC) is cataloging the biological molecules affected by physical activity in humans, identifying some of the key molecules that underlie the systemic effects of physical activity and characterizing their function. Program progress was slowed due to interruption of clinical studies during the COVID-19 pandemic, so additional years of funding are required for this program to achieve maximum impact while still complying with the long-standing CF policy of supporting programs for a maximum of 10 years. Funds requested in FY 2024 will continue to support human and animal physical activity studies and associated molecular analysis of samples. For more information, see the section

non-competing commitments from the FY 2021 cohort of New Innovator awards, and will allow for continued support of highly creative, high-impact projects.

Human BioMolecular Atlas Program (HuBMAP)

HuBMAP is developing a framework for mapping the human body at single cell resolution to provide a new foundation for understanding human health and diagnosing, monitoring, and treating disease. In complex, multicellular organisms like humans, the proper functioning of organs and tissues is dependent on the interaction, spatial organization, and specialization of individual cells. However, since there are an estimated 37 trillion cells in an adult human body, determining the functions of and relationship among these cells is a monumental undertaking. To address this challenge, HuBMAP is developing an open and global platform to map healthy cells in the human body, generating foundational tissue maps, and developing tools, technologies, and resources for broad dissemination to the entire biomedical research community.

Budget Policy. The FY 2024 President's Budget request is $34.6 million, a decrease of $10.1 million or 22.5 percent compared with the FY 2023 Enacted level. Decreased funding requested in FY 2024 reflects the planned scaling down of technology development and tissue mapping efforts, while continuing to support data coordination, integration, and analysis. This level of funding will support ongoing data coordination, integration, and analysis within the HuBMAP program.

Illuminating the Druggable Genome (IDG)

Three protein families – G-protein coupled receptors, ion channels, and protein kinases – are well-established "druggable" protein families that have potential to be targets of pharmaceuticals. However, only a small number of proteins within each of these families are well-studied, representing an opportunity to greatly expand the druggable genome by catalyzing research into these understudied proteins. These well-studied proteins are often present in many cells throughout the body, and drugs that target these proteins might therefore cause widespread adverse effects. In contrast, the lesser-known members of these protein families may be present in fewer tissues, and thus have potential as specific drug targets that lead to fewer side effects. IDG is developing data, tools, and technologies to enable investigation of understudied proteins

within these three protein families, expanding the repertoire of potential drug targets that may have high potential to impact human health. Having largely completed the goals of developing these resources for the biomedical research community, IDG will undergo a planned scaling down of the program in FY 2024.

Budget Policy. The FY 2024 President's Budget request is $0.4 million, a decrease of $7.5 million or 95.1 percent compared with the FY 2023 Enacted level. This decrease reflects the planned scaling down of the program.

Nutrition for Precision Health, powered by the *All of Us* Research Program (NPH)

Nutrition plays an integral role in human development and in the prevention and treatment of disease. However, there is no perfect, "one size fits all" diet. The goal of the NPH program is to develop algorithms that predict individual responses to food and dietary patterns. Ultimately, the predictive algorithms developed through NPH are anticipated to enable tailored dietary recommendations to be provided by physicians, as well as development of tools to allow individuals to make more informed decisions about healthy food choices. NPH will leverage the *All of Us* infrastructure and recent advances in biomedical science, such as artificial intelligence (AI) and microbiome research, to provide unprecedented opportunities to examine associations between nutrition and a variety of long-term outcomes.[272] This program addresses some of the important scientific opportunities identified in the first Strategic Plan for NIH Nutrition Research.[273] Additionally, this program is closely coordinated with activities of the Office of Nutrition Research to ensure NIH-wide nutrition efforts are complementary, not duplicative. Funds requested in FY 2024 will support ongoing clinical nutrition studies, data analysis, AI and data modeling, processing and storage of biosamples, and research coordination.

Budget Policy. The FY 2024 President's Budget request is $39.3 million, a decrease of $1.5 million or 3.7 percent compared with the FY 2023 Enacted level. This level of support will enable continued clinical studies and associated activities to generate nutrition-related data sets and resources for the research community.

Somatic Cell Genome Editing (SCGE)

The SCGE program aims to develop quality tools to perform safe and effective genome editing in human patients, ultimately reducing the time and cost to develop new therapies for diseases caused by changes to the genetic code. These tools will need to function specifically on the disease gene to minimize unintended consequences. They will also need to be delivered selectively to the cells within the body that are affected by the disease, avoiding unaffected cells and reproductive cells so that changes are not passed on to future generations. The second phase of the SCGE program is launching in FY 2023 and aims to accelerate the development of genome-editing therapies by developing data, resources, and best practices that will enable the research community to conduct genome-editing clinical trials that align with U.S. Food and Drug Administration (FDA) standards and regulations. These program activities include facilitating Investigational New Drug (IND)-enabling studies, establishing pathways to regulatory approval, and disseminating successful strategies for initiating first-in-human clinical trials. Funds

[272] allofus.nih.gov/
[273] niddk.nih.gov/about-niddk/strategic-plans-reports/strategic-plan-nih-nutrition-research

requested in FY 2024 will provide additional support for platform clinical trials of genome editors in multiple diseases.

Budget Policy. The FY 2024 President's Budget request is $51.8 million, an increase of $4.8 million or 10.2 percent compared with the FY 2023 Enacted level. This increase will provide additional support for platform clinical trials, as well as support for ongoing efforts in technology development and optimization of genome editing-based therapeutic leads to enable IND studies.

Somatic Mosaicism across Human Tissues (SmaHT)

The SmaHT program aims to transform our understanding of how somatic mosaicism, or genetic variation within an individual, influences biology and disease. Somatic mosaicism arises over the lifetime as changes to the inherited DNA sequence occur in different cells, resulting in genetically distinct cells within an individual. There is mounting evidence that somatic mosaicism plays important roles in biological processes such as development, aging, and disease. However, technical challenges in detecting rare somatic variations mean this phenomenon is understudied. Launching in FY 2023, SmaHT will catalog somatic variants in select tissues from diverse human donors, develop innovative sequencing tools and analyses methods, and create a workbench to integrate analysis of somatic variation with the human genome. Funds requested in FY 2024 will be used to support these activities.

Budget Policy. The FY 2024 President's Budget request is $25.9 million, an increase of $3.0 million or 13.1 percent compared with the FY 2023 Enacted level. This increase will support efforts in somatic variant discovery, technology and tool development, data analyses, and program-wide coordination.

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

The SPARC program is accelerating the development of novel neuromodulatory therapeutic devices to advance bioelectronic medicine through provision of foundational data and tools. Modulation of nerve function has the potential to treat a variety of diseases and conditions, but there is an urgent need to better understand the precise pattern of connections between nerves and their end organs, so that the nerves can be precisely and specifically stimulated. SPARC is addressing this need by generating maps and tools to identify and influence therapeutic targets within the neural circuitry of a wide range of organs and tissues. Ultimately, this therapeutic strategy could offer new treatment options for diverse diseases and conditions such as hypertension, heart failure, gastrointestinal disorders, type 2 diabetes, inflammatory disorders, and more. Now in its second stage, SPARC is investigating the anatomy and functional connectivity of the human vagus nerve, developing open-source neural engineering technologies, and supporting challenges for innovators to demonstrate proof of principle neuromodulation therapeutic benefits.

Budget Policy. The FY 2024 President's Budget request is $39.3 million, an increase of $7.5 million or 23.7 percent compared with the FY 2023 Enacted level. This increased level of support will enable new Challenge competition prizes, while also maintaining efforts in mapping the human vagus nerve and developing new technologies.

Transformative High Resolution Cryo-Electron Microscopy (CryoEM)

The CryoEM program is enabling novel discoveries in structural biology by broadening access to cutting-edge cryo-electron microscopy and cryo-electron tomography techniques and training.[274] These approaches enable researchers to determine the structure of biological molecules with unprecedented detail and accuracy. However, the high cost of required equipment and a lack of training in these techniques mean that many researchers cannot leverage these critical approaches, and therefore opportunities for novel discoveries are missed. By providing increased access, the CryoEM program is anticipated to catalyze fundamental biological discoveries, as well as accelerate development of vaccines and therapeutics.

Budget Policy. The FY 2024 President's Budget request is $4.3 million, a decrease of $21.2 million or 83.3 percent compared with the FY 2023 Enacted level. The decreased support from the Common Fund reflects a planned transition of cryo-electron microscopy centers and training activities to other NIH sources of support.

Transformative Research to Address Health Disparities and Advance Health Equity

The Transformative Research to Address Health Disparities and Advance Health Equity program is a bold approach to fund unusually innovative research projects with the potential to have a major impact on inequalities in health outcomes through development, dissemination, and/or implementation of innovative and effective interventions that address health disparities and advance health equity. Additionally, through dedicated support for researchers at under-resourced institutions that educate significant numbers of students from underrepresented backgrounds, this initiative also aims to expand the research base dedicated to health disparities research at minority-serving institutions. Examples of current research projects include a multisector coalition to transform mental health services in Harlem, investments in Black neighborhoods to address social determinants of racial health disparities, and interventions to disrupt social determinants of poverty among youth and young adults. Originally included as an initiative within the HRHR program, this program now is a stand-alone program within the Common Fund budget. Funds requested in FY 2024 will continue to support innovative research with the potential to generate transformative interventions that support equitable health outcomes for all.

Budget Policy. The FY 2024 President's Budget request is $17.0 million, a decrease of $2.9 million or 14.5 percent compared with the FY 2023 Enacted level. This decrease results from a temporary increase in funding in FY 2023 to provide a limited-term opportunity to researchers from underresourced institutions to strengthen a promising application for NIH funding. FY 2024 funds will continue to support the two cohorts of investigators receiving awards through the Transformative Research to Address Health Disparities and Advance Health Equity program.

[274] commonfund.nih.gov/CryoEM

Strategic Planning, Evaluation, and Infrastructure

Common Fund management requires that certain activities be undertaken for the benefit of the Common Fund as a whole. These include activities related to strategic planning, evaluation, and infrastructure.

Strategic planning is undertaken every year to identify new scientific challenges and opportunities that may be prime for dedicated investment via a Common Fund program. The Common Fund strategic planning first identifies broad scientific areas that are priorities for the NIH as a whole and then establishes a focused strategy for investments that will catalyze research progress in those areas. The initial idea (or concept) gathering phase of strategic planning often involves input from stakeholders with diverse expertise, as well as internal discussions about shared challenges and emerging opportunities. The strategy development phase of strategic planning involves specific consultations with external experts, analysis of NIH and worldwide research portfolios, and literature reviews to articulate specific gaps and areas of biomedical and behavioral research where opportunities for transformative progress are possible.

Since Common Fund programs are goal-driven, evaluation is critical to monitoring progress and developing strategies to adapt program management. Evaluation includes both formal and informal evaluative activities. Informal evaluation involves convening grantees and NIH-wide teams to review progress, discuss new challenges, and develop strategies to adapt as part of routine program management. It also involves gathering input from external consultants and using their input, together with internal analysis, to help guide the implementation of the program. Formal evaluations involve the development of baseline data for new programs and the development of multiple metrics of outcomes. The utility of data, resources, technologies, and other program outputs is assessed through surveys, expert opinion, and the analysis of bibliometric data such as citation analyses.

Funds Available for New Initiatives

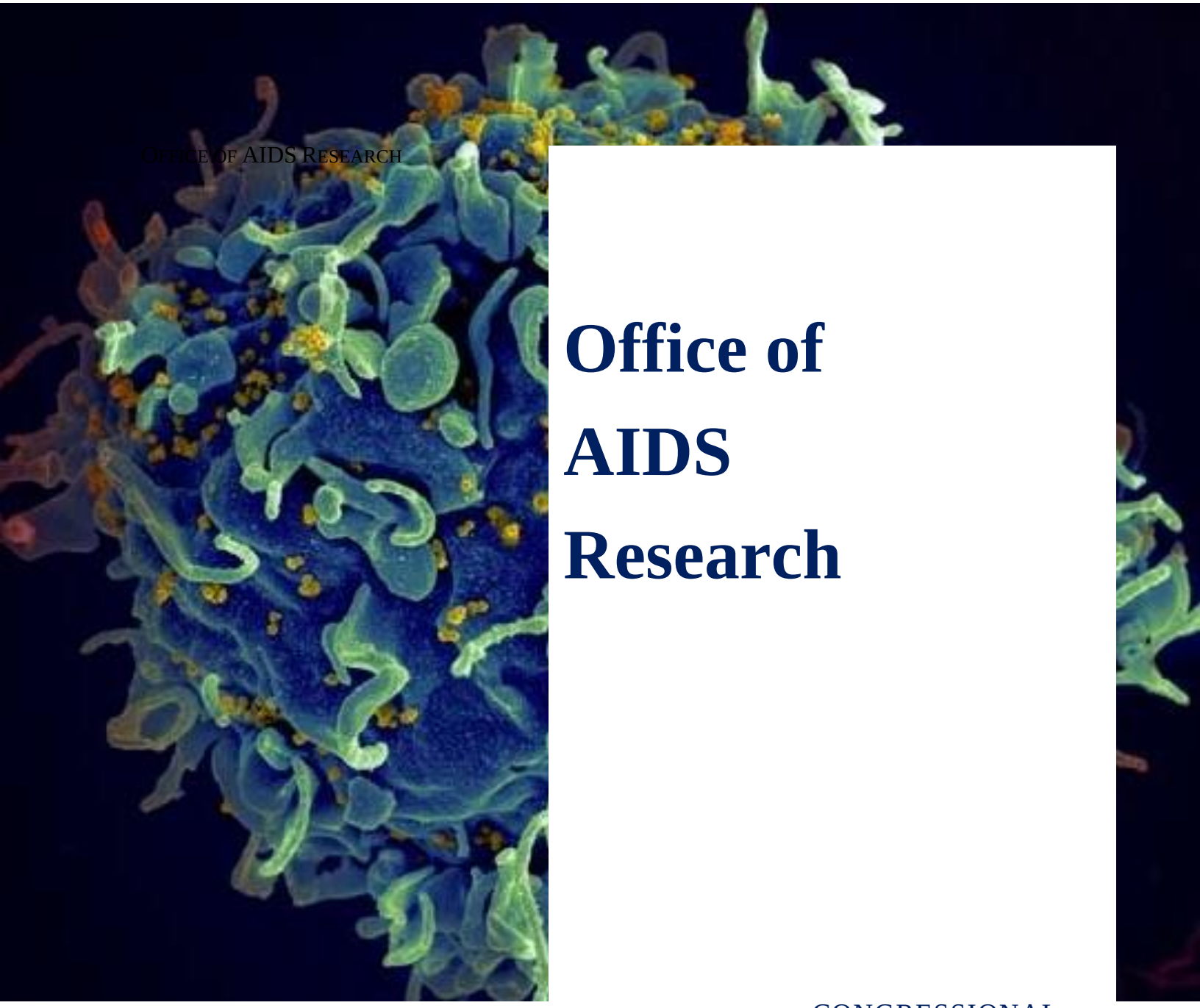
Planning for potential new FY 2024 Common Fund programs leveraged the wide-ranging expertise of NIH's senior leadership and scientific staff. Planning efforts led to the identification and further development of three potential program ideas:

- Advancing Health Communication Science and Practice – to investigate, develop, test, and disseminate new approaches for effective and equitable health communication, including measuring communication exposure and impact, addressing misinformation, engaging communities, and building trust[275]
- Human Virome Program – to characterize the enormous number of viruses that healthy humans harbor and determine their impact on immune function and human health[276]
- Advancing Non-Animal Approaches – to foster development of sophisticated non-animal approaches, including cell-based methods, computer modeling/simulation, and human

[275] commonfund.nih.gov/healthcommsresearch
[276] commonfund.nih.gov/humanvirome

tissue studies, with consideration for the complexity of the biomedical research area and the current applicability and translatability of the non-animal model

Additionally, the CFDE will launch a second stage of investment, building on the success of the initial efforts as described above.



Office of AIDS Research

CONGRESSIONAL JUSTIFICATION

FY 2024

Department of Health and Human Services

National Institutes of Health

NIH National Institutes of Health
Office of AIDS Research

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research (OAR)

FY 2024 Budget Table of Contents

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Director's Overview

Maureen M. Goodenow, Ph.D.

Associate Director for AIDS Research and Director, Office of AIDS Research

Global health emergencies underscore how public investment in basic, clinical, behavioral, social, and implementation research protects and promotes human health. Over 40 years ago, the discovery of the human immunodeficiency virus (HIV) challenged scientists and policymakers to work together on acquired immunodeficiency syndrome (AIDS), which was then an untreatable, fatal disease. Thanks to the concerted effort of people from every sector of society and sustained U.S. government support, the development and implementation of evidence-based therapeutic, clinical, and behavioral strategies have turned HIV into a manageable chronic condition such that a person with HIV has a near-normal life expectancy.

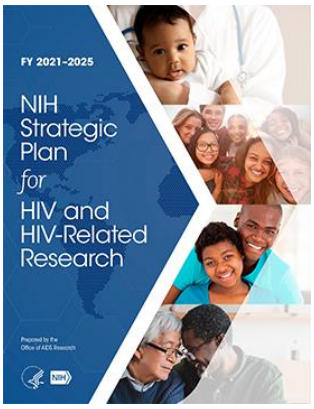
Through the National Institutes of Health (NIH), investments in HIV/AIDS research have led to groundbreaking advances in our understanding of the virology, immunology, and pathogenesis of HIV. While there has been significant progress, the HIV/AIDS research community continues to face setbacks as a result of the COVID-19 pandemic. In addition, data indicate that persons with or at risk of HIV experienced significant obstacles due to closures, quarantines, and HIV service delivery interruptions.[277] In addition, medical mistrust and supply-chain shortages persist, both domestically and internationally, hindering access to HIV clinical care. Ongoing support for HIV/AIDS research is needed to advance scientific progress, enhance partnerships, and address critical research and implementation opportunities to end the HIV/AIDS pandemic.

The Office of AIDS Research (OAR) was authorized initially by the Health Omnibus Programs Extension (HOPE) Act of 1988, P.L. 100-607, a statute amending the Public Health Service Act. These amendments legislated the appropriation of federal funding for prevention, testing, research, and fellowship and training programs related to AIDS. Subsequently, the NIH Revitalization Act of 1993, P.L. 103-43, authorized OAR to plan, coordinate, and evaluate AIDS research conducted or supported across NIH. OAR aims to:

- Oversee, coordinate, and manage all NIH HIV/AIDS research.
- Establish HIV-related research priorities and develop the NIH-wide strategic plan for HIV and HIV-related research.
- Identify areas of highest scientific priority for investment.
- Address emerging scientific needs and opportunities.
- Develop and allocate the NIH AIDS research budget and track and report funding.

[277] UNAIDS. In Danger: UNAIDS Global AIDS Update 2022. July 27, 2022. Accessed October 14, 2022. www.unaids.org/en/resources/documents/2022/in-danger-global-aids-update

We operationalize these mandated authorities through four Strategic Goals, outlined in the *Fiscal Year (FY) 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* (NIH HIV Strategic Plan)[278] to:



- Advance rigorous and innovative research to end the HIV/AIDS pandemic and improve the health of people with, at risk for, or affected by HIV across the lifespan.
- Ensure that the NIH HIV/AIDS research program remains flexible and responsive to emerging scientific opportunities and discoveries.
- Promote dissemination and implementation of research discoveries for public health impact across agencies, departments, and stakeholders within the U.S. government and globally.
- Strengthen human resource and infrastructure capacity to enhance sustainability of HIV/AIDS research discovery and the implementation of findings by a diverse and multidisciplinary workforce.

The Strategic Goals also provide the framework for OAR to promote the NIH Director's theme of *Turning Discovery into Health: Science for Everyone by Everyone.*

To ensure health at all stages of life for all people, we prioritize HIV treatment and prevention for persons of all ages across the lifespan. One significant achievement is the current rate of perinatal HIV transmission of less than two percent in the United States, reflecting, in part, increased routine HIV screening of pregnant persons and uptake of antiretroviral therapy (ART) for treatment and prevention.[279]

Adolescents with HIV infection face unique challenges during the transition from pediatric to adult health care settings, including interruptions in HIV care, changes in socioeconomic status and health insurance, and stigma and disclosure issues. Young adults with HIV often face issues related to cognitive development and mental health; medication adherence; and sexual, reproductive, and gender health concerns. In 2020, more than half of all people with HIV in the United States were age 50 or older, and about 17 percent of new infections occurred in persons older than age 50.[280] Chronic HIV infection and long-term use of ART can contribute to complications, coinfections, and comorbidities in people with HIV, particularly as they age. NIH supports basic, translational, and clinical research across the Institutes, Centers, and Offices (ICOs) to increase understanding of these comorbidities and their prevention and management, as well as their relationship to aging and HIV.

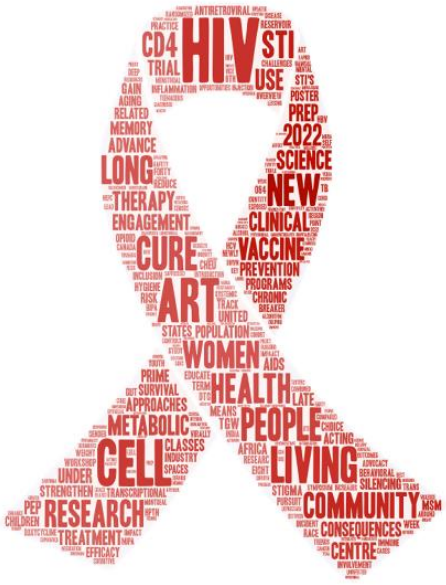
[278] National Institutes of Health Office of AIDS Research. FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research. 2020. Accessed October 14, 2022. oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf

[279] Nesheim SR, FitzHarris LF, Mahle Gray K, Lampe MA. Epidemiology of perinatal HIV transmission in the United States in the era of its elimination. *Pediatr Infect Dis J.* 2019;38(6):611-616. doi:10.1097/INF.0000000000002290. pubmed.ncbi.nlm.nih.gov/30724833

[280] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf

Black/African American and Hispanic/Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups. In 2020, Black/African American persons represented 13.6 percent of the U.S. population, but accounted for 42 percent of people with HIV. Hispanic/Latino persons represented 18.9 percent of the U.S. population, but 27 percent of people with HIV.[281,282] NIH supports research to better address underlying HIV-associated health disparities and inequities related to age, race, ethnicity, sex, gender, economic status, and geographic location. NIH is committed to promoting community engagement across the research continuum, with an emphasis on diverse populations, to ensure that community input informs the development of new research concepts and implementation of best practices.

To discover new strategies for prevention and treatment, OAR continues to support cutting-edge research. We were inspired by the advances showcased at the 24th International AIDS Conference (AIDS 2022), held in Montreal, Canada, which presented recent breakthroughs in HIV testing, prevention, and treatment and highlighted scientific gaps and opportunities for continued discovery. Recent NIH studies on long-acting injectable pre-exposure prophylaxis (PrEP) and treatment as prevention, both of which are preventive tools for people at risk of HIV acquisition, were presented at AIDS 2022. Access to and implementation of PrEP and self-testing are growing worldwide. Long-acting injectable PrEP may improve adherence and reduce stigma. Multipurpose prevention technologies for HIV, delivered through modalities such as vaginal rings, implants, or injectables, combine HIV prevention with interventions that prevent other sexually transmitted infections (STIs) and/or unintended pregnancy. Innovative mRNA technology has accelerated initial Phase I trials of HIV vaccine candidates.



To inspire the next generation of scientists, OAR promotes efforts to improve outreach to HIV/AIDS researchers early in their careers, including early stage investigators (ESIs). NIH is committed to developing and implementing a long-term plan to support, sustain, and improve the diversity of the next generation of the HIV/AIDS research workforce.[283] Outreach to ESIs emphasizes diversity, equity, inclusion, and accessibility within the HIV/AIDS research workforce.[284] NIH is committed to supporting HIV/AIDS researchers from underrepresented

[281] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf
[282] U.S. Census Bureau. U.S. Population Data by Race From U.S. Census Bureau. *Quick Facts*. 2020. Accessed October 14, 2022. www.census.gov/quickfacts/fact/table/US/RHI125221
[283] Lauer M, Tabak L, Collins F. Opinion: The Next Generation Researchers Initiative at NIH. *Proc Natl Acad Sci U S A*. 2017;114(45):11801-11803. doi:10.1073/pnas.1716941114. pubmed.ncbi.nlm.nih.gov/29114085
[284] National Institutes of Health. Chief Officer for Scientific Workforce Diversity (COSWD) Strategic Plan for Fiscal Years 2022–2026. April 2022. Accessed October 14, 2022. diversity.nih.gov/sites/coswd/files/images/NIH_COSWD_Strategic_Plan_for_Fiscal_Years_2022-2026_508c.pdf

communities, expanding research capacity in historically under-resourced academic institutions, and ensuring that research is culturally appropriate and attentive to the needs of diverse communities. In spring 2022, OAR convened a listening session to determine how best to support the next generation of HIV/AIDS researchers and address training and capacity-building needs. We subsequently convened a "Workshop for Early Career Investigators in HIV/AIDS" to facilitate interactions between researchers, mentors, and NIH program staff. We plan to make materials from this workshop available to higher education institutions, including those serving minority and/or underrepresented researchers, as part of regular OAR outreach activities. The ESI initiative includes the launch of a highly visited webpage related to grant opportunities, training, and capacity-building programs.[285]

To promote team-based and interdisciplinary science, OAR convenes the NIH HIV/AIDS Executive Committee (NAEC) across the NIH ICOs to expand implementation, promote community engagement, and disseminate research findings. We will expand research focused on women's health and HIV by ensuring women are represented in HIV/AIDS research in collaboration with the NIH Office of Research on Women's Health (ORWH). NIH will continue to promote interdisciplinary research to better address comorbidities in people aging with HIV, as well as HIV-related psychosocial conditions, in partnership with several ICOs. Another inter-NIH collaboration focuses on reviewing pharmacy-based approaches to increase access to HIV testing, prevention, and care. NIH will continue research partnerships across academia, community, and government.

The omnibus appropriations bills for FY 2022 and FY 2023 provided NIH with the first significant increases for HIV and HIV-related research since FY 2014. OAR allocated this funding to the NIH ICOs to support focused investments in areas aligned with the goals of the NIH HIV Strategic Plan,[286] as well as the objectives of the *National HIV/AIDS Strategy* (NHAS)[287] and the accompanying *NHAS Federal Implementation Plan*,[288] including the *Ending the HIV Epidemic in the U.S.* (EHE) initiative.[289] Specific priorities in FY 2022 and FY 2023 for HIV/AIDS research were related to: direct support to the EHE initiative through the Centers for AIDS Research (CFARs); HIV and aging; vaccines; long-acting antiretroviral formulations; new therapeutic targets and technologies; cellular viral reservoirs; neurologic complications; management of comorbidities; health disparities; stigma; implementation science; social determinants of health; and workforce expansion and diversification.

For the past 35 years, OAR has catalyzed, coordinated, convened, and communicated HIV/AIDS research across NIH, alongside other government agencies and academia, with community and

[285] National Institutes of Health Office of AIDS Research. Early Career Investigator Resources. Accessed October 14, 2022. www.oar.nih.gov/trans-nih-hiv-research-program/hiv-early-career-resources
[286] National Institutes of Health Office of AIDS Research. FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research. 2020. Accessed October 14, 2022. oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf
[287] The White House. National HIV/AIDS Strategy for the United States 2022–2025. December 2021. Accessed October 14, 2022. www.whitehouse.gov/wp-content/uploads/2021/11/National-HIV-AIDS-Strategy.pdf
[288] The White House. National HIV/AIDS Strategy Federal Implementation Plan. August 2022. Accessed October 14, 2022. files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.pdf
[289] What is *Ending the HIV Epidemic in the U.S.?* HIV.gov. Updated July 1, 2022. Accessed October 14, 2022. www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

non-governmental organizations. Around the world, these partnerships have come together in unique ways to translate research into action, encourage a holistic response to the HIV/AIDS pandemic, and stimulate innovation. Accomplishments in HIV/AIDS research have propelled progress for other public health crises, such as COVID-19 vaccines and treatments. With a clear vision and achievable goals, we can collectively end the HIV/AIDS pandemic. Now is the time.

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FACT SHEET

National Institutes of Health
Office of AIDS Research

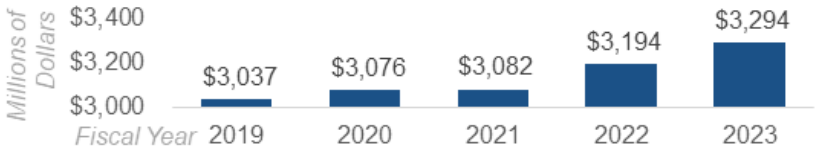
NIH Vision advance research to end the HIV/AIDS pandemic and improve health outcomes for people with HIV

OAR Mission ensure that NIH HIV/AIDS research funding is directed at the highest priority research areas and facilitate maximal return on the investment

The National Institutes of Health (NIH) provides the largest public investment in HIV/AIDS research in the world. HIV spans nearly every area of medicine and scientific investigation. NIH HIV/AIDS research has helped turn HIV from a once-fatal disease into a manageable chronic condition with effective treatment.

In 1988, Congress authorized the **NIH Office of AIDS Research (OAR)** to oversee, coordinate, and manage the NIH HIV/AIDS research portfolio. OAR is one of the coordinating offices within the Office of the NIH Director, in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). OAR collaborates across the U.S. government and with researchers, community groups, and global partners to identify priorities for HIV and HIV-related research.

NIH HIV/AIDS Funding: FY 2019 to FY 2023



The FY 2024 President's Budget request for the NIH-wide HIV/AIDS research program is $3.294 billion, the same as the FY 2023 Enacted level. Funding at this level will expedite NIH efforts to end the HIV pandemic.

NIH HIV/AIDS Research Highlights: FY 2022

- **New methods for HIV prevention** through preexposure prophylaxis (PrEP) have been approved by the FDA: an injectable drug administered every two months and a daily pill.
- **A clinical trial launched an HIV mRNA vaccine candidate that** utilized technology similar to the vaccine for COVID-19.
- **New reports of HIV remission** were documented in individuals who received a stem cell transplant.
- **Treatment involving bNAbs** (antibodies that can combat multiple HIV variants) could help individuals with HIV suppress the virus without daily pills.
- **Different sugar molecules** on the surface of immune cells affect their vulnerability to HIV infection, which could help discover a cure for HIV.
- **Removing precancerous lesions** in people with HIV could decrease their risk of anal cancer by more than half.

@NIH_OAR
oarinfo@nih.gov

basics and care: **HIVinfo.nih.gov**
clinical guidelines: **clinicalinfo.nih.gov**
research: **oar.nih.gov**

Maureen M. Goodenow, Ph.D. serves as the Associate Director for AIDS Research and the Director of the Office of AIDS Research at the NIH

Facts & Figures

1.2M	*approximate number of people in the U.S. who have HIV (CDC data, 2019)*
$3.2B	*NIH funding for HIV/AIDS research in FY 2022*
7%	*of overall NIH budget dedicated to HIV/AIDS research in FY 2022*
100%	*of NIH HIV/AIDS research projects align with priorities defined by OAR in the NIH Strategic Plan for HIV and HIV-related Research*
>3,500	*projects in the NIH HIV/AIDS research portfolio, both domestic and international, spanning 96 countries*
22	*NIH institutes, centers, and offices receive funding for HIV/AIDS research through annual allocations managed by OAR*
18	*voting members on OARAC, the federal advisory committee that provides advice and guidance on HIV/AIDS research to OAR, the NIH Director, and HHS Secretary*
1	*The NIH OAR is the only NIH office focused on a single health condition.*

NIH National Institutes of Health
Office of AIDS Research

1981 *First report of the disease that will be named "acquired immune deficiency syndrome" (AIDS)*

1987 *AZT is the first drug approved by the FDA for treatment of people with human immunodeficiency virus (HIV)*

1988 *Congress establishes OAR to coordinate HIV/AIDS research across the NIH*

1996 *Combinations of antiretroviral therapy become widely available.*

1997 *CDC reports 47% decline in AIDS-related deaths in the U.S.*

2003 *U.S. government launches President's Emergency Plan for AIDS Relief (PEPFAR)*

2012 *FDA approves pre-exposure prophylaxis (PrEP) that prevents HIV transmission*

2017 *U = U (Undetectable = Untransmittable) Low viral levels not detectable on tests = no risk of transmitting HIV*

2021 *FDA approves first long-acting HIV treatment and prevention options*

2023 *Congress increases funding to NIH for HIV/AIDS research by an additional $100M*

Future Initiatives

- **Support innovative research** aligned with scientific priorities identified in the NIH Strategic Plan for HIV and HIV-related Research, Professional Judgment Budget for NIH HIV/AIDS Research, National HIV/AIDS Strategy (NHAS), and the *Ending the HIV Epidemic in the U.S. (EHE)* initiative.
- **Improve health outcomes** of people with HIV and comorbid conditions throughout the lifespan through multi-disciplinary and community-responsive research.
- **Understand the pathology and severity of co-infections** affecting the HIV-affected community, such as COVID-19 and mpox.
- **Develop diagnostic, vaccine, and therapeutic technologies** to support HIV/AIDS research, leveraging COVID-19 research platforms.
- **Identify new partners** for academic, governmental, industry, and community HIV/AIDS research collaborations to implement lessons learned, both domestically and globally.
- **Expand professional opportunities** for early career HIV/AIDS researchers.
- **Communicate the impact** of NIH HIV/AIDS research.

Recent Accomplishments

CATALYZE

Developed funding opportunities for HIV/AIDS **research infrastructure** with NIH offices to serve underrepresented or underserved populations

CONVENE

Continued hosting **listening sessions** and community events to gather stakeholder input on NIH HIV/AIDS research priorities

COORDINATE

Coordinated NIH input to strengthen the research components of the NHAS and its Federal Implementation Plan

COMMUNICATE

Authored articles with federal partners in national journals on HIV-related intersectional stigma and discrimination, as well as the NIH role in EHE

Current Activities

CATALYZE

Increase the number and diversity of HIV/AIDS **early career investigators** through workshops, digital resources, mentoring, stakeholder events

CONVENE

Facilitate knowledge exchange on topics related to HIV/AIDS research, such as **HIV and women, aging, diagnostics and clinical monitoring**

COORDINATE

Work across NIH to support cutting-edge methods and technologies, expand implementation, promote community engagement, and disseminate findings

COMMUNICATE

Support panels that provide **clinical guidelines**, developed through the OAR Advisory Council, with websites providing fact sheets and clinical resources

Recent Publications by OAR Staff
https://pubmed.ncbi.nlm.nih.gov/35703750/
https://pubmed.ncbi.nlm.nih.gov/35763747/
https://pubmed.ncbi.nlm.nih.gov/35763741/
https://pubmed.ncbi.nlm.nih.gov/33886010/

basics and care: **HIVinfo.nih.gov**
clinical guidelines: **clinicalinfo.nih.gov**
research: **oar.nih.gov**
contact: **OARinfo@nih.gov**

BUDGET POLICY STATEMENT

The FY 2024 President's Budget request for the NIH-wide HIV/AIDS research program is $3.294 billion, equal to the FY 2023 Enacted level. Funding at this level will expedite NIH efforts to end the HIV epidemic in the United States and globally; expand HIV prevention, treatment and cure strategies; and address the consequences of aging with HIV. NIH will continue to leverage HIV research and infrastructure to respond to public health needs, engage with early-career investigators (ECIs), as well as established investigators, to develop effective approaches for diversifying the HIV research workforce, and prioritize research training and development across the NIH ICOs to expand the pool of ECIs in HIV research. NIH will capitalize on the use of new technologies and platforms and will continue the critical examination of health disparities in research and medicine. NIH will continue to advance dissemination and implementation research and strategies to identify efforts to optimize effective HIV prevention and treatment strategies to develop and implement effective community outreach and communication strategies.

BUDGET AUTHORITY BY INSTITUTE, CENTER, AND OFFICE

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Institute, Center, and Office
(Dollars in Thousands)

Institute, Center, and Office	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
NCI	$248,940	$256,734	$256,734	$0
NHLBI	89,280	92,953	92,953	0
NIDCR	19,562	20,174	20,174	0
NIDDK	37,524	38,699	38,699	0
NINDS	40,206	41,206	41,206	0
NIAID	1,853,338	1,911,364	1,911,364	0
NICHD	147,716	152,881	152,881	0
NEI	234	-	-	0
NIEHS	5,505	5,512	5,512	0
NIA	26,038	28,538	28,538	0
NIAMS	4,727	4,875	4,875	0
NIDCD	2,193	2,262	2,262	0
NIMH	193,525	199,584	199,584	0
NIDA	270,077	278,533	278,533	0
NIAAA	34,150	35,219	35,219	0
NINR	16,848	17,375	17,375	0
NHGRI	824	824	824	0
NIBIB	1,895	1,954	1,954	0
NIMHD	24,224	24,982	24,982	0
NCCIH	689	689	689	0
FIC	25,132	25,919	25,919	0
NLM	7,685	7,685	7,685	0
OD	143,688	146,038	146,038	0
OAR	65,489	67,589	67,589	0
ORIP	78,199	78,449	78,449	0
Subtotal, OD	143,688	146,038	146,038	0
TOTAL, NIH	**$3,194,000**	**$3,294,000**	**$3,294,000**	**$0**

BUDGET MECHANISM TABLE

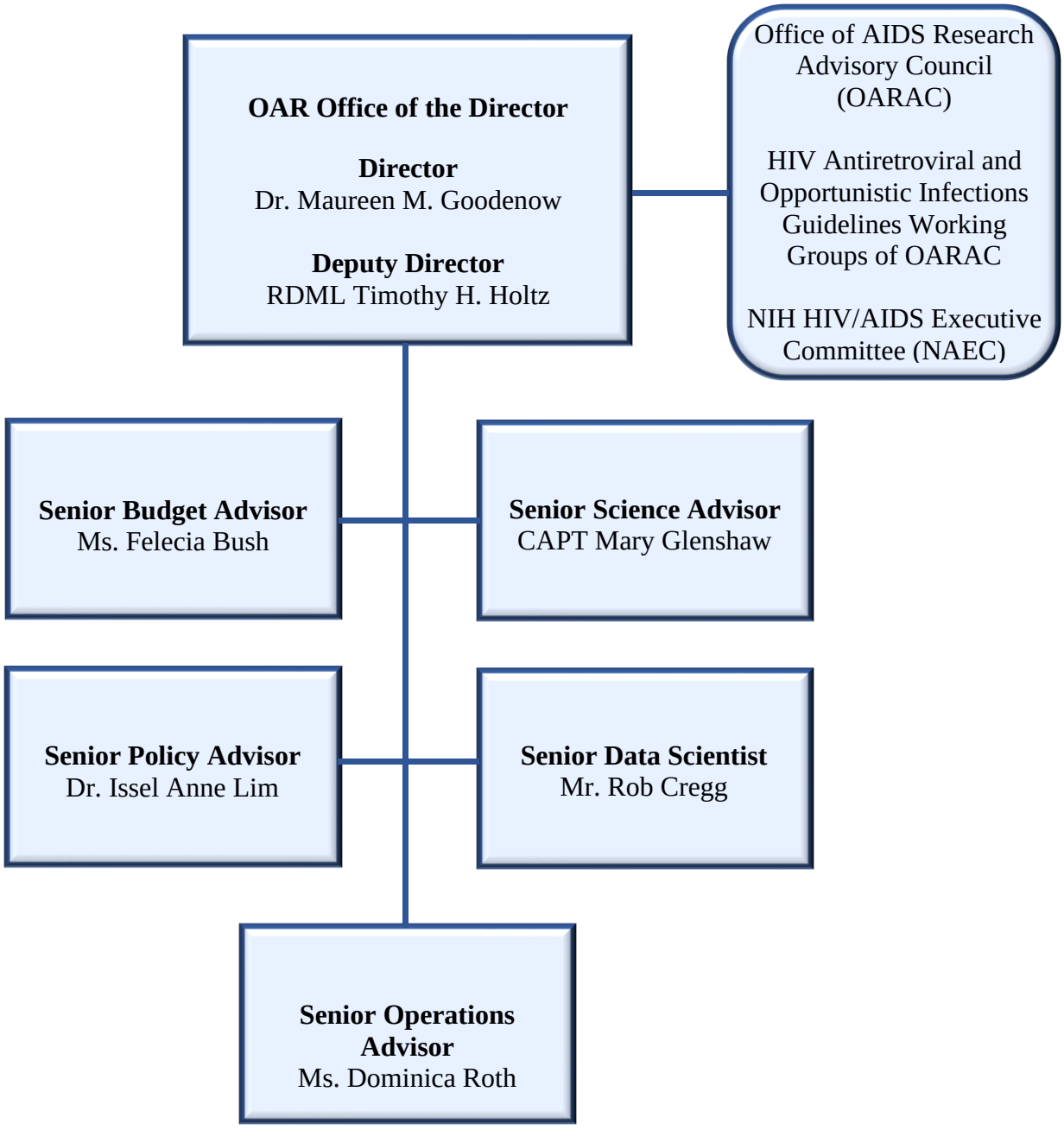
NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Mechanism - AIDS [1]
(Dollars in Thousands)

Mechanism	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,406	$1,463,353	1,412	$1,566,421	1,442	$1,549,307	30	-$17,114
Administrative Supplements	*(114)*	43,008	*(66)*	14,241	*(64)*	17,199	*(2)*	2,958
Competing	468	307,444	448	294,030	460	310,077	12	16,047
Subtotal, RPGs	1,874	$1,813,805	1,860	$1,874,692	1,902	$1,876,583	42	$1,891
SBIR/STTR	30	18,769	29	18,458	27	17,321	-2	-1,137
Research Project Grants	1,904	$1,832,574	1,889	$1,893,150	1,929	$1,893,904	40	$754
Research Centers:								
Specialized/Comprehensive	58	$149,683	63	$156,657	59	$153,376	-4	-$3,281
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	19	73,213	19	70,626	19	70,956	0	330
Research Centers in Minority Institutions	1	4,413	5	5,040	5	5,040	0	0
Research Centers	78	$227,309	87	$232,323	83	$229,372	-4	-$2,951
Other Research:								
Research Careers	265	$46,840	242	$42,595	244	$40,533	2	-$2,062
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	6	2,721	18	12,167	18	14,164	0	1,997
Biomedical Research Support	18	1,605	18	1,600	18	1,648	0	48
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	116	64,739	108	61,225	99	56,311	-9	-4,914
Other Research	405	$115,905	386	$117,587	379	$112,656	-7	-$4,931
Total Research Grants	2,387	$2,175,788	2,362	$2,243,060	2,391	$2,235,932	29	-$7,128
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs			
Individual Awards	85	$3,879	80	$3,716	69	$3,479	-11	-$237
Institutional Awards	240	14,726	245	15,891	241	15,745	-4	-146
Total Research Training	325	$18,605	325	$19,607	310	$19,224	-15	-$383
Research & Develop. Contracts	91	$408,648	97	$419,048	93	$422,980	-4	$3,932
(SBIR/STTR) (non-add)	*(7)*	*(3,898)*	*(5)*	*(3,898)*	*(5)*	*(3,898)*	*(0)*	*0*
Intramural Research		$356,467		$366,817		$368,511		$1,694
Res. Management and Support		169,003		177,879		179,764		1,885
Res. Management & Support (SBIR Admin) (non-add)		*0*		*0*		*0*		*0*
Office of the Director - Appropriation [2]		*143,688*		*146,038*		*146,038*		*0*
Office of the Director - Other		65,489		67,589		67,589		0
ORIP (non-add) [2]		*78,199*		*78,449*		*78,449*		*0*
Total, NIH Discretionary B.A.		**$3,194,000**		**$3,294,000**		**$3,294,000**		**$0**

[1] All items in italics and brackets are non-add entries.

2 Number of grants and dollars for the ORIP component of OD are distributed by mechanism and are noted here as a non-add. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

ORGANIZATION CHART



BUDGET AUTHORITY BY ACTIVITY

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Activity
(Dollars in Thousands)

Research Priorities	FY 2020 Actual [1]	FY 2021 Actual [1]	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Reduce the Incidence of HIV	$719,217	$684,570	$689,324	$704,951	$698,941	-$6,010
Develop Next-Generation HIV Therapies	345,378	331,927	348,034	356,093	362,406	$6,313
Research Toward a Cure for HIV	209,133	224,737	223,450	227,310	226,463	-$847
Address HIV-Associated Comorbidities, Coinfections, and Complications	554,452	560,766	630,948	653,705	664,581	$10,876
Cross-Cutting Areas	1,247,881	1,279,897	1,302,244	1,351,941	1,341,609	-$10,332
Total	**$3,076,061**	**$3,081,897**	**$3,194,000**	**$3,294,000**	**$3,294,000**	**$0**

1/ Reflects effects of Secretary's transfer

JUSTIFICATION OF BUDGET REQUEST

Office of AIDS Research (OAR)

Budget Authority (BA):

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
BA	$3,194,000,000	$3,294,000,000	$3,294,000,000	$0

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

Overall Budget Policy: The FY 2024 President's Budget request for OAR is $3.294 billion, which is equal to the FY 2023 Enacted level. This level of funding will support the priorities of the NIH HIV research agenda, as described below, namely to reduce the incidence of HIV; develop next-generation HIV therapies; support research toward a cure; address HIV-associated comorbidities, coinfections, and complications; and advance cross-cutting areas of research in the basic sciences, behavioral and social sciences, epidemiology, implementation science, information dissemination, and research training.

Program Descriptions

Reduce the Incidence of HIV

At the end of 2020, an estimated 1.1 million persons in the United States and 6 dependent areas were living with diagnosed HIV infection, approximately 87 percent of whom were aware of their positive HIV status. During 2020, over 18,400 people with HIV died (due to any cause) and nearly 30,700 persons acquired a new HIV infection, with the highest rate occurring among young persons ages 25–34 years.[290] According to the U.S. Centers for Disease Control and Prevention (CDC), these numbers should be interpreted with caution, given disruptions in health care services due to the COVID-19 pandemic; therefore, these statistics may be an underestimate.

Despite the persistence of the HIV/AIDS pandemic, decades of public investment and the steadfast efforts of the scientific community have led to discoveries with the potential to radically change these statistics. The effective utilization of those treatment and prevention resources is essential to reduce HIV incidence and end the HIV/AIDS pandemic.

[290] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf

Recently developed exciting new therapeutics have the potential to be used for more than one purpose. For example, long-acting antiretroviral formulations developed for HIV treatment also provide an effective prophylactic tool for HIV prevention. The HIV Prevention Trials Network studies of HPTN 083,[291] which studied cisgender men who have sex with men (MSM) and transgender women, and HPTN 084,[292] which studied cisgender women, demonstrated the safety and efficacy of long-acting injectable cabotegravir (CAB-LA) for PrEP, compared to daily oral PrEP. Long-acting injectable PrEP expands HIV prevention options and is now incorporated into regulatory requirements and World Health Organization (WHO) HIV guidelines.[293] NIH will continue support of research aiming to optimize use of injectable PrEP, as well as to understand the physiological consequences of long-term PrEP use. In addition, HIV vaccine research is a top funding priority in order to achieve an end of the HIV/AIDS pandemic.

Budget Policy: The FY 2024 President's Budget request to promote research to reduce HIV incidence is $699.0 million, a decrease of $6.0 million or -0.9 percent compared to the FY 2023 Enacted level.

Develop Next-Generation HIV Therapies

Promising new technologies, such as 3D printing, microfluidics, and nanotechnology, could revolutionize HIV treatment and prevention strategies. New product delivery

Ending the HIV Epidemic in the U.S. (EHE) Initiative

Launched in 2019, the EHE initiative aims to reduce new HIV infections in the United States by 75 percent in 2025 and by 90 percent in 2030. To achieve maximum impact, Phase I of EHE efforts focused on 57 jurisdictions, including 48 counties where more than 50 percent of new HIV diagnoses occurred in 2016 to 2017, as well as 7 states with a disproportionate occurrence of HIV in rural areas. These hotspots included Washington, DC, and San Juan, Puerto Rico.

NIH's primary role in the EHE initiative is to develop, test, and disseminate best practices based on state-of-the-art biomedical and social/behavioral research findings. Initiated from FY 2019 to FY 2022, NIH EHE projects address the four EHE pillars: diagnose, prevent, treat, and respond. In total, NIH EHE funding has been awarded to 201 highly meritorious projects. Focal areas include priority populations, communications strategies, and minority-serving institutions. In FY 2022, NIH funded 66 EHE projects that use data science, health equity strategies, behavioral economics, and status-neutral approaches with a focus on strategic partnerships across jurisdictions. There are 26 Centers for AIDS Research (CFARs), administered by the National Institute of Allergy and Infectious Diseases (NIAID), and AIDS Research Centers (ARCs), administered by the National Institute of Mental Health (NIMH), participating in the EHE initiative, with 10 CFARs serving as regional hubs for implementation science support. Over 50 state, local, and territorial public health departments and over 275 community organizations have participated in implementing NIH EHE research.

[291] A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men. HIV Prevention Trials Network protocol number: HPTN 083 (20725). Accessed October 17, 2022. www.hptn.org/research/studies/hptn083

[292] A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women. HIV Prevention Trials Network protocol number: HPTN 084 (38070). Accessed October 17, 2022. www.hptn.org/research/studies/hptn084

[293] World Health Organization. Consolidated Guidelines on HIV, Viral Hepatitis and STI Prevention, Diagnosis, Treatment and Care for Key Populations. July 29, 2022. Accessed October 14, 2022. www.who.int/publications/i/item/9789240052390

platforms and devices are being tested in specific populations, such as pediatric, adolescent, pregnant, and postpartum persons. NIH-funded researchers are studying early, intensive administration of ART in newborns to gauge the possibility of early HIV remission, as well as the pharmacokinetics and safety of early ART in this population.[294]

Innovative technologies for viral load testing (measuring the amount of virus in the body) that are sufficiently sensitive and simple to use could help determine effectiveness of and adherence to emerging HIV therapies. Real-time rapid viral load monitoring could enable careful integration of analytical treatment interruption; specifically, when study participants stop using their usual ART to determine if a new investigational HIV drug can be as effective in delaying or preventing viral rebound. New combinations of modalities for HIV treatment, based on broadly neutralizing antibodies (bNAbs), are also being tested for prevention.

Multipurpose prevention technologies (MPTs) could allow the combination of HIV prevention and treatment with interventions for other health conditions or indications, such as contraception, prevention of STIs, and hormone replacement therapy for postmenopausal women. These MPTs can be delivered through different modalities, such as vaginal rings, implants, or injectables. This is a crucial next step in the development of behaviorally congruent products that fit into people's lifestyles to improve HIV prevention and treatment uptake and adherence.

In the wake of scientific advancement and successes in HIV self-testing during the COVID-19 pandemic, communities are expressing interest in self-administered, affordable, and accessible products to monitor and maintain their health. Several studies are investigating person-centered, holistic, and integrated intervention approaches for groups disproportionately affected by the HIV/AIDS epidemic in the United States, including transgender people (HPTN 091),[295] people who inject drugs (HPTN 094),[296] and Black MSM in the South (HPTN 096).[297] NIH will continue to expand its support of multidisciplinary research designed to advance the development, future use, and equitable delivery of long-acting and extended delivery regimens for HIV prevention and treatment, as well as self-testing and monitoring technologies.

[294] Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission. ClinicalTrials.gov identifier: NCT02140255. Updated November 4, 2021. Accessed October 14, 2022. clinicaltrials.gov/ct2/show/NCT02140255
[295] Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition and HIV Transmission for Transgender Women in the Americas: A Vanguard Feasibility and Acceptability Study. HIV Prevention Trials Network protocol number: HPTN 091 (38695). Accessed October 17, 2022. www.hptn.org/research/studies/hptn091
[296] INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care. HIV Prevention Trials Network protocol number: HPTN 094 (38715). Accessed October 17, 2022. www.hptn.org/research/studies/hptn094
[297] Getting to Zero Among Black MSM in the American South: Testing the Efficacy of an Integrated Intervention Strategy. HIV Prevention Trials Network protocol number: HPTN 096 (38561). Accessed October 17, 2022. www.hptn.org/research/studies/hptn096

Budget Policy: The FY 2024 President's Budget request to support research to develop next-generation HIV therapies is $362.4 million, an increase of $6.3 million or 1.8 percent compared to the FY 2023 Enacted level.

Research Toward HIV Cure

Groundbreaking research advances in HIV treatment have helped turn HIV into a manageable, chronic condition—but current treatments do not cure HIV. HIV cure research is focused on two broad aims: sustained viral remission and, in the longer term, viral eradication.

HIV is a complex virus that can hide from the immune system, but NIH investment in HIV virology will continue to advance the current understanding of viral reservoirs and long-term viral suppression. Latent HIV viral reservoirs are groups of cells that are infected with HIV, but are not actively producing new virus. These small amounts of latent HIV persist even in people taking ART, presenting a significant challenge for an HIV cure because the virus can reactivate at any time. Additionally, HIV reservoirs can be found in certain "sanctuary" sites in the body; that is, cells where the virus is protected from both the person's immune system and ART, such as in the central nervous system (CNS) and other tissues. To work towards a cure for HIV, NIH supports studies to develop novel approaches and treatments that target these HIV reservoirs. Current scientific findings suggest that the first step toward a potential HIV cure may require viral remission (a state in which the virus is suppressed without ART), also known as a functional cure. Potential cure-inducing treatments must be as safe, effective, and available for widespread use as today's ART regimens. Viral eradication, or elimination of the virus entirely, is a more challenging, longer-term goal. Integration of real-time, rapid viral load monitoring with analytical treatment interruption may also enable clinical evaluation of promising new approaches to achieving a cure for HIV.

Methods using a combination of donated cord blood stem cells and cells from a related donor hold major promise for a potential HIV cure.[298] There are a few, rare examples of having achieved an HIV cure (currently, only four cases worldwide) that provide a glimpse into the areas of research needed to better understand the dynamics of viral reactivation (the process by which the virus becomes active from its latent state).

NIH also supports research on the host's genetic factors that may influence the size and composition of latent viral reservoirs in people with HIV on ART regimens, interactions between the virus and immune cells, and strategies to prevent the development of drug resistance. Several experimental techniques, including single-cell imaging technologies, gene assays, and testing new molecular treatments, are being used to better understand how HIV can reactivate from latently infected cells. Latency-reversing agents can make HIV visible to the immune system so it can be eliminated. Other experimental treatments include genetically engineered immune cells that are resistant to HIV infection, therapeutic vaccines, and long-acting antiretrovirals that can suppress virus for a few months or even longer. Another strategy is gene editing using CRISPR-Cas9 that potentially could cut and remove viral HIV integrated into the

[298] Marley G, Tan RKJ, Tang W. Stem cell research finds possible HIV cure with cord blood transplant. *Innovation (Camb)*. 2022;3(3):100238. doi:10.1016/j.xinn.2022.100238. pubmed.ncbi.nlm.nih.gov/35601216

genomic DNA of people with HIV. In September 2021, the U.S. Food and Drug Administration (FDA) approved the initiation of the first clinical trial investigating CRISPR-based gene therapy as a possible approach to achieve an HIV cure.[299] Additional NIH-funded studies are planned in this area.

Research focused on prevention also can help drive discovery toward an HIV cure. An NIH-funded study found that individuals with HIV who began taking ART in the early stages of infection, then stopped ART and received two infusions of bNAbs, achieved a lengthy period of HIV suppression.[300,301] Since bNAbs can be engineered to recognize a broad array of HIV variants, they could help remove viral variants and induce remission.

NIH will expand support for multidisciplinary research teams to analyze processes to establish and maintain latent HIV reservoirs in various tissues (e.g., gastrointestinal, male genital tract, kidney, and adipose tissues). NIH will advance nanotechnology approaches to target reservoirs and promote new research models to replicate viral-host cell interactions, especially for privileged sanctuary sites like the brain. NIH will also advance behavioral and social science research to ascertain which cure strategies would be most effective in different populations with HIV. The ultimate goal of integrating behavioral, biomedical, and implementation science approaches in cure research is to develop safe, effective, scalable, and sustainable strategies that will be available to all people with HIV around the globe, thus maximizing the impact of this research.

Budget Policy: The FY 2024 President's Budget request to promote research toward an HIV cure is $226.5 million, a decrease of $0.8 million or -0.4 percent compared to the FY 2023 Enacted level.

Address HIV-Associated Comorbidities, Coinfections, and Complications

People with HIV who adhere to ART regimens have a near-normal life expectancy. However, comorbidities, coinfections, and other complications can affect the health and well-being of persons with HIV at all ages. The aggregate of multiple concomitant conditions, known as multimorbidity, can significantly jeopardize the quality of life of persons with HIV. Common HIV-associated coinfections, including tuberculosis, hepatitis, malaria, and STIs, have posed long-standing challenges worldwide. New emerging infectious diseases bring additional challenges and require critical attention to improving the health and well-being of persons with HIV. In recent years, two emerging infectious diseases, COVID-19 and mpox (formerly monkeypox), have significantly affected people with or at risk of HIV acquisition.

[299] Study of EBT-101 in Aviremic HIV-1 Infected Adults on Stable ART. ClinicalTrials.gov identifier: NCT05144386. Updated October 19, 2022. Accessed October 25, 2022. clinicaltrials.gov/ct2/show/NCT05144386

[300] Combination anti-HIV antibody infusions suppress virus for prolonged period. Media Advisory. National Institutes of Health. June 1, 2022. Accessed October 14, 2022. www.nih.gov/news-events/news-releases/combination-anti-hiv-antibody-infusions-suppress-virus-prolonged-period

[301] Sneller MC, Blazkova J, Justement JS, et al. Combination anti-HIV antibodies provide sustained virological suppression. *Nature.* 2022;606(7913):375-381. doi:10.1038/s41586-022-04797-9. pubmed.ncbi.nlm.nih.gov/35650437

Biospecimens and clinical data from ongoing, large NIH-funded cohort studies, such as the Multicenter AIDS Cohort Study (MACS)/Women's Interagency HIV Study (WIHS) Combined Cohort Study (also known as MWCCS), are being leveraged to better understand the impact of the COVID-19 pandemic among men and women in the United States with or at risk of HIV infection and to evaluate host factors that contribute to disease acquisition, expression, severity, and recovery.[302,303] Recent MWCCS survey data show that, despite similar testing rates and COVID-19 mitigation efforts, persons with HIV were more likely to have a positive SARS-CoV-2 test and report more symptoms than persons who are not infected with HIV.[304] Additionally, investigators are documenting the psychosocial health effects related to the COVID-19 pandemic in people with HIV and proposing structural and social interventions.[305] NIH's clinical guidelines panels, under the auspices of the OAR Advisory Council (OARAC), published guidance for COVID-19 and people with HIV.[306] Expanded research efforts will focus on investigating the challenges and barriers that account for these health disparities.

HIV and Aging

According to CDC, over half of persons with HIV in the United States are age 50 years or older, and nearly 17 percent of new infections in 2020 occurred in this age group. With expanded ART use, the number of people aging with HIV is increasing rapidly. Individuals aging with HIV are more likely to experience the effects of accelerated aging, higher rates of neurocognitive and cardiovascular complications, some malignancies, and metabolic and bone disorders. These conditions are most likely caused by chronic low-level activation of the immune system. Older people with HIV have higher levels of comorbidities compared to people of similar age without HIV. Furthermore, people aging with HIV face both age-related and HIV-related stigma.

An interdisciplinary approach that includes geroscience (the study of the intersection between basic aging biology and chronic disease) and the social sciences is required to address the increasing health concerns and improve health outcomes in people aging with HIV. OAR collaborates with the National Institute on Aging (NIA) to support research on HIV and aging.

Preliminary CDC data from May to July 2022 suggest that MSM comprised a high proportion of mpox cases in the United States early in the mpox outbreak, and nearly 40 percent of those occurred in persons with HIV. In addition, people with HIV experience more severe symptoms of mpox infection. Significant racial disparities exist among people who have both HIV and mpox, with higher rates in Black and Hispanic individuals compared to White individuals and

[302] D'Souza G, Bhondoekhan F, Benning L, et al. Characteristics of the MACS/WIHS Combined Cohort Study: Opportunities for Research on Aging With HIV in the Longest U.S. Observational Study of HIV. *Am J Epidemiol*. 2021;190(8):1457-1475. doi:10.1093/aje/kwab050. pubmed.ncbi.nlm.nih.gov/33675224

[303] MACS/WIHS Combined Cohort Study. Accessed October 25, 2022. statepi.jhsph.edu/mwccs

[304] D'Souza G, Tong W, Gustafson D, et al. SARS-CoV-2 infection among people living with HIV compared with people without HIV: Survey results from the MACS-WIHS Combined Cohort Study. *J Acquir Immune Defic Syndr*. 2022;89(1):1-8. doi:10.1097/QAI.0000000000002822. pubmed.ncbi.nlm.nih.gov/34878431

[305] Friedman MR, Kempf MC, Benning L, et al. Prevalence of COVID-19-related social disruptions and effects on psychosocial health in a mixed-serostatus cohort of men and women. *J Acquir Immune Defic Syndr*. 2021;88(5):426-438. doi:10.1097/QAI.0000000000002799. pubmed.ncbi.nlm.nih.gov/34757972

[306] Guidelines Working Groups of the NIH Office of AIDS Research Advisory Council. Guidance for COVID-19 and People with HIV. Updated February 22, 2022. Accessed October 14, 2022. clinicalinfo.hiv.gov/en/guidelines/guidance-covid-19-and-people-hiv/whatsnew-covid-19-and-hiv-guidance

other populations.[307] NIH is screening novel therapeutic compounds and planning more extensive clinical testing of drug candidates, since a specific treatment is not approved for mpox virus infection. The NIH-funded AIDS Clinical Trials Group (ACTG) network is conducting a clinical trial to test the drug tecovirimat (TPOXX) for treatment of mpox virus in individuals with underlying immunodeficiency, including persons with HIV.[308] Additional research will continue to investigate the high rate of mpox co-occurrence with HIV, with investments in diagnostics and vaccine efficacy in this population.

Other Comorbidities Across the Lifespan

Common comorbidities in people with HIV, which continue to persist despite effective ART, include neurological complications, cardiovascular disease, diabetes, some cancers, kidney and liver disease, bone loss, and complications due to long-term ART.[309,310] The risk of fracture is higher and increases about 10 years earlier in people with HIV, compared to the general population.[311] People with HIV are also at a high risk of developing mental health, cognitive, and/or substance use disorders.[312] Optimizing approaches to integrated service delivery are needed to address comorbidities, frailty, polypharmacy, social and mental health, and sexual health.

Immune dysfunction and chronic immune activation are thought to be the primary drivers of CNS comorbidities in people with HIV on ART. These CNS comorbidities include neurologic, neurocognitive, and mental health problems; however, considerable gaps exist in understanding these HIV-associated comorbidities. Recent studies show that HIV specifically alters the immune system and the microbiome in the gut, resulting in immune dysfunction, as well as higher levels of systemic inflammation, which may alter brain development, neurotransmitter systems, signaling pathways, and other CNS functions.[313] Current NIH research in the neuro-HIV field is focused on studying the mechanisms underlying microbiome-immune-neuronal interactions, how these mechanisms are affected by HIV even with individuals receiving ART,

[307] Centers for Disease Control and Prevention. Severe Manifestations of Monkeypox Among People Who Are Immunocompromised Due to HIV or Other Conditions. September 29, 2022. Accessed October 14, 2022. emergency.cdc.gov/han/2022/han00475.asp

[308] National Institute of Allergy and Infectious Diseases. Monkeypox Treatment. Reviewed October 13, 2022. Accessed October 14, 2022. www.niaid.nih.gov/diseases-conditions/monkeypox-treatment

[309] Go AS, Reynolds K, Avula HR, et al. Human immunodeficiency virus infection and variation in heart failure risk by age, sex, and ethnicity: The HIV HEART Study. *Mayo Clin Proc*. 2022;97(3):465-479. doi:10.1016/j.mayocp.2021.10.004. pubmed.ncbi.nlm.nih.gov/34916054

[310] HIV linked to increased risk for heart failure. News release. National Heart, Lung, and Blood Institute. January 21, 2022. Accessed October 14, 2022. www.nhlbi.nih.gov/news/2022/hiv-linked-increased-risk-heart-failure

[311] Biver E. Osteoporosis and HIV infection. *Calcif Tissue Int.* 2022;110(5):624-640. doi:10.1007/s00223-022-00946-4. pubmed.ncbi.nlm.nih.gov/35098324

[312] National Institute of Mental Health. HIV/AIDS and Mental Health. Accessed October 14, 2022. www.nimh.nih.gov/health/topics/hiv-aids

[313] Le LT, Price RW, Gisslén M, et al. Correlation between CD4/CD8 ratio and neurocognitive performance during early HIV infection. HIV Med. 2022; online ahead of print. doi: 10.1111/hiv.13411. https://pubmed.ncbi.nlm.nih.gov/36134890/

and how these disruptions impact neuronal function.[314,315] OAR and NIA are partnering to support cross-disciplinary studies on the similarities and differences between the mental and physical declines in Alzheimer's disease and HIV-associated neurocognitive disorder (HAND).[316] In 2022, NIA released a Notice of Special Interest (NOSI) to accelerate new knowledge related to the science of HIV and aging and to expand the pool of researchers conducting studies at the intersection of HIV and aging.[317]

People with HIV who are aging experience significant metabolic complications; however, the mechanisms by which these complications occur are not fully understood. Studies have shown that long-term ART may contribute to potentially detrimental lipid storage in multiple tissues, which in turn may lead to chronic inflammation and metabolic dysfunction, resulting in comorbidities such as diabetes and cardiovascular disease.[318] NIH is supporting research to investigate the mechanisms by which the immune system contributes to this abnormal lipid distribution to advance diagnostic and therapeutic interventions to improve the metabolic health of people with HIV.

NIH will continue to foster basic and translational research, focusing on how HIV infection and HIV treatment impacts systemic disease progression and pathogenesis, resulting in HIV-associated comorbidities. Additional research will focus on identifying and developing etiological targets and biomarkers for diagnosis and therapeutic interventions. In addition, NIH will expand support for multidisciplinary approaches to better understand the underlying mechanisms of long-term HIV comorbidities.

Budget Policy: The FY 2024 President's Budget request to support research to address HIV-associated comorbidities, coinfections, and complications is $664.6 million, an increase of $10.9 million or 1.7 percent compared to the FY 2023 Enacted level.

Cross-Cutting Areas

Basic Science: Expanding the basic biomedical research portfolio is critical to advance discovery in HIV virology, immunology, and pathogenesis. The unique characteristics of the viral life cycle, including the ability of HIV to become part of the host cell genome, present significant challenges to the development of effective vaccine and cure strategies. Another

[314] National Institutes of Health. RFA-MH-21-250. Deciphering Immune-CNS interactions in people living with HIV on Anti-Retroviral therapy. August 19, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-250.html

[315] National Institutes of Health. RFA-MH-22-230. Understanding the role of Gut Immune dysfunction and Gut Microbiome in pathogenesis of Central Nervous System co-morbidities in people living with HIV. April 25, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-230.html

[316] National Institutes of Health Office of AIDS Research. Office of AIDS Research and National Institute on Aging Launch Collaboration. Reviewed June 8, 2020. Accessed October 14, 2022. www.oar.nih.gov/trans-nih-hiv-research-program/project-spotlightnational-institute-on-aging-collaboration

[317] National Institutes of Health. NOT-AG-22-014. Notice of Special Interest: Administrative Supplements for HIV/AIDS and Aging Research. February 22, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/notice-files/NOT-AG-22-014.html

[318] Bailin SS, Gabriel CL, Fan R, et al. Relationship of Subcutaneous Adipose Tissue Inflammation-Related Gene Expression With Ectopic Lipid Deposition in Persons With HIV. *J Acquir Immune Defic Syndr.* 2022; 90(2):175-183. doi: 10.1097/QAI.0000000000002926.pubmed.ncbi.nlm.nih.gov/35125474/

challenge is the diversity of immune cells the virus can infect. Recently, an NIH-funded team found that patterns of sugars at the surface of human immune cells affect their vulnerability to HIV infection. These data suggest that infected immune cells harboring HIV could be located by identifying the sugar profiles on the surface of these cells.[319,320]

Behavioral and Social Sciences Research: NIH continues to support research at the intersection of HIV, mental health, and substance use to accelerate testing of effective prevention interventions and address underlying social determinants of health. Several ongoing and recent studies focus on key populations, including MSM, Black/African American women, people who use alcohol and other drugs, and other priority populations in geographic hotspots such as in the Southern United States. Initiatives aimed at developing and testing novel behavioral and social science interventions along the HIV continuum of care, such as multilevel, combination prevention approaches, and the deployment of digital tools for HIV testing and clinical monitoring show promising outcomes, particularly in youth. Advancing similar strategies in diagnostics and distribution approaches has the potential to facilitate HIV self-testing, expand access to health care, and reduce stigma for persons with and risk for HIV acquisition. NIH plans to expand research to better understand the causal pathways between core psychosocial factors and HIV outcomes, including health disparities and inequalities, to inform development of sociostructural interventions and develop appropriate metrics and methodologies for assessing health systems, organizational contexts, and implementation processes and outcomes in diverse settings.

Information Dissemination and Health Communications: The health communications landscape has been radically transformed by the widespread use of social media, mobile app-based services, and other new communication technologies that enable users to access real-time information, which then can be rapidly disseminated and amplified. Accurate and fact-based scientific information can be a powerful public health tool, whereby the channels and content of health communications reflect the needs and concerns of diverse communities. An example of a highly successful HIV-related health communications campaign has been promotion of the message that undetectable (HIV) is untransmittable, or U=U. The NIH Advancing Health Communication Practice and Science program will investigate new ways to engage with diverse HIV communities and capitalize on the benefits of more than 40 years of public investment in HIV science.[321] Future research will develop and test novel health communication strategies to improve the introduction, explanation, and rollout of new HIV scientific tools and discoveries, such as those to inform and support acceptance and uptake of future vaccine candidates that

[319] Tabak, L. Finding HIV's 'Sweet Spot.' *NIH Director's Blog*. July 19, 2022. Accessed October 14, 2022. directorsblog.nih.gov/2022/07/19/finding-hivs-sweet-spot

[320] Ma T, McGregor M, Giron L, et al. Single-cell glycomics analysis by CyTOF-Lec reveals glycan features defining cells differentially susceptible to HIV. *Elife*. 2022;11:e78870. doi:10.7554/eLife.78870. pubmed.ncbi.nlm.nih.gov/35787792

[321] National Institutes of Health Office of Strategic Coordination – The Common Fund. Advancing Health Communication Science and Practice. Reviewed September 13, 2022. Accessed October 14, 2022. commonfund.nih.gov/healthcommresearch

Promoting a Diverse Workforce

The NIH HIV Strategic Plan highlights a goal to "build human resource and infrastructure capacity to enhance sustainability of HIV research discovery and the implementation of findings by a diverse and multidisciplinary workforce." Researchers who are starting to build their careers are critical to the long-term stability of all scientific research. OAR works with NIH ICOs to develop and support HIV-focused initiatives that will support HIV/AIDS researchers who are early in their careers.

OAR conducted multiple stakeholder events and gathered comprehensive input on how to improve outreach to this group of HIV/AIDS researchers. OAR improved access to training in grant writing and peer review, offering consultations with HIV/AIDS senior scientists and mentors. OAR also developed online resources to centralize all relevant information for HIV/AIDS researchers and provide easy access to relevant grant opportunities, training, and capacity-building programs. OAR convened a successful workshop in April 2022 to stimulate scientific collaborations among the next generation of HIV/AIDS researchers and enhance career development skills. An additional workshop is planned for FY 2023.

would protect against HIV acquisition, a key NIH priority. Another priority is research on the prevention, mitigation, and/or counteraction of HIV-related misinformation and deliberate disinformation campaigns. OAR will continue its series of listening sessions and community engagement meetings in various locations to obtain stakeholder input on recent research findings, research priorities, and optimal translation and dissemination strategies.

Implementation Science: NIH supports research to identify effective HIV interventions and strategies to optimize provision and uptake of HIV prevention, care, and treatment, particularly as these further the goals of the NHAS, the *NHAS Federal Implementation Plan*, and the EHE initiative. NIH-wide input strengthened the NHAS research component in FY 2022, noting gaps in knowledge and implementation practices. The NHAS research-focused objectives cover a broad range of basic, clinical, behavioral/social sciences, implementation, and communications science. Planned activities include strengthening interventions and implementation strategies that target social and structural determinants of health and ultimately improve HIV outcomes (including retention in care and adherence to treatment) and reduce health inequities. NIH also supports implementation research on the development of health care strategies tailored for older people with HIV.[322,323]

Training, Infrastructure, and Capacity-Building: NIH is committed to supporting the next generation of HIV/AIDS researchers and ensuring the HIV/AIDS research workforce is diverse and representative of historically underrepresented groups through support of virtual workshops and other focused outreach activities. Multidisciplinary training also provides innovative perspectives on HIV and geriatrics research, which could inform responses to the health care needs of a growing population of people who are aging with HIV. NIH will increase its support

[322] National Institutes of Health. U24HL15442. Implementation Research Strategies for Heart, Lung, and Blood Co-morbidities in People Living with HIV - Research Coordinating Center. September 15, 2022. Accessed October 14, 2022. reporter.nih.gov/project-details/10477320

[323] National Institutes of Health. K76AG064545. Tailored Geriatric Assessment and Management for HIV Care Settings. May 4, 2022. Accessed October 14, 2022. reporter.nih.gov/project-details/10361518

for research infrastructure by funding alterations, renovation, equipment, and resources for facilities conducting HIV/AIDS research.

Budget Policy: The FY 2024 President's Budget request to support research to address HIV/AIDS research in cross-cutting areas is $1,341.6 million, a decrease of $10.3 million or -0.8 percent compared to the FY 2023 Enacted level.

RESOURCE SUMMARY

Drug Control Program
Department of Health and Human Services
National Institutes of Health (NIH)[1]

(Dollars in Millions)

Resource Summary	FY 2022 Final	FY 2023 Enacted[2]	FY 2024 Request
Drug Resources by Function			
Research and Development: Prevention	$482.844	$498.487	$498.271
Research and Development: Harm Reduction	$183.813	$189.685	$190.193
Research and Development: Treatment	$903.515	$947.479	$946.678
Research and Development: Recovery	$99.340	$103.935	$104.443
Total, Drug Resources by Function	**$1,669.512**	**$1,739.586**	**$1,739.586**
Drug Resources by Decision Unit			
National Institute on Alcohol Effects and Alcohol-Associated Disorders (NIAAA)[3]			
Research and Development: Prevention	$63.990	$66.410	$66.410
Research and Development: Treatment	$9.453	$9.811	$9.811
National Institute on Drugs and Addiction (NIDA)[3]			
Research and Development: Prevention	$418.854	$432.077	$431.861
Research and Development: Harm Reduction	$183.813	$189.685	$190.193
Research and Development: Treatment	$894.062	$937.668	$936.867
Research and Development: Recovery	$99.340	$103.935	$104.443
Total, Drug Resources by Decision Unit	**$1,669.512**	**$1,739.586**	**$1,739.586**
Drug Resources Personnel Summary			
Total FTEs (direct only)	396	398	416
Drug Resources as a Percent of Budget			
Total Agency Discretionary Budget (Dollars in Billions)[4]	$43.727	$46.125	$46.400
Drug Resources Percentage	3.82%	3.77%	3.75%

[1] Numbers may not total due to rounding.
[2] FY 2023 Enacted level includes the effects of the FY 2023 HIV/AIDS transfer.
[3] The FY 2024 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction and to rename the National Institute on Alcohol Abuse and Alcoholism to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.
[4] Excludes funding for Advanced Research Projects Agency for Health.

PROGRAM SUMMARY

MISSION

The National Institute on Drugs and Addiction (NIDA) and the National Institute on Alcohol Effects and Alcohol-Associated Disorders (NIAAA), 2 of the 27 Institutes and Centers of the National Institutes of Health (NIH), support research in pursuit of the objectives of the National Drug Control Strategy.[324]

NIDA is the lead federal agency supporting scientific research on drug use and its consequences. Its mission is to advance science on drug use and addiction and apply that knowledge to improve individual and public health. This includes basic and clinical research on drug use (including nicotine), addiction, and the underlying neurobiological, behavioral, and social mechanisms involved. NIDA also works to ensure the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use disorder (SUD) and overdose, and to enhance public awareness of addiction as a brain disorder.

NIAAA's mission is to generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being, and apply that knowledge to improve diagnosis, prevention, and treatment of alcohol-related problems, including alcohol use disorder, across the lifespan. A major priority within NIAAA's mission is research on the prevention and treatment of underage drinking and its harmful consequences.

Alcohol misuse has profound effects on the health and well-being of individuals, families, and communities, costing the United States an estimated $249 billion per year. NIAAA is committed to reducing the burden of alcohol misuse for individuals at all stages of life and supports a diverse portfolio of research to accomplish this goal. Research areas include biological and behavioral mechanisms underlying alcohol misuse, alcohol use disorder (AUD), and alcohol-related health conditions; epidemiological assessments of patterns and trends in alcohol use; and the development and evaluation of interventions to identify, prevent, and treat alcohol misuse and its consequences, including among youth. NIAAA also supports efforts to translate research findings to improve prevention and treatment of alcohol-related problems and co-occurring conditions and to disseminate evidence-based information to health care providers, researchers, policy makers, and the public. These ongoing efforts have significantly broadened our understanding of alcohol misuse and AUD and have provided support for the integration of alcohol prevention and treatment services into mainstream health care.

METHODOLOGY

NIDA's entire budget is drug-related and classified as a part of the National Drug Control Budget.

The prevention and treatment components of NIAAA's underage drinking research program are classified as a part of the National Drug Control Budget. Underage drinking research is defined

[324] The FY 2024 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction and to rename the National Institute on Alcohol Abuse and Alcoholism to the National Institute on Alcohol Effects and Alcohol-Associated Disorders.

as research that focuses on alcohol use by youth (individuals under the legal drinking age of 21), as well as the negative consequences of underage alcohol use (e.g., alcohol-related injuries, impact on adolescent development including on the developing brain, and risk for AUD). It includes basic biological and behavioral research, epidemiological research, screening studies, the development and testing of preventive and treatment interventions, and efforts to disseminate evidence-based information. NIAAA's methodology for developing estimates for the drug control budget is a two-step process. First, NIAAA identifies its underage drinking projects using NIH's automated, electronic text mining system for research, condition, and disease categorization. Once these projects are verified as underage drinking projects, NIAAA conducts a manual review of the project listing and codes each verified project as relevant to prevention or treatment.

BUDGET SUMMARY

The FY 2024 Request for drug-related activities at NIH is $1,739.6 million ($1,663.4 million for NIDA and $76.2 million for NIAAA), unchanged from the FY 2023 Enacted Level.

National Institute on Drugs and Addiction
FY 2024 Request: $1,663.4 million
(flat to the FY 2023 Enacted Level)

In 2021, fatal overdoses claimed nearly 107,000 Americans, a devastating record driven in part by the synthetic opioid fentanyl, which was involved in more than two-thirds of overdose deaths.[325] There are effective treatments for SUD that could have prevented many of these deaths—but of the 40 million people who had SUD that year, only about 6 percent received such treatments.[326] These data speak to the persistent need to improve and disseminate evidence-based interventions for SUD, overdose, and related harms. To that end, in the coming years, NIDA will strengthen its research investments in prevention, treatment, harm reduction, and recovery services related to substance use, in alignment with the priorities of the Office of National Drug Control Policy and with additional funding made available through the NIH HEAL Initiative®.

In the prevention area, NIDA will continue working to understand risk and protective factors for substance misuse and SUD, which will enable more targeted and effective prevention programs. Research shows that adverse early childhood experiences are associated with early substance misuse, which may in turn alter brain development in ways that increase the risk of SUD in adulthood.[327] Yet, much remains to be learned about how a vast constellation of early-life experiences, combined with a person's genetic makeup, affects vulnerability to SUD and other psychiatric disorders. Led by NIDA, NIAAA, and the National Cancer Institute, the Adolescent Brain Cognitive Development (ABCD) Study is collecting brain imaging, genetic, and environmental data from more than 12,000 children aged 9-10 and following them through adulthood to help fill this knowledge gap. With funding from the HEAL Initiative®, the HEALthy Brain and Child Development (HBCD) Study, will complement the ABCD study by following brain development in thousands of children from birth through their first decade of life.

In the treatment area, it is critical to improve the reach of existing evidence-based treatments for SUD, such as medications for opioid use disorder (MOUD), which can reduce opioid craving, use, and risk of overdose. As is the case with SUD treatment generally, MOUD are vastly under-prescribed, especially among people of color.[328] NIDA-funded research has helped identify barriers to MOUD—such as lack of integration between primary care and specialized addiction services—and is investigating approaches to overcome them and improve MOUD access. At the same time, saving lives from overdose will also require novel medications. MOUD may be less

[325] cdc.gov/nchs/products/databriefs/db457.htm; cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm
[326] samhsa.gov/data/report/2021-nsduh-annual-national-report
[327] pubmed.ncbi.nlm.nih.gov/29690790/
[328] pubmed.ncbi.nlm.nih.gov/31066881/; cdc.gov/mmwr/volumes/71/wr/mm7129e2.htm

effective in treating addiction to fentanyl (which is 50 times stronger than heroin)[329] and are ineffective against stimulants, which have become implicated in more overdose deaths in recent years.[15] For this reason, NIDA continues to support development of novel treatments, including long-acting drug formulations, neuromodulation therapies, immunotherapies, and sequestrants designed to stop drugs from entering the brain.

NIDA also prioritizes research in harm reduction, which aims to reduce the risk of overdose and other drug-related harms—including transmission of HIV and hepatitis C virus, and risk of infections that can damage the heart. Harm reduction approaches such as syringe service programs (SSP) and distribution of the opioid overdose reversal agent naloxone have been shown to reduce morbidity and mortality from substance use.[330] Yet, because most harm reduction studies have focused on urban areas hit hard by the opioid crisis, there is a need to investigate these approaches in rural areas and to target unique harms from stimulants.

Finally, given that addiction is a chronic, relapsing disorder, NIDA is prioritizing research to identify best practices in addiction recovery and relapse prevention. There are a variety of recovery service models—including peer-based mutual aid groups, recovery housing, and youth programs—but there is little evidence regarding which kind of program works best for different people. Moreover, many such programs focus on short-term medical treatments and may lack support for participants to receive long-term MOUD.[331] In 2020, NIDA established recovery research networks program to develop tools, resources, and training to grow this area of research. With additional support from the HEAL Initiative®, this program has expanded and is testing new and existing recovery models through clinical trials.

NIDA's research efforts are organized into the following programmatic areas: Neuroscience and Behavior; Epidemiology, Services and Prevention Research; Therapeutics and Medical Consequences; the NIDA Clinical Trials Network; Translational Initiatives and Program Innovations; HEAL Initiative® programs; Intramural Research Program (IRP); and Research Management and Support (RMS). Dollars budgeted to the HEAL Initiative® for the purpose of opioid research are used to supplement base funding for opioid and pain research that are included within other NIDA program areas. Funding for the HEAL Initiative® in NIDA will remain equal to the FY 2023 level.

Division of Neuroscience and Behavior
FY 2024 Request: $534.0 million
($2.4 million below the FY 2023 Enacted Level)

NIDA's Division of Neuroscience and Behavior (DNB) supports research to understand the biological mechanisms that underlie drug use and addiction, and to inform the development of novel prevention and treatment strategies for SUD. This includes identifying the effects of illicit drugs on brain structure and function throughout the lifespan; and how genes, the environment, and other factors such as sex and gender influence the risk of SUD and its outcomes. DNB also

[329] pubmed.ncbi.nlm.nih.gov/36055727/
[330] pubmed.ncbi.nlm.nih.gov/34686281/; pubmed.ncbi.nlm.nih.gov/28061909/
[331] pubmed.ncbi.nlm.nih.gov/34700201/

supports research on drug pharmacology; non-pharmacological SUD treatments; data science; and technology that enables study of the living brain from cells to circuits to networks. With support from the HEAL Initiative® and NIDA and other NIH Institutes and Centers, DNB administers the HBCD Study, which will examine the neurologic, cognitive, social, and emotional development of about 7,500 children from the prenatal period to age 10. Before the study began recruiting families in late 2021, it had to address the challenges of conducting magnetic resonance imaging (MRI) with young children. One challenge was how to keep infants asleep and still during MRI, for which HBCD investigators developed an MRI-compatible crib that can rock infants to sleep and then position them in the MRI scanner without disturbing them. Investigators also surveyed families living near HBCD Study sites and found differences in potential barriers and incentives to their participation. For example, free childcare and playgroups during study visits were more incentivizing to Black respondents than white respondents. These data are helping investigators implement recruitment strategies that will ensure diverse participation in the study.[332]

DNB supported several recent studies that have found molecular and cellular targets for potential SUD therapies. One study explored the possibility that medications used to treat high blood pressure—called angiotensin-converting enzyme (ACE) inhibitors—might hold clues to treating addiction. The investigators found that in mice, ACE inhibitors stimulate certain natural opioids (endorphins) and counteract the addictive effects of fentanyl, suggesting the potential to redesign and repurpose them for treating SUD.[333] Other NIDA-funded research has produced evidence that cells called astrocytes play a protective role in addiction. Astrocytes surround neurons and can "vacuum up" the chemical signals that neurons release, providing a kind of circuit breaker. Recent studies show that astrocytes respond dynamically to opioid exposure by moving closer to synapses and turning up their vacuum power.[334] Therapeutics that boost these responses could help treat or prevent SUD.

DNB also supported an innovative new approach to screen massive virtual chemical libraries. Such libraries are a trove of potential therapeutics but screening them can be time- and cost-prohibitive. The new approach, called V-SYNTHES, starts by screening virtual chemical fragments for their likely engagement of a target (e.g., a receptor). Fragments that show the strongest engagement are pursued by adding modular pieces to them and screening them again in repeated cycles. The inventors of V-SYNTHES used it to screen a virtual library of some 11 billion compounds and identified 21 compounds that bind to brain cannabinoid receptors.[335]

Division of Epidemiology, Services, and Prevention Research
FY 2024 Request: $372.6 million
($1.7 million below the FY 2023 Enacted Level)

NIDA's Division of Epidemiology, Services, and Prevention Research (DESPR) supports research to understand and address the interactions between individuals and environments that contribute to drug use, addiction, and related health problems. DESPR supports a broad

[332] pubmed.ncbi.nlm.nih.gov/34242880
[333] pubmed.ncbi.nlm.nih.gov/35201898
[334] pubmed.ncbi.nlm.nih.gov/34888837; pubmed.ncbi.nlm.nih.gov/35947652
[335] pubmed.ncbi.nlm.nih.gov/34912117

portfolio that informs evidence-based strategies to support prevention, harm reduction, treatment, and recovery for people at risk or with SUDs. This includes two nationally representative studies—the Monitoring the Future (MTF) survey, which measures substance use and related attitudes among adolescents, and the Population Assessment of Tobacco and Health (PATH) Study, which focuses on tobacco use, attitudes, and health outcomes of people aged 12 and older.

MTF and PATH continue to add to our understanding of trends in substance use and their impact on health. For example, while past studies suggested that most teens reduce drug use as they enter adulthood, MTF recently found that teens with symptoms of severe SUD were likely to experience such symptoms in adulthood. The PATH Study recently analyzed use of e-cigarettes (e-cigs) and health outcomes among adults and found that for smokers of conventional cigarettes who have no intention to stop, e-cigs may help them reduce their smoking or quit over time. However, consistent with other research, PATH has also found that compared to smokers and never-smokers, e-cig users have an intermediate risk of short-term respiratory problems such as wheezing and cough.[336] The long-term health risks of e-cig use remain unknown.

DESPR also supports research examining the efficacy and implementation of harm reduction efforts, including reducing the risk of HIV and Hepatitis C Virus (HCV) infection associated with injection drug use. SSPs provide sterile syringes, HIV and HCV testing, and linkage to treatment for these conditions and for SUD but have a limited capacity to reach rural areas. To address this gap, NIDA-funded researchers developed a system wherein SSPs use telehealth to connect patients to an HIV specialist. In a pilot study, 35 people received antiretroviral therapy through this intervention, and of those, nearly 80 percent had clinically suppressed HIV levels at 6 months.[337] A large trial of this intervention is now underway.

Additionally, DESPR supports the ABCD Study, which is following children from ages 9-10 to adulthood to identify risk factors for SUD. Recently, the study explored differences in brain structure associated with alcohol use disorder (AUD), which were long theorized to be caused by alcohol toxicity. But the investigators found that among children never exposed to alcohol, those with genetic risk factors for AUD were likely to have the brain differences previously only seen in adults with AUD. Thus, rather than being a consequence of AUD, those differences could predispose people to AUD and could help inform preventive strategies.[338] Another analysis from the ABCD Study found that children whose mothers had used cannabis after the first 5-6 weeks of pregnancy were more likely to have social, behavioral, and attentional problems at age 11-12.[339] This adds to the evidence that cannabis use during pregnancy can adversely affect prenatal development, with impacts for the child's health many years into the future. In addition to its focus on early-life substance exposures and SUD risk factors, the ABCD Study has led to broader advances in understanding child health, including the impact of the COVID-19 pandemic on children's mental health and the importance of sleep in brain development.[340]

[336] pubmed.ncbi.nlm.nih.gov/34962556; pubmed.ncbi.nlm.nih.gov/34304335
[337] pubmed.ncbi.nlm.nih.gov/34781096
[338] pubmed.ncbi.nlm.nih.gov/34092032
[339] pubmed.ncbi.nlm.nih.gov/36094599
[340] pubmed.ncbi.nlm.nih.gov/35090817; pubmed.ncbi.nlm.nih.gov/35914537

Division of Therapeutics and Medical Consequences
FY 2024 Request: $129.3 million
($0.6 million below the FY 2023 Enacted Level)

NIDA's Division of Therapeutics and Medical Consequences (DTMC) supports research to evaluate the safety and efficacy of pharmacotherapies, behavioral interventions, and medical devices to prevent and treat SUDs and drug overdose. This work spans all phases of medical product development including synthesis and preclinical evaluation of potential therapeutics, clinical trial design and execution, and preparing regulatory submissions.

DTMC supports the development of new medications for SUD, as well as the repurposing of drugs currently used to treat other conditions. For example, among people recovering from OUD, sleep disturbances are often part of withdrawal and can increase the risk of relapse. But taking common sleep aids like sedatives could further increase the risk of relapse and overdose. Thus, DTMC supports research on unique sleep medications that target orexins, proteins in the brain that help promote wakefulness and modulate dopamine-producing brain cells, which drive the rewarding effects of drugs. Preliminary results show that an orexin receptor blocker, suvorexant, reduces withdrawal and improves sleep for people with OUD.[341]

Among current studies on behavioral interventions is a project to improve treatment for chronic pain and depression associated with OUD. These conditions affect 40-60 percent of people with OUD and can increase the risk of opioid misuse if not treated.[342] Researchers are developing an approach in which primary care providers and behavioral health specialists will collaborate to treat such patients.

Funding from the NIH HEAL Initiative® has enabled NIDA to expand its medication development portfolio, including support for research on new types of MOUD. For example, clinical trials are testing subcutaneous implants of extended-release naltrexone that are designed to last for months. Oral extended release levomethadone is also being evaluated as a safer, more accessible alternative to methadone. DTMC also supports development of novel biologics to treat SUD, such as monoclonal antibodies designed to neutralize drugs before they reach the brain. DTMC also supports research on neuromodulation therapies to correct the activity of brain circuits involved in addiction. For example, a current trial is evaluating the feasibility of treating OUD with deep brain stimulation, which is FDA-approved for Parkinson's disease and severe epilepsy.

Center for Clinical Trials Network
FY 2024 Request: $40.8 million
($0.2 million below the FY 2023 Enacted Level)

The NIDA Clinical Trials Network (CTN) provides a collaborative framework for healthcare providers, researchers, and patients to conduct clinical trials on the safety and efficacy of SUD interventions. The CTN includes 16 research nodes across the country and more than 240 community-anchored treatment programs. This unique structure enables the CTN to investigate

[341] pubmed.ncbi.nlm.nih.gov/35731889
[342] pubmed.ncbi.nlm.nih.gov/12746360; pubmed.ncbi.nlm.nih.gov/28476267

behavioral, pharmacological, and integrated therapies across diverse settings and populations, and to develop implementation strategies that help bring research results into practice. Active protocols focus on a variety of areas, including primary prevention of SUD; increasing patient access and adherence to medications for OUD (MOUD), especially in rural and underserved populations; evaluating potential medications for stimulant use disorder; and addressing stigma and other barriers to SUD treatment. Some examples are highlighted below.

Among the 2.5 million people who had OUD in 2020, only 11.2 percent received MOUD, such as methadone, buprenorphine, or naltrexone.[343] Because people with OUD often receive acute care for overdose or other conditions in the emergency department, this presents an opportunity for starting MOUD treatment. A CTN study found that providing high-dose buprenorphine during emergency care was safe for patients with OUD who did not respond well to low doses—an approach that may help such patients control cravings and withdrawal and engage in follow-up care.[344]

The CTN is exploring many other approaches to expand patients' access to MOUD. For example, because most people visit their community pharmacist more often than they see their doctor, the CTN tested a physician-pharmacist collaborative model of care. In that study, about 70 adults with OUD were transitioned from physician management of buprenorphine to management by their pharmacy. Among the 90 percent of patients who completed the study, 95 percent adhered to buprenorphine treatment.[345] The CTN is studying the potential for community pharmacies to provide other MOUD types and to conduct OUD screening and referrals.

The CTN also recently explored the association between OUD and depression, and how patients with both conditions respond to MOUD. In a study of nearly 600 patients with OUD, nearly half had depression when they started MOUD. After four weeks, two-thirds of those patients improved in their depression, but those with severe depression were less likely to improve.[346] The findings suggest that patients with OUD should be screened for depression and that when depression does not improve after MOUD, additional therapies may be needed.

Office of Translational Initiatives and Program Innovations
FY 2024 Request: $42.7 million
($0.2 million below the FY 2023 Enacted Level)

NIDA's Office of Translational Initiatives and Program Innovations (OTIPI) translates discoveries in addiction research into candidate health applications. OTIPI supports translational research through NIDA's Small Business Innovation Research/Technology Transfer (SBIR/STTR) programs, as well as Challenge competitions. OTIPI also develops training programs that help scientists move their discoveries from the lab to the real world.

[343] www.samhsa.gov/data/report/2020-nsduh-annual-national-report
[344] pubmed.ncbi.nlm.nih.gov/34264326
[345] pubmed.ncbi.nlm.nih.gov/33428284
[346] pubmed.ncbi.nlm.nih.gov/35452194

OTIPI supports innovative addiction research and therapeutics development by startup companies. For example, recognizing the therapeutic potential of psychedelic drugs such as psilocybin, in FY 2023, NIDA announced a new program to support small businesses to develop psychedelic-based therapies for SUD. In the telehealth field, NIDA has funded online systems that connect people to addiction treatment and related services. This includes apps to deliver interventions such as cognitive behavioral therapy, enable people to manage MOUD through virtual care, and maintain 24/7 engagement with recovery and relapse prevention services.

Through OTIPI, NIDA also funds new technologies to measure community substance use patterns through wastewater monitoring. This includes funding for Biobot, which uses an algorithm to select sewer access sites (manholes) that will best represent community substance use, then deploys a robotic device inside each manhole to collect samples, and tests for opioids and other drugs in those samples using standard laboratory methods. During the COVID-19 pandemic, Biobot technology was also used to test community levels of SARS-CoV-2 in wastewater, including in a collaboration with the NIH Rapid Acceleration of Diagnostics–Underserved Populations (RADx-UP) program.[347] NIDA also funds development of lab-on-a-chip technology that was recently shown to detect opioids in wastewater with similar sensitivity to standard methods. This platform holds potential for rapid, cost-effective measurement, without the need to take samples to a lab for processing.[348]

OTIPI also supports development of technology to reduce prescription drug diversion, including by healthcare workers. While rates of such diversion are unknown, most hospitals attempt to reduce diversion by using automated drug dispensing cabinets with monthly audits to detect anomalous dispensing. Unfortunately, those systems are slow and prone to error and manipulation. To develop a more effective system, NIDA-funded scientists developed artificial intelligence-powered software that monitors automated dispensing cabinets and employee time clocks to detect potential diversion in real time. The researchers have tested their system against a historical dataset of about 28 million drug transactions including 22 known diversions; it detected all of them, at an average 160 days faster than the time taken for actual discovery.[349]

Finally, OTIPI has coordinated several recent Challenge competitions to take on complex problems in addiction science by seeking innovative solutions from the public, in addition to the scientific community. For example, the "Start an SUD Startup" Challenge invited competitors to propose a startup venture focused on a novel product or approach to address drug addiction. Winning proposals, announced in January 2022, included apps to connect recovery support specialists to clients and peers; portable devices and wearables to detect fentanyl and other substances; and neuromodulation therapy combining music and tactile stimulation. Each winning team received $10,000 and entrepreneurial mentorship, with the goal that some will form startups that can compete successfully for SBIR or STTR funding. Other recent Challenges focused on development of product prototypes to combat drug craving and novel postmortem toxicology tools to improve investigation of suspected drug overdose deaths.

[347] pubmed.ncbi.nlm.nih.gov/34863144
[348] pubmed.ncbi.nlm.nih.gov/34863144
[349] pubmed.ncbi.nlm.nih.gov/35136913

NIH HEAL Initiative®
FY 2024 Request: $355.3 million[350]
(flat compared with the FY 2023 Enacted Level)

NIDA coordinates several innovative HEAL Initiative® programs that are developing and testing evidence-based interventions for opioid misuse and overdose in diverse populations and settings. For example, The HEALing Communities Study is testing an integrated model of evidence-based care to reduce overdose deaths in 67 communities hit hard by the opioid crisis. The study has three core components: (1) a menu of evidence-based practices (EBPs) designed to increase the use of MOUD, widen distribution of naloxone, and reduce high-risk opioid prescribing; (2) community engagement to select the EBPs and strategies that best meet each community's needs; and (3) communications to address stigma about OUD and disseminate EBPs.[351]

The Justice Community Opioid Innovation Network (JCOIN) is studying approaches to improve evidence-based treatment for people with OUD in justice settings, including prisons and jails. It is estimated that half of incarcerated individuals have an SUD and that only about one in four receive any SUD treatment.[352] Recent JCOIN studies show that ensuring access to MOUD in prisons and jails could significantly reduce overdose deaths and recidivism among incarcerated people in the years following their release.[353] Ongoing JCOIN studies are evaluating strategies to help recently incarcerated people find and engage in SUD treatment in their communities.[354]

A new harm reduction research network will develop, test, and implement strategies to prevent overdose, transmission of HIV and HCV, and other harms associated with drug use. The network includes a coordinating center and nine projects focused on a variety of strategies and outcomes, including delivery of harm reduction services during emergency care, via mobile vans for hard-to-reach patients, and in combination with peer-based contingency management.

Another new program, HEAL Data2Action (HD2A), is supporting research to help health systems build real-time data analytics capacity to identify and address service gaps in prevention and treatment of OUD, recovery support, and harm reduction. HD2A currently funds projects focused on areas such as clinical decision support for chronic pain, improving overdose fatality review, stabilizing people at risk for overdose through linkage to MOUD treatment, and improving MOUD access and treatment retention through coordinated care and safe take-home methadone dosing. HD2A also assists researchers with data infrastructure, implementation of evidence-based solutions to service gaps, and long-term sustainability of these solutions.

Intramural Research Program
FY 2024 Request: $113.8 million
($2.5 million above the FY 2023 Enacted Level)

[350] Includes funding for RMS to support the HEAL Initiative.
[351] pubmed.ncbi.nlm.nih.gov/33248391
[352] nap.nationalacademies.org/read/25310/chapter/6; pubmed.ncbi.nlm.nih.gov/34304335
[353] pubmed.ncbi.nlm.nih.gov/32712165; pubmed.ncbi.nlm.nih.gov/35063323
[354] pubmed.ncbi.nlm.nih.gov/33531212

The NIDA Intramural Research Program (IRP) conducts state-of-the-art basic, preclinical, and clinical research to inform strategies for prevention and treatment of SUD and related health outcomes. The IRP portfolio includes research to elucidate the mechanisms underlying development of SUDs, evaluate potential new therapies, and identify and characterize emerging drugs such as synthetic opioids, stimulants, and cannabinoids.

IRP scientists led a recent study to better understand brain mechanisms of reward and reinforcement, which are disrupted in addiction.[355] The scientists used MRI to examine brain activity in mice given rewards for pressing a lever, and in people as they watched TikTok videos associated with binge-watching. By initially focusing on a brain region called the prefrontal cortex (PFC), which has previously been implicated in addiction, they found that the PFC is part of a positive feedback circuit that is activated by reinforcing stimuli. The findings could help guide future use of neuromodulation therapies to adjust the brain circuitry underlying addiction.

The Neuroimaging Core contributed to another study with implications for neuromodulation therapies. This study investigated why accidental brain lesions (e.g., from a stroke) sometimes cause smokers to quit.[356] Previously, such lesions have been found in many brain regions, and none were consistently associated with smoking cessation. By mapping the lesions for their connectivity to other brain areas, the study identified a brain circuit that, when damaged, is associated with reduced addiction to nicotine and alcohol. This circuit, which includes parts of the PFC, could be an ideal target for neuromodulation.

Other IRP scientists are conducting innovative research on dopamine signaling develop potential new medications for SUD. While drugs that block the function of dopamine D3 receptors offer the potential to treat SUD, they also have adverse effects on the heart. The scientists, who helped solve the structure of the D3 receptor 10 years ago, have used that structure to design new more selective compounds. They have found that two such compounds reduce craving for opioids and cocaine in rodent models of addiction without cardiotoxicity.[357]

Research Management and Support
FY 2024 Request: $74.8 million[358]
($2.6 million above the FY 2023 Enacted Level)

NIDA Research Management and Support (RMS) activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. Staff supported by NIDA's RMS budget also coordinate training and career development programs to sustain a talented, diverse workforce of addiction scientists. Other RMS functions include strategic planning, coordination, dissemination of latest research findings and funding opportunities, program evaluation, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. RMS staff also play key roles in coordinating NIDA's involvement in the NIH HEAL® Initiative and in managing HEAL-supported research. In addition to the infrastructure required

[355] pubmed.ncbi.nlm.nih.gov/35296648
[356] pubmed.ncbi.nlm.nih.gov/35697842
[357] pubmed.ncbi.nlm.nih.gov/27508895; pubmed.ncbi.nlm.nih.gov/30555159; pubmed.ncbi.nlm.nih.gov/31562201
[358] Excludes funding for RMS to support the HEAL Initiative.

to support research and training, NIDA strives to provide evidence-based resources and educational materials about substance use and addiction. To this end, the RMS portfolio incorporates education and outreach activities to inform public health policy, and to provide the public with timely, accessible, trustworthy information about substance use research in English and Spanish. In addition, NIDA's RMS portfolio includes the NIDAMED initiative, which is aimed at engaging and educating clinicians in the latest addiction science.

National Institute on Alcohol Effects and Alcohol-Associated Disorders
FY 2024 Request: $76.2 million
(unchanged from the FY 2023 Enacted Level)

Although the rate of underage drinking in the United States has declined over the past several decades, alcohol remains the most widely used substance among youth. Binge drinking[359] and high intensity drinking[360] among young people remain significant concerns. These drinking patterns are particularly troubling as they increase risks for poor academic performance, alcohol-related blackouts, injuries, overdoses, sexual assault, unsafe sexual behavior, alcohol use disorder (AUD), and other detrimental consequences. NIAAA supports a broad range of basic, translational, and clinical research to improve our understanding of the impact of alcohol exposure on adolescent health and to improve interventions for alcohol-related problems among youth in community and healthcare settings. NIAAA also disseminates information about evidence-based interventions through the development of resources for the public.

Basic research is key to informing the development of innovative prevention and treatment strategies for underage drinking. A key initiative within NIAAA's adolescent brain research portfolio is the National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA), a longitudinal study of approximately 800 youth ages 12-21 to identify brain characteristics that may predict alcohol misuse or occur because of adolescent alcohol exposure. Data from NCANDA, for example, has demonstrated that adolescent binge drinking is associated with accelerated decline of gray matter volume in the brain, with the most significant effects observed in the frontal regions. Gray matter, which consists primarily of neuron cell bodies, is important in normal, daily functioning, including controlling movement, seeing, hearing, forming memories, and regulating emotions. Frontal regions are important for executive functioning, such as performing complex tasks and decision-making.

Another major program within NIAAA's portfolio on adolescent brain research is the Neurobiology of Adolescent Drinking in Adulthood (NADIA) consortium to examine, using animal models, the mechanisms by which adolescent drinking leads to changes in brain structure and function that persist into adulthood. NADIA researchers previously demonstrated that binge drinking produces epigenetic changes in the brain that can lead to increased anxiety and alcohol consumption in adulthood. In a new study, the researchers used CRISPR/dCas9 DNA editing techniques to reverse some of the binge drinking consequences in the brain, and the changes

[359] NIAAA defines binge drinking as a pattern of drinking that increases an individual's blood alcohol concentration to 0.08 percent or higher. This typically occurs after 4 drinks for women and 5 drinks for men – in about 2 hours. Research suggests that fewer drinks in the same timeframe result in the same blood alcohol concentration in youth.
[360] NIAAA defines high intensity drinking two or more times the gender-specific binge drinking thresholds.

were associated with reduced anxiety and alcohol consumption in adulthood. Although much work remains before any potential application in humans, the new findings underscore the long-lasting effects of early binge drinking on the brain and adds to the growing body of evidence demonstrating the potential utility of gene editing in addressing health and disease.

Prevention of underage drinking has long been one of NIAAA's top priorities. NIAAA's portfolio in this area includes studies to develop, evaluate, and implement evidence-based prevention programs for youth. These programs include individual-, family-, school-, community-, and environmental-level interventions for underage individuals. For college settings, NIAAA provides the College Alcohol Intervention Matrix (CollegeAIM), an online resource that rates over 60 evidence-based alcohol interventions in terms of effectiveness, cost, and other factors, allowing school officials to select among the many potential interventions to address harmful and underage student drinking. NIAAA supports research to better understand trends in alcohol use among college students to improve interventions based on that knowledge. For example, a recent NIAAA-funded study revealed changes in the social context and frequency of drinking during the first year of the pandemic among a large cohort of college students. Alcohol-related harms were different depending on the context, for example, whether they drank outside the home with others or drank at home alone. These data suggest future interventions could be tailored based on drinking context. NIAAA also supports research to address alcohol misuse among young adults in in the military, workforce, and other non-college settings. Interventions tailored for underserved populations is another important area within NIAAA's prevention research portfolio. For example, NIAAA-funded researchers recently demonstrated the effectiveness of the Qungasvik (Tools for Life) intervention as a universal suicide and alcohol prevention strategy for young people ages 12-18 living in rural Alaska Native communities. This study builds on a decades-long collaboration between NIAAA-supported researchers at the University of Alaska, Fairbanks, and the Yup'ik Alaskan Native community to examine how tapping into a community's culture can provide a cornerstone for youth alcohol and other substance misuse and suicide prevention efforts.

Increasing implementation of alcohol screening and brief intervention in primary care and developing evidence-based behavioral therapies to reduce underage drinking is another priority area for NIAAA. For example, NIAAA developed the Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide to assist pediatric and adolescent health practitioners in identifying patients at risk for underage drinking and associated problems. This screening resource has been validated among youth in pediatric emergency room settings, in school settings, in primary care settings (including among racially and ethnically diverse youth), and among youth with chronic health conditions. NIAAA also supports studies to evaluate the effectiveness of digital health technologies in improving access to and quality of interventions for adolescents. For example, a new NIAAA-supported study is assessing whether a centralized, telehealth version of alcohol screening, brief intervention, and referral to treatment can improve early identification and treatment of alcohol and comorbid mental health problems among adolescents at high risk for these conditions. The telehealth intervention will be delivered by a centralized behavioral health clinician accessible to pediatric primary care clinics in the study, and it will be compared to in-person alcohol screening and brief intervention, also delivered by a behavioral health clinician.

Equity

Equity is a vital consideration in NIDA and NIAAA efforts to support the objectives of the National Drug Control Strategy. Both NIDA and NIAAA support the NIH UNITE initiative that was established to identify and address structural racism within the NIH-supported and greater scientific community. Both Institutes are also part of NIH's broader efforts to advance health equity research by improving minority health, reducing health disparities, and removing barriers to advancing health disparities research as well as the agency's efforts to expand, sustain, and promote scientific workforce diversity.

NIAAA supports a range of efforts aimed at reducing health disparities and promoting health equity. One area of interest is the social determinants of health that influence the initiation of underage alcohol use. Underserved populations bear a greater burden of alcohol misuse and its adverse effects. Current studies are exploring factors that drive alcohol misuse—including sleep quality, adverse childhood experiences, and family or peer stress—among minority adolescent populations. Understanding the social and environmental factors that influence alcohol misuse can inform targeted prevention approaches. NIAAA also supports development of culturally adapted interventions to reduce underage drinking. For example, NIAAA-funded researchers have developed effective alcohol prevention, screening, and brief intervention approaches tailored to American Indian and Alaska Native youth.