

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

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/

technology and social media use 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 PRenancy 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 Conference²⁶; 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 interdisciplinary 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 2019²⁹: (1) stay on course to accomplish the original goals set out in the BRAIN[®] 2025 report (published in 2014³⁰) (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 Research⁴², 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.

⁴²dpcpsi.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 plan⁴³ 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-\(sepa\)](https://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](https://www.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	FY 2023	FY 2024	
	Final ⁷	Enacted ⁷	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
<i>Pandemic Preparedness Mandatory via PHSSEF (non-add)⁴</i>	<i>\$0</i>	<i>\$0</i>	<i>\$2,690,000</i>	<i>\$2,690,000</i>
<i>Number of Competing RPGs</i>	<i>11,333</i>	<i>10,961</i>	<i>10,414</i>	<i>-547</i>
<i>Total Number of RPGs</i>	<i>42,596</i>	<i>43,620</i>	<i>44,410</i>	<i>790</i>
<i>FTE⁵</i>	<i>18,689</i>	<i>20,366</i>	<i>20,943</i>	<i>577</i>
<i>Nonrecurring Expenses Fund:⁶</i>				
<i>ORF/ORS/NIAID Support Facilities, Rocky Mountain Laboratories, MT</i>		<i>40,650</i>		<i>-40,650</i>
<i>Electrical Power Reliability, Building 10</i>		<i>22,490</i>		<i>-22,490</i>
<i>Replace Cooling Towers 18, 19 and Chillers 17, 18, 19</i>			<i>40,000</i>	<i>40,000</i>
<i>Building 11 Provide Sprinkler Protection</i>			<i>11,370</i>	<i>11,370</i>
<i>Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C</i>			<i>29,300</i>	<i>29,300</i>
<i>Repair Parking Garages, Bethesda</i>			<i>13,360</i>	<i>13,360</i>
<i>Electrical Power Reliability for the CCC</i>			<i>26,100</i>	<i>26,100</i>

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%
<i>Common Fund (non-add)</i>	<i>\$735.001</i>	<i>\$735.001</i>	<i>0.0%</i>
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 Level⁴	\$49,178.485	\$51,098.124	3.9%
Total, Program Level excluding ARPA-H	\$47,678.485	\$48,598.124	1.9%
<i>Mandatory Pandemic Preparedness via PHSSEF (non-add)⁵</i>		<i>\$2,690.000</i>	<i>NA</i>

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.