

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.¹ 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. NIH works to develop, maintain, and renew scientific, human, and physical resources that will ensure the Nation's capability to address the public health concerns of the Nation as well as to treat and prevent disease and poor health. 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.

¹ In 2021, the Advisory Committee to the NIH Director (ACD) Working Group on Diversity, Subgroup on Individuals with Disabilities issued a report, including a recommendation to update the NIH mission statement to remove "reducing disability". A proposed revised mission statement was developed, and public feedback was requested through a Request for Information (RFI) (NOT-OD-23-163). NIH is currently reviewing the responses to inform its decision.

OVERVIEW OF BUDGET REQUEST

Introduction

For Fiscal Year (FY) 2025, the National Institutes of Health (NIH) requests a total program level of \$50.1 billion, a \$2.4 billion increase from the FY 2023 Final level.² The NIH budget level is intended to support critical research conducted in service to the agency's mission and support new and ambitious priority investments necessary for improving the health of the Nation.

NIH's investment in biomedical research is critical to advancing healthcare discovery that benefits the health and well-being of the Nation. The agency's primary goals are to facilitate important advances in biomedical research, ensure the accessibility of NIH-funded research, and maintain the highest levels of public trust in the biomedical research enterprise. NIH strives to produce translatable, transparent findings that result in robust, reproducible data, and to ensure the data is shared with the public in an accessible manner. NIH also continues to promote the principles of scientific integrity and rigor within the biomedical research community, to ensure that NIH-supported researchers and staff are held to the highest ethical standards to support the best science.

Key to the promotion of the best biomedical science is building and maintaining the biomedical workforce. NIH appreciates the importance of harnessing unique ideas from diverse perspectives, which in turn leads to diversity of thought and discovery. NIH seeks the brightest minds from every stage of the biomedical career trajectory, including early-stage, mid-career, and late-career scientists. This commitment underscores the critical importance of inspiring the next generation of biomedical researchers who will make the scientific discoveries of tomorrow.

Historically, NIH has been a leader in biomedical research worldwide, and discoveries made possible by NIH funding have saved countless lives and continue to have a positive impact on the health and well-being of the Nation. NIH intends to maintain this trajectory of discovery into the future. This will be accomplished through the continued development of a robust workforce with diverse perspectives, leveraging lessons learned from recent and ongoing public health challenges, and developing innovative science that will fuel the discoveries of tomorrow.

A History of Excellence: The Returns from Long-Term Investments in NIH Basic, Translational, and Clinical Research

Prior investments in NIH have saved lives and will continue to drive further discoveries. This can most easily be identified in advances in medical interventions resulting from clinical research – that is, research that directly studies the use of new diagnostic and treatment advances in people. However, these clinical advances would not be possible without decades of prior basic and translational research paving the way for clinical discovery. No greater testament of this can be found than the fact that NIH has supported a total of 169 researchers who have

² This program level excludes the Advanced Research Projects Agency for Health (ARPA-H). The FY 2025 Budget request for ARPA-H, which reports directly to the Secretary of Health and Human Services, is outlined in a separate Congressional Justification volume.

received or shared 101 Nobel Prizes. One of the latest additions to this legacy of excellence is the NIH-funded work that led to the award of the 2022 Nobel Prize for the development of a transformative scientific approach known as “click chemistry.”³ This form of chemistry has made it possible for researchers to snap together molecular building blocks to form hybrid biomolecules, often with easy-to-track imaging agents attached. Not only has click chemistry expanded our ability to explore the molecular underpinnings of a wide range of biological processes, but it has provided us with new tools for developing drugs, diagnostics, and a wide array of “smart” materials.⁴

NIH’s lengthy history of biomedical excellence is measured not only in the awards received by the researchers it funds but also in the lasting impact that NIH research has had on people’s lives – from major medical advances to simple everyday health choices. For example, NIH – in partnership with the Food and Drug Administration (FDA) – recently celebrated the 10th anniversary of the Tobacco Regulatory Science Program (TRSP), which aims to reduce the public health impact of tobacco use across the country. This unique partnership represents a new field of study called tobacco regulatory research, which informs proposed regulations for tobacco products through the continued development of strong scientific evidence. The TRSP brings together scientists from diverse fields, such as epidemiology, chemistry, toxicology, addiction, and psychology, to shed light on why people try and continue to use tobacco, how tobacco use affects health, and which policies might help reduce the risk of harm. This extremely productive partnership has resulted in more than 400 research grants,⁵ all peer-reviewed and designed to increase our understanding of existing and emerging tobacco products and their associated health risks. These studies include research unpacking the impacts of menthol cigarettes on nicotine dependence and assessing how flavored tobacco products target socioeconomically disadvantaged populations.⁶ The TRSP is a prime example of how NIH’s long-term investments yield expansive, far-reaching data.

One of the most recent and noteworthy examples of NIH leveraging its long commitment to basic and translation research is its role in the development of vaccines for SARS-CoV-2. Decades of NIH-supported research, including investments in HIV research, revolutionized vaccine development, leading to the first two FDA-approved vaccines for COVID-19 and the 2023 Nobel Prize in Physiology or Medicine.⁷ These vaccines use messenger RNA (mRNA) to train the body to recognize SARS-CoV-2, the virus that causes COVID-19. The development of these vaccines has led to countless lives being saved and has aided the Nation in the process of emerging from the COVID-19 pandemic.

³ nobelprize.org/prizes/chemistry/2022/press-release/

⁴ directorsblog.nih.gov/2022/10/11/the-chemistry-clicked-two-nih-supported-researchers-win-2022-nobel-prize-in-chemistry/

⁵ prevention.nih.gov/tobacco-regulatory-science-program/funded-research-tobacco-regulatory-science-program

⁶ directorsblog.nih.gov/2023/05/09/10-years-of-protecting-public-health-through-tobacco-regulatory-research/

⁷ nobelprize.org/prizes/medicine/2023/press-release/

Addressing Today’s Challenges: NIH Continues to Fund Biomedical Research That Saves Lives

While it is important to acknowledge the decades of previous biomedical advancements made possible by NIH investments, it is imperative to continue addressing the vast array of public health challenges that persist, which can affect health across the lifespan. NIH supports biomedical and behavioral research applicable to the full spectrum of public health challenges and needs, and NIH continues to invest in research that benefits the well-being of all individuals across their lifespan, regardless of their background, race, age, gender, sexual orientation, or health status.

Addressing Public Health Across the Lifespan

21st Century Cures Act

The FY 2025 request level provides \$127.0 million in funding authorized under the 21st Century Cures Act (Cures Act) for the *All of Us* Research Program and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, a decrease of -\$742.0 million in Cures Act funding for these programs compared to FY 2023. The request proposes a corresponding increase of \$742.0 million in non-Cures Act discretionary resources to hold *All of Us* and BRAIN flat to FY 2023, for a total of \$1,221.4 million in Cures Act and non-Cures Act funding. In addition, NIH proposes to continue discretionary funding for the Cancer Moonshot – for which authorized Cures Act funding ended in FY 2023 – requesting non-Cures Act discretionary funding of \$716.0 million in FY 2025, an increase of \$500.0 million from the \$216.0 million of Cures Act funding provided in FY 2023, while also adding \$1,448.0 million in new mandatory funding.

All of Us. With a total request of \$541.0 million in FY 2025, including \$36.0 million in 21st Century Cures Act authorized funding and \$505.0 million in non-Cures Act base funding to hold the program flat to the FY 2023 Final 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 protects participant privacy while catalyzing 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 way to enrolling one million or more participants by the end of 2026, with nearly 758,000 participants from all 50 states, D.C., and Puerto Rico enrolled as of January 2024, of whom 520,000 have completed the initial steps of the program. More than 3,600 researchers across more than 435 institutions have registered to access *All of Us* data. Nearly half of the participants self-report being racial and ethnic minorities, and over 80 percent report being from communities historically underrepresented in biomedical research.

All of Us provides researchers with access to one of the world’s largest and most diverse datasets of its kind, and this resource has the ability to inform thousands of studies across all sectors of the biomedical research ecosystem and influence a new era in which researchers, health care providers, technology experts, community partners, and the public work together toward the development of individualized health care. *All of Us* is

revolutionizing large genomic studies that have historically lacked diversity through a partnership with participants and diverse communities across the country. Participants share data about themselves, including physical measurements, survey responses, electronic health records, DNA samples, and data from wearable devices (e.g., Fitbits). Researchers have access to nearly 250,000 genome sequences, 313,000 genotyping arrays, and more than 1,000 detailed long-read sequenced genomes. Data accessible via the Researcher Workbench is broadly available to researchers from academic, nonprofit, or health care organizations with a signed agreement that helps ensure data is shared in a way that protects participant privacy and security concerns. The resource is also being used by both intramural and extramural labs, and more than 7,410 researchers have registered to use the data from in excess of 600 institutions, including 93 minority-serving institutions, to inform more than 7,100 ongoing research projects.

All of Us has a special focus on engaging American Indian/Alaska Native (AI/AN) communities interested in medical research, to close information gaps and help increase health equity. To support the participation of AI/AN individuals in the *All of Us* program, a series of virtual information sessions for Tribal communities and Urban Indian Organizations were conducted in partnership with the Tribal Health Research Office (THRO) in the NIH Office of the Director. In line with the March 2021 *All of Us* Tribal Consultation Report,⁸ recruitment and engagement on Tribal lands is prohibited without approval from Tribal Nations, and the program developed a Tribal engagement plan to support program commitments to Tribes and incorporated Tribal priorities, such as Tribal data sovereignty, cultural sensitivity and awareness of AI/AN specific policies, training and education, data protections, research transparency, and the return of information to Tribal communities. In support of those efforts, *All of Us* also announced three awards in September 2023 totaling \$1.5 million to institutions partnering with AI/AN and Indigenous communities to advance Tribally-led participation in precision medicine research and to enhance AI/AN workforce development.

Additional non-Cures funding as requested to maintain total *All of Us* funding at \$541.0 million, will support enrollment of new participants, aiming to reach the 2026 enrollment goal and begin planned pediatric enrollment, while supporting activities to provide the program's robust and rich data to researchers.

NIH BRAIN Initiative®. With nearly 100 billion neurons and 100 trillion connections, the human brain remains one of the greatest mysteries in science and one of the greatest challenges in medicine. 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. The National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Mental Health (NIMH) are leading partners in the NIH BRAIN Initiative®, working with eight other NIH Institutes, Centers, and Offices (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, and physicians in individual labs and

⁸ allofus.nih.gov/all-us-research-program-tribal-consultation-final-report

inter-disciplinary teams. The BRAIN Initiative® has also led to 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 \$680.4 million for FY 2025, including \$91.0 million in 21st Century Cures Act authorized funding and \$589.4 million in non-Cures Act base funding to hold the program flat to the FY 2023 Final level, the BRAIN Initiative® promotes scientific advances that provide opportunities to understand the structure and function of the brain at an unprecedented level of detail. Researchers throughout neuroscience are rapidly adopting these advances, and the BRAIN Initiative® is both dramatically enhancing existing methods and developing entirely new technologies to study and manipulate brain circuits. BRAIN Initiative® activities will continue to be guided by the three overarching priorities as recommended in the BRAIN® 2.0 Working Group reports published in 2019: (1) stay on course to accomplish the original goals set out in the BRAIN® 2025 report (published in 2014); (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. Additional non-Cures funding as requested to maintain total BRAIN® funding at \$680.4 million will support FY 2025 commitments for existing research projects and planned investments in new competing awards, including the launch of the large-scale transformative projects under BRAIN® 2.0.

Cancer Moonshot. The overall request for Biden Cancer Moonshot for FY 2025 is \$2,164.0 million, supporting President Biden’s ambitious but attainable goal of reducing age-adjusted cancer death rates by 50 percent over the next 25 years. The whole-of-government Cancer Moonshot approach to reach this goal must rest on a foundation of scientific research. The National Cancer Institute (NCI) is uniquely positioned to lead this research and offers this bold budget proposal to meet the President’s goal and end cancer as we know it for all people. To support these objectives, the FY 2025 request level includes \$716.0 million in discretionary funding, an increase of \$500.0 million from the FY 2023 Final level. Because FY 2023 marks the final authorization of appropriations of Moonshot funding for NCI under the Cures Act, this funding will enable NCI to sustain research that will make vital scientific contributions to the seven pillars of Cancer Moonshot. As first proposed in the FY 2024 President’s Budget (PB), the request also proposes to extend the Cures Act Cancer Moonshot authorization through 2026, providing \$1,448.0 million in mandatory funding in each of FY 2025 and FY 2026.

Since 2015, overall cancer death rates have declined about 2 percent a year, but this progress is not fast enough to reach the goal of reducing cancer death rates by 50 percent over the next 25 years. A recently published study by NCI-supported researchers showed

that we must accelerate the decline in age-adjusted cancer death rates to reach the 50 percent goal by 2047.

This budget proposal includes six areas for investment to stimulate progress:

1. Innovate Cancer Prevention and Treatment
2. Transform Cancer Screening and Diagnosis
3. Revolutionize Cancer Clinical Trial Accrual and Completion Rates
4. Ensure Rapid Dissemination of Standards of Care
5. Sustain 21st Century Cures Act Progress and Fundamental Research
6. Support the Cancer Moonshot Scholars Program

These areas address needs across the entirety of cancer research to discover, develop, test, and deliver new approaches to prevent, detect, and treat cancer. The areas are interconnected and must be simultaneously supported and executed to deliver research findings and other evidence-based knowledge into clinical practice and change standards of care and outcomes for all people with cancer and those at risk for the disease.

Children and adolescent brain development

Led by the National Institute on Drugs and Addiction (NIDA),⁹ the cross-NIH Adolescent Brain Cognitive Development (ABCD) study¹⁰ is the largest long-term study of child health and development ever conducted in the United States. Following nearly 12,000 children, this study will help us understand how childhood and adolescent experiences such as drug use, sports, video games, social media, and unhealthy sleep patterns shape brain development and other outcomes. More than 600 scientific papers have been published utilizing data from the ABCD study. One analysis¹¹ utilizing brain imaging data of children aged 9-11 years found sex differences in brain connectivity and cognitive performance that likely reflect earlier brain development in girls than boys. The findings may help explain why young boys are more prone to substance use and other risky behaviors compared to girls. Another study found that children ages 9-10 years old who engaged in excessive non-school-related screen time showed structural brain changes that were associated with higher levels of internalizing symptoms. The structural changes were in brain regions linked to early initiation of alcohol use, suggesting possible shared neurobiological mechanisms between screen time addiction and drug/alcohol addiction.¹² In a separate study, researchers found that prenatal cannabis exposure was associated with a more than twofold increase in cannabis use initiation by early adolescence.¹³

Maternal Health

U.S. populations experience the highest rates of maternal deaths and severe maternal morbidity (SMM) relative to people living in other high-income nations. In 2021, the U.S. maternal mortality rate increased to 32.9 deaths per 100,000 live births from a rate of 23.8 in 2020 and 20.1 in 2019.¹⁴ Disparities in maternal outcomes are particularly striking among marginalized

⁹ The FY 2025 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.

¹⁰ abcdstudy.org/about/

¹¹ jamanetwork.com/journals/jamanetworkopen/fullarticle/2801653

¹² akjournals.com/view/journals/2006/12/1/article-p80.xml

¹³ jamanetwork.com/journals/jamapediatrics/fullarticle/2806205

¹⁴ cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf

groups such as African Americans, American Indians/Alaska Natives, Native Hawaiian/Pacific Islanders, and populations residing in rural maternity care deserts that lack providers offering obstetric care. NIH confronts the leading causes of SMM and maternal mortality (MM) with multifaceted, innovative research approaches to reduce preventable maternal deaths and improve maternal health before, during, and after delivery. Through the NIH-wide Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative, NIH supports research to mitigate preventable MM, decrease SMM, and promote health equity in the United States. In FY 2023, the IMPROVE initiative awarded \$24.4 million to fund the first of seven years of the Maternal Health Research Centers of Excellence, which aim to develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and reduce health disparities in partnership with communities. IMPROVE emphasizes the importance of community involvement to improve maternal health outcomes through other program dimensions as well. The Connecting the Community for Maternal Health Challenge incentivizes local organization capacity building to perform research at the community level, and the IMPROVE Community Implementation Program works with local communities to implement evidence-based practices to improve maternal health outcomes in maternity care deserts. The RADx Tech for Maternal Health Challenge complements community-based work in underserved regions by awarding prizes for the development of remote and point-of-care technologies for assessment and care delivery that may improve access to and delivery of postpartum care. IMPROVE builds upon other NIH programs that explore facets of maternal morbidity, including prevention of perinatal depression, reducing intimate partner violence in populations of pregnant and postpartum people, detection of gestational diabetes and cardiovascular and other maternal health conditions, models for maternal recovery from opioid use disorder, and clinical trials with the potential to reduce maternal complications. NIH works to synergize these research efforts with interagency initiatives such as the HHS Maternal Health Action Plan, the White House Maternal Health Blueprint, the Maternal Mental Health Task Force, and the implementation of recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women with the aspiration that together we can make progress toward reducing MM and SMM, improve maternal health outcomes, and advance maternal health equity for all. The FY 2025 Budget request for IMPROVE is \$43.4 million for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), an increase of \$13.4 million from NICHD's FY 2023 final funding level.

Alzheimer's Disease and Related Dementias

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 research into Alzheimer's disease and related dementias. NIA plays a lead role in the 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.

With increased investment in research into Alzheimer's disease and related dementias, NIH has been able to spearhead incredible progress over the last decade. The 2023 NIH Scientific

Progress Report, *Advancements Build Momentum: 10 Years of Alzheimer’s Disease and Related Dementias Research*, features a summary of the past 10 years of achievements made possible through NIH-funded intramural and extramural research. Through enhanced collaboration and innovative partnerships with industry, other agencies, and people living with dementia and their families, NIH has advanced understanding of the risk factors, genetics, and mechanisms of disease in dementia; diversified and de-risked the therapeutic pipeline for disease-modifying drugs; advanced drug repurposing and combination therapy development; discovered tools to detect, diagnose, and monitor dementia; advanced clinical research on lifestyle interventions; increased understanding of how social and physical environmental factors affect dementia risk and disparities; and expanded research on dementia care and care partner supports.¹⁵

Addressing Risk and Burden of Disease

Community Violence Interventions

Firearms deaths constitute an urgent and significant public health crisis. The overall death rate by firearms was up 21 percent and the rate of homicides by firearms was up 35 percent from 2019 to 2022. Additionally, firearm-related suicides increased to their highest ever recorded level in 2022, and firearms remain the leading cause of death for children and youth ages 1 to 19. Significant disparities by race, ethnicity, and poverty remain. 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. With \$12.5 million in funding provided to NIH in FY 2023 to conduct research on firearm injury and mortality prevention, NIH released a Notice of Funding Opportunity (NOFO)¹⁶ to add additional research sites to the Community Firearm Violence Prevention Network (CFVP) that was launched in FY 2022. The network now is comprised of six sites that are developing, implementing, and evaluating innovative structural interventions in partnership with communities to prevent firearm and related violence, injury, and mortality. In addition, NIH published two NOFOs^{17,18} focused on advanced training and career development for established NIH investigators in related fields to obtain the necessary skills and expertise to integrate firearm injury prevention work into their research. These awards will be a critical first step to expanding the field of qualified researchers and building capacity for the future.

In addition to the Community Violence Interventions (CVI) focus in the CFVP network, several ongoing projects seek to develop or evaluate CVIs to reduce the risk of future firearm violence and identify barriers to 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 street lighting interventions, and comprehensive programs that focus on service provision and community engagement among particularly high-risk populations. One project is developing, implementing, and evaluating a burnout prevention program for CVI staff. This project recently completed the pilot phase and is moving on to complete the full intervention trial to determine the intervention’s impact. If successful, this program to support

¹⁵ nia.nih.gov/news/nih-releases-alzheimers-disease-and-related-dementias-research-progress-report-and-fiscal-year

¹⁶ grants.nih.gov/grants/guide/pa-files/PAR-23-066.html

¹⁷ grants.nih.gov/grants/guide/pa-files/PAR-23-107.html

¹⁸ grants.nih.gov/grants/guide/pa-files/PAR-23-108.html

frontline violence intervention staff could have far-reaching implications for the long-term sustainability of effective CVI programs.¹⁹

The FY 2025 request for firearm research in the Office of the Director is \$25.0 million, an increase of \$12.5 million from the FY 2023 Final level.

Innovations in Mental Health Research and Treatment

Scientific and clinical advances are rapidly advancing mental health care in the United States. Progress in basic science has led to new tools and resources that enable investigators to gain significant insight into the complex interactions between the brain, environment, and disease. Intervention research continues to enhance the understanding and effectiveness of evidence-based care in a broad range of settings. NIMH supports innovative research to transform the understanding and treatment of mental illness to pave the way for prevention, recovery, and cure. In 2023, NIMH-funded investigators discovered a potential new target for developing improved treatments for mental disorders like anxiety and depression,²⁰ identified a new connection between the amygdala and the nucleus accumbens in the brains of mice that is sensitive to early life adversity and affects how mice respond to rewards,²¹ and successfully reconstructed the firing of many neurons to get an in-depth look at how they fire together during neuronal avalanches to create order in the brain.²² These and other innovations continue to improve mental health care for those in greatest need. Looking forward, NIMH hopes to change the game for precision medicine in psychiatry with a groundbreaking new initiative. NIMH's Individually Measured Phenotypes to Advance Computational Translation in Mental Health (IMPACT-MH) initiative will support research that tests new ways of adding data, such as performance on computerized behavioral tasks or information about activity levels, to traditional clinical information in ways that could help mental health providers and their patients make informed decisions about the future. Studies supported through the IMPACT-MH initiative will test whether combining these different kinds of data improves predictions about mental health treatment responses and outcomes, enabling a vision for precision psychiatry of the future.

In his Unity Agenda for mental health,²³ the President has emphasized strategies for addressing our national mental health crisis, including scalable approaches for prevention and early intervention. In alignment with this agenda, NIMH is focused on building and disseminating a robust evidence base for effective preventive and treatment interventions for mental and behavioral disorders, which requires investment in implementation science and collaboration with partner agencies. The Budget request includes a \$200.0 million increase for mental health initiatives above the FY 2023 Final level for NIMH, including \$10.0 million to support behavioral health prevention implementation science, focusing on sustainable prevention and early intervention approaches.

¹⁹ news.northwestern.edu/stories/2022/03/harnessing-positive-emotions-to-prevent-burnout-among-gun-violence-interrupters/

²⁰ science.org/doi/10.1126/science.add7150

²¹ nature.com/articles/s41467-023-36780-x

²² nature.com/articles/s41467-023-37976-x

²³ whitehouse.gov/briefing-room/statements-releases/2023/05/18/fact-sheet-biden-harris-administration-announces-new-actions-to-tackle-nations-mental-health-crisis/

Research has yielded effective, evidence-based preventive interventions for people at high risk of mental and behavioral disorders, as well as interventions that, when delivered early in the course of illness, can significantly improve mental and behavioral health. For example, preventive and early interventions can be effective for alleviating depression, anxiety, schizophrenia, suicide risk, and substance use disorders, and for improving educational attainment. However, there is still a pressing need for research to validate which interventions work best. To address this need, NIMH supports targeted initiatives^{24,25,26} that encourage:

1. Research focused on streamlining and optimizing evidence-based preventive and early interventions and services for mental and behavioral disorders, and evaluating their effectiveness when implemented in accessible settings (e.g., community clinics, schools, primary care); and
2. Implementation research focused on developing and testing strategies to promote the adoption and sustained use of research-informed, high-quality interventions and services, including strategies for training and supporting providers to ensure provider competency and sustained fidelity in the wide-scale delivery of effective preventive and early interventions.

In addition to these targeted initiatives, NIMH strives to incorporate evidence-based practices into service initiatives and programs spearheaded by collaborating with partner agencies, including the Substance Abuse and Mental Health Services Administration, the Administration for Children and Families, and the Department of Education. As an example of these cross-agency collaboration efforts, NIMH and NIDA are consulting with the Health Resources and Service Administration (HRSA) and the Agency for Healthcare Research and Quality to leverage the HRSA-administered Bright Futures program²⁷ to expand access to evidence-based behavioral health preventive services in community and pediatric primary care settings. Most recently, this cross-agency workgroup met to review potential formats, key questions, and associated costs for a scoping review of evidence-based programs.

By sustaining and expanding these targeted implementation science initiatives and cross-agency collaborations, NIMH aims to accelerate the identification and widespread adoption of sustainable, effective, evidence-based preventive and early interventions for a broad range of mental and behavioral disorders.

Opioid and Stimulant Misuse

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. The need for new treatments is real and urgent. 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

²⁴ grants.nih.gov/grants/guide/notice-files/NOT-MH-22-170.html

²⁵ nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/early-psychosis-intervention-network-epinet

²⁶ nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/practice-based-suicide-prevention-research-centers

²⁷ aap.org/en/practice-management/bright-futures

2022, there were over 110,000 drug overdose deaths in the United States.²⁸ 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.²⁹ At the same time, rates of depression and anxiety continue to rise, and the grief, trauma, and physical isolation that many have experienced continue to drive these trends. One aspect of hope amid the tragedy is that the crisis has spurred unprecedented resources and human ingenuity toward finding novel scientific solutions that may one day make addiction a thing of the past.

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 science on opioid misuse, addiction, and pain. HEAL has funded over \$3 billion in research, representing more than 1,000 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. In order to continue to respond to these evolving challenges, the FY 2025 request includes funding for the HEAL Initiative® of \$635.6 million, maintaining the FY 2023 Final level. This HEAL funding is in addition to funding for opioid and pain research across the NIH ICs, which is maintained at \$1.2 billion, the same as the FY 2023 Final level.

Harm reduction is an evidence-based, often life-saving approach that directly engages people who use drugs to prevent overdose, disease transmission, and other harms. Through the HEAL Harm Reduction Research Network,³⁰ NIH is supporting a range of novel approaches to delivering harm reduction supplies, such as naloxone, a lifesaving medication to reverse overdose, and fentanyl test strips, which people can use to determine if drugs contain fentanyl. These include moving harm reduction services into communities via mobile vans, peer support specialists, smartphone-based tools, and other approaches. The network is also examining the impact of harm reduction policies and practices at state and local levels, such as policies that deter the use of mail-based delivery of harm reduction services.

Health Disparities

The FY 2025 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 recent increases of \$95.0 million for health disparities research by the National Institute on Minority Health and Health Disparities, National Institute of Nursing Research, National Institute of General Medical Sciences, and Fogarty International Center. NIH will also continue to support the following initiatives to advance health disparity research

²⁸ cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

²⁹ ncbi.nlm.nih.gov/pmc/articles/PMC6688196/pdf/collins-1536332.pdf

³⁰ nida.nih.gov/news-events/news-releases/2022/12/nih-launches-harm-reduction-research-network-to-prevent-overdose-fatalities

both in communities and address disparities within the biomedical research enterprise:

NIH UNITE Initiative

The NIH UNITE initiative has facilitated support for funding opportunities on the impact of structural racism on minority health (MH) and transformative research to address health disparities (HD). A UNITE recommendation led to the development of the Common Fund Transformative Research to Address Health Disparities and Advance Health Equity Initiative. This initiative supports research projects to prevent, reduce, or eliminate HD, advance health equity (HE), and expand HD research, including at minority-serving institutions (MSIs). UNITE recommendations have also led to the establishment of the Common Fund's Community Partnerships to Advance Science for Society (ComPASS), which aims to bolster funding for HD/MH research.³¹

Tribal Training Grants

Research is critically needed to address the health needs of urban American Indian and Alaska Native (AI/AN) communities, who comprise the majority (approximately 70 percent) of the AI/AN population and experience a significant and distinctive burden of socioeconomic and health disparities. At NIH, the Tribal Health Research Office (THRO) is the central point of contact at NIH for federally recognized AI/AN Tribes throughout the United States and the coordination hub for Tribal health research activities at NIH. NIH recently issued Supplemental Information on Responsible Management and Sharing of AI/AN Participant Data to complement the recently implemented NIH Policy for Data Management and Sharing. The Supplemental Information includes Considerations and Best Practices for NIH-sponsored researchers working with Tribal Nations, such as emphasizing the importance of respect for Tribal sovereignty, proactive engagement with Tribes, establishing mutual goals for data management and sharing, and addressing data management and sharing plans in the informed consent process. NIH expects that this will enhance the ability of Tribal Nations to participate in biomedical research. NIH is also developing supplemental information for the ethical conduct of research with American Indians and Alaska Natives residing in urban areas outside of the legal geographical jurisdiction of Tribal lands. This research raises important questions about Tribal sovereignty and governance that should be considered when conducting biomedical research. NIH remains committed to working with Tribal communities and Tribal Colleges and Universities to further develop educational and research opportunities for Native American students. NIH supports student research programs with Tribal Nations through regional training hubs. These programs are designed to prepare junior and senior high students for careers in science. Additionally, NINDS also supports the Health Disparities in Tribal Communities Summer Internship Program. This program is designed to prepare undergraduate and graduate students for careers in science by offering students the opportunity to work side by side with investigators.

NIH Advancing Prevention Research for Health Equity (ADVANCE)

The Office of Disease Prevention (ODP) within the Office of the Director launched ADVANCE in 2022. ADVANCE is an NIH-wide initiative to develop new preventive interventions and implement existing evidence-based interventions and preventive

³¹ commonfund.nih.gov/healthdisparitiestransformation

services in populations that experience health disparities and inequities. ADVANCE emphasizes supporting research that specifically tests preventive intervention strategies that address social and structural determinants of health by integrating the latest knowledge and methodological advances in both prevention science and health disparities science. The ODP is facilitating and coordinating ADVANCE to solicit and support high-impact research that falls across the missions and subject areas of multiple NIH ICOs. Four NIH-wide ADVANCE workgroups are developing funding announcements on preventive intervention research to address long-standing health disparities and inequities.

Women’s Health

The mission of the NIH Office of Research on Women’s Health (ORWH) is to enhance research related to diseases, disorders, and conditions affecting women, help ensure that women are appropriately represented in NIH-supported biomedical research, and improve the advancement of women in biomedical careers. The ORWH FY 2025 budget request is \$153.9 million, a \$76.4 million increase over FY 2023. In FY 2025, ORWH plans to use the additional funds to support a range of new and ongoing activities to enhance research into women’s health issues, including increasing the number of hubs in the Maternal and Pediatric Precision in Therapeutics Centers of Excellence (MPRINT) initiative to increase the knowledge, tools, and expertise in maternal therapeutics available to the broader research, regulatory science, and drug development communities; expanding trial capacity for the Maternal-Fetal Medicine Unit Network to advance specific treatment approaches to leading drivers of maternal morbidity and mortality, and establishing clinical trials to test technologies developed through the RADx-Tech Maternal Health Challenge based on levels of readiness of the technology in rural and remote locations. The funds will also support new research into important topics such as menopause and diabetes, opioid use disorder in pregnant women, and alcohol use during pregnancy, and will allow ORWH to support cross-NIH initiatives to promote sex and gender equity across all domains of research.

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 diseases, 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 are 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.³² The NIH strategic framework will seek to understand the health impacts and

³² nih.gov/climateandhealth

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 2025 budget request of \$40.0 million sustains the FY 2023 Final increase to boost research on the human health impacts of climate change.

Transforming Nutrition Science

Over the past several years, NIH has bolstered nutrition research, given the broad impact that nutrition has on health and disease. The Office of Nutrition Research (ONR) in the NIH Office of the Director (OD) accelerates progress in nutrition research by planning, coordinating, and tracking progress toward achieving the objectives of the 2020-2030 Strategic Plan for NIH Nutrition Research.³³ The FY 2025 request of \$1.3 million for ONR sustains its level in FY 2023, enabling OD to support the objectives of the Strategic Plan.

The Food is Medicine Networks and Centers of Excellence Program is an NIH-wide, nutrition-focused initiative. A lack of good nutrition is the number one driver of poor health outcomes in the United States.³⁴ 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. Poor diets also exacerbate health inequities, as exemplified by individuals with lower incomes, living in rural communities, and from historically marginalized racial and ethnic groups being most affected. Moreover, poor diets are harming the United States economy in that the combined health care spending and lost productivity from poor diets cost over \$1 trillion each year. Yet a focus on nutrition is currently missing in the health care system, which in large part explains the rising disease burdens, costs, and inequities in diet-related chronic diseases. The Food is Medicine Networks and Centers of Excellence Program will specifically address this gap by supporting programs that respond to the critical link between diet and health with the provision of healthy food, as well as having health care organizations as their nexus. The program will also address current barriers that exist both in communities and within health care systems that severely limit the ability to reduce obesity and other diet-related diseases (e.g., cardiovascular disease, cancer, and diabetes). Significantly, this innovative program will also support implementation science and intervention and health quality research on culturally sensitive Food is Medicine initiatives and other strategies to improve public health and address barriers to care.

Another timely nutrition-focused initiative is centered on the reciprocal relationship between climate and environmental changes and food systems and its impact on food/nutrition security and health. For example, heat, drought, and floods are having dramatic effects on the food supply, while greenhouse gas emissions, air and water pollution, and environmental toxins are altering the nutritional quality of food. Concurrently, the many components of the food system contribute to the changing climate and impact the availability of natural resources. Importantly, these relationships are related in that not only does the changing environment affect food systems, but food systems have important impacts on the environment in ways we are just

³³ dpcpsi.nih.gov/onr/strategic-plan

³⁴ cdc.gov/chronicdisease/about/costs/index.htm

beginning to understand. This initiative is centered on increasing our understanding of these reciprocal relationships to improve nutrition and human health.

Emerging from the COVID-19 Pandemic and Continuing to Study the Lingering Effects of SARS-CoV-2

Long COVID

Millions of Americans have recovered from SARS-CoV-2 infections, but unfortunately, many people are still dealing with the long-term effects, known as post-acute sequelae of SARS-CoV-2 (PASC, 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 NINDS, along with several other NIH Institutes and the OD, are leading NIH's Researching COVID to Enhance Recovery (RECOVER) initiative,³⁵ a national research program to understand PASC. The NIH RECOVER initiative, launched with \$1.15 billion in COVID supplemental appropriations in FY 2021 and continued with an additional \$515 million in funds from the Public Health and Social Services Emergency Fund, 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.

In 2023, the NIH RECOVER initiative launched and opened enrollment for phase II clinical trials that will evaluate at least four potential treatments for Long COVID, with additional clinical trials to test at least seven more treatments expected in the coming months. Treatments will include drugs, biologics, medical devices, and other therapies. The trials are designed to evaluate multiple treatments simultaneously to identify more swiftly those that are effective. These trials were informed by findings from other RECOVER research over the past two years and focus on several of the symptoms described as most burdensome by people experiencing Long COVID. With its complementary research efforts, RECOVER has positioned NIH to design and conduct trials that have the potential to provide Long COVID patients who experience varying symptoms with relief sooner than any individual study can alone.

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 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 NIDA 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.³⁶ Sudden parental death can be traumatizing to children

³⁵ recovercovid.org/

³⁶ doi.org/10.1542/peds.2021-053760

and leave families unprepared to deal with the consequences. 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. Studies have also demonstrated that youth emergency department visits for mental health increased during the pandemic,³⁷ and that adolescents living through the pandemic experienced increased incidence of symptoms of anxiety and depression.³⁸ While it is not clear if these mental health effects are 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. 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, NIMH is supporting research in children to clarify how, when, and for whom trauma exposure increases the risk for adverse physical and mental health outcomes. The FY 2025 budget request includes funding in NICHD to sustain the \$10.0 million provided in FY 2023 for research into the effects of COVID-19 on children, including multisystem inflammatory syndrome in children (MIS-C), and the \$3.0 million provided 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.

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 2019,³⁹ and the pandemic only exacerbated this issue. 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.⁴⁰ This initiative includes NIMH-supported research on the impact of COVID-19 mitigation efforts on socioeconomic disparities in mental health and health care utilization;⁴¹ the effectiveness of digital health apps like Headspace as a just-in-time approach to immediate, personalized behavioral health care;⁴² the effectiveness of a digital platform on depression/anxiety symptoms of healthcare workers during the COVID-19 pandemic;⁴³ 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.⁴⁴ The FY 2025 request includes \$25.0 million for research into the impact of COVID-19 on mental health, sustaining the FY 2023 Final

³⁷ doi.org/10.1001/jamapsychiatry.2023.2195

³⁸ doi.org/10.1016/j.bpsgos.2022.11.002.

³⁹ Institute of Health Metrics and Evaluation. ghdx.healthdata.org/gbd-results-tool accessed October 2021.

⁴⁰ covid19.nih.gov/news-and-stories/covid19-ripple-effects

⁴¹ reporter.nih.gov/search/_E4VoHbiwU293-ndTNu8Kw/project-details/10490467

⁴² reporter.nih.gov/search/nG0a0LRnBk2HZbig_DW6ew/project-details/10402904

⁴³ reporter.nih.gov/search/EMyREeTC3kan_rHKVyS6Fw/project-details/10451636

⁴⁴ reporter.nih.gov/search/Wz5OqrJM_keh6fQgmV9ZMg/project-details/10246656

funding level.

The Community Engagement Alliance (CEAL) Against COVID-19 Disparities

The Community Engagement Alliance (CEAL) works closely with the communities that were most impacted by COVID-19.⁴⁵ The CEAL research teams focus on COVID-19 awareness and education research, especially among African Americans, Hispanics/Latinos, and American Indians/Alaska Natives (AI/AN)—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 has made a significant impact since its launch; 21 CEAL teams across 21 states, the District of Columbia, and Puerto Rico have reached nearly 91 million people in 101 counties. These CEAL teams are collaborating with almost 1,000 organizations, including health care providers and hospital systems, academic and research organizations, schools, associations, and independent businesses. Most importantly, over half of those partners are community-service, faith-based, grassroots, nonprofit, social service, and civic community-based organizations. Working with these partners, CEAL research teams have held more than 3,000 local events, reaching over 600,000 participants. This includes vaccination events at which over 300,000 people received the COVID-19 vaccine. Over 2,600 people have signed up to participate in COVID-19-related clinical trials.

As the country shifts to an endemic phase of COVID-19, CEAL continues to be leveraged as a foundation and platform for addressing the host of health disparities that remain within CEAL communities. NHLBI is leveraging this platform for scientific initiatives addressing public health issues that have a disproportionate impact on the same communities that bore the brunt of COVID-19. While CEAL continues to operate with the principles of trust and partnership, it now broadens to include research focus areas of community interest like maternal health (MH-CIP),⁴⁶ the impact of climate on health,⁴⁷ and ensuring access to accurate and timely public health information. Additional upcoming initiatives are under development and include enriching research capacities within AI/AN communities, and the interests of other Institutes like NHGRI's work to increase the understanding of and participation in genomic research in diverse communities.

As CEAL expands, NIH is committed to continue reporting the accomplishments, lessons learned and promising practices in community engaged research to address these issues. The FY 2025 request level includes \$30.0 million for CEAL, maintaining the FY 2023 Final level, to expand the program beyond COVID-19 to focus on other health issues in communities experiencing health disparity such as climate health, maternal health, gaps in public health knowledge, and more.

Pandemic Preparedness

The FY 2025 Budget provides \$20.0 billion in mandatory funding through the Public Health and Social Services Emergency Fund (PHSSEF) to NIH, FDA, the Centers for Disease Control and Prevention (CDC), and the Administration for Strategic Preparedness and Response (ASPR) to

⁴⁵ nhlbi.nih.gov/news/2020/COVID-19-nih-funds-community-engagement-research-efforts-areas-hardest-hit

⁴⁶ maternalhealthcip.org/

⁴⁷ nih.gov/climateandhealth

prepare for and respond rapidly and effectively to future pandemics and other high-consequence biological threats. 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 were so critical to addressing the COVID-19 pandemic. Finally, NIH will leverage the successful Rapid Acceleration of Diagnostics (RADx) initiative to develop next-generation diagnostics that fill critical gaps, such as the need for affordable and accessible at-home tests that are as reliable as lab-based PCR tests. For more information on the Department-wide pandemic preparedness mandatory proposal, please see the detailed narrative in the PHSSEF Congressional Justification.

The Future of Biomedical Research at NIH – New Approaches to Scientific Discovery

NIH continues to leverage scientific advances and innovative research methodologies of today to foster the discoveries of tomorrow. This scientific advancement requires a cadre of diverse minds ready to tackle complicated scientific problems. NIH supports the training and development of the next generation of scientists who will bring diverse perspectives, skillsets, and backgrounds. For this reason, NIH reaffirms its commitment to support diversity, equity, inclusion, and accessibility in its workforce and beyond.

Inspiring the Next Generation of Biomedical Researchers by Bolstering the NIH Biomedical Workforce

Working Group on Re-envisioning NIH-Supported Postdoctoral Training

Science, Technology, Engineering, and Math (STEM) doctorate holders are critical to the health of the national and global scientific ecosystem. Within the U.S. research enterprise, postdoctoral scholars, predominantly based in academic research labs, are a bellwether of its sustainability. These labs train postdoctoral scholars to pursue broad, intellectually curious questions, often underpinning innovation that precipitates new treatments or devices. However, the existing postdoctoral research system is not optimally supporting the current biomedical research ecosystem, nor is it building the best foundation for a diverse, inclusive, productive, successful, and sustainable future. Among other issues, postdoctoral scholars often receive low compensation and benefits relative to their education and work experience; they confront job insecurity, insufficient support for professional development, and uncertain career prospects; and they are subject to a power imbalance that favors the institutional establishment. Further, postdoctoral scholars from historically marginalized groups and international postdoctoral scholars face disproportionate structural and implicit barriers in academia, exacerbating the challenges experienced for these groups. Recognizing these complex issues, in January 2023 the Acting NIH Director charged a new NIH Advisory Committee to the Director (ACD) Working Group on *Re-envisioning NIH-Supported Postdoctoral Training*,⁴⁸ building upon work from

⁴⁸ acd.od.nih.gov/working-groups/postdocs.html

previous groups.^{49,50} NIH hosted four public listening sessions⁵¹ and posted a Request for Information⁵² to engage the community on issues affecting and possible solutions to the challenges facing postdocs. Informed by this feedback, the Working Group's final report was published in December 2023,⁵³ and includes recommendations for improving the postdoctoral experience to optimize the effectiveness of postdoctoral training and professional development to benefit engaged individuals and the scientific enterprise as a whole. NIH is currently evaluating these recommendations and next steps for implementation.

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 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 Award 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) 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 student DEIA. In 2022, UNITE released its inaugural Progress Report,⁵⁴ which describes the actions that NIH has taken to identify and address structural racism that may exist within the NIH and in the biomedical and behavioral research enterprise. Also, in April 2023, NIH launched the NIH Institutional Excellence in Diversity, Equity, Inclusion, and Accessibility in Biomedical and Behavioral Research Prize Competition,⁵⁵ administered by the Chief Officer for Scientific Workforce Diversity Office in close collaboration with UNITE and 24 Institutes and Centers. The prize competition aims to recognize transformative cultures, systems, projects, and processes developed by academic institutions to promote inclusive excellence and create environments that foster and value a culture of DEIA. The prize competition will also identify practices for enhancing DEIA within faculty, postdoctoral scholars, and student bodies that can be disseminated for adoption by other institutions.

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 through grade 12 students and stimulate the

⁴⁹ acd.od.nih.gov/working-groups/nextgen.html

⁵⁰ acd.od.nih.gov/working-groups/bwf.html

⁵¹ acd.od.nih.gov/documents/IMOD_Postdoc_Listening_Sessions_summary.pdf

⁵² acd.od.nih.gov/documents/RFI_Postdocs_Report_2023.pdf

⁵³ acd.od.nih.gov/documents/presentations/12152023_Postdoc_Working_Group_Report.pdf

⁵⁴ nih.gov/sites/default/files/research-training/initiatives/ending-structural-racism/UNITE-progress-report-2022.pdf

⁵⁵ diversity.nih.gov/blog/2023-04-04-announcing-nih-institutional-excellence-deia-prize-competition

types of scientific curiosity and inquiry-based approaches used in biomedical research.⁵⁶ 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.⁵⁷ 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.⁵⁸

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.^{59,60}

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 attracted and retained a diverse class of fellows.^{61,62} 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)

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 careers. 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. The program includes a symposium at which students present their research results and gain continued mentorship after the summer. With NIDDK grant support, academic and non-profit

⁵⁶ nigms.nih.gov/capacity-building/division-for-research-capacity-building/science-education-partnership-awards-sepa

⁵⁷ biobeat.nigms.nih.gov/2022/06/the-league-of-vetahumanz-encouraging-kids-to-use-their-powers-for-good/

⁵⁸ science.education.nih.gov/

⁵⁹ nigms.nih.gov/training/MARC/Pages/USTARAWards.aspx

⁶⁰ nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx

⁶¹ nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx

⁶² In its first two years, the MOSAIC program supported 82 scholars, 76 percent of whom were women, and 71 percent from under-represented backgrounds.

institutions across the country serve as STEP-UP coordinating centers to identify mentors, coordinate student recruitment, help students find research sites close to their home or school, and manage other aspects of the program. Evaluation of STEP-UP's first two decades showed that many of the participants have pursued careers as researchers, physicians, and physician-scientists. Building on this success, NIDDK renewed the program in 2022⁶³ and expanded the undergraduate component to provide support for year-round research. NIDDK also plans to expand STEP-UP to include a coordinating center that will operate a high school program in the upper west to reach out to students from Wyoming, Utah, Montana, the Dakotas, and other states where there has been low participation in the STEP-UP program to date. STEP-UP is an important component of NIH's multifaceted efforts to develop a talented and diverse biomedical research workforce, where opportunity is defined by talent, not zip code.

DEIA Strategic Plan

In FY 2023, NIH released the Fiscal Years 2023–2027 NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA) to articulate NIH's vision for embracing, integrating, and strengthening DEIA across all NIH activities to achieve the NIH mission.⁶⁴ The Strategic Plan lays out the current and future NIH activities to meet that strategic vision and is organized around accomplishments, needs, opportunities, and challenges in addressing DEIA in the NIH intramural and extramural workforce, its structure and culture, and the research it supports. The Strategic Plan was developed in part as a response to directives included in the House FY 2022 appropriations report calling for a diversity strategic plan⁶⁵ and is responsive to *Executive Order 14035* and the *Government-Wide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce*.⁶⁶ The Strategic Plan highlights NIH's efforts to foster DEIA within the biomedical, behavioral, and social sciences research enterprise, and NIH created a two-page overview that summarizes the content of the Strategic Plan.⁶⁷ NIH's implementation of the Strategic Plan is described in more detail in the OD chapter of the NIH Congressional Justification.

Fostering Scientific Innovation and Harnessing New Technologies

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 NIH-wide 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 interdisciplinary projects that employ engineering and/or physical science approaches to

⁶³ grants.nih.gov/grants/guide/rfa-files/RFA-DK-22-510.html

⁶⁴ nih.gov/about-nih/nih-wide-strategic-plan-diversity-equity-inclusion-accessibility-deia

⁶⁵ congress.gov/116/crpt/hrpt450/CRPT-116hrpt450.pdf

⁶⁶ whitehouse.gov/briefing-room/presidential-actions/2021/06/25/executive-order-on-diversity-equity-inclusion-and-accessibility-in-the-federal-workforce/

⁶⁷ nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-two-page-overview.pdf

problems in biology and medicine. The program made six two-year awards, ranging in amount from \$194,000 to \$250,000 per year.

Undiagnosed Diseases Network (UDN)

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. The FY 2025 request includes \$18.0 million in NINDS to continue these activities, an increase of \$16.0 million in base funding in order to complete the transition of this program from the Common Fund.

Rare Diseases and Translational Science Research

When it comes to tackling the undiscovered and developing novel health interventions, one way we can accomplish this is by supporting innovative work to address many diseases at one time. The critical need for platform-based, multi-disease approaches is underscored when considering the collective impact of rare diseases. The public health need for applying innovation to rare diseases research is clear: there are over 7,000 different rare diseases, and 1 in 10 individuals has a rare disease. Recent reports estimate that this results in approximately \$400 billion per year in medical costs for patients in the United States and upwards of \$1 trillion in total costs.⁶⁸ Some of this economic burden reflects the long odyssey that many patients must take to receive a correct diagnosis, only to realize that 90 percent of rare diseases lack a treatment. As home to translational science and a leader in rare diseases research, the National Center for Advancing Translational Sciences (NCATS) is positioned to tackle many scientific opportunities of high public health need to address the significant challenges faced by patients, particularly those with rare diseases.

NCATS has already embarked on optimization of gene-directed therapies such as the Platform Vector for Gene Therapy (PaVe-GT) Program and the Accelerating Medicines Partnership® Bespoke Gene Therapy Consortium (BGTC). These programs seek to advance rare diseases research by expanding treatment development and interventions for diseases and include:

- Data-science and informatics, personalized medicine, and novel diagnostics;
- Clinical trial infrastructure innovations and increased integration and coordination of the Rare Diseases Clinical Research Network (RDCRN) and rare diseases research with the Clinical and Translational Science Awards (CTSA) program; and
- Shortening the diagnostic odyssey for rare disease patients by using real-world data and real-world evidence, such as leveraging and expanding the NCATS National COVID Cohort Collaborative, which bridges together clinical data from CTSA-affiliated clinics

⁶⁸ healthaffairs.org/doi/10.1377/forefront.20220128.987667

and hospitals for research use and has demonstrated its ability to identify three different types of Long COVID.

Leveraging Discoveries and Lessons Learned to Combat Infectious Disease

The rapid successes and generational leaps that have occurred in the field of biomedical research throughout the course of the COVID-19 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.

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 Centers for Disease Control and Prevention (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 vaccines to increase their immunogenicity and effectiveness. Earlier this year, scientists at NIAID's Vaccine Research Center (VRC) reported in two new studies that an experimental influenza vaccine designed to elicit immunity against a broad range of influenza viruses performed well in a small trial of volunteers.⁶⁹ In fact, the vaccine has advanced to a second trial led by scientists at Duke University through NIAID's Collaborative Influenza Vaccine Innovation Centers (CIVICs). Continued investment in this research will enable the development of universal influenza vaccines to protect millions of people from infection. The FY 2025 budget request includes \$270.0 million for universal influenza vaccine research, the same as the FY 2023 Final 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 that have a significant and disproportionate occurrence of HIV in rural areas. The EHE initiative, announced in 2019, 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,

⁶⁹ niaid.nih.gov/news-events/vrc-uni-flu-vax

community-based groups, and other HHS agencies involved in the EHE initiative, including the CDC and HRSA.⁷⁰ 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 acquisition. 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 the HIV epidemic. NIH's multi-institute response is centrally coordinated within the NIH OD in the Office of AIDS Research (OAR). The \$26.0 million request sustains the level for EHE into FY 2025 and reflects plans to expand implementation research to additional types of awardees in order to broaden geographical coverage and build partnerships with unrepresented communities across the country.

Investing In Tomorrow's Discoveries by Supporting Robust Research Resources, Policies, and Infrastructure

As NIH continues to address the ongoing public health challenges that threaten the Nation while anticipating the potential threats of the future, it is imperative to continue supporting the infrastructure that underpins the NIH biomedical enterprise. This includes both the physical and digital infrastructure, as well as the policies that NIH promotes.

Impactful Policy to Shape Biomedical Research

Data

The lifeblood of a research-driven Agency is its data, and for NIH, this includes data spanning fundamental research (basic science) generated in laboratories, large health care systems, and individual communities. NIH seeks to reach the full potential of all biomedical, behavioral, and social sciences research and clinical care data to develop new treatments, prevention approaches, and health care delivery methods that improve the lives of all people. NIH will continue to work with grantees and across other HHS agencies to develop a modern infrastructure that optimally supports data sharing and use.

In January 2023, a new NIH Policy for Data Management and Sharing⁷¹ went into effect. Newly funded research projects must add a description of how the researchers will produce data that can be used by others to uncover new insights and, when applicable, reproduce their research results.

⁷⁰ [nih.gov/news-events/news-releases/nih-bolsters-funding-hiv-implementation-research-high-burden-us-areas](https://www.nih.gov/news-events/news-releases/nih-bolsters-funding-hiv-implementation-research-high-burden-us-areas)

⁷¹ grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

NIH will support the 2023 - 2028 HHS Data Strategy,⁷² to integrate data from basic and social sciences research, public health, and clinical care. Emphasis will be placed on obtaining inclusive, diverse, and secure data from all clinical care environments. The NIH OD is exploring options to expand clinical research capacity to reach communities of all types via a new NIH-wide network focused on primary care. In addition, the OD will partner with all HHS agencies to further develop the electronic health record as a vehicle for engaging the people who represent the full diversity of our society in biomedical research.

NIH envisions the National Library of Medicine (NLM) to serve as a focal point to support data sharing and use for biomedical, behavioral, and social sciences research across the Nation. In response to user community needs, the NIH Office of Data Science Strategy (ODSS) will work with NLM to increase capacity for data hosting, development of policies, programs, and infrastructure to deliver minimal cost access to open-industry data standards, support for broad access to advanced analytics and computational power, and support for education and workforce development, particularly for population groups not currently represented. The FY 2025 Budget requests a \$30.0 million increase for NLM to support a new Clinical Data initiative to develop the tools, computational resources, and datasets necessary to extend NIH clinical research capabilities, including supporting artificial intelligence research and development.

Scientific Integrity

Promoting and integrating scientific integrity principles throughout the research enterprise helps ensure that science is conducted, managed, communicated, and used in ways that preserve its accuracy and objectivity and protect it from suppression, manipulation, and inappropriate influence. NIH has always sought to incorporate robust scientific integrity principles and practices throughout every level of its scientific enterprise. To provide an overarching framework for the agency's commitment to supporting scientific integrity, NIH has developed a Draft Scientific Integrity (SI) Policy.⁷³ The Draft Policy aligns with the January 2021 "Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking," which tasks NIH and other agencies to update their SI policies as appropriate to ensure agency alignment with the principles set forth in the January 2022 "Protecting the Integrity of Government Science" report from the National Science and Technology Council's Scientific Integrity Fast-Track Action Committee and the Draft HHS SI Policy. The Draft NIH Scientific Integrity Policy articulates the procedures and processes in place at NIH that aid in maintaining rigorous scientific integrity practices and proposes several new functions to further enhance scientific integrity at NIH and throughout the NIH-funded biomedical research enterprise. The draft policy includes a federal definition of SI that aligns across the federal government, establishes key roles and responsibilities for those who will lead the agency's scientific integrity program, and, as appropriate, establishes relevant reporting and evaluation mechanisms. The policy will be finalized in early 2024.

Modernizing Data Ecosystems and Maximizing Access to Publications and Data that Result from Research

⁷² cdo.hhs.gov/s/hhs-data-strategy

⁷³ federalregister.gov/documents/2023/09/25/2023-20733/request-for-information-on-the-draft-scientific-integrity-policy-of-the-national-institutes-of

NIH’s vision for a modernized, integrated biomedical data ecosystem, as outlined in the NIH Strategic Plan for Data Science⁷⁴ and the NIH Policy for Data Management and Sharing (DMS Policy)⁷⁵ aims to promote responsible sharing of and access to data collected from NIH-supported research. The DMS Policy, which took effect in January 2023, reflects NIH’s longstanding commitment to making the results of the research it supports with public funds available to the public by expecting NIH-supported researchers to prospectively plan to maximize appropriate data sharing.

NIH has a longstanding Public Access Policy that expects the submission to PubMed Central of NIH-funded final, peer-reviewed manuscripts upon acceptance for publication. The manuscripts, or in some cases the final versions of record, are made publicly available after a maximum 12-month embargo from the official date of publication. In August 2022, the White House Office of Science and Technology Policy (OSTP) released a Memorandum on “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research” that establishes new guidance for improving public access to scholarly publications and data resulting from Federally supported research.⁷⁶ In February 2023, NIH released its Plan to Enhance Public Access to the Results of NIH-Supported Research for public comment.⁷⁷ The Plan provides a roadmap for how NIH will update its existing Public Access Policy to align with the OSTP Memorandum, including by removing the allowable embargo period for publications. The public comment period closed on April 24, 2023, and NIH is using this input to inform a draft revised Public Access Policy that will be released for comment in 2024.

Data modernization activities include improving the AI-readiness of NIH-funded data,⁷⁸ enhancing researcher training, and enabling NIH-funded data repositories to adopt best practices to align with OSTP’s May 2022 guidance, “Desirable Characteristics Of Data Repositories For Federally Funded Research.”⁷⁹ Other examples include funding opportunities for data repositories and knowledge bases as well as strategic partnerships such as the Generalist Repository Ecosystem Initiative (GREI).⁸⁰ NIH will continue to support data interoperability to facilitate complex integrations of data including data analysis in the cloud. For example, CloudLab,⁸¹ a cloud-based platform for learning and exploration of data, was established in the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative.⁸² To promote streamlining and standardizing processes for researchers to access NIH data, ODSS is developing strategies for updating existing data access systems and centralizing search capabilities and automation that will further the OSTP’s 2022 Directive.⁸³ These examples of NIH-wide efforts to modernize data ecosystems and maximize

⁷⁴ datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf

⁷⁵ sharing.nih.gov/data-management-and-sharing-policy

⁷⁶ whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf

⁷⁷ grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html

⁷⁸ datascience.nih.gov/artificial-intelligence/initiatives/Improving-AI-readiness-of-Existing-Data

⁷⁹ whitehouse.gov/wp-content/uploads/2022/05/05-2022-Desirable-Characteristics-of-Data-Repositories.pdf

⁸⁰ datascience.nih.gov/data-ecosystem/exploring-a-generalist-repository-for-nih-funded-data

⁸¹ cloud.nih.gov/resources/cloudlab/

⁸² datascience.nih.gov/strides

⁸³ whitehouse.gov/ostp/news-updates/2022/05/26/new-guidance-to-ensure-federally-funded-research-data-equitably-benefits-all-of-america/

access show that NIH is committed to ensuring data are in line with OSTP’s guidance regarding equitable access to federally funded research.

Anti-Harassment Efforts

NIH is committed to promoting safe, respectful, and healthful work environments conducive to high-quality research. NIH is committed to creating and maintaining a work environment that is free of harassment and other inappropriate conduct and holding all NIH community members accountable for such behaviors regardless of position or status. For example, the NIH Civil program provides the entire NIH community with reporting tools and a process to review all allegations, identify inappropriate behaviors, and refer findings. The NIH-wide Anti-Harassment Steering Committee, chaired by the OD, is regularly informed of the NIH Civil work and findings, and responds by making recommendations on the implementation of new anti-harassment policies and updates to procedures for handling allegations and findings of harassment.

NIH will continue working towards ensuring safe and respectful workplaces, free from harassment and discrimination, wherever NIH-funded research is conducted. Over the past several years, NIH has taken many substantive actions within the extent of NIH’s grant authorities to address harassment and discrimination in NIH extramural biomedical science, including the development and implementation of policies and processes. NIH expects recipient institutions to have policies and practices in place that foster an environment free from harassment, including sexual harassment, discrimination, and other forms of inappropriate conduct that can result in a hostile work environment.⁸⁴ Through regular outreach, notifications, and engagement with the recipient community, NIH conveys to institutions and researchers that such behaviors are not acceptable.^{85,86} In December 2022, NIH revised the NIH Grants Policy Statement setting the expectation for recipients to establish codes of conduct, which define expectations of integrity and ethical values and criteria of competence of personnel involved in the work supported by NIH grant funds. This includes assuring work environments are free of harassment and are safe and conducive to the production of high-quality work. In May 2022, NIH published a guide notice informing recipients of their statutory obligation to notify NIH when an individual on an NIH award has been removed from their position or has been otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation, or hostile working conditions involving Senior/Key Personnel. Recognizing the support from Congress, the efforts of NIH staff, and enhanced institutional awareness, NIH is now much better positioned to prevent “passing the harasser.” Allegations and notifications related to harassment (including sexual harassment), discrimination, and hostile work environments have increased substantially since NIH started tracking these in 2018.⁸⁷ This rise in numbers is likely due in part to the heightened awareness⁸⁸ and attention about harassment in the scientific workforce,

⁸⁴ grants.nih.gov/grants/policy/harassment/policy-requirement.htm

⁸⁵ grants.nih.gov/grants/policy/harassment/related-statements.htm

⁸⁶ nexus.od.nih.gov/all/2023/07/17/case-study-in-research-integrity-banned-from-supervising-cant-go-in-lab-but-no-impact-on-nih-funded-research/

⁸⁷ nexus.od.nih.gov/all/2023/03/22/trends-in-extramural-research-integrity-allegations-received-at-nih/

⁸⁸ nih.gov/about-nih/who-we-are/nih-director/statements/creating-meaningful-reforms-end-sexual-harassment-science

together with NIH's outreach efforts and strengthened recipient notification requirements.⁸⁹ NIH regularly updates the data publicly reported on harassment allegations and outcomes.⁹⁰

Optimizing Levers to Transfer NIH-Funded Technologies into Private Sector Product Development

NIH funding is critical to stimulating new knowledge and discoveries driving innovation across sectors, and the agency is committed to thinking carefully about its role in making federally funded inventions accessible to the public. To that end, on July 31, 2023, NIH hosted a workshop titled *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer*, focused on how NIH, as a research institution, approaches patenting and licensing of inventions.⁹¹ The workshop panels tracked the path an invention can take from discovery to licensing, and panelists explored how NIH decides what to patent and license, who NIH partners with, and how NIH negotiates those agreements. Throughout the day, panelists shared perspectives on how NIH can best approach these questions to fulfill public health goals. NIH invited technology transfer professionals from inside and outside NIH, as well as patient advocates, academics, legal experts, and industry. There was also a separate oral public comment period and opportunities for written public comments.

Continuing to Promote Safe and Secure Research

NIH is committed to ensuring the safe and secure conduct of research to preserve critical advances while appropriately managing the potential risks. One example is a recent effort of the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), which is an advisory committee that provides recommendations to the NIH Director and provides a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. In 2020, NExTRAC was charged to consider issues associated with conducting research with gene drive modified organisms (GDMOs) safely and responsibly. During its deliberations, the Committee consulted with subject matter experts and held a public workshop. Ultimately, the NExTRAC produced key recommendations for strengthening NIH's existing policies and guidance which are outlined in its final report to NIH,⁹² and which helped inform a proposed policy update to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.⁹³ The proposed revisions would strengthen biosafety practices and incorporate specific considerations and requirements for NIH-supported research involving GDMOs in contained research settings. Furthermore, NIH continues to promote biomedical research that prioritizes biosecurity. For example, NIH supports the activities of the National Science Advisory Board for Biosecurity (NSABB),⁹⁴ a federal advisory committee chartered to provide advice and guidance to the U.S. Government on issues related to biosecurity and dual-use research, and any other issues as directed by the HHS Secretary. In 2023, NSABB provided

⁸⁹ nexus.od.nih.gov/all/2022/05/10/congress-strengthens-nih-ability-to-address-harassment-in-nih-funded-activities/

⁹⁰ grants.nih.gov/grants/policy/harassment/data

⁹¹ osp.od.nih.gov/events/workshop-on-transforming-discoveries-into-products-maximizing-nih-levers-to-catalyze-technology-transfer/

⁹² osp.od.nih.gov/wp-content/uploads/NExTRAC-Gene-Drives-Final-Report.pdf

⁹³ federalregister.gov/d/2023-17178

⁹⁴ osp.od.nih.gov/policies/national-science-advisory-board-for-biosecurity-nsabb#tab0/

several recommendations⁹⁵ in fulfillment of a charge delivered by NIH.⁹⁶ These recommendations are helping to inform U.S. Government revisions to two major U.S. biosecurity policy frameworks, which aim to effectively balance science and security while safely enabling critical, lifesaving research.

Enhancing Patient and Community Engagement

Key to NIH efforts to continue to promote responsible and effective research is engagement – not only with members of the broader biomedical sciences community to ensure that NIH policies are keeping pace as science evolves, but also addressing the needs of patients, caretakers, partners in patient advocacy groups, and the communities most impacted by NIH-supported research. In August 2023, the NExTRAC was charged to develop a harmonized and implementable vision and framework for including public voices in the design and planning of NIH-funded clinical research and to define pathways for widespread dissemination of study findings. This framework will outline approaches appropriate for the breadth and diversity of NIH-funded clinical research studies and assess the potential opportunities and challenges of varying levels of engagement activities for different types of clinical research studies, as well as the impact and value of engagement with patients, communities, and the broader public on clinical research. To address this charge, the NExTRAC will consult with the ACD and convene public consultations with a wide range of relevant parties. Through this framework and community convenings, the Committee will provide recommendations regarding different engagement methods, the optimal timing for meaningful engagement activities, and equitable and inclusive approaches for engagement.

Bolstering Infrastructure Needed to Tackle New Challenges

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, develop safe and effective novel treatments such as cellular therapy, and more. Support for NIH’s physical and digital infrastructure ensures that it can continue to produce the best biomedical products.

Buildings and Facilities

Facilities must co-evolve with science for NIH to achieve its full potential. NIH requests a funding level for Buildings and Facilities (B&F) of \$350.0 million, equal to the FY 2023 Final level. This amount will assist in addressing 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. NIH’s Backlog of Maintenance & Repair (BMAR) was approximately \$3.8 billion at the end of FY 2023. Together, the B&F request, continued use of the appropriations general provision allowing use of IC funding for B&F purposes within certain limits, and the planned FY 2025 allocation of \$120.6 million from the Nonrecurring Expenses Fund would enable NIH to improve the condition of its facilities and curtail the growth of the BMAR. The COVID-19 pandemic has made biomedical research and the facilities that support it more important than ever. Research facilities will play an important

⁹⁵ osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf

⁹⁶ osp.od.nih.gov/wp-content/uploads/2022/06/Tabak_and_Jorgenson-2022_Charge_to_the_NSABB.pdf

role in NIH's ability to continue to respond to national and global health threats. This budget aims to adapt NIH buildings and infrastructure to a changing biomedical research landscape, while maintaining the safety and reliability of its buildings and infrastructure.

NIH is considering alternative means of stemming the deterioration of NIH facilities and providing the necessary infrastructure for cutting-edge science. One such strategy is to prioritize whole-building projects that replace outdated BMAR-intensive facilities and also create swing space to renovate facilities more efficiently while activities are relocated elsewhere, as discussed in the separate B&F Congressional Justification chapter.

Cybersecurity

NIH continues to promote cross-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. Estimated cybersecurity funding of \$251.4 million in FY 2025 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 NIH-wide cybersecurity investments and improvements to support NIH 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.

Research Resource Infrastructure

The National Primate Research Centers (NPRCs) and other nonhuman primate (NHP) facilities are national resources that serve NIH and federal investigators, as well as researchers in private biomedical research foundations and the biotechnology and pharmaceutical industries. NHPs are critical for understanding a wide range of human diseases and informing the development of vaccines and therapeutics. Beyond the need for NHPs in responding to emerging infectious diseases, these animal 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 NHP models have been in the fields of regenerative medicine and gene therapy.

The COVID-19 pandemic increased the demand for nonhuman primates,⁹⁷ because these preclinical models are the most relevant to disease and treatment in humans. The increased demand highlighted the already limited availability of research NHPs and the infrastructure

⁹⁷ [nature.com/articles/s41684-021-00760-9](https://www.nature.com/articles/s41684-021-00760-9)

required to support them. Failing to adequately expand U.S. NHP resources and expertise available through NPRCs and other NHP research centers will adversely affect our Nation’s ability to respond to emerging infectious disease threats and the development of new vaccines and therapeutics. In addition, with limited research resources, maintaining pandemic preparedness and ongoing SARS-CoV-2 research such as for post-COVID sequelae also slows research in other biomedical fields such as Alzheimer’s disease, diabetes, or other illnesses.

During the COVID-19 pandemic, NIH rapidly recognized the need to increase domestic rhesus macaque colonies, improve infrastructure, provide biocontainment facilities, and ensure research and animal welfare expertise at the NPRCs.^{98,99,100} NPRCs were awarded funds from the CARES Act to modernize and improve housing for rhesus macaque breeding colonies, improve animal care infrastructure support, purchase equipment, and renovate high-containment research facilities. Thus, these funds supported a necessary, but limited increase in the overall efficiency of breeding colonies and accessibility of Biosafety Level-3 laboratories, providing rapid support for COVID-19 research. CARES Act funds were a one-time investment and expired in FY 2024. Expanding support for NHP research infrastructure is needed to ensure that the Nation’s critical biomedical research enterprise is improved and remains competitive worldwide.

The NIH Office of Research Infrastructure Programs (ORIP) supports a well-coordinated national consortium of seven NPRCs and five other NHP breeding colonies that collectively address current and emerging research needs, best husbandry practices, maintenance of genetic diversity, standardization of animal models, scientific rigor, and reproducibility. The FY 2025 NIH request includes \$10.0 million for improvements to NHP infrastructure, as part of total support of \$120.0 million for the NPRCs. This request would provide critical funding to improve facilities used to house NHPs, which require continual updates and maintenance. The funds would be distributed by soliciting applications from the existing NHP research centers to improve facilities. Several NHP facilities are over 60 years old, and housing enclosures require frequent repair and replacement. New construction for research facilities would include improvements to animal holding and animal care rooms, updated equipment – including centrifuges, ultrasound devices, clinical analyzers, veterinary clinical support, and psychological and environmental enrichment, which necessitates highly skilled technical staff and additional resources to provide proper care of the nonhuman primates. This FY 2025 request builds on earlier investments in these research centers to maximize their use for a broad range of NIH research.

Catalyzing the Use and Development of Novel Alternative Methods (NAMs)

From its foundation to the present day, NIH has funded research into the development and application of Novel Alternative Methods (NAMs, sometimes referred to as New Approach Methodologies, or non-animal models) as valuable tools in supporting its mission. These experiments *in chemico* (cell-free models), *in vitro* (cultured cells), and *in silico* (computational modeling and simulation) can complement and sometimes replace and refine the use of animal studies. NIH investment in NAMs has increased dramatically over the past 15 years alongside the agency’s ever-expanding technological capabilities. By continuing to increase its portfolio

⁹⁸ orip.nih.gov/sites/default/files/ORIP_Nonhuman_Primate_Resources_Fact_Sheet.pdf

⁹⁹ orip.nih.gov/resource-directory/national-primate-research-centers

¹⁰⁰ nprcresearch.org

investment in NAMs, NIH aims to provide researchers with complementary tools to existing animal models that hold great promise in establishing more accurate and reliable research into human health and disease. In January 2023, the Acting NIH Director charged a new ACD Working Group on *Catalyzing the Use and Development of Novel Alternative Methods* (Working Group) to identify where NAMs are currently being used and to make recommendations on where NAMs are positioned to be most applicable or beneficial, especially in terms of advancing our understanding of human health.¹⁰¹ This Working Group includes members with expertise in a wide range of technologies, scientific fields, and backgrounds, including members from academia, industry, and federal partners with *ex officio* members. The establishment of this Working Group follows on the recommendation included in the ACD Working Group on *Enhancing Rigor, Transparency, and Translatability in Animal Research*'s June 2021 report.¹⁰² The final report was published in December 2023 and identifies seven thematic clusters of high priority needs that should be addressed moving forward.¹⁰³ NIH is simultaneously conducting planning activities to inform a potential Common Fund research program called Complement Animal Research In Experimentation (Complement-ARIE) aimed at the development, standardization, validation, and use of NAMs that will more accurately model human biology.¹⁰⁴

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 conduct science with the highest standards of rigor and integrity to achieve the NIH mission of improving the health and well-being of all Americans. Each year, NIH awards over 60,000 grants that directly support more than 300,000 researchers at more than 2,500 different institutions. 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 eight years. In rural states, each \$1.00 of NIH spending generated an average \$1.80 of total economic impact.¹⁰⁵ This economic activity then generates significant revenues for state and local governments, quantified by a 2019 study as an average of \$22 million per state for applicable taxes and fees paid by businesses and employees.¹⁰⁶

A healthier nation is a more productive and economically sound nation. As one example, NIH-supported research on drug development for eye diseases has saved \$28.5 billion in health care costs over 10 years and reduced legal blindness due to wet age-related macular degeneration by 50 percent.¹⁰⁷ 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

¹⁰¹ acd.od.nih.gov/working-groups/novel-alternatives.html

¹⁰² acd.od.nih.gov/documents/presentations/06112021_ACD_WorkingGroup_FinalReport.pdf

¹⁰³ acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf

¹⁰⁴ commonfund.nih.gov/complementarie/strategicplanning

¹⁰⁵ sciencepolicy.colorado.edu/students/envs_5100/Toole2007.pdf

¹⁰⁶ unitedformedicalresearch.org/wp-content/uploads/2019/03/NIH-Research-Rural-States-ExecutiveSummary-FINAL-3.13.19.pdf

¹⁰⁷ pubmed.ncbi.nlm.nih.gov/32681907/

Americans. A full cure could be worth more than three times today's Gross Domestic Product.¹⁰⁸ The benefits of NIH research can be felt in the near term through the 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.

¹⁰⁸ 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 advance the development and adoption of new diagnostics, therapeutics, and preventive measures to improve health.

The FY 2025 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. As outlined in the *NIH-Wide Strategic Plan for FY 2021-2025*,¹⁰⁹ NIH supports a wide spectrum of biomedical and behavioral research and engages in a full range of activities that enable research. Because of this diversity and complexity, NIH uses a set of representative performance measures that reflects the priorities enumerated in the *Plan* and allows for tracking progress on the *Plan*. Collectively, NIH's measures reflect the Agency's objectives to: 1) advance biomedical and behavioral sciences; 2) develop, maintain, and renew scientific research capacity; and 3) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. 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. 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.

¹⁰⁹ www.nih.gov/about-nih/nih-wide-strategic-plan

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 communities; 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 and newly identified barriers, and frequently involves 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 the 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.^{110, 111} 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.

¹¹⁰ 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.

¹¹¹ The standing working groups are: Board of Scientific Directors; Clinical Center Governing Board; Data Science Policy Council; Diversity, Equity, Inclusion, and Accessibility Working Group; Extramural Activities Working Group; Enterprise Information Technology Council; Facilities Working Group; Management and Budget Working Group; Research Services Working Group; Scientific Data Council; and UNITE.

ALL PURPOSE TABLE

(Dollars in Millions) ^{1,2,3}	FY 2023	FY 2024	FY 2025	
	Final ⁷	CR	President's Budget	+/- FY 2023 Final
Total, NIH Program Level	\$49,178.485	\$48,609.035	\$51,616.517	\$2,438.032
Less mandatory and funds allocated from different sources:				
PHS Program Evaluation	\$1,412.482	\$1,412.482	\$2,018.482	\$606.000
Mandatory Type 1 Diabetes Research – Baseline ⁴	\$141.450	\$150.000	\$0.000	-\$141.450
Mandatory Type 1 Diabetes Research – Proposed	<u>\$0.000</u>	<u>\$100.000</u>	<u>\$260.000</u>	<u>\$260.000</u>
Mandatory Type 1 Diabetes Research Subtotal	\$141.450	\$250.000	\$260.000	\$118.550
Mandatory Cancer Moonshot	\$0.000	\$0.000	\$1,448.000	\$1,448.000
Total, NIH Discretionary Budget Authority	\$47,624.553	\$46,946.553	\$47,890.035	\$265.482
Interior Budget Authority	\$83.035	\$83.035	\$83.035	\$0.000
Total, NIH Labor/HHS Budget Authority	\$47,541.518	\$46,863.518	\$47,807.000	\$265.482
Total, NIH Program Level, excluding ARPA-H	\$47,678.485	\$47,109.035	\$50,116.517	\$2,438.032
<i>Pandemic Preparedness Mandatory via PHSSEF (non-add)</i>	<i>\$0.000</i>	<i>\$0.000</i>	<i>\$2,690.000</i>	<i>\$2,690.000</i>
<i>Number of Competing RPGs</i>	<i>11,106</i>	<i>9,739</i>	<i>10,273</i>	<i>-833</i>
<i>Total Number of RPGs</i>	<i>43,176</i>	<i>42,973</i>	<i>43,636</i>	<i>460</i>
<i>FTE⁵</i>	<i>19,180</i>	<i>20,942</i>	<i>21,256</i>	<i>2,076</i>
Nonrecurring Expenses Fund:⁶	\$63.140	\$120.130	\$120.555	
<i>ORF/ORS/NIAID Support Facilities, Rocky Mountain Laboratories, MT</i>	<i>\$40.650</i>			
<i>Electrical Power Reliability, Building 10</i>	<i>\$22.490</i>	<i>\$26.100</i>	<i>\$30.000</i>	
<i>Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C</i>		<i>\$29.300</i>		
<i>Replace Cooling Towers 18,19 and Chillers 17,18,19</i>		<i>\$40.000</i>		
<i>Repair Parking Garages, Bethesda</i>		<i>\$13.360</i>		
<i>Building 11 Provide Sprinkler Protection</i>		<i>\$11.370</i>		
<i>Upgrade Existing Site Electrical Distribution System, Bethesda Campus</i>			<i>\$52.875</i>	
<i>Research Triangle Park, Generator For Campus Emergency Chilled Water Service</i>			<i>\$37.680</i>	

¹ Numbers may not add due to rounding.

² Includes 21st Century Cures Act funding and ARPA-H.

³ All columns reflect a reduction by transfer of \$5.0 million from OD to the HHS Office of Inspector General.

⁴ Amount in FY 2023 reflects a reduction of \$8.550 million for Budget Control Act sequestration; baseline reflects assumed reauthorization at level of \$150.0 million in FY 2024.

⁵ Includes 4 NIH FTEs funded by PHS trust funds in all years.

⁶ FY 2024 NEF project requests are currently under review and pending OMB approval. HHS has not yet notified for FY 2025.

⁷ Excludes emergency and supplemental funding of \$27.5 million in the Disaster Relief Supplemental Appropriations Act (P.L. 117-328, Division N).

IMPACT OF BUDGET LEVEL ON PERFORMANCE

Programs and Measures (Dollars in Millions, except where noted)	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Research Project Grants	\$26,580.896	\$26,307.866	\$27,141.249	2.1%
Competing Average Cost (in thousands)	\$611	\$579	\$591	-3.3%
Number of Competing Awards (whole number)	11,106	9,739	10,273	-7.5%
Estimated Competing RPG Success Rate	21.4%	17.5%	18.4%	-3.0%
Research Centers	\$2,881.155	\$2,852.909	\$2,931.206	1.7%
Other Research	\$3,336.712	\$3,189.658	\$3,917.757	17.4%
Training	\$984.331	\$1,021.440	\$1,034.208	5.1%
Research & Development Contracts	\$4,032.891	\$3,857.225	\$4,582.467	13.6%
Intramural Research	\$5,046.199	\$5,133.445	\$5,274.376	4.5%
Research Management and Support	\$2,331.451	\$2,442.336	\$2,689.558	15.4%
<i>Common Fund (non-add)</i>	<i>\$735.001</i>	<i>\$735.001</i>	<i>\$722.401</i>	<i>-1.7%</i>
Advanced Research Projects Agency for Health (ARPA-H) ¹	\$1,500.000	\$1,500.000	\$1,500.000	0.0%
Buildings & Facilities Appropriation	\$350.000	\$350.000	\$350.000	0.0%
Other Mechanisms ^{2,3}	\$2,134.849	\$1,954.155	\$2,195.696	2.9%
Total, Program Level⁴	\$49,178.485	\$48,609.035	\$51,616.517	5.0%
Total, Program Level excluding ARPA-H	\$47,678.485	\$47,109.035	\$50,116.517	5.1%
<i>Mandatory Pandemic Preparedness via PHSSEF (non-add)</i>			<i>\$2,690.000</i>	<i>N/A</i>

¹ FY 2023 and FY 2024 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 for Type 1 Diabetes and Cancer Moonshot.