

## 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 to apply that knowledge to optimize health and prevent or reduce illness for all people. As the largest public funder of biomedical and behavioral research in the world, NIH is the driving force behind decades of advances that improve health, revolutionize science, and serve society.

NIH fuels the biomedical research enterprise—cultivating world-class scientists and catalyzing new scientific fields, tools, and resources that have changed science. Discoveries emerging from NIH-supported research have led to new ways to prevent, diagnose, and treat illness, ultimately improving the health of the nation and the world. Additionally, NIH-supported research leads to improvements in health that can bolster the economy, improve productivity, and reduce the costly burden of illness in the United States and worldwide. NIH funding also spurs economic growth, both by supporting jobs in research and by generating biomedical innovations that lead to growth in the biotechnology sector. Through careful stewardship of public resources in pursuit of its mission, NIH enhances health for all.

## OVERVIEW OF BUDGET REQUEST

### **Summary**

For Fiscal Year (FY) 2026, the National Institutes of Health (NIH) requests a total program level of \$27.9 billion, a \$18.1 billion reduction from the \$46.0 billion program level in the FY 2025 full-year continuing resolution (CR).<sup>1</sup> This request seeks to maximize the impact of NIH research by streamlining processes and more efficiently providing funding to NIH-supported institutions. NIH's budget level will continue to support critical research conducted in service of the agency's mission and administration priorities as well as support new and ambitious priority investments necessary for Making America Healthy Again.

NIH strategically leverages its budget by supporting researchers in every state to ensure that all communities benefit from research. Through these investments, NIH pursues innovative research proposals and cutting-edge scientific techniques to address our most difficult healthcare challenges. Current priority issues such as finding treatments and interventions for devastating diseases such as cancer, diabetes, and HIV/AIDS; reducing maternal mortality rates; supporting the scientific workforce; fully understanding the causes of autism spectrum disorders (ASD); and combatting the ongoing opioid crisis remain critical areas of concern. Moving forward, NIH will also prioritize improving population health, solving the reproducibility crisis, embracing innovation and collaboration, maintaining research safety and transparency, and ensuring academic freedom.

NIH-funded researchers and staff are expected to uphold the highest ethical standards to support the best science. NIH promotes the principles of scientific integrity and rigor within the biomedical research community and ensures that results of research are effectively reported and disseminated. NIH is also pursuing the best methods for incorporating the voices of people and communities most directly impacted by healthcare challenges into the research lifecycle, which will in turn lead to improved healthcare outcomes. Finally, NIH announced a new initiative in FY 2025 to expand innovative, human-based science using new and emerging technologies to help biomedical researchers answer previously difficult or unanswerable questions.<sup>2</sup> Developing and using cutting-edge alternative non-animal research models aligns with the U.S. Food and Drug Administration's (FDA) recent initiative to replace animal models that have low translational confidence.

With these goals in mind, NIH will continue to build on its foundational legacy of groundbreaking biomedical research to address current and future healthcare challenges and support the highest quality basic, translational, and clinical research to improve health for all.

### **NIH – A History of Scientific Discovery and Biomedical Research Advancement**

NIH has always maximized investments to support basic, translational, and clinical research to develop health research advances that benefit all people. The discoveries made possible by NIH-

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<sup>1</sup> The FY 2026 President's Budget proposes to relocate the National Institute for Environmental Health Sciences (NIEHS) outside of NIH, in the Administration for a Healthy America. The FY 2025 funding level is adjusted to remove NIEHS funding for comparability.

<sup>2</sup> [nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies](https://nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies)

supported research have led to a vast number of treatments, interventions, prevention strategies and more that have helped ease the burden of disease, promote wellbeing, and extend life. To get the most out of this investment, NIH promotes science that emphasizes rigor and reproducibility through every stage of the scientific process, from conception of ideas to the conduct of the research to the dissemination of results and beyond. NIH research is conducted with the utmost integrity. When presenting the findings from NIH-funded research, NIH promotes a culture of transparency to ensure that the results of research advances reach the people that will benefit the most – the public. This includes incorporating public voices early and often throughout the course of the biomedical research lifecycle, ensuring that NIH-funded science meets the needs of patient communities, and promotes transparency.

The culmination of this foundation is research that has a tremendous impact on lives. However, the treatments and interventions that have been developed as the result of NIH clinical research could not have been achieved without years of basic foundational research. This underscores the need to bridge laboratories, clinics, and communities to work synergistically to achieve common goals. NIH is actively building upon this legacy of basic and clinical research excellence. Since its inception in 1953, the NIH Clinical Center has been involved in numerous medical milestones, from pioneering cancer treatments, to developing interventions to treat HIV and AIDS, to the development of diagnostic and imaging technologies. The advances developed in part by NIH research have saved, and continue to save, lives every day.

No greater testament of NIH’s past and continued success in scientific endeavors can be found than the fact that NIH has supported 174 researchers who have received or shared 104 Nobel Prizes. An NIH-funded researcher received the Nobel Prize in 2024 for the development of groundbreaking artificial intelligence (AI) tools to predict the complex structure of proteins – tools that have already been used by millions of researchers across the globe.<sup>3</sup>

While NIH has a strong history of conducting and supporting groundbreaking research and medical advances, it must reestablish trust and realign priorities to focus on conditions plaguing the Nation. As NIH enters its next era, it will continue to bridge basic, translational, and clinical research in novel and innovative ways to continue developing new advances and maintain its status as the world leader in health science research.

### **Maximizing The Impact of NIH Research**

American taxpayers invest precious resources into NIH and expect a positive return on that investment. To maximize that return, NIH must deeply reflect on its structure, policies, and research. This budget request proposes significant changes to the organization to streamline activities and produce the most robust scientific findings possible.

First, the Budget proposes to eliminate the National Institute of Nursing Research (NINR), the National Center for Complementary and Integrative Health (NCCIH), the Fogarty International Center (FIC), and the National Institute on Minority Health and Health Disparities (NIMHD). Further, to minimize redundancies and maximize collaboration, the Budget proposes to reorganize the remaining Institutes and Centers with direct appropriations into an eight-Institute

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<sup>3</sup> [nobelprize.org/prizes/chemistry/2024/press-release/](https://nobelprize.org/prizes/chemistry/2024/press-release/)

structure, while maintaining the Office of the Director and the Buildings and Facilities accounts. Table 1 illustrates the new plan.

**Table 1 – Proposed Institute Structure**

<b>New Institute Structure</b>	<b>Current Institutes and Centers</b>
National Cancer Institute (NCI)	NCI
National Institute of Allergy and Infectious Diseases (NIAID)	NIAID
National Institute on Aging (NIA)	NIA
National Institute on Body Systems (NIBS)	National Heart, Lung, and Blood Institute (NHLBI), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Neuroscience and Brain Research (NINBR)	National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Neurological Disorders and Stroke (NINDS), National Eye Institute (NEI)
National Institute of General Medical Sciences (NIGMS)	NIGMS, National Human Genome Research Institute (NHGRI), National Library of Medicine (NLM), National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Center for Advancing Translational Sciences (NCATS)
National Institute for Child and Women's Health, Sensory Disorders, and Communication (NICWHSDC)	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD), National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Behavioral Health (NIBH)	National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH)

In addition to the proposed reorganization within NIH, one institute will be relocated within the Department of Health and Human Services. The National Institute of Environmental Health Sciences (NIEHS) will reside within the Administration for a Healthy America.

Another way in which the Budget will maximize the impact of NIH research investments is to increase the share of each dollar awarded for research grants that goes directly toward research. In addition to direct costs for particular research or projects, NIH awards funds for Facilities and Administration (F&A) costs of grantee institutions, also known as “indirect costs.” The amount awarded to each institution varies based on negotiated rates, and the way the money is used is unclear and often ambiguous. To increase transparency in NIH funding and maximize the research supported by the taxpayers’ investments, this budget proposes to continue the policy of capping F&A costs at 15 percent of the applicable direct cost base for each award, and to eliminate the appropriations general provision regarding changes to NIH F&A cost policies.

In FY 2026, the Budget will continue the FY 2025 policy of reserving half of the NIH budget allocation for competing research project grants (RPGs) for awards that fully fund their outyear commitments as part of the initial grant obligation, to facilitate efficient management of resources across multiple years. Traditionally, most NIH research grants have been awarded for more than one year and funded incrementally; each year's commitment is obligated from that year's appropriation. Under this incremental funding approach, grants are classified as competing in the first year of award or renewal, and noncompeting in the remaining years of each award. Providing the grantee with funding for every year of the RPG from the start will increase NIH budget flexibility by no longer encumbering large portions of each year's appropriation for the continuation of research projects that were initiated in previous years.

The Budget also proposes to increase the efficiency of NIH intramural research by capping the base pay of staff paid under Title 42 at the maximum rate payable for senior-level positions under 5 USC 5376 (\$225,700 in 2025). The current salary range for these employees goes up to \$350,000, due to their leadership roles and the much higher compensation earned by their counterparts at academic institutions and hospitals.

### **Major Health Impacts Now – NIH Funds Biomedical Research That Saves Lives**

While it is important to acknowledge the decades of previous biomedical advancements made possible by NIH investments, many public health challenges remain that affect health across populations and the lifespan. NIH supports biomedical and behavioral research to meet the full spectrum of public health needs and continues to invest in research that benefits all people across their lifespans.

#### **Investments for Public Health across Populations**

##### **Tackling the Chronic Disease Crisis**

Despite significant investment in U.S. health care, our country's health is declining. America has the highest rates of chronic disease compared to other wealthy countries.<sup>4</sup> The United States ranks last in terms of health among developed nations, and life expectancy is declining for many groups of Americans. By establishing the new National Institute on Body Systems (NIBS), which combines the National Heart, Lung, and Blood Institute (NHLBI); the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK); and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH is poised to address the needs of Americans with chronic diseases in a coordinated and streamlined manner.

A poor diet is the leading cause of U.S. mortality and is directly related to malnutrition and chronic diseases including obesity, type 2 diabetes, cardiovascular disease, and many cancers. Approximately one million people die annually in this country from diet-related chronic diseases, and this number continues to rise. Diet-related chronic diseases also disproportionately affect underserved communities and exacerbate health conditions.<sup>5,6</sup> Moreover, nutrition has not

<sup>4</sup> [commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019](https://commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019)

<sup>5</sup> [frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1339859/full](https://frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1339859/full)

<sup>6</sup> [pubmed.ncbi.nlm.nih.gov/28267855/](https://pubmed.ncbi.nlm.nih.gov/28267855/)

been prioritized in either medical education or routine primary care medicine.<sup>7,8</sup> The Food is Medicine Centers of Excellence Program<sup>9</sup> will specifically address the existing gap between nutrition support and clinical care 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., type 2 diabetes, cardiovascular disease, and cancer). 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. Additionally, the Nutrition for Precision Health (NPH)<sup>10</sup> initiative powered by the *All of Us* Research Program seeks to develop algorithms that predict individual responses to food and dietary patterns. The NPH program will build on recent advances in biomedical science including AI, microbiome research, as well as the infrastructure and large participant group of the *All of Us* Research Program.<sup>11</sup> These advances provide unprecedented opportunities to generate new data to provide insight into personalized nutrition, also referred to as precision nutrition.

Under the new NIH-FDA Nutrition Regulatory Science Program (NRSP), announced in May 2025, the agencies will implement and accelerate a comprehensive nutrition research agenda that will provide critical information to inform effective food and nutrition policy actions to help make Americans' food and diets healthier.<sup>12</sup> The initiative, led and coordinated by the NIH Office of Nutrition Research (ONR), an office within the Office of the Director (OD), will aim to answer questions such as: how and why can ultra-processed foods harm people's health; how might certain food additives affect metabolic health and possibly contribute to chronic disease; and what is the role of maternal and infant dietary exposures on health outcomes across the lifespan, including autoimmune diseases? Answering these questions and many others will enable effective policy development and help inform Americans about the foods they are eating and how those foods can impact their health. The FDA will provide its critical expertise in regulatory science and NIH will provide the infrastructure for the solicitation, review, conduct, and management of scientific research. This initiative will bring together experts in many disciplines—including chronic disease, nutrition, toxicology, risk analysis, behavioral science, and chemistry—all with the goal to advance the gold standard of nutrition and food science. NIH and FDA will work together to develop a research agenda for the NRSP and are committed to ensuring all research conducted under the Program is fair, independent, and free of conflicts of interest. The new Program will also enable effective policy development and ensure that Americans understand the health impacts of the foods they eat.

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<sup>7</sup> [pubmed.ncbi.nlm.nih.gov/8424377/](https://pubmed.ncbi.nlm.nih.gov/8424377/)

<sup>8</sup> [pubmed.ncbi.nlm.nih.gov/38705195/](https://pubmed.ncbi.nlm.nih.gov/38705195/)

<sup>9</sup> [dpcpsi.nih.gov/sites/default/files/Day-1-155PM-ONR-Concept-Food-is-Medicine-Lynch-background-508.pdf](https://dpcpsi.nih.gov/sites/default/files/Day-1-155PM-ONR-Concept-Food-is-Medicine-Lynch-background-508.pdf)

<sup>10</sup> [commonfund.nih.gov/nutritionforprecisionhealth](https://commonfund.nih.gov/nutritionforprecisionhealth)

<sup>11</sup> [allofus.nih.gov/](https://allofus.nih.gov/)

<sup>12</sup> [nih.gov/news-events/news-releases/fda-nih-announce-innovative-joint-nutrition-regulatory-science-program](https://nih.gov/news-events/news-releases/fda-nih-announce-innovative-joint-nutrition-regulatory-science-program)

### Understanding the Cause of Autism

The incidence of ASD in the United States has increased from 1 in 36 in 2020 children to 1 in 31 children in 2022.<sup>13</sup> Identifying the root causes of the childhood chronic disease crisis, including ASD, is a priority for HHS and NIH.

Currently, NIH supports research to better understand the full range of symptoms that people with ASD may experience. This includes research to identify biological and behavioral characteristics to understand symptoms, how symptoms and needs may change over time, and the best treatments, services, and support.

NIH also supports research to find better ways to meet the individual needs of people with ASD. This includes research to improve early screening so that children with ASD can be connected with appropriate services and support as early as possible. This also includes research on supporting people with ASD as they age, from childhood to adolescence and throughout adulthood.

The Autism Centers of Excellence Program<sup>14</sup> is an NIH-wide initiative that supports large-scale multidisciplinary studies on ASD, with the goal of determining the disorder's causes and potential treatments. The program, established in 2007, includes research centers that foster collaboration between teams of specialists who share the same facility to address a particular research problem in depth, and research networks that consist of researchers at many facilities throughout the country, all of whom work together on a single research question.

NIH and the Centers for Medicare and Medicaid Services announced an initiative in 2025 to integrate diverse data that will enable researchers to examine complex factors influencing ASD rates.<sup>15</sup>

### Research to Understand and Improve the Health of Older Adults

Thanks to advances in health and technology, the United States and global populations are living longer. NIH has long supported a portfolio focused on the health of aging populations and on conditions that primarily or disproportionately affect older adults. Since its establishment over 50 years ago, the National Institute on Aging (NIA) has been at the forefront of the nation's research activities dedicated to understanding the nature of aging; supporting the health and wellbeing of older adults; and extending the healthy, active years of life. NIA is the designated NIH Institute for research into the health of older adults and collaborates across the agency to ensure that this important work is integrated across disciplines and scientific fields. For example, NIA collaborates with other NIH partners to fund research and develop research priorities specific to Alzheimer's disease and Alzheimer's disease related dementias (AD/ADRD), which include Lewy body dementias, frontotemporal dementias, and vascular contributions to cognitive impairment and dementia. This coordination includes implementation of the National Alzheimer's Project Act's national plan to accelerate research on AD/ADRD, and to provide

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<sup>13</sup> [cdc.gov/mmwr/volumes/74/ss/ss7402a1.htm?s\\_cid=ss7402a1\\_w](https://www.cdc.gov/mmwr/volumes/74/ss/ss7402a1.htm?s_cid=ss7402a1_w)

<sup>14</sup> [nichd.nih.gov/research/supported/ace](https://nichd.nih.gov/research/supported/ace)

<sup>15</sup> [nih.gov/news-events/news-releases/nih-cms-partner-advance-understanding-autism-through-secure-access-select-medicare-medicaid-data](https://www.nih.gov/news-events/news-releases/nih-cms-partner-advance-understanding-autism-through-secure-access-select-medicare-medicaid-data)

better clinical care and services for people living with dementia and their families.

With increased investment in AD/ADRD, NIH has led incredible progress over the last decade. Through innovative collaborations across NIH and with other federal agencies and industry and the broader community – including 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; identified lifestyle and behavioral interventions to reduce risk; deepened understanding of how social and physical environmental factors affect dementia risk and disparities; and expanded research on dementia care and care partner support.<sup>16</sup>

Based on these important advancements, NIH is now enabling precision medicine advances by funding a range of clinical trials in AD/ADRD. NIH researchers are testing a variety of novel and diverse therapeutic targets, such as those implicated in inflammation, synaptic plasticity, resilience, and neuroprotective mechanisms. In addition to drug trials, NIH-funded investigators are studying promising behavioral and lifestyle interventions to reduce dementia risk and improve cognition and memory. For example, recent NIH-funded clinical trials identified interventions such as controlling blood pressure, correcting hearing loss, and personalizing health coaching that can reduce cognitive decline and dementia risk. These examples add to the growing body of evidence for modifiable behaviors that can reduce dementia risk, highlighting that this area is a vibrant field for ongoing and future research.

NIH is also deeply committed to funding basic research to better understand how we can live longer and healthier lives. In recent years, researchers have turned to the growing field of geroscience, which seeks to translate knowledge gained from biology of aging research into methods and interventions to prevent, minimize, or reverse detrimental age-related changes and functional decline in older individuals. By studying what happens during the aging process at the cellular and molecular level, NIH investigators hope to identify interventions to extend the portion of life spent in good health, also known as “healthspan” in older adults. A particularly promising avenue of research involves studying cellular senescence, a cellular state during which damaged cells resist cell death, linger, and harm neighboring normal cells. To identify and characterize how different types of senescent cells affect multiple tissues to impact human health, disease, and lifespan, the NIH Common Fund launched the Cellular Senescence Network (SenNet). A deeper understanding of cellular senescence will help researchers to develop new therapies that encourage beneficial effects of senescent cells while suppressing their tissue-damaging effects. Additionally, NIH-funded researchers have found that treatment with drugs that remove senescent cells, called ‘senolytics,’ delayed the onset of several age-related ailments in mice compared to untreated peers. Senolytics are currently being tested in clinical trials of various conditions to determine their potential to ultimately help treat age-related conditions. More research must be conducted to test the translation of these and other geroscience findings more broadly into the clinic.

Collectively, NIH is committed to advancing discovery on age-related diseases and conditions and general aging processes to help ensure that Americans are living longer and healthier lives.

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<sup>16</sup> [nia.nih.gov/about/professional-judgment-budget-proposal](https://nia.nih.gov/about/professional-judgment-budget-proposal)

### Landmark Progress in Type 1 Diabetes

The Special Statutory Funding Program for Type 1 Diabetes Research, or Special Diabetes Program, is a special funding program supporting research on the prevention, treatment, and cure of type 1 diabetes and its complications. The Special Diabetes Program has led to landmark progress that is improving the health and quality of life of people with and at risk for type 1 diabetes. For example, Special Diabetes Program-supported research has culminated in recent FDA approvals of the first drug (teplizumab) that can delay onset of type 1 diabetes diagnosis in people at high risk for developing the disease; the first cellular therapy (islet transplantation) to treat adults with type 1 diabetes who have recurrent episodes of dangerously low blood glucose levels; and hybrid artificial pancreas devices that have greatly eased the burden of type 1 diabetes management.<sup>17</sup> Ongoing research is addressing urgent areas, such as investigating the neurocognitive impact of type 1 diabetes in children; identifying mechanisms that promote the development of heart disease in people with type 1 diabetes; identifying factors that restore awareness of hypoglycemia in adults with type 1 diabetes and impaired awareness of hypoglycemia; and developing next-generation hybrid artificial pancreas systems. This research is critical for improving health outcomes in people with type 1 diabetes. The budget request includes \$159.0 million to extend the Special Diabetes Program through FY 2026.

### Pioneering Personalized Medicine through the Undiagnosed Disease Network

Approximately 30 million Americans are living with a rare disorder. The Undiagnosed Disease Network (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. 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 and researchers new, powerful information to help understand and treat rare diseases. Since its launch in 2013, the UDN has made over 800 diagnoses, including 77 newly described conditions, and has identified more than 100 disease-linked genes and genomic variants. The network includes 22 new and continuing Diagnostic Centers of Excellence that are poised to expand geographic coverage and access for groups that experience health disparities. Moving forward, the UDN is exploring the use of AI to further enhance diagnostic capabilities, as well as additional, non-genomic diagnostic strategies that consider environmental, metabolic, immunologic, or other contributors to disease.

### 21<sup>st</sup> Century Cures Act

FY 2026 marks the final authorizing year for the 21<sup>st</sup> Century Cures Act, which was signed into law on December 13, 2016. Over a 10-year period, the Cures Act authorized \$4.8 billion for NIH to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies. The Cures Act notably provided multi-year funding for four Innovation Projects: *All of Us*, Brain Research through Advancing Innovative Neurotechnologies (BRAIN®) Initiative, Cancer Moonshot<sup>SM</sup>,<sup>18</sup> and the Regenerative Medicine

<sup>17</sup> [niddk.nih.gov/about-niddk/budget-legislative-information/how-special-diabetes-program-creating-hope-living-with-type-1-diabetes](https://niddk.nih.gov/about-niddk/budget-legislative-information/how-special-diabetes-program-creating-hope-living-with-type-1-diabetes)

<sup>18</sup> [cancer.gov/research/key-initiatives/moonshot-cancer-initiative](https://cancer.gov/research/key-initiatives/moonshot-cancer-initiative)

Innovation Project. Authorized funding for *All of Us* and BRAIN in FY 2026 totals \$226.0 million. There is no authorized funding for Cancer Moonshot in FY 2026, as Cures Act authorized funding for Cancer Moonshot ended in FY 2023. The Budget will provide these two programs with a solid base of funding to continue program activities following the complete expiration of Cures Act funding after FY 2026.

## **Preparing for and Preventing Emerging and Continued Public Health Threats**

### Advancing Universal Vaccines

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 9.3 million and 41 million illnesses, between 120,000 and 710,000 hospitalizations, and between 6,300 and 52,000 deaths annually between 2010 and 2024,<sup>19</sup> all of which results in an estimated \$87.1 billion in total annual economic burden.<sup>20</sup> 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 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. Several universal influenza vaccine candidates developed by the National Institute of Allergy and Infectious Diseases (NIAID) are currently being tested in clinical trials, including those using protein nanoparticle and inactivated virus platform technologies. Some of the candidate vaccines are capable of inducing antibody responses against several influenza strains. Additionally, NIH-supported researchers are actively identifying and developing novel adjuvants for influenza vaccines to increase their effectiveness and durability. Continued investment in this research will enable the development of universal influenza vaccines to protect millions of people from infection.

In May 2025, HHS and NIH announced the development of the next-generation, universal vaccine platform, Generation Gold Standard, using a beta-propiolactone (BPL)-inactivated, whole-virus platform.<sup>21</sup> This initiative represents a decisive shift toward transparency, effectiveness, and comprehensive preparedness, funding the development of universal influenza and coronavirus vaccines, including candidates BPL-1357 and BPL-24910. These vaccines aim to provide broad-spectrum protection against multiple strains of pandemic-prone viruses such as H5N1 avian influenza and coronaviruses including SARS-CoV-2, SARS-CoV-1, and MERS-CoV.

#### Generation Gold Standard:

- Recalibrates America’s pandemic preparedness. Unlike traditional vaccines that target specific strains, BPL-inactivated whole-virus vaccines preserve the virus’s structural

<sup>19</sup> [cdc.gov/flu-burden/php/about/index.html](https://www.cdc.gov/flu-burden/php/about/index.html)

<sup>20</sup> [pubmed.ncbi.nlm.nih.gov/17544181/](https://pubmed.ncbi.nlm.nih.gov/17544181/)

<sup>21</sup> [nih.gov/news-events/news-releases/hhs-nih-launch-next-generation-universal-vaccine-platform-pandemic-prone-viruses](https://www.nih.gov/news-events/news-releases/hhs-nih-launch-next-generation-universal-vaccine-platform-pandemic-prone-viruses)

integrity while eliminating infectivity. This approach induces robust B and T cell immune responses and offers long-lasting protection across diverse viral families. Moreover, the intranasal formulation (i.e., taken through the nose) of BPL-1357 is currently in Phase Ib and II/III trials and is designed to block virus transmission—an innovation absent from current flu and COVID-19 vaccines.

- Embodies efficient, transparent, and government-led research.
- Marks the future of vaccine development. In addition to influenza and coronavirus, the BPL platform is adaptable for future use against respiratory syncytial virus (RSV), metapneumovirus, and parainfluenza. It also offers the unprecedented capability to protect against avian influenza without causing mutations in the virus that allow it to evade immune response—a major step forward in proactive pandemic prevention.

### **The Future is Bright: NIH’s Innovative Approaches for Scientific Discovery**

NIH uses scientific advances and innovative, cutting-edge research methodologies today to create the basic and clinical research discoveries of tomorrow. NIH also fosters and develops the next generation of biomedical researchers, whose innovative ideas will be the backbone of future of biomedical research.

#### **NIH Clinical Research Engagement Efforts**

Individuals, communities, and members of the public are essential and equal partners in the success of clinical research. During a series of in-person conversations held in six communities across the country by NIH in support of efforts of the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC),<sup>22</sup> members of the public emphasized the importance of engagement early and often during the clinical research process to build trust and transparency between NIH-funded researchers and the broader public. More information is needed on how to incorporate meaningful public engagement across the full clinical research lifecycle. To address this issue, NIH asked the NExTRAC to form the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group, a group of patients, advocates, researchers, clinicians, and non-profit representatives tasked with developing a vision and framework for incorporating public voices in all phases and types of clinical research.

In its first year, the ENGAGE Working Group has drafted a definition of clinical research engagement, developed a vision and goal, and is creating a framework for incorporating public voices in clinical research. Its progress was presented during a public meeting of the NExTRAC in June 2024.<sup>23</sup> NIH has launched a website<sup>24</sup> focused on clinical research engagement that includes case studies<sup>25</sup> describing successful tools and methods for engaging the public in NIH-funded clinical research. In July 2024, NIH, in support of the ENGAGE Working Group, hosted a virtual listening session<sup>26</sup> to understand public perspectives on clinical research engagement and has since hosted six in-person conversations<sup>27</sup> around the country to speak directly to

<sup>22</sup> [osp.od.nih.gov/wp-content/uploads/2023/02/Tab3\\_NIH\\_UCSD\\_Workshop\\_Community\\_Conversation\\_Summary\\_230227\\_508.pdf](https://osp.od.nih.gov/wp-content/uploads/2023/02/Tab3_NIH_UCSD_Workshop_Community_Conversation_Summary_230227_508.pdf)

<sup>23</sup> [partnersinresearch.nih.gov/events/novel-and-exceptional-technology-and-research-advisory-committee-meeting/](https://partnersinresearch.nih.gov/events/novel-and-exceptional-technology-and-research-advisory-committee-meeting/)

<sup>24</sup> [partnersinresearch.nih.gov/](https://partnersinresearch.nih.gov/)

<sup>25</sup> [partnersinresearch.nih.gov/case-studies/](https://partnersinresearch.nih.gov/case-studies/)

<sup>26</sup> [partnersinresearch.nih.gov/events/nih-engage-virtual-webinar-and-listening-session/](https://partnersinresearch.nih.gov/events/nih-engage-virtual-webinar-and-listening-session/)

<sup>27</sup> [partnersinresearch.nih.gov/community-conversations/](https://partnersinresearch.nih.gov/community-conversations/)

communities on their needs, perspectives, and goals for clinical research engagement. The information gathered during these conversations will inform NExTRAC’s report on how to meaningfully engage the public during all phases of clinical research.

### **Cutting-Edge Technologies to Progress Biomedical Research Forward**

Increasing use of new and improved biomedical technologies, such as gene editing, AI, and induced pluripotent stem cells, is fundamentally changing the way science is done. Harnessing the power of emerging technologies to advance novel scientific approaches holds tremendous promise for helping us better understand fundamental biology to advance human health.

#### Integrating Artificial Intelligence Across the Biomedical Research Enterprise

AI has spurred tremendous advances in medical research to enhance human health and longevity. For example, using AI, researchers can enable real-time mental health interventions through digital health devices, better forecast which seasonal flu viruses may circulate to manage public health, and integrate across large volumes of multi-modal data to guide personalized medicine. NIH advances the safe and responsible use of AI in biomedical research by 1) supporting development of algorithms and models for research; 2) contributing to AI-ready data and infrastructure, including computing and datasets that accelerate discovery; and 3) encouraging multi-disciplinary partnerships that drive transparency, privacy, and equitable health. At the same time, without proper safeguards, AI models and algorithms may exacerbate ongoing challenges associated with large datasets such as protecting privacy. Fortunately, NIH has a robust suite of relevant research policies to protect research participants and the privacy of their data while prioritizing public health and safety. Finally, NIH is actively piloting mechanisms to ease administrative processes through AI and train members of the workforce on when and how to employ AI responsibly. Detailed illustrations of NIH AI efforts include:

#### Scoping the use of AI across biomedical research through focused research funding

For example, the Bridge to AI (B2AI) program sets the stage for widespread adoption of AI in medicine by defining best practices for AI analyses, establishing training curricula, and generating new, ethically sourced “flagship” data sets for broad community use. This program and work by other NIH-funded investigators have already contributed to studies demonstrating that AI can speed identification of genetic variations underlying Alzheimer’s and rare diseases, “read” X-rays to provide earlier detection and more accurate prognosis for certain cancers, and assess heart disease and risk of stroke through non-invasive imaging of the eye.

#### Resources to cultivate a culture of safe and responsible use of AI in biomedical research

To guide investigators and mitigate risks, NIH has a robust system of policies relevant for research with AI.<sup>28</sup> For example, the “Common Rule” ensures institutional oversight for research with human participants through Institutional Review Boards,<sup>29</sup> the NIH Certificates of Confidentiality policy protects research data from unauthorized disclosure,<sup>30</sup> and the NIH Policy on Data Management and Sharing ensures NIH review of investigators’ plans for responsible data sharing and management.<sup>31</sup> NIH also supports investigator costs for data sharing,

<sup>28</sup> [osp.od.nih.gov/policies/artificial-intelligence/](https://osp.od.nih.gov/policies/artificial-intelligence/)

<sup>29</sup> [grants.nih.gov/grants/guide/notice-files/NOT-OD-19-050.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-050.html)

<sup>30</sup> [grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc](https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc)

<sup>31</sup> [sharing.nih.gov/data-management-and-sharing-policy](https://sharing.nih.gov/data-management-and-sharing-policy)

management and storage to maximize reuse of data, and provides processes and infrastructure for controlled access to sensitive data. Importantly, recognizing that AI may raise new challenges, NIH's Advancing Health Research through Ethical, Multimodal AI Initiative aims to improve our understanding of the complexities of human disease by finding ethically appropriate ways to leverage powerful multimodal AI approaches.<sup>32</sup> Administered from the NIH Office of Data Science Strategy (ODSS), the program will establish a portfolio of innovative projects that address systems level biomedical challenges using collaborative and participatory approaches for multimodal AI that will elucidate unique opportunities, risks, and challenges.

#### Commitment to integration of AI appropriate for a more effective workforce

NIH has supported development and application of AI in research for decades. Internally, NIH employees are testing AI analysis of research portfolios to identify emerging research priorities and ease the administrative burden associated with grant applications and referrals. Additionally, the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative aims to provide researchers with equal access to powerful cloud computing systems. Through the STRIDES Cloud Lab, NIH and NIH-funded institutions use cloud-based computational architecture as a testbed to learn how to share and analyze data, including through AI applications. Finally, NIH has several incipient efforts to integrate AI into day-to-day work, including a generative AI community of practice where hundreds of staff share AI tools, training, and lessons learned and generative AI chatbots in beta testing within a secure environment. NIH expects these activities to yield productivity-enhancing tools that are used responsibly and expand on NIH's existing use of AI in grants management processes.

#### Charting the Course for the Development and Use of New Approach Methods

From its founding to the present day, NIH has funded research into the development and application of new approach methods/methodologies (NAMs) 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 refine the use of animals in research. 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 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 distinct settings. In January 2023, the Acting NIH Director charged an Advisory Committee to the Director's Working Group on *Catalyzing the Use and Development of Novel Alternative Methods* to consider how NAMs are being used and to make recommendations on where NAMs may be most applicable or beneficial, especially to advance our understanding of human health.<sup>33</sup> This Working Group included 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 final report, published in December 2023, identified bold, ambitious, and equitable high priority areas for future investment and highlighted opportunities to integrate the work of different disciplines, sectors, technologies, and data.<sup>34,35</sup> Consistent with the report, NIH announced a new NIH-wide

<sup>32</sup> [datascience.nih.gov/artificial-intelligence/MultimodalAI](https://datascience.nih.gov/artificial-intelligence/MultimodalAI)

<sup>33</sup> [acd.od.nih.gov/working-groups/novel-alternatives.html](https://acd.od.nih.gov/working-groups/novel-alternatives.html)

<sup>34</sup> [acd.od.nih.gov/documents/presentations/12142023\\_NAMs\\_Working\\_Group\\_Report.pdf](https://acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf)

<sup>35</sup> [acd.od.nih.gov/documents/presentations/12142023\\_NAMs\\_Working\\_Group\\_Report.pdf](https://acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf)

Common Fund program called Complement Animal Research in Experimentation (Complement-ARIE), to catalyze the development, standardization, validation, and use of human-based NAMs.<sup>36</sup> Complement-ARIE has already awarded \$1 million in a crowdsourcing prize competition and plans to publish funding opportunities to create Technology Development Centers, a NAMs Data Hub and Coordinating Center, and a Validation and Qualification Network.<sup>37</sup> The program is expected to launch in full in winter of 2025.

In April 2025, NIH announced a new initiative to expand innovative, human-based science while reducing animal use in research.<sup>38</sup> Developing and using cutting-edge alternative non-animal research models aligns with the FDA's recent initiative<sup>39</sup> to reduce testing in animals. While traditional animal models continue to be vital to advancing scientific knowledge, using new and emerging technologies can offer unique strengths that, when utilized correctly or in combination, can expand the toolbox for researchers to answer previously difficult or unanswerable biomedical research questions.

To integrate innovative human-based science, NIH intends to establish the Office of Research Innovation, Validation, and Application (ORIVA) within NIH's Office of the Director. The new office will coordinate NIH-wide efforts to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection.

ORIVA will expand funding and training in non-animal approaches and awareness of their value in translational success. New funding opportunities will include evaluation criteria that assess methods based on their suitability for the research question, context of use, translatability, and human relevance. Infrastructure for non-animal approaches will also be expanded to make these methods more accessible to researchers.

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

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

#### **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

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<sup>36</sup> [commonfund.nih.gov/complementarie/strategicplanning](https://commonfund.nih.gov/complementarie/strategicplanning)

<sup>37</sup> [commonfund.nih.gov/complementarie/](https://commonfund.nih.gov/complementarie/)

<sup>38</sup> [nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies](https://nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies)

<sup>39</sup> [fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs](https://fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs)

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 for a Changing Biomedical Research Landscape

Facilities must co-evolve with science for NIH to achieve its full potential. In the FY 2026 President's Budget, the NIH request for Buildings and Facilities (B&F) is \$210.0 million, a \$140.0 million decrease from the FY 2025 Full-Year CR. These amounts 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 and Repair (BMAR) was approximately \$4.1 billion at the end of FY 2024. The B&F request would enable NIH to improve the condition of its facilities and continue to curtail the growth of the BMAR. Research facilities will play an important role in NIH's ability 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.

### Modernizing Data Ecosystems

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

### **Impactful Policy to Shape Biomedical Research**

Ensuring the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science is paramount to cultivating trust. NIH has for many years been a leader in promoting practices, policies, and procedures that help ensure that the research it funds and conducts is done in accordance with the highest possible standards.

### Establishing an NIH Academic Freedom Policy

NIH seeks to foster a culture in which scientists are incentivized to engage in open academic discourse in pursuit of NIH's mission to seek fundamental knowledge and improve the health of all Americans. Open debate is the cornerstone of scientific progress as interrogating evidence and challenging the status quo are essential for ensuring scientific rigor and meaningful results.

NIH will undertake a comprehensive review of all policies and practices within its Intramural Research Program (IRP) to establish academic freedom as the rule and not the exception.<sup>40</sup> With principles of academic freedom in place, NIH scientists can be certain they are afforded the ability to engage in open academic discourse as part of their official duties and in their personal capacities without risk of official interference, professional disadvantage or workplace retaliation.

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<sup>40</sup> [nih.gov/about-nih/who-we-are/nih-director/statements/nih-reviews-policies-promote-academic-freedom](https://nih.gov/about-nih/who-we-are/nih-director/statements/nih-reviews-policies-promote-academic-freedom)

NIH policies have always supported the public dissemination of research. However, academic freedom matters most in the edge cases where scientists are pursuing evidence that others find inconvenient or objectionable. By prioritizing academic freedom across the agency, NIH can work to restore public trust in NIH's ability to carry out its mission.

### Maximizing Access to Publications and Data that Result from NIH-Supported Research

Building public trust in science is an important aspect of public health. The responsible stewardship and sharing of scientific research data with the public is an important part of building trust, as is ensuring the results of NIH-funded research are publicly available in a timely manner. NIH has a long-standing commitment to supporting data access and to ensuring public access to publications resulting from NIH funding.

In January 2023, after several years of communications with the research community, NIH implemented the Data Management and Sharing Policy (issued in October 2020) to promote the sharing of scientific data.<sup>41</sup> Under this policy, NIH expects investigators and institutions to: 1) plan and budget for the managing and sharing of data; 2) submit a data management and sharing plan for review when applying for funding; and 3) comply with the approved data management and sharing plan. This policy expects researchers to maximize appropriate sharing of scientific data underlying peer-reviewed journal articles while protecting privacy, the rights of research participants, and compliance with laws, regulations, and policies. Planning for how scientific data will be managed and ultimately shared is a crucial step in enhancing the impact of NIH-supported research and will aid in accelerating biomedical research discovery by enabling validation of research results, providing access to high-value datasets, and promoting data reuse for future research studies.

NIH's longstanding commitment to making publications resulting from NIH funding available is reflected in its 2008 Public Access Policy, which requires the submission of such publications to NIH's PubMed Central with a maximum embargo period of 12 months before they must be publicly available. In June 2024 NIH released its Draft Public Access Policy, which outlines the proposal to require that NIH-funded publications be freely available and publicly accessible upon publication without embargo, for public comment.<sup>42</sup> To accelerate access to research results, NIH recently moved up the implementation date of the Public Access Policy from December 31, 2025; it will now be effective July 1, 2025.<sup>43</sup> The revised Public Access Policy will replace the 2008 Policy. To develop the Draft Public Access Policy, NIH sought the input of partners and the public. NIH considered ideas gathered through a public listening session, an NIH-sponsored workshop held by the National Academies of Science, Engineering and Medicine, and comments submitted in response to the request for information (RFI) on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research.<sup>44</sup> Implementing timely access to publications resulting from NIH funding offers many benefits to the scientific community and the public who funded the underlying work. The ability for patients, families, and members of the public to rapidly access published findings resulting from NIH funding enables them to better understand

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<sup>41</sup> [grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html)

<sup>42</sup> [federalregister.gov/documents/2024/06/18/2024-13373/request-for-information-on-the-national-institutes-of-health-draft-public-access-policy](https://federalregister.gov/documents/2024/06/18/2024-13373/request-for-information-on-the-national-institutes-of-health-draft-public-access-policy)

<sup>43</sup> [sharing.nih.gov/public-access-policy/public-access-policy-overview](https://sharing.nih.gov/public-access-policy/public-access-policy-overview)

<sup>44</sup> [grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html)

and address the most critical public health concerns facing their communities. It also allows researchers, students, and health care providers in all communities to have access to such content. This access can accelerate future research, lead to collaboration, and allow interested readers and patients to keep up more closely with critical advances.

Additionally, as indicated in NIH's Plan to Enhance Public Access to the Results of NIH-Supported Research, NIH is working to ensure the appropriate uses of metadata and persistent identifiers related to authors, scholarly publications, and scientific data. Specifically, NIH is considering how NIH-supported authors, manuscripts, and data will be identified with metadata that are conveyed in public access repositories to ensure proper attribution and versioning. An updated plan to achieve these goals was published in December 2024,<sup>45</sup> with a final policy to be implemented by 2027. These efforts strive to promote the highest level of scientific integrity and public accountability while also promoting recognition of researchers' contributions.

#### NIH's Commitment to Promoting Safe and Secure Research

Research focused on understanding how pathogens evolve and spread is critical for protecting public health and safeguarding national security. To ensure this research is conducted safely and securely, the United States must implement a comprehensive biosafety, biocontainment, and biosecurity oversight system. This system must be built on a robust foundation of regulations, guidelines, and policies that create an interlocking set of responsibilities shared across federal and local governments, research funders, research institutions, and researchers themselves.

In May 2025, the President issued an Executive Order (EO) on *Improving the Safety and Security of Biological Research*. The EO addresses risks associated with dangerous gain-of-function research and the procurement of synthetic nucleic acids. NIH is working with the Office of Science and Technology Policy and the National Security Council to implement the provisions of the EO and ensure effective and consistent implementation. In FY 2026, NIH will continue to prioritize its stewardship over biosafety and biosecurity oversight at NIH-supported institutions, including by furthering work toward implementing these policies and continuing to strengthen education and outreach to ensure effective implementation of these and all other relevant United States policies.

#### Patient Access Planning

NIH funding is critical to stimulating new knowledge and discoveries driving innovation across sectors, and the agency seeks to drive effective partnerships that foster a shared commitment to transforming knowledge into improved health for all. NIH recognizes that all too often, however, patients across the country and across the globe may be unable to access medical products they need: a treatment for their disease may not yet exist or it might exist but be out of reach because it is too expensive or difficult to take. NIH has proposed a new patient access planning policy within the NIH IRP, which would involve incorporating patient access consideration into the commercialization process for NIH-owned inventions.<sup>46</sup> NIH has proposed a flexible approach to allow licensees to pursue tailored, commercially reasonable strategies that promote patient access across a range of medical technologies. Such early access planning can be a crucial step in

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<sup>45</sup> [grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html)

<sup>46</sup> [osp.od.nih.gov/policies/innovation-and-translation#tab1/](https://osp.od.nih.gov/policies/innovation-and-translation#tab1/)

advancing equitable patient access to emerging biomedical technologies, and NIH is committed to helping licensees achieve access goals.

### **Conclusion**

The Nation's investment in NIH is born from the recognition that a healthy population is a productive and thriving population. NIH fosters 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 NIH's mission of improving the health and wellbeing for all. Each year, NIH awards thousands of competitive grants that directly support researchers at research institutions across the country.

A healthier nation is a more productive and economically sound nation. Each permanent one percent reduction in cancer deaths alone has been approximated to have a value of nearly \$500 billion to current and future generations of Americans. A full cure could be worth more than three times today's GDP.<sup>47</sup> The benefits of NIH research can be felt in the near term through development of novel health interventions and continue well into the future as transformations in the diagnosis, prevention, and treatment of disease today become standard practice tomorrow.

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<sup>47</sup> [ucema.edu.ar/u/je49/capital\\_humano/Murphy\\_Topel\\_JPE.pdf](http://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 to apply 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 2026 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*,<sup>48</sup> NIH supports a wide spectrum of biomedical and behavioral research and engages in a full range of activities that enable research. Because of this variability 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.

### **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 its component Institutes 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 Institutes and helps identify needs and opportunities, especially for efforts that involve multiple institutes. The

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<sup>48</sup> [nih.gov/about-nih/nih-wide-strategic-plan](https://www.nih.gov/about-nih/nih-wide-strategic-plan)

Institutes 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, challenges, and new opportunities; 4) oversight by institute 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 institute and OD office leadership to enhance activities; 6) regular reviews of priorities, progress, and outcomes by the NIH Director and Institute 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 National Advisory Councils of the Institutes. 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.<sup>49</sup> 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 Institute

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<sup>49</sup> As of February 2025, the standing working groups are: Board of Scientific and Clinical Directors; Clinical Center Governing Board; Data Science Policy Council; Extramural Activities Working Group; Enterprise Information Technology Council; Facilities Working Group; Management and Budget Working Group; Research Services Working Group; and the Scientific Data Council.

Directors with the NIH Director, will foster the collaborative identification of corporate issues and a transparent decision-making process. With active participation by the Institute Directors in NIH-wide governance, NIH can maximize its perspective and expertise in the development and oversight of policies common to NIH and its components. 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 Institute Directors. The NIH Director meets with the Institute 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 Institute and OD Office Directors. Similarly, the Institute Directors monitor performance through regular meetings with the Division Directors and Scientific/Clinical Directors in their respective Institutes.

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.

## ALL PURPOSE TABLE

(Dollars in Millions) <sup>1,2,3,4</sup>	FY 2024	FY 2025	FY 2026	
	Final	Enacted	President's Budget	+/- FY 2025 Enacted
<b>Total, NIH Program Level</b>	<b>\$46,357.946</b>	<b>\$46,001.287</b>	<b>\$27,915.100</b>	<b>-\$18,086.187</b>
<b>Less mandatory and funds allocated from different sources:</b>				
PHS Program Evaluation	\$1,412.482	\$1,412.482	\$250.000	-\$1,162.482
Mandatory Type 1 Diabetes Research - Baseline	\$195.753	\$119.094	\$0.000	-\$119.094
Mandatory Type 1 Diabetes Research - Proposed	<u>\$0.000</u>	<u>\$0.000</u>	<u>\$159.000</u>	<u>\$159.000</u>
Mandatory Type 1 Diabetes Research - Subtotal	<u>\$195.753</u>	<u>\$119.094</u>	<u>\$159.000</u>	<u>\$39.906</u>
<b>Total, NIH Discretionary Budget Authority<sup>5</sup></b>	<b>\$44,749.711</b>	<b>\$44,469.711</b>	<b>\$27,506.100</b>	<b>-\$16,963.611</b>
<i>Number of Competing RPGs</i>	<i>10,086</i>	<i>6,095</i>	<i>4,312</i>	<i>-1,783</i>
<i>Total Number of RPGs</i>	<i>42,143</i>	<i>38,069</i>	<i>27,478</i>	<i>-10,591</i>
<i>FTE<sup>6,7</sup></i>	<i>19,089</i>	<i>19,031</i>	<i>16,297</i>	<i>-2,734</i>

<sup>1</sup> Numbers may not add due to rounding.

<sup>2</sup> Includes 21st Century Cures Act funding; excludes supplemental and emergency funding.

<sup>3</sup> The FY 2026 Budget proposes to relocate NIEHS and NIEHS Superfund from NIH to the Administration for a Healthy America. Funding levels in this table are displayed comparably and as a result do not include \$993.521 million in each of FY 2024 and FY 2025 for these programs. For information on these programs, please see the AHA Congressional Justification.

<sup>4</sup> The FY 2024 and FY 2025 columns reflect a reduction by transfer of \$5.0 million from OD to the HHS Office of Inspector General.

<sup>5</sup> All budget authority is within the Labor/HHS appropriations subcommittee.

<sup>6</sup> Includes 4 NIH FTEs funded by PHS trust funds in all years.

<sup>7</sup> FY 2026 FTE levels reflect estimates and are subject to change.

## IMPACT OF BUDGET LEVEL ON PERFORMANCE

<b>Programs and Measures<sup>1</sup></b> (Dollars in Millions, except where noted)	<b>FY 2024 Final</b>	<b>FY 2025 Full-Year CR</b>	<b>FY 2026 President's Budget</b>	<b>FY 2026 +/- FY 2025</b>
Research Project Grants	\$26,221.126	\$26,683.583	\$15,112.853	-43.4%
Competing Average Cost (in thousands)	\$598	\$969	\$863	-10.9%
Number of Competing Awards (whole number)	10,086	6,095	4,312	-29.3%
Estimated Competing RPG Success Rate	18.5%	10.3%	7.3%	-29.1%
Research Centers	\$2,706.087	\$2,612.069	\$1,484.319	-43.2%
Other Research	\$3,135.587	\$3,109.077	\$1,860.681	-40.2%
Training	\$978.924	\$1,013.730	\$654.470	-35.4%
Research & Development Contracts	\$3,742.850	\$3,128.497	\$2,027.602	-35.2%
Intramural Research	\$4,924.989	\$4,942.933	\$3,625.439	-26.7%
Research Management and Support	\$2,429.454	\$2,492.469	\$1,757.570	-29.5%
<i>Common Fund (non-add)</i>	\$685.001	\$685.001	\$347.401	-49.3%
Buildings & Facilities Appropriation	\$350.000	\$350.000	\$210.000	-40.0%
Other Mechanisms <sup>2,3</sup>	\$1,868.929	\$1,668.929	\$1,182.166	-29.2%
<b>Total, Program Level<sup>4</sup></b>	<b>\$46,357.946</b>	<b>\$46,001.287</b>	<b>\$27,915.100</b>	<b>-39.3%</b>

<sup>1</sup> The FY 2026 Budget proposes to relocate NIEHS and NIEHS Superfund from NIH to the Administration for a Healthy America. Funding levels in this table are displayed comparably and as a result exclude NIEHS and NIEHS Superfund in FY 2024 and FY 2025. For NIEHS and Superfund amounts excluded are \$993.5 million (FY 2024 and FY 2025).

<sup>2</sup> Includes Office of the Director-Other, and Buildings and Facilities funding in the National Cancer Institute.

<sup>3</sup> Amounts in FY 2024 and FY 2025 reflect directive transfer of \$5.0 million to the HHS Office of Inspector General.

<sup>4</sup> Includes discretionary budget authority received from Labor/HHS appropriations bill. Also includes program evaluation financing and mandatory budget authority for Type 1 Diabetes.