

INTRODUCTION AND MISSION

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

As the Nation's premier 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 economic well-being, particularly as we face COVID-19, the greatest public health crisis of our generation. NIH also works to develop, maintain, and renew scientific, human, and physical resources that will ensure the Nation's capability to prevent disease and disability. The biomedical research enterprise depends upon not only NIH's support of cutting-edge science and technology, but also its wise investment of tax dollars. Through careful stewardship of public resources in pursuit of its mission, NIH strives to enhance the lives of all Americans.

OVERVIEW OF BUDGET REQUEST

Introduction

The National Institutes of Health (NIH) requests a total program level for FY 2022 of \$52.0 billion, which is \$9.0 billion more than the FY 2021 Enacted level. Included in the request is a bold new investment of \$6.5 billion to establish the Advanced Research Projects Agency for Health (ARPA-H), which aims to drive transformational health research innovation and speed medical breakthroughs by tackling ambitious challenges requiring large-scale, sustained, and cross-sector coordination.

The request incorporates strategic investments to address several national priorities, including combatting the COVID-19 pandemic through countermeasures and researching its effects on mental health and the health of children, fighting the opioid epidemic, eradicating HIV in the United States, addressing health disparities and inequities, continuing efforts to tackle maternal mortality and morbidity, researching the human health impacts of climate change, and strengthening cybersecurity at NIH.

NIH is developing the *NIH-Wide Strategic Plan, Fiscal Years 2021–2025*. This plan will outline a vision for biomedical research to capitalize on new opportunities for scientific exploration and address new challenges for human health. Being developed with input from hundreds of stakeholders and scientific advisers, and in collaboration with leadership and staff of NIH’s Institutes, Centers, and Offices (ICOs), the plan is being designed to complement the ICOs’ individual strategic plans, which align with their congressionally mandated missions. The agency has also released the NIH-wide COVID-19 Strategic Plan, which provides a framework for accelerating the development of therapeutic interventions, vaccines, and diagnostics.¹

The Buildings & Facilities (B&F) account budget request is \$250.0 million, a \$50.0 million increase from the FY 2021 Enacted level. NIH’s backlog of maintenance and repair (BMAR) was \$2.5 billion at the end of FY 2020. The budget also increases flexibility for Institutes and Centers to fund construction, repair, and improvement projects. These two proposals are part of a long-term effort to strengthen stewardship of NIH facilities. An independent review of the facility needs of NIH’s main campus by the National Academies of Sciences, Engineering, and Medicine that was released in 2019 supports additional investments in NIH facilities alongside reforms to the NIH capital planning and funding process, including prioritizing projects of highest functional research value.² In addition to efforts to improve physical infrastructure, the request invests in NIH’s information technology infrastructure through a \$100.0 million increase to enhance NIH-wide cybersecurity efforts.

In striving to achieve its mission, NIH supports a world-class research workforce that aims to better understand the fundamental nature of disease. The knowledge from this research can then be harnessed to move the biomedical research enterprise forward, ultimately benefiting the human and economic health of our country.

¹ www.nih.gov/research-training/medical-research-initiatives/nih-wide-strategic-plan-covid-19-research

² www.nationalacademies.org/our-work/assessing-the-capital-needs-of-the-national-institutes-of-health-main-campus

More than 80 percent of the NIH's funding is awarded for extramural research, largely through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state. A recent study showed that NIH directly supported the training of more than 9,500 pre-doctoral and almost 5,900 post-doctoral fellows through training grants.³ To date, 163 NIH-supported researchers, including 26 intramural investigators, have been awarded the Nobel Prize.⁴ The Lasker Prize, which is often called "America's Nobel," recognizes researchers and clinicians for their contributions to medicine and has been awarded to 195 NIH-supported researchers, including 33 intramural investigators to date.⁵

NIH and the biomedical research community are coming together in unprecedented ways to meet the challenges of developing safe and effective therapeutic treatments and vaccines, accurate and reliable testing technologies, and behavioral and community prevention practices in response to the COVID-19 pandemic. The community must also grapple with the unprecedented impacts and massive disruption to the research enterprise. Many NIH-supported research projects across the Nation have ground to a halt as universities and other research institutions have suspended operations. In some instances, this has resulted in the loss of critical biological resources that will have to be recreated. Similarly, the research workforce, particularly early-career scientists, faces significant challenges as the opportunity to generate and collect data has been disrupted.

Science in Service to Society

Answering the Call

NIH research has proven its value to the United States and the world over the years by rising to meet the tests of polio, AIDS, and many other formidable health challenges. Now, we face what may be the greatest public health crisis of our generation: COVID-19. To address the challenge that the COVID-19 pandemic poses to our health and economy, it is imperative that NIH and all sectors of society work together in unprecedented ways and with unprecedented speed. Enabled by the strong support of Congress and other partners in the public and private sectors, NIH has mounted a vigorous research response against COVID-19 since the beginning of the pandemic. The agency has expanded efforts to understand viral biology and pathogenesis of SARS-CoV-2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease. By April 2020, the agency announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. Later in April 2020, NIH launched the Rapid Acceleration of Diagnostics (RADxSM) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. The breathtaking pace and scope of this response have been made possible by decades of NIH-funded basic research, which built a priceless foundation for the current efforts to combat COVID-19.

³ www.ncbi.nlm.nih.gov/pubmed/26625903

⁴ www.nih.gov/about-nih/what-we-do/nih-almanac/nobel-laureates

⁵ www.nih.gov/about-nih/what-we-do/nih-almanac/lasker-awards

As researchers make stunning progress on treatments and vaccines to combat COVID-19, the long-term health impacts remain unclear. NIH is supporting studies in diverse populations, including pregnant women, infants, and children, supported by \$1.15 billion in emergency supplemental appropriations enacted in December 2020.⁶ The FY 2022 Budget request includes an additional \$15.0 million for research on multisystem inflammatory syndrome in children (MIS-C) and the spectrum of SARS-CoV-2 pediatric risks. For many Americans, this pandemic has been overwhelming, affecting their mental health. Prior research on disasters and epidemics has shown that in the immediate wake of a traumatic experience, large numbers of affected people report distress, including new or worsening symptoms of depression, anxiety, and insomnia. To aid in mental health recovery from the COVID-19 pandemic, \$25.0 million is requested to increase research on the impact of the pandemic on mental health and the mental health delivery system. This will be done in part by utilizing participants of the *All of Us* Research Program, who will be surveyed on the effect of the pandemic and various mitigation measures on their physical and mental health.

The public health crisis of opioid misuse and addiction in America continues, exacerbated by the coronavirus pandemic. In 2019, 70,630 people in the United States died of overdose, including 49,860 dying from opioid overdose (70.6 percent of all drug overdose deaths).⁷ Moreover, more than 50 million Americans suffer from chronic pain, and of those, 25 million live with daily chronic pain and lack effective and safe non-opioid options for pain management.⁸ The widespread use of opioids to treat acute and chronic pain contributed to the approximately 10.3 million people aged 12 years and older in the United States in 2018 who misused opioids, including heroin.⁹ These staggering numbers are likely underestimates. They fail to capture the full extent of the damage of the opioid crisis, which reaches across every domain of family and community life — from lost productivity and economic opportunity, to intergenerational and childhood trauma, to extreme strain on community resources, including first responders, emergency rooms, hospitals, and treatment centers. NIH launched the Helping to End Addiction Long-termSM Initiative, or NIH HEAL Initiative, to provide scientific solutions to the opioid crisis and offer new hope for individuals, families, and communities affected by this devastating crisis. The FY 2022 Budget includes total funding of \$2.2 billion to address the opioid crisis across the ICUs, an increase of \$626.6 million over the FY 2021 funding level. The use of opioids, together with stimulants, such as methamphetamine, is increasing; and deaths attributed to using these combinations are likewise increasing. Taking note of these trends, FY 2021 appropriation language expanded allowable used of HEAL funds to include research related to stimulant misuse and addiction. Identifying how opioids and stimulants interact in combination to produce increased toxicity will enhance our ability to develop medications to prevent and treat comorbid opioid and stimulant use disorders and overdoses associated with this combination of drugs.

⁶ www.congress.gov/bill/116th-congress/house-bill/133/text

⁷ www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf

⁸ pubmed.ncbi.nlm.nih.gov/26028573/

⁹ www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf

Another area of immense importance and concern is maternal morbidity and mortality. Maternal health spans a wide array of topics on the health of pregnant women and mothers, including pregnancy-related disorders -- preeclampsia, pregnancy-induced hypertension, gestational diabetes (GDM) preterm labor, hemorrhage, and other complications that pose acute risks and may have long-term consequences. Renewed awareness that the United States lags markedly behind other developed countries in preventing maternal mortality and morbidity lends urgency to basic and clinical research on multiple determinants of maternal health. Collaborative efforts of NIH ICOS focus on both basic mechanisms that set the course of healthy pregnancies and the disease processes that are implicated in pregnancy complications. Critical research goals are to identify new treatments, determine how to test existing therapies for safety and effectiveness in the unique physiology of pregnant women and lactating women, and develop effective strategies to prevent adverse maternal outcomes. Triggering particular urgency is the growing recognition that Black and American Indian/Alaska Native women are disproportionately affected by maternal morbidity and mortality.

In response to the rising maternal mortality (MM) in the United States, the FY 2022 Budget provides \$30.0 million for the Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative, which will support research on how to mitigate preventable MM, decrease severe maternal morbidity (SMM), and promote health equity in the United States. The initiative will address the leading causes of SMM/MM during pregnancy, at delivery, and up to one year post-partum. It will build on ongoing efforts among federal and other partners and stakeholders to accelerate progress and maximize reach and impact by leveraging existing resources (*e.g.*, previously studied cohorts and archived biospecimens) and developing new studies. IMPROVE proposes to launch a national network of Maternal Health Research Centers of Excellence that supports integrated biological and biopsychosocial research. The research projects will incorporate local community needs and perspectives to expand and complement existing research efforts by developing, implementing, and evaluating community-tailored interventions to address health disparities in SMM/MM, as well as investigate biological, behavioral, sociocultural, and structural risk factors and mechanisms of the leading causes of SMM/MM. Through this multidimensional strategy, IMPROVE aims to build an evidence-based approach to reducing SMM/MM and its associated health disparities.

Among the still other public health crises our Nation faces are the health threats brought by climate change and gun violence. As the climate continues to change, the risks to human health will grow, exacerbating existing health threats and creating new public health challenges. While all Americans will be affected by climate change, populations of concern are disproportionately vulnerable. These populations of concern include children, the elderly, outdoor workers, and those living in disadvantaged communities. The FY 2022 Budget includes a \$100.0 million increase for research on the human health impacts of climate change. Violence is a widespread public health problem that has profound impacts on lifelong health, opportunity, and well-being. When firearms are involved with violent events, the risk for injury and mortality as well as both acute and chronic physical, mental, and behavioral health conditions increases. The NIH is committed to supporting scientific research to understand and prevent injury and mortality associated with firearm violence through public health interventions. A \$12.5 million increase is included in the Office of the Director (OD) for gun violence research, which doubles funding for this important research.

Closing the Gap in Health Disparities

The COVID-19 pandemic has brought into sharp focus the dramatic health disparities that exist across the American population. For example, 22 percent of U.S. counties that are disproportionately African American accounted for 52 percent of our Nation’s COVID-19 cases and 58 percent of COVID-19 deaths.¹⁰ NIH is engaging in several efforts to ensure the inclusion of minorities in COVID-19 research. One of the most notable is the RADx Underserved Populations (RADx-UP) initiative, which leverages existing community partnerships to build community-engaged implementation projects focused on understanding the factors associated with disparities in COVID-19 morbidity and mortality.¹¹ This initiative aims to lay the foundation to reduce disparities for those underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates of, and/or are most at risk for complications or poor outcomes associated with the COVID-19 pandemic. But health disparities extend well beyond the current pandemic, and the time is right for an enhanced research agenda. The Budget proposes a \$330.0 million increase for research managed by the National Institute on Minority Health and Health Disparities (NIMHD), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR) and the Fogarty International Center to address these disparities. Also included in the request is \$30.0 million for NHLBI for the Community Engagement Alliance (CEAL) Against COVID-19 Disparities,¹² an initiative connecting researchers to trusted leaders and organizations in communities hardest hit by COVID-19, helping them work together to address misinformation, increase the use of practices to prevent spread of the virus, and ensure that clinical trials include people in these communities, so that the treatments and vaccines developed will work for everyone.

Beyond COVID-19, NIMHD is leading the advancement of the science of minority health and health disparities in several ways such as by redefining minority health and health disparities research; developing a research framework that underscores the key health determinants, levels of influence, and domains of influence researchers should consider in conducting research on minority health and health disparities; and developing methods and measurements for minority health and health disparities research. As a blueprint for the new opportunities, the “NIH Minority Health and Health Disparities Strategic Plan 2021-2025: Taking the Next Steps” was released on March 31, 2021.¹³ It was developed by NIMHD, in collaboration with other NIH ICOS, and outlines the agency’s research, research-sustaining activities, and outreach priorities and goals for minority health and health disparities.

In addition to looking at health disparities through the lens of racial and ethnic diversity, the agency is also working to understand health inequities from other perspectives. For example, the *All of Us* Research Program is seeking a million or more participants from all backgrounds who reflect the rich diversity of the United States to ensure that all people benefit from the new biomedical advancements made with program data. *All of Us* is achieving its diversity goals through partnership with organizations that have ties to, and can guide the long-term engagement

¹⁰ www.medrxiv.org/content/10.1101/2020.05.04.20090274v1

¹¹ www.nih.gov/research-training/medical-research-initiatives/radx

¹² covid19community.nih.gov/

¹³ [www.nimhd.nih.gov/about/strategic-plan/](https://nimhd.nih.gov/about/strategic-plan/)

of, participants from communities that have been historically underrepresented in biomedical research.

Capitalizing on Foundational Investments and Beyond

Years of basic science allowed us to respond effectively

Investments in basic research that generate fundamental knowledge about the nature and behavior of living systems provide the building blocks that allow us to respond effectively to old and new challenges. In pursuit of its mission, NIH invests more than half of its research budget in fundamental discovery, which provides the key for unlocking the secrets of how living systems function.¹⁴ With this substantial level of support, NIH lays the groundwork for discoveries that will ultimately lead to novel interventions, treatments, and cures. In fact, a recent study found that NIH funding contributed to published research associated with every single one of the 210 new drugs approved by the Food and Drug Administration (FDA) from 2010 through 2016.¹⁵ More than 90 percent of this NIH funding was for basic research.

From basic neuroscience to innovative technologies

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® is a key example of NIH’s approach to fostering basic research.¹⁶ The BRAIN Initiative aims to revolutionize our understanding of the human brain by supporting the development and application of innovative technologies that allow researchers to study how individual cells and complex neural circuits interact in both time and space. By catalyzing the development of new research technologies, the BRAIN Initiative supports advancements that will allow scientists across disciplines, not just those funded by the initiative, to push the frontiers of their research, from manipulating and monitoring neural activity at unprecedented scales to understanding the molecular “census” of the cells in the brain well enough to manipulate highly specific populations. In one study, researchers with funding from the BRAIN Initiative pioneered the pairing of a 3D live-imaging microscope with an ultra-fast camera.¹⁷ This technique, called Swept Confocally Aligned Planar Excitation (SCAPE) 2.0 microscopy, enables scientists to image in a wide range of experiments where they can present stimuli or probe an animal’s behavior—all while imaging how cells drive and depict those behaviors. Using SCAPE 2.0, researchers can rapidly image large fixed, cleared, and expanded tissues such as the retina, brain, and spinal cord—enabling tracing of the shape and connectivity of cellular circuits.

Alongside BRAIN Initiative-funded research, NIH funds other groundbreaking basic neuroscience research to build a solid foundation for new innovations or discoveries. For example, NIH-funded researchers found yet another link between sleep and brain health: sleep triggers rhythmic waves of blood and cerebrospinal fluid that appear to function much like a washing machine’s rinse cycle, which may help to regularly clear the brain of toxic waste.¹⁸ These findings and others may help explain why poor sleep or loss of sleep has previously been

¹⁴ nexus.od.nih.gov/all/2016/03/25/nih-s-commitment-to-basic-science/

¹⁵ Galkina Cleary E. Contribution of NIH funding to new drug approvals 2010-2016. Proc Natl Acad Sci USA. 2018;115(10):2329-2334. PMID: 29440428 www.pnas.org/content/115/10/2329

¹⁶ braininitiative.nih.gov/

¹⁷ directorsblog.nih.gov/2019/12/05/3d-neuroscience-at-the-speed-of-life/

¹⁸ directorsblog.nih.gov/2020/03/05/discovering-the-brains-nightly-rinse-cycle/

associated with the spread of toxic proteins and worsening memory loss in people with Alzheimer’s disease.

INCLUDE high-risk, high-reward basic science

A major component of the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) project is to fund targeted, high-risk, high-reward basic science studies on chromosome 21, which is present in an extra copy in Down syndrome.¹⁹ INCLUDE funded projects investigate conditions that disproportionately affect individuals with Down syndrome, such as Alzheimer’s disease/dementia, autism, cataracts, celiac disease, congenital heart disease and diabetes. Basic research on chromosome 21 will improve understanding of the biology of Down syndrome and support the development of new treatments for health conditions experienced by individuals with Down syndrome. With advances in technology, researchers can further explore the effects of multiple genes on chromosome 21 and identify genetic pathways that may be most responsive to new therapies for co-morbid conditions.

The Potential for Future Advances Is Extraordinary!

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 the translation of that knowledge into the development of new diagnostics, therapeutics, and preventive measures to improve health. These strategies, which could develop a potential medication, a new vaccine, a medical device, a community-based prevention program, or a wide range of other intervention types, are then optimized and tested in clinical or real-world settings to assess their efficacy and effectiveness. NIH is deliberate in its support of translational and clinical sciences, following the guidance of the *NIH-Wide Strategic Plan, Fiscal Years 2016–2020* to fund those studies in which the scientific opportunities are ripe, and the public health needs, whether emerging or chronic, are greatest. As with basic research, NIH not only supports translational and clinical studies directly, but also supports the creation of the infrastructure, resources, and tools to provide a platform for innovation. To facilitate an integrated understanding of health and disease at all levels, from molecular underpinnings to social factors to treatment response, NIH is investing in large population studies to learn more about how we are the same and how we are different. This integration will allow for unprecedented precision in the ways in which health is addressed, making it possible for every individual to receive preventive and therapeutic care tailored specifically to their needs, ushering in an era of precision medicine.

The new Advanced Research Projects Agency for Health (ARPA-H) will be a key component to drive transformational innovation in health research. The FY 2022 Budget includes \$6.5 billion for ARPA-H to build platforms and capabilities to deliver cures for cancer, Alzheimer’s disease, diabetes, and other diseases. This investment in bold and emergent research opportunities is both high-risk and high-reward, and will collapse barriers and speed the development, application, and implementation of urgently needed health breakthroughs. ARPA-H will fund projects with the potential to transform entire areas of medicine and health by:

¹⁹ www.nih.gov/include-project

- Tackling bold challenges requiring large scale, sustained, cross-sector coordination
- Creating new capabilities (*e.g.*, technologies, data resources, disease models)
- Supporting high-risk exploration that could establish entirely new paradigms
- Overcoming market failures through critical solutions, including financial incentives

Modeled after the Defense Advanced Research Projects Agency, ARPA-H will recruit visionary term-limited program managers who can identify and fund traditional and non-traditional partners to take on critical challenges that are unlikely to move forward quickly without this catalytic assistance. ARPA-H will leverage novel public-private partnerships, use directive approaches that will provide quick funding decisions to support projects that are results-driven and time-limited, and identify emergent opportunities through advanced systematic horizon scans of academic and industry efforts. Potential areas of transformative research driven by ARPA-H include an “innovation funnel” for accurate, wearable, ambulatory blood pressure technology, preparation of mRNA vaccines against common forms of cancer, or accelerating development of efficient gene/drug delivery systems to target any organ, tissue, or cell type – a zip code for the human body.

ARPA-H will be operationally unique from NIH’s Institutes and Centers, with a distinctive culture and organizational structure that provides agility to advance biomedical science in bold new ways. It will make broad use of flexible hiring and procurement authorities, such as the use of Other Transactions Authority. ARPA-H will have a Federal advisory panel that will provide an avenue for interagency coordination and idea generation, and will include the heads and/or designated staff of major science agencies within and outside HHS. Importantly, this advisory panel will not set the research agenda, or oversee ARPA-H funding or programs. Decisions on funding and programs will be made by program managers in consultation with the ARPA-H Director to ensure decisions are timely, independent, and informed by project performance. Funding is requested with a three-year period of availability, which will allow for both scale-up in FY 2022 and redeployment of resources in the next two years if projects fail to meet performance milestones. Funding will support extramural research, with only a small percentage retained to support a lean workforce and administrative functions. ARPA-H will benefit from NIH’s existing infrastructure and relationships with Federal and non-Federal entities. While most awards would go to industry, universities, and non-profit research institutions, ARPA-H may also enter into agreements with other Federal entities. ARPA-H will not have its own intramural program to preserve flexibility in funding bold, high-risk projects. ARPA-H is designed to complement NIH’s existing research portfolio and its activities will be coordinated with other components of NIH and other HHS agencies.

Advancing testing and diagnostics for early detection of disease

The emergence of COVID-19 as a global pandemic has highlighted the importance of testing and diagnostics for early detection of infection, but the critical importance of testing and diagnostics to understanding, treating, and preventing disease is well known to health researchers. NIH-funded researchers are getting closer to a blood test to diagnose Alzheimer’s disease and distinguish it from other neurodegenerative conditions. Advances like this expedite the identification and validation of biological targets of disease.

To spur the creation of new approaches that can rapidly expand access to testing for COVID-19, NIH launched the Rapid Acceleration of Diagnostics (RADxSM) program in late April 2020.²⁰ This effort, conducted in partnership with the Office of the Assistant Secretary of Health, the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense, was started with \$1.5 billion in emergency supplemental funding. As one component of RADxSM, the RADx-Tech initiative aims to speed the development, validation, and commercialization of innovative point-of-care and home-based tests, and improve clinical laboratory tests, that can directly detect the virus. RADx-Tech expands the Point-of-Care Technologies Research Network (POCTR) established several years ago by NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB). The network uses a flexible, rapid process to infuse funding and enhance technology designs at key stages of development, with expertise from technology innovators, clinical testing, regulatory affairs, entrepreneurs, and business leaders. ARPA-H will be well-positioned to apply the lessons learned from RADx to a wide variety of applications.

Advances in data science: artificial intelligence, big data, and machine learning

Advances in data science, artificial intelligence, and machine learning will help to speed the analysis of data and application of the insights provided. Already, NIH-funded researchers have used artificial intelligence to classify a broad range of heart arrhythmias from individual patient ECGs, provided a low-cost mobile approach to cervical cancer screening,²¹ and sped up brain tumor diagnosis.²²

NIH supports multiple data science efforts to ensure that COVID-19 research data are findable, accessible, interoperable, and reusable (the FAIR principles).²³ By enhancing existing and creating new data science resources and analytical tools, NIH is facilitating the use of COVID-19 data to the greatest extent possible, both by those generating the data and by other researchers. These investments support the development of diagnostic tools, survey instruments, risk assessment models, public health surveillance tools, and portals to share data, among others (e.g., NIH Repository of COVID-19 Research Tools, OpenData Portal, PhenX, SHIELD [Systemic Harmonization and Interoperability Enhancement for Laboratory Data Collaborative], and SPHERES [SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance]). NIH investments to develop shared metrics and terminologies across research projects facilitate and maximize the use of a wide breadth of data, from chemical structures to clinical trial results.

To accelerate the pace of discovery of diagnostics, treatments, and vaccines for COVID-19, NIH launched the Medical Imaging and Data Resource Center (MIDRC), an ambitious effort that will harness the power of artificial intelligence and medical imaging to fight COVID-19.²⁴ The multi-institutional collaboration, led by NIBIB, will create new tools that physicians can use for early detection and personalized therapies for COVID-19 patients. The MIDRC goals are to lead

²⁰ directorsblog.nih.gov/2020/07/23/racing-to-develop-fast-affordable-accessible-tests-for-covid-19/

²¹ directorsblog.nih.gov/2019/01/17/using-artificial-intelligence-to-detect-cervical-cancer/

²² directorsblog.nih.gov/2020/01/14/artificial-intelligence-speeds-brain-tumor-diagnosis/

²³ www.nih.gov/sites/default/files/research-training/initiatives/covid-19-strategic-plan/coronavirus-strategic-plan-20200713.pdf

²⁴ www.nih.gov/news-events/news-releases/nih-harnesses-ai-covid-19-diagnosis-treatment-monitoring

the development and implementation of new diagnostics, including machine learning algorithms, that will allow rapid and accurate assessment of disease status and help physicians optimize patient treatment.

New tools and technologies for treatments and cures

NIH-funded researchers are achieving transformative results through technology and shedding new light on how biological systems function in health and disease. These insights are leading to faster, more accurate diagnostics, less invasive screening and treatment procedures, and hope for therapies and cures for previously intractable diseases. Gene editing, three-dimensional (3D) tissue printing, single-cell biology, and neurotechnologies are just a few of the areas in which innovative discoveries are moving towards tangible results in delivering the promise of biomedical research for human health.

Gene vector production and innovation

Gene therapy and gene editing approaches are some of the most promising treatment modalities for a growing number of disease conditions. Vectors are the “vehicle” by which a gene can be delivered to a targeted location in the body, and adeno-associated viruses (AAVs) are currently the most prevalent type of vector used in both gene therapy and gene editing studies. Wait times to produce vector therapies that meet the manufacturing standards necessary for clinical trials are long, often 1 to 2 years. Resolving this production bottleneck is critical for gene-based therapies to reach all people who need them.

One example of how gene vectors can be used as an effective therapy comes from research on sickle cell disease. Researchers at NIH have developed a new and improved viral vector—a virus-based vehicle that delivers therapeutic genes—for use in gene therapy for sickle cell disease.²⁵ Researchers report that the new vector was up to 10 times more efficient at incorporating corrective genes into bone marrow stem cells than the conventional vectors currently used in advanced lab tests using animal models, and its carrying capacity is up to 6 times higher. The development of the vector could make gene therapy for sickle cell disease much more effective and pave the way for wider use of it as a curative approach for the painful, life-threatening blood disorder. Sickle cell disease affects about 100,000 people in the United States and millions worldwide.

Advances in cancer treatment

Cancer remains a leading cause of death in the United States and around the world. Complicating matters is the fact that cancer is not a single disease but is a complex of more than 100 diseases in which genetic changes disrupt cell function. Given the complicated nature of cancer, it is essential to harness new technologies and approaches to treat this often-deadly condition. Leveraging new knowledge of the precise factors that influence disease, NIH is pioneering the use of precision medicine in treatment approaches to better target the right treatments to the right people.

Beau Biden Cancer Moonshot. The initiative is designed to accelerate cancer research, to make more therapies available to more patients, while also improving our ability to prevent cancer and

²⁵ www.nih.gov/news-events/news-releases/nih-researchers-create-new-viral-vector-improved-gene-therapy-sickle-cell-disease

detect it at an early stage.²⁶ Because of the broad scope of the Moonshot, this initiative has the potential to impact all cancer patients, including the 1.9 million U.S. patients who are expected to be diagnosed with cancer in 2021, and the nearly 18 million cancer survivors in the United States.²⁷ More effective prevention, diagnostic, and treatment methods will help to reduce the financial and psychosocial burdens placed on cancer patients and their families.

Pediatric cancers. Enormous strides have been made in the treatment of childhood acute leukemia, where the cure rate now stands at well over 90 percent. But the science of understanding other types of pediatric cancer is especially challenging, and too many children and adolescents still die from rare brain tumors, sarcomas, and other malignancies. Many others endure lifelong adverse effects from their cancers or their treatment.

The Childhood Cancer Data Initiative (CCDI) is building a data resource that will aggregate data from pediatric cancer cases and coordinate with partners that maintain data sets on pediatric patients to create a federated, comprehensive, and shared resource to support research to develop new, more effective, and safer treatments for childhood cancers, and will complement ongoing research within the National Cancer Institute (NCI) and the Cancer Moonshot. This knowledge, spanning from basic biology to clinical outcomes, can provide a path for changing the course of cancer in all children.

In June 2020, the Board of Scientific Advisors (BSA) Ad Hoc Working Group (WG) in Support of the CCDI released a report to provide general guidance to NCI regarding considerations for future CCDI priorities.²⁸ The report, which was unanimously accepted, provided guidance to NCI in implementing the CCDI so that this new resource will enable broad, rapid data sharing in ways that will optimally facilitate childhood, adolescent and young adult (AYA) cancer research and accelerate the development of better and less toxic therapies for the benefit of pediatric and AYA cancer patients and their families.

Disease Prevention and Health Promotion

Disease prevention has been a central component of the NIH mission from its earliest days. Today, along with investments in fundamental science and treatments and cures, the NIH continues to emphasize health promotion and disease prevention as a key strategy for advancing opportunities in biomedical research. Prevention research targets biology, individual behavior, factors in the social and physical environments, and health services, and informs and evaluates health-related guidelines, policies, and regulations. Advances in these areas are possible because of a comprehensive approach to research that includes basic, translational, clinical, population science, and epidemiology.

Vaccines

Vaccines represent the safest, most cost-effective, and efficient way to reduce the burden of infectious diseases—by preventing them altogether. Creating a safe and effective vaccine often requires understanding how a particular virus or bacteria infects the human body, as well as the

²⁶ www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

²⁷ seer.cancer.gov/statfacts/html/all.html

²⁸ www.cancer.gov/research/areas/childhood/childhood-cancer-data-initiative

various molecules that the immune system might use to target it, requiring a multi-pronged research approach. NIH engages in vaccine research to prevent many diseases, including both emerging threats and recurring maladies.

The COVID-19 pandemic has shone light on the importance of vaccines for a healthy and prosperous nation. Building on previous research on Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), NIH scientists and grantees were positioned to rapidly develop COVID-19 vaccine candidates for testing in clinical trials. A coordinated effort across the U.S. government is supporting the rapid conduct of these clinical trials and making sure that millions of doses of safe and effective vaccines are available to the public.²⁹ With major contributions from the ACTIV³⁰ initiative, a remarkable public-private partnership involving multiple biopharmaceutical companies, academic experts, non-profit organizations, and federal agencies, NIH experts have advised on the protocol design for each of the trials. Additionally, NIH experts are members of each trial oversight group—along with the sponsor and BARDA—that receives recommendations from the vaccine trials' Data and Safety Monitoring Board. A summary of clinical trials of COVID-19 vaccine candidates is available on the NIH ACTIV vaccines page.³¹

Eliminating HIV/AIDS

NIH-supported basic research has allowed us to gain a deep understanding of the biology of HIV. This, in turn, has led to the development of effective treatments, rapid diagnostics, and other approaches that now allow HIV-infected individuals to live a nearly normal lifespan. This is an amazing accomplishment considering that at the beginning of the HIV epidemic, there were limited treatment options, aside from palliative care, and infection meant early death.

Ending the HIV Epidemic (EHE). As part of the new effort, Centers for AIDS Research (CFAR) and HIV/AIDS Research Centers (ARCs) will build on existing relationships with local health authorities, community-based groups, and other HHS agencies involved in the EHE initiative, including the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA).³² With these partners, researchers work to identify and evaluate 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. With much of the needed research infrastructure already in place, this effort is expected to yield critical findings with modest funding. This new initiative focuses on implementing proven HIV treatment and prevention tools. These include daily 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 three days of exposure and taken for an additional 28 days. Implementation strategies that demonstrate

²⁹ www.niaid.nih.gov/diseases-conditions/covid-19-vaccine-faq#OWS

³⁰ www.nih.gov/research-training/medical-research-initiatives/activ

³¹ www.nih.gov/research-training/medical-research-initiatives/activ/sars-cov-2-vaccine-clinical-trials-using-activ-informed-harmonized-protocols

³² www.nih.gov/news-events/news-releases/nih-bolsters-funding-hiv-implementation-research-high-burden-us-areas

success in these initial research locations will be shared as best practices to inform efforts in other jurisdictions. The FY 2022 Budget includes a \$10.0 million increase for CFARs to support the EHE initiative.

Personalized Nutrition

Good nutrition is essential for healthy development and basic survival, but it is also integral to well-being and disease prevention. Health conditions linked to poor diet constitute the most frequent and preventable causes of death in the United States and are major drivers of health care costs, estimated in the hundreds of billions of dollars annually.³³ The 2020-2030 Strategic Plan for NIH Nutrition Research, released in May 2020, presents a bold, unifying vision emergent as “Precision Nutrition.”³⁴ An important constituent of Precision Medicine, Personalized Nutrition in research and practice considers multiple, synergistic levels of influence: dietary habits, genetic background, health status, microbiome, metabolism, food environment, physical activity, socioeconomic, psychosocial characteristics, and environmental exposures. This emerging research agenda promises to deepen understanding of the interactions between what, when, why, and how we eat; how our body systems process our diet and influence the microbiome; as well as how food environments influence health and disease.

Areas of Continued Investment

This is a remarkable time in biomedical research. Truly exciting, world-class science is taking place through NIH support, and leading to breakthroughs in multiple areas as described above. However, there is still much to be done. NIH sees the opportunity for many promising areas of research in the future.

Increasing Research Capacity Through Partnerships

Translating NIH’s basic research findings into treatments and cures requires efficient collaborations within NIH as well as with other government, academic, industry, and non-profit partners. NIH works closely with federal partners to streamline processes, collaborate on research projects, and share the agency’s evidence base to catalyze efforts across the government to improve health for all Americans. Partnerships also enable the public and private sectors to work synergistically toward medical advances, accomplishing goals that cannot readily be achieved by acting alone. Leveraging resources and expertise, NIH is engaged in several significant partnerships addressing issues from Alzheimer’s disease to HIV through bold public-private partnerships (PPPs) such as the Accelerating Medicines Partnership (AMP), the Partnership for Accelerating Cancer Therapies (PACT), and now ACTIV. In one such effort, NIH has partnered with The Bill & Melinda Gates Foundation to develop affordable, gene-based cures for sickle cell disease and HIV.³⁵ Continued emphasis on PPPs will ensure NIH’s careful stewardship of public funds and increase the pace of research to benefit patients more quickly.

³³ www.cdc.gov/chronicdisease/about/costs/index.htm

³⁴ www.niddk.nih.gov/about-niddk/strategic-plans-reports/strategic-plan-nih-nutrition-research

³⁵ www.nih.gov/news-events/news-releases/nih-launches-new-collaboration-develop-gene-based-cures-sickle-cell-disease-hiv-global-scale

Communicating Results to Inform Future Research

NIH continues to promote policies and programs that foster and ensure a strong foundation and culture of good scientific stewardship. As critical research needs arise, NIH will respond by ensuring the scientific community has flexibility to quickly adapt and address urgent public health issues. This is exemplified by the NIH response to the COVID-19 pandemic with the rapid emergence of the OpenData COVID-19 portal,³⁶ expanded access to coronavirus literature through PubMed Central® (PMC),³⁷ as well as a preprint pilot to accelerate dissemination of research related to the SARS-CoV-2 virus and COVID-19.³⁸

These new resources are built on existing NIH platforms for the communication of research results such as *PubMed* and *ClinicalTrials.gov*. *PubMed* is the most heavily used biomedical literature citation database in the world and enables the communication and discovery of scientific literature across the globe. PMC provides public access to the full text of more than 6 million scientific articles. PMC offers text mining access to over 3 million articles, facilitates linking between articles and associated data, and supports discovery of these data by aggregating data citations, data availability statements, and supplementary materials. Results from clinical studies are made available through NIH's *ClinicalTrials.gov*, the largest public clinical research registry and results database in the world. It provides patients, health care providers, and researchers with information on over 330,000 registered studies, including studies with summary results, many of which are not otherwise available through the published literature. A multi-year effort is underway to modernize *ClinicalTrials.gov* to deliver an improved user experience on an updated platform that will accommodate growth and improve efficiency.

Conclusion

The Nation's investment in NIH is born from the recognition that a healthy population is a productive and thriving population. The benefits of NIH research may 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. For example, thanks in large part to NIH research, survival rates for respiratory distress syndrome in newborns have improved from 5 percent in the 1960s to 95 percent currently. The infants who now survive what was once a deadly condition will live to become productive adults, potentially with children of their own and on into future generations.

A healthier nation is a more productive and economically sound nation. Each permanent 1 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.³⁹

³⁶ opendata.ncats.nih.gov/covid19/

³⁷ www.nlm.nih.gov/news/Expanding_Access_Coronavirus_Literature.html

³⁸ www.nlm.nih.gov/news/Preprint_Pilot.html

³⁹ ucema.edu.ar/u/je49/capital_humano/Murphy_Topel_JPE.pdf

NIH is at the vanguard of biomedical research, leading the world in support of groundbreaking science. Strategically investing in scientific opportunities such as those described above will help NIH ensure the United States remains at the forefront of innovation and discovery.

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 the translation of that knowledge into the development of new diagnostics, therapeutics, and preventive measures to improve health. Investments in translational research are leading to the identification of new targets and pathways for the development of new therapeutics.

The FY 2022 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 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. To increase transparency and promote effective use of resources, NIH began reporting the amount of indirect costs paid per grant on its Research Portfolio Online Reporting Tools website (NIH RePORT⁴⁰) in October 2013. NIH supports a wide spectrum of biomedical and behavioral research and engages in a full range of activities that enable research, its management, and the communication of research results. Because of this diversity and complexity, NIH uses a set of performance measures that is representative of its activities and is useful for tracking progress in achieving performance priorities. This representative approach has helped NIH to share progress of its performance priorities with HHS, the rest of the Executive Branch, the Congress, and the public.

Collectively, the NIH performance measures reflect the Agency's overall goals to: 1) advance the full continuum of biomedical research; 2) strengthen the scientific workforce and biomedical research infrastructure; 3) facilitate the communication of research findings and transfer of knowledge to other sectors for further development; and 4) enhance internal management processes, policies, and systems to support programmatic and organizational oversight. Furthermore, the measures support the Administration's goal of protecting and improving the health and well-being of the American people. In particular, NIH substantially contributes to HHS Strategic Goal 4 – Foster Sound, Sustained Advances in the Sciences. For example, in

⁴⁰ <https://report.nih.gov/>

support of Objective 4.3 (Advance basic science knowledge and conduct applied prevention and treatment research to improve health and development) under Goal 4, NIH continues to support promising research with the goals of: 1) developing, optimizing, and evaluating the effectiveness of nano-enabled immunotherapy (nano-immunotherapy) for one cancer type; 2) evaluating the safety and effectiveness of one to three long-acting strategies for the prevention of HIV; and 3) identifying risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease.

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 administrative management functions.

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

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

The vast majority of scientific research carried out through NIH support is subjected to a rigorous and consistently applied review process. For example, the Extramural Research Program, which accounts for the majority of NIH-funded research, utilizes two levels of peer review. The first level, in which scientific excellence is assessed, consists of chartered scientific review groups composed of outside experts in particular scientific disciplines. The second level,

in which public health relevance is assessed, is conducted by National Advisory Councils of the ICs. For the Intramural Research Program, the progress of individual scientists and their laboratories is evaluated once every four years by Boards of Scientific Counselors composed of external experts. These reviews enable ongoing assessments of all intramural labs and the accomplishments of the scientists who contribute to them. It is through this well-honed system of peer review that NIH maintains its focus on supporting research of the highest possible quality with the greatest potential of furthering NIH's mission. The ARPA-H program will utilize a more nimble approach to funding decisions, following the DARPA model where expert program managers are provided with considerable flexibility in recruiting participants, and given authority to make decisions about project initiation, expansion, or termination built around rigorous milestones.

The NIH approach to performance management is undergirded by the NIH Governance Structure. That structure includes the NIH Steering Committee and standing Working Groups.⁴¹,⁴² 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.

⁴¹ 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.

⁴² The standing working groups are: Extramural Activities, Diversity, Facilities, Management and Budget, Scientific Data Council, Administrative Data Council, Data Science Policy Council, Clinical Center Governing Board, Board of Scientific Counselors, and Research Services Working Group.

ALL-PURPOSE TABLE

(Dollars in Thousands) ^{1,2}	FY 2020 Final ⁵	FY 2020 Supplemental Funding ⁶	FY 2021 Enacted ⁵	FY 2021 Supplemental Funding ⁷	FY 2022 President's Budget ⁵	FY 2022 +/- FY 2021
Total, NIH Program Level	\$41,685,000	\$3,587,400	\$42,935,500	\$1,250,000	\$51,952,703	\$9,017,203
Less mandatory and funds allocated from different sources:						
PHS Program Evaluation	1,230,821		1,271,505		1,271,505	0
Mandatory Type 1 Diabetes Research	150,000		150,000		141,450	-8,550
Total, NIH Discretionary Budget Authority	\$40,304,179	\$3,587,400	\$41,513,995	\$1,250,000	\$50,539,748	\$9,025,753
Interior Budget Authority	81,000		81,500		83,540	2,040
Total, NIH Labor/HHS Budget Authority	\$40,223,179	\$3,587,400	\$41,432,495	\$1,250,000	\$50,456,208	\$9,023,713
<i>Number of Competing RPGs</i>	<i>11,395</i>		<i>11,189</i>		<i>12,664</i>	<i>1,475</i>
<i>Total Number of RPGs</i>	<i>41,643</i>		<i>42,083</i>		<i>44,343</i>	<i>2,260</i>
<i>FTE³</i>	<i>17,623</i>		<i>18,785</i>		<i>19,303</i>	<i>518</i>
<i>NEF⁴</i>						
<i>Surgery, Radiology, and Laboratory Medicine Building</i>	<i>212,400</i>		<i>225,000</i>		<i>NA</i>	<i>NA</i>
<i>Building 10 Building Automation System Replacement</i>	<i>12,600</i>		<i>0</i>		<i>NA</i>	<i>NA</i>

¹ Numbers may not add due to rounding.² Includes 21st Century Cures Act funding.³ FTE levels include 4 NIH FTEs funded by PHS trust funds in FY 2020 through FY 2022.⁴ Amounts for FY 2020 reflect amounts allocated for NIH from the NEF by sec. 237 of Division A of P.L. 116-94. Amounts for FY 2021 reflect amounts allocated for NIH from the NEF by sec. 237 of Division H of P.L. 116-260.⁵ Amounts for FY 2020 through FY 2022 reflect directive transfer of \$5.0 million from OD to the HHS Office of Inspector General.⁶ Shows supplemental funds post-transfer.⁷ This column includes funding appropriated in P.L. 116-260, post-transfer.

IMPACT OF BUDGET LEVEL ON PERFORMANCE

Programs and Measures (Dollars in Millions, except where noted)	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Research Project Grants	\$24,559.013	\$26,227.757	6.8%
Competing Average Cost (in thousands)	\$580.276	\$567.892	-2.1%
Number of Competing Awards (whole number)	11,189	12,664	13.2%
Estimated Competing RPG Success Rate	20.1%	22.1%	10.0%
Research Centers	\$2,778.539	\$2,872.575	3.4%
Other Research	\$2,996.908	\$3,096.571	3.3%
Training	\$951.864	\$1,019.196	7.1%
Research & Development Contracts	\$3,362.683	\$3,561.276	5.9%
Intramural Research	\$4,548.996	\$4,695.985	3.2%
Research Management and Support	\$2,090.554	\$2,184.166	4.5%
<i>Common Fund (non-add)</i>	\$648.539	\$658.539	1.5%
Advanced Research Projects Agency for Health	\$0.000	\$6,500.000	N/A
Buildings & Facilities Appropriation	\$200.000	\$250.000	25.0%
Other Mechanisms ^{1,2}	\$1,446.943	\$1,545.176	6.8%
Total, Program Level³	\$42,935.500	\$51,952.703	21.0%

¹ 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.

² Amounts reflect directive transfer of \$5.0 million to the HHS Office of Inspector General.

³ Includes discretionary budget authority received from Labor/HHS appropriations bill and the Interior appropriations bill (Superfund). Also includes program evaluation financing and mandatory budget authority derived from the Type 1 Diabetes account.