DEPARTMENT of HEALTH and HUMAN SERVICES

FISCAL YEAR 2019

NATIONAL INSTITUTES OF HEALTH - Volume I

Overview

Justification of Estimates for Appropriations Committees

As the Director of the National Institutes of Health (NIH), I present the Congressional Justification of the NIH fiscal year (FY) 2019 budget. This request for a $34.8 billion total program level includes the consolidation of targeted HHS research programs within NIH as three new institutes. The Agency for Healthcare Research and Quality (AHRQ) would become the National Institute for Research on Safety and Quality (NIRSQ), the National Institute for Occupational Safety and Health (including the Energy Employees Occupational Illness Compensation Program) would move to NIH from the Centers for Disease Control and Prevention, and the National Institute on Disability, Independent Living, and Rehabilitation Research would move to NIH from the Administration for Community Living.

As part of a larger government-wide effort to address the opioid crisis, NIH has prioritized the investment of $850 million (including $750 million from an HHS-wide $10 billion investment) in an ambitious series of project, including a multi-year public-private partnership to accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose, and to help optimize their implementation. In consultation with experts from government, industry, and academia, NIH has proposed a coordinated strategy with two primary aims: developing new formulations and combinations of medications to treat opioid use disorders and to prevent and reverse overdose; and accelerating development of new non-addictive pain therapies.

The Budget gives priority to critical needs in additional areas. To help create a stable path for the next generation workforce and ensure the best and brightest scientists remain in research, NIH launched the Next Generation Researchers Initiative (NGRI). The Budget includes a dedicated fund of $100 million in the Office of the Director that Institutes and Centers would be able to draw on to supplement the NGRI efforts undertaken with their own appropriations. To begin a long-term effort to provide the necessary funding for stewardship of NIH facilities, especially the NIH Clinical Center, the Buildings & Facilities (B&F) account is increased to $200 million. There is also $50 million in the Common Fund for additional prize competitions to encourage innovation and complement traditional forms of NIH financial support, and $30 million to support data science activities.

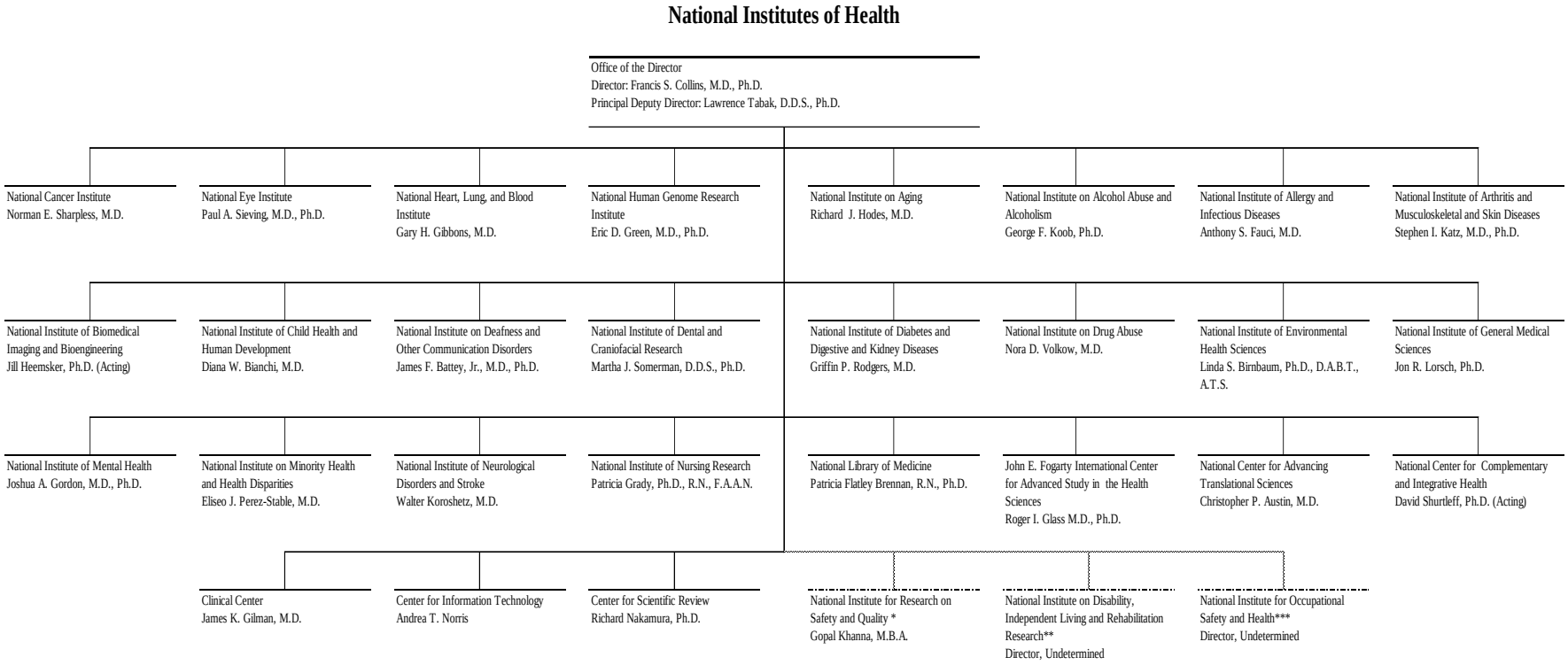
NIH continues to highlight scientific opportunities that could transform the prevention, diagnosis, and treatment of disease as described in the *NIH-wide Strategic Plan 2016-2020*. These include the four projects supported by the Innovation Fund established in the 21st Century Cures Act. The Budget includes full funding of $711 million for these projects, which will continue to make important strides in FY 2019. The *All of Us* Research Program began its beta phase of enrolling participants in May 2017 ahead of a full-scale launch in the spring of 2018.

I look forward to discussing NIH's plans for the future.

Francis S. Collins, M.D., Ph.D.

TABLE OF CONTENTS

ORGANIZATION CHART



* The FY 2019 Budget proposes to consolidate the Agency for Healthcare Research and Quality into NIH as the National Institute for Research on Safety and Quality

** The FY 2019 Budget proposes to transfer the National Institute on Disability, Independent Living and Rehabilitation Research into NIH from the Administration for Community Living

*** The FY 2019 Budget proposes to transfer the National Institute for Occupational Safety and Health into NIH from the Centers for Disease Control and Prevention

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 or supports research designed to understand the basic biology of human health and disease; apply this understanding towards designing new approaches for preventing, diagnosing, and treating disease and disability; and ensure that these new approaches are available to all.

As the Nation's biomedical research agency, NIH plays a unique role in turning basic scientific discovery into improved health. Investment by NIH in basic research today lays the foundation for health care breakthroughs in the future. NIH's support of clinical research gives patients new options for treatment and possible cures. The translation of NIH research into treatments and cures depends on a broader ecosystem of stakeholders, including both other federal agencies and private sector companies, and NIH partners with those stakeholders to maximize the impact of its resources. The U.S. biomedical research enterprise depends upon not only NIH's support of cutting edge science and technology but also its investment in nurturing the brightest scientific minds. NIH research also helps drive the economy by creating opportunities for new jobs and new businesses. Through careful stewardship of public resources in pursuit of its mission, NIH aims to enhance the lives of all Americans.

OVERVIEW OF BUDGET REQUEST

Introduction

For FY 2019, NIH requests a total program level of $34.8 billion, which is $0.7 billion above the FY 2018 Annualized Continuing Resolution level.

The Budget supports NIH's mission to seek fundamental knowledge about the nature and behavior of living systems, and applying that knowledge to enhance health, lengthen life, and reduce illness and disability. As a leader of the biomedical research enterprise, NIH leverages public and private resources to tackle major health challenges and take advantage of emerging scientific opportunities to improve diagnosis, prevention, and treatment options for numerous diseases and disorders. Targeted investments in new technology today will push the boundaries of what is possible tomorrow in areas such as imaging, device design, health monitoring, bioinformatics, as well as, countless others. The possibilities for groundbreaking approaches to better human health never have seemed greater, thanks in large part to the rich evidence base of fundamental knowledge of living systems, technological advances, and the ability to integrate and translate vast amounts of information into innovative interventions.

The Budget proposes to begin a long-term effort to provide the necessary funding for stewardship of NIH facilities. NIH owns 281 facilities with over 15 million gross square feet of space, including its research hospital, laboratories, and offices. It has a large and growing backlog of maintenance and repair. At Congressional direction, an independent review is being conducted of the capital needs of the NIH main campus[1]. The Budget increases the B&F account from $128 million to $200 million in order to begin implementing the recommendations of that review, which will be completed by FY 2019.

The President's Budget also proposes the consolidation of targeted HHS research programs within NIH as three new institutes. The Agency for Healthcare Research and Quality (AHRQ) would become the National Institute for Research on Safety and Quality (NIRSQ). The Budget includes $256 million in budget authority for NIRSQ, to preserve key activities to improve the quality and safety of American health care while reducing or eliminating lower priority programs that may potentially overlap with activities administered by other components of HHS. In addition, NIRSQ is projected to receive $124 million in mandatory resources from the Patient-Centered Outcomes Research Trust Fund. The National Institute for Occupational Safety and Health, would move to NIH from the Centers for Disease Control and Prevention with $255 million in budget authority, including $55 million in mandatory resources for the Energy Employees Occupational Illness Compensation Program. The National Institute on Disability, Independent Living, and Rehabilitation Research would move to NIH from the Administration for Community Living, with $95 million in budget authority.

In FY 2017, Congress enacted the 21st Century Cures Act, authorizing $4.8 billion over ten years in support of high priority NIH initiatives and research areas: 1) the Precision Medicine Initiative's All of Us Research Program, 2) the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, 3) the Beau Biden Cancer Moonshot, and 4) Regenerative Medicine. The FY 2019 Budget includes the full $711 million authorized for

[1] House Report 115-244.

these initiatives. The funding for the Cancer Moonshot ($400 million) is to be transferred to the National Cancer Institute; and the funding for the BRAIN Initiative is to be transferred to the National Institute of Neurological Disorders and Stroke ($57.5 million) and the National Institute of Mental Health ($57.5 million).

NIH's FY 2019 research investments will be guided by the NIH-Wide Strategic Plan for FY 2016-2020.[2] Some of the strategies the Plan identified as highest priority for FY 2019 are summarized in the following themes:

1. Tackling Complex Challenges by Leveraging Partnerships
   NIH is exploring ways of partnering that leverage both public and private resources to tackle major public health issues, create efficiencies of scale, and assure careful stewardship of public funds. Through its partnerships, NIH will collaborate across the government and with private partners to ensure strategic investments, reduce redundancies, and hasten the translation of research into practice.

2. Supporting Basic Research to Drive New Understanding of Health and Disease
   Basic research is the foundation for all progress in biomedical research. NIH plans to invest in new and ongoing initiatives to learn more about how biological systems function, and to develop tools to study these systems, from the behavior of whole organisms down to the individual cell and its components.

3. Investing in Translational and Clinical Research to Improve Health
   For a discovery to move from the lab into practice, fundamental scientific knowledge must undergo a rigorous translational and clinical research agenda that will test and optimize potential health interventions and approaches based upon it. Increasingly, NIH is investing in translational and clinical research designed to provide all patients with interventions tuned to their individual characteristics.

4. Fostering an Inclusive and Talented Biomedical Research Workforce for Today and Tomorrow
   NIH will invest in recruiting and retaining a robust, talented research workforce to sustain our progress and spur future innovation. Focusing on early and mid-career stages will ensure the vitality of the next generation of researchers.

By using these themes to guide strategic investments, NIH hopes to significantly advance its mission towards improving the health of all Americans.

Theme 1: Tackling Complex Challenges by Leveraging 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

[2] https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf

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 cancer biomarkers to the opioid crisis (see box under Theme 3 below). Continued emphasis on public-private partnerships will ensure NIH's careful stewardship of public funds and increase the pace of research to benefit patients more quickly.

Accelerating Medicines Partnership

One of NIH's most successful partnership models is the Accelerating Medicines Partnership (AMP), a public-private partnership between NIH, the Food and Drug Administration (FDA), 10 biopharmaceutical companies, and multiple non-profit organizations. Managed by the Foundation for NIH (FNIH), AMP aims to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics. Ultimately, the goal is to increase the number of new diagnostics and therapies for patients and to reduce the time and cost of developing them. AMP was launched in 2014 with three projects: Alzheimer's disease (AD), type 2 diabetes (T2D), and the autoimmune disorders rheumatoid arthritis and systemic lupus erythematosus (RA/Lupus). An additional partnership on Parkinson's disease has just been initiated. A critical component of the partnership is that all partners are making the AMP data publicly accessible for further analysis by the broader biomedical community. Each project has already made significant contributions: AMP-AD has provided the field with tools and data to significantly enhance understanding of how AD alters the brain; the T2D Knowledge Portal now makes available genetic and clinical data sets covering many ethnicities, as well as European data, for diabetes research; and the RA/lupus project released data in the fall of 2017 derived from new methods to isolate and analyze individual cells important to understanding autoimmune diseases. Based on the successes of these projects and partner interest, AMP anticipates launching a fourth project in early 2018 focusing on Parkinson's disease (PD). Collectively, the AMP projects allow research, regulatory, and industry ideas and personnel to work together to increase the number and effectiveness of targeted therapies.

Partnerships for Accelerating Cancer Therapies

Capitalizing on the scientific opportunities presented by the Beau Biden Cancer Moonshot, NIH is building partnerships to spur the development of new cancer therapeutics. Cancer immunotherapy, which bolsters the immune system's natural capacity to attack cancer cells, have yielded dramatic, positive results for many patients with several types of cancer. These approaches do not work for all cancer patients, however, and better understanding the mechanisms by which these treatments and others work or do not work in patients will improve patient outcomes. For instance, the identification of biomarkers, molecular indicators of disease, could be used to predict how a patient will respond to a particular treatment. Joining forces to build a better evidence-base to understand cancer treatment, NIH, the FDA, and 11 biopharmaceutical companies formed the Partnership for Accelerating Cancer Therapies (PACT) in October 2017. This 5-year, $215 million public-private partnership aims to bring cancer therapies to patients in less time. Managed by the Foundation for NIH, PACT initially will focus

on developing and standardizing new biomarkers to predict response to cancer therapy. Once developed and validated, such biomarkers may be used to enable faster regulatory approval. Furthermore, the partnership will provide the research community with a widely available database for PACT research and other data. This cross-sector collaborative effort will enable shared expertise and resources to advance science for the maximum benefit of patients.

Also in support of the Cancer Moonshot, in January 2017, the National Cancer Institute (NCI) launched the NCI Formulary, a public-private partnership between NCI and pharmaceutical and biotechnology companies. By working with the NCI Formulary, investigators eliminate the need to negotiate directly with companies, thus expediting the start of clinical trials by up to 18 months and facilitating faster development of new therapies for patients. Since its launch, the NCI Formulary has nearly doubled the number of agents it offers, providing researchers with access to a total of 27 targeted agents through partnerships with nine companies as of December 2017. As the ability to target the selection of cancer therapies to individual characteristics grows, the NCI Formulary's role in enabling investigators to conduct combination studies with multiple agents from different companies will become even more vital.

National Collaborative on Childhood Obesity Research

Collaborating with other federal agencies to address an expanding public health need, NIH plays an active role in the National Collaborative on Childhood Obesity Research (NCCOR). Obesity during childhood can lead to numerous negative physical and psychological effects including high blood pressure, breathing problems, musculoskeletal discomfort, depression, and low self-esteem, among others.[3] This problem is growing; approximately one in five school-aged children in the U.S. are obese, which is more than three times greater than the percentage of children who were obese in the 1970s.[4] To address this issue, NIH joined the Centers for Disease Control and Prevention (CDC), U.S. Department of Agriculture, and the Robert Wood Johnson Foundation to form NCCOR in 2009. NCCOR's focus is on evaluating and identifying effective interventions (particularly policy and environmental interventions) at the individual, community, and population levels in the areas of nutrition, physical activity, and weight control with a special emphasis on the lower-income and racial/ethnic populations at highest risk. From late 2017 through 2020, NCCOR will focus on efforts to accelerate progress against childhood obesity through better and more consistent measurement, including better tools and practices for measuring food intake and physical activity. Better measures will allow for further standardization, meta-analysis, and synthesis within the childhood obesity research field.

Innovation through Competition

Another type of partnership that NIH plans to expand is the use of prize competitions to complement traditional forms of financial support for the nation's biomedical researchers (i.e. grants, contracts, etc.). The Budget allocates $50 million for prize competitions under the authority of Section 105 of the America COMPETES Reauthorization Act of 2010. This will focus on the types of innovation highlighted in Section 2002 of the 21st Century Cures Act, including monitoring the effect of innovations funded through prize competitions on advancing

[3] https://www.cdc.gov/obesity/childhood/causes.html
[4] https://www.cdc.gov/healthyschools/obesity/facts.htm

biomedical science or improving health outcomes. The prize funding will be housed in the Common Fund and available for competitions sponsored by any NIH Institute, Center, or Office.

Theme 2: Supporting Basic Research to Drive New Understanding of Health and Disease

NIH is the largest single funder of basic biomedical research in the U.S, providing a critical research foundation for both the public and private sectors to build upon. NIH supports a robust basic research portfolio which studies both how healthy living systems function outside the context of a particular disease as well as research to understand the mechanisms of disease. Studies of healthy systems help researchers recognize how such systems go wrong in cases of disease and injury, and which elements might need to be restored in order to treat such conditions. Characterizing the underlying mechanisms of disease enables scientists to comprehend the causes of disease onset and progression, identify key risk factors, or scout out new potential targets for therapies and cures.

It is difficult to predict where dramatic new scientific breakthroughs will arise, given that many involve unexpected connections among otherwise incremental advances. In order to maintain the flexibility to capture unanticipated breakthroughs as well as making steady progress in as many research areas as possible, NIH funds a broad spectrum of basic science research. In addition, NIH provides the resources, infrastructure, and overarching vision that allows the field to capitalize on scientific opportunities as they arise.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a key example of NIH's approach to fostering basic research. 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. For example, one project looked at improving mathematical methods for analyzing human brain activity from functional magnetic resonance imaging (fMRI) scans to better understand the underlying networks of neural connections within the brain. These improved methods allowed researchers to look at how those underlying networks are changed in patients with an early stage of dementia called mild cognitive impairment, which one day may allow for earlier diagnosis of the disease. In FY 2019, NIH will support research projects to advance progress toward the goals outlined in *BRAIN 2025: A Scientific Vision*[5].

Transformative High-Resolution Cryo-Electron Microscopy (Cryo-EM) Program

The NIH Common Fund supports transformative, trans-NIH research that capitalizes on scientific opportunities, often with the goal of advancing basic research. The Transformative

[5] https://www.braininitiative.nih.gov/pdf/BRAIN2025_508C.pdf

High-Resolution Cryo-Electron Microscopy (Cryo-EM) program is one example of how the Common Fund drives basic research. [6] Cryo-EM, named Nature Methods' "Method of the Year" in 2016, is a technique used to image frozen biological molecules without the use of structure-altering dyes or fixatives, providing a more accurate picture of the molecules and greater understanding of biological function. An accurate, high-resolution understanding of the structure of biological molecules can provide essential information about how molecules function, and can reveal potential targets for therapies in disease. For example, cryo-EM has been used to create a detailed structure of the protein CFTR, which is mutated in patients with cystic fibrosis, allowing researchers to better understand how the protein's function is disrupted, and how it might be rescued. This Common Fund program aims to provide nationwide access for researchers to cryo-EM through the creation of national service centers, improvement of the technology, and the development of an expert workforce, broadening access to transformative tools for researchers across the country.

Human BioMolecular Atlas Program (HuBMAP)

Another NIH Common Fund program supporting basic research is the Human BioMolecular Atlas Program (HuBMAP). Humans are made up of diverse cell types formed during the course of development, each with unique functions and roles that contribute to physiological structures and processes within the body. The organization and variability of these cells have a profound impact on the function of different tissues, the process of aging, and the emergence of diseases and conditions. New technologies are allowing researchers to explore molecular differences and characterize new types of cells down to the individual cellular level. HuBMAP supports technology development and research to take a census of cell types in human tissues, to understand the relationships between cellular organization and function, and to understand how much individual cells vary within a particular cell type. By generating a detailed molecular "atlas" of cell types within the human body, basic researchers will provide data that can be used to better understand disease states and develop new, targeted therapies.

Exploring the Frontiers of Gene Editing

Gene editing techniques to precisely change specific sequences in the human genome raises the possibility of a fundamentally new approach to treat diseases, such as genetically engineered immune cells to fight cancer (immunotherapy) or use of the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) method to "fix" the mutations that cause sickle cell disease. However, efficacy, specificity, and delivery of modified cells remain challenging. The NIH Common Fund is launching a new program called "Somatic Cell Genome Editing" in FY 2018 to improve the efficacy and specificity of genome editing approaches. The research tools developed through this program will be made widely available to the research community to reduce the time and cost required to develop new therapies.

NIH believes that these programs, and others like them, represent a crucial investment in the early stages of biomedical research, providing essential information on how living systems work. By making a substantial investment in basic research, NIH fulfills its role as the foundation of

[6] https://commonfund.nih.gov/CryoEM

the biomedical research enterprise, feeding discoveries into the system that will ultimately lead to interventions, treatments, and cures.

Theme 3: Investing in Translational and Clinical Research to Improve Health

Building on a robust foundation of basic research, NIH supports translational research that applies fundamental knowledge to discover new strategies for intervening in disease processes through better detection, prevention, or treatment. 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 its strategic plan 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 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.

Regenerative Medicine

Fundamental understanding of development, cellular and organ functioning, and other factors have given rise to the promising multidisciplinary field of regenerative medicine, which seeks to develop functional tissues and organs to repair or replace biological structure and function that has been lost due to injury, disease, or aging. These aims are achieved by integrating tissue engineering and cell-based therapy techniques. For example, NIH supports the (Re)Building a Kidney Consortium, whose goal is to coordinate and support studies that will result in the ability to replicate or repair kidney function. The Consortium supports a variety of translational research approaches, including bioengineering, 3D printing, and developing novel in vitro models to study organ structure and function.

Preclinical studies have demonstrated that regenerative medicine approaches may be effective, and some clinical trials on the safety and efficacy of these therapies are underway. Given the potential promise of regenerative medicine therapies, the 21st Century Cures Act (P.L.114-255) included a Regenerative Medicine Innovation project, providing $30 million over 4 years for clinical research with adult stem cells. In September 2017, NIH issued the first awards under this project, funding eight clinical research projects to advance understanding of and discover new treatments for common diseases such as diabetes, anemia, eye diseases, and chronic skin ulcers, as well as rare diseases such as idiopathic pulmonary fibrosis, sickle cell disease, and inherited skin diseases. These awards were made in coordination with FDA, which will facilitate a smoother regulatory approval process as therapies are developed. The FY 2019 request includes $10 million in Innovation Funds for this area of research, which will be augmented by matching funds and individual IC support.

Universal Influenza Vaccine

The flu (influenza) virus remains a deadly and costly pathogen, placing a substantial health and economic burden on the U.S. and across the world each year. In the U.S., CDC estimates that the flu has resulted in between 9.2 million and 35.6 million illnesses, between 140,000 and 710,000 hospitalizations, and between 12,000 and 56,000 deaths annually since 2010,[7] all of which results in an estimated $27 billion in health costs alone.[8] Vaccination is the most effective way to reduce flu morbidity and mortality. Annual seasonal flu vaccines confer protection against some, but not all, flu strains and must be developed months in advance of the flu season. This strategy relies heavily on scientists being able to predict ahead of time which strains will be in circulation each year. The result is that a vaccine may be less effective if a strain not included in vaccine development predominates—a particular concern in the case of rare but unpredictable pandemic outbreaks. This underscores the need for new approaches to flu vaccine R&D, in particular, the development of a single "universal flu vaccine" that would provide safe, effective and long-lasting immunity against a broad spectrum of flu viruses, both seasonal and novel. NIH-funded researchers are making progress toward this goal by targeting a particular protein on the surface of the flu virus, several versions of which are being evaluated for further clinical study. In addition, clinical trials already are underway for an alternative approach involving a DNA-based vaccine and a seasonal booster. Continued investment in this research will enable the fastest possible vaccine development to protect millions of people from infection.

Addressing Zika Virus Infection

Threats to public health evolve as new disease-causing pathogens emerge or familiar ones reemerge with new properties, and NIH is at the forefront of defending against these threats. In 2015, the threat from the Zika virus rose as infection spread rapidly across Central and South America. The Zika virus is primarily transmitted to humans through mosquitoes, and for most people symptoms generally are mild. However, transmission from an infected pregnant woman to her baby can result in serious birth defects, including microcephaly; a concern which has grown since the first case of locally transmitted Zika virus in the continental United States was confirmed in July 2016. To address this problem, NIH is working with government, academic, and industry partners to accelerate research to understand how the Zika virus causes disease, as well as to develop treatments and vaccines. Currently underway are two population studies: the first to understand the effect of Zika infection on pregnant women and babies, and the second to gain insight on outcomes of infection acquired after birth in babies and children.

In addition, mouse models have been used to help NIH and their partners to develop vaccine candidates to restrict Zika virus transmission from mother to fetus in pregnant mice. Mouse models also have shown that Hydroxychloroquine, a drug approved by the FDA to treat malaria and certain autoimmune diseases in pregnant women, appears to reduce transmission of Zika virus from pregnant mice to their fetuses. Through the NIH drug repurposing screening program, two further classes of compounds have been identified that might be effective against Zika. As translational research bears fruit, NIH is now beginning to launch clinical trials in humans. In 2017, NIH launched an efficacy trial on an experimental DNA vaccine against Zika

[7] https://www.cdc.gov/flu/about/disease/burden.htm.
[8] https://www.niaid.nih.gov/sites/default/files/univflu508b.pdf.

in the U.S. and Central and South America. Early reports from Phase I clinical trials show that the vaccine is safe and induces an immune response in healthy humans.[9]

Tissue Chip for Drug Screening Program

Translating how a basic finding from the laboratory might work in the human body is a challenging process. NIH supports a number of initiatives and projects to develop new tools and resources to overcome these challenges and hasten progress. One such initiative, the Tissue Chip for Drug Screening program, is designed to facilitate faster development of new therapeutics by creating novel model systems to screen potential new drugs that more accurately mimic the human body than current models. Conducted in collaboration with the Defense Advanced Research Projects Agency (DARPA), and the FDA, the program aims to develop microfabricated chips—called "tissue chips" or "organs-on-chips"— capable of maintaining living human cells and tissues. These cells and tissues are organized to model intact human organ systems, with the goal of eventually creating an integrated human-body-on-a-chip. Once developed and integrated, researchers can use these models to predict whether a candidate drug, vaccine, or biologic agent is safe or toxic in humans in a faster and more effective way than current methods. For example, a team of scientists have created EVATAR™, a miniature working 3-D representation of the female reproductive tract, along with the liver.[10] Tissue chips may be used to study both normal function and disease states. In September 2017, NIH announced 13 new awards to study a wide range of common and rare diseases.[11] In the second phase of these awards, researchers will partner with pharmaceutical companies to evaluate the usefulness of these models in assessing the effectiveness of candidate drugs.

All of Us Research Program

Far too many diseases do not have a proven means of prevention or effective treatment, and in particular, what works for one person may not always work for another. Precision medicine is a revolutionary approach for disease prevention and treatment that takes into account individual differences in lifestyle, environment, and biology, such as genetics. The first step in this approach is to provide a window into these different factors to understand their respective and combined influences on both health and disease. This understanding would enable the development of interventions tailored towards individuals for optimal success and efficiency. Spearheading this approach, the *All of Us* Research Program, launched in FY 2016, is an ambitious effort to gather data over many years from one million or more people living in the United States. Unlike research studies that are focused on a specific disease or population, *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions. At the same time, participants may be able to learn more about their own health and contribute to an effort that may advance the health of generations to come.

[9] Gaudinski, M.R., et al. *Lancet* 2017;S0140-6736(17)33105-7. PMID: 29217376.
[10] Xiao S, et al. A microfluidic culture model of the human reproductive tract and 28-day menstrual cycle. *Nat Commun* 2017;8:14584. PMID: 28350383
[11] https://www.nih.gov/news-events/news-releases/nih-awards-15-million-support-development-3-d-human-tissue-models

The *All of Us* Research Program collaborates with other federal agencies within HHS and across the government, including the FDA, the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), the Department of Veterans Affairs (VA), the Department of Defense (DoD), and the Department of Energy (DoE). Indicative of the importance of this initiative, the 21st Century Cures Act included nearly $1.5 billion for *All of Us* over the next decade, and several key implementation milestones already have been reached. In May 2017, participant enrollment began at select sites. This first wave of beta testers is helping to identify and fix problems with the system before full enrollment is launched in the spring of 2018. NIH also has invested in a state-of-the-art biobank and built big data IT systems to transfer and store data for use by researchers, with safeguards in place to keep participants' information private and secure. In July 2017, NIH announced its first four community partner awards, totaling $1.7 million, to begin building a national network of trusted leaders to motivate diverse communities to join the *All of Us* Research Program. Shortly after, NIH announced fourteen national community groups and health care provider association awards, totaling $1 million, to help raise awareness about the program by educating communities about the benefits of participation in this landmark program. NIH has also established a partnership with the National Network of Libraries of Medicine, totaling $4.5 million, to support community engagement efforts by public libraries across the nation and improve participant access. Representing a new era of treatment and disease prevention, continued support of this groundbreaking effort will accelerate research and improve health.

Environmental Influences on Child Health Outcomes (ECHO) Program

NIH is supporting another cohort study to better understand the impact of the environment on health. In FY 2016, NIH launched the Environmental Influences on Child Health Outcomes (ECHO) program to investigate the effect of a broad range of exposures—from air pollution and chemicals in our neighborhoods, to societal factors such as stress, to individual behaviors like sleep and diet—during the sensitive developmental window from conception through early childhood. In addition to leveraging existing cohorts, another critical component of ECHO is leveraging the NIH-funded Institutional Development Awards (IDeA) program to build state-of-the art pediatric clinical research networks in rural and medically underserved areas so that children from these communities can more easily participate in clinical trials. ECHO studies will focus on key pediatric outcomes that have a high public health impact, including upper and lower airway health and development, obesity, brain development, and positive health. With $157 million in awards announced in FY 2016 to build infrastructure and capacity, the ECHO program is off to a promising start. In FY 2017, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the IDeA States Clinical Trials Network are collaborating to support the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW) study. ACT NOW will fund research on opioids and pregnancy outcomes by addressing critical gaps on how best to treat and manage opioid withdrawal syndrome in newborns. Every baby should have the best opportunity to remain healthy and thrive throughout childhood; ECHO answers this call, helping us understand with better precision the factors that contribute to optimal health in children.

Advances in Cancer Treatment

Cancer remains a leading cause of death in the U.S. 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. For example, in FY 2015, the National Cancer Institute (NCI) launched Molecular Analysis for Therapy Choice (NCI-MATCH), a unique precision medicine Phase 2 clinical trial, to determine whether targeted therapies for people whose tumors have specific gene mutations will be effective regardless of their cancer type. Building on this approach, in July 2017, enrollment began for Pediatric MATCH. Similar to MATCH, this nationwide Phase 2 trial will explore whether targeted therapies can be effective for children and adolescents with cancer tumors that have specific genetic signatures and have progressed during or after standard therapy. Precision medicine trials like MATCH have the potential to accelerate progress in identifying more effective treatments for people with cancer, and these clinical trials illuminate the way for future endeavors.

Cancer immunotherapy is another rapidly advancing approach to cancer treatment. Patients with a variety of cancers, including melanoma, non-small cell lung cancer, leukemia, colorectal cancer, and breast cancer have already benefitted from immunotherapy, and NIH-supported researchers hope to expand these results to other disease areas. Two major advances in this area include Keytruda, the first immunotherapy to be FDA-approved for all cancers with a specific biomarker, regardless of where the cancer is found in the body,[12] and chimeric antigen receptor T-cells (CAR-T), a treatment that uses a patient's own immune cells to more effectively combat cancer.[13] To harmonize research efforts in this area, the Cancer Moonshot Blue Ribbon Panel established the Cancer Immunology Working Group. This working group will create and implement a national strategy to discover and evaluate novel immunotherapies that, in the short term, increase the cure rate in cancer patients and eventually provide the opportunity to develop immune-based approaches that prevent cancers of all types.[14] Furthermore, NIH-supported researchers are also combining precision medicine and cancer immunotherapy approaches to understand how some cancers become resistant to cancer immunotherapy.[15] Cancer immunotherapy alone, or in combination with other treatments such as chemotherapy, has the potential to more effectively treat patients with many types of cancer.

[12] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm560167.htm
[13] https://directorsblog.nih.gov/2017/08/30/fda-approves-first-car-t-cell-therapy-for-pediatric-acute-lymphoblastic-leukemia/
[14] https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/cancer-immunology-working-group-report.pdf
[15] https://projectreporter.nih.gov/project_info_description.cfm?aid=9087003&icde=32574780

Combatting the Opioid Epidemic

Opioid misuse and addiction is an ongoing and rapidly evolving public health crisis. According to the Centers for Disease Control and Prevention (CDC), in 2016 alone more than 42,000 deaths involved opioid use. Driven by the abuse and misuse of prescription pain relievers such as oxycodone, synthetic opioids such as fentanyl, and the illegal drug heroin, the opioid epidemic not only poses a tremendous public health challenge, but also threatens our social and economic welfare. The urgency and scale of this crisis calls for innovative scientific solutions.

As part of a larger government-wide effort to address the opioid crisis, NIH will enhance existing research efforts, investing $850 million (including $750 million from an HHS-wide $10 billion investment) in an ambitious series of projects, including a multi-year public-private partnership to accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose and to help optimize their implementation. In consultation with experts from government, industry, and academia, NIH has proposed a coordinated strategy with two primary aims: 1. Develop new formulations and combinations of medications to treat opioid use disorders and prevent and reverse overdose; and 2. Accelerate development of new non-addictive pain therapies.

Several effective therapies exist to treat opioid use disorder and reverse overdose from opioid drugs. Medication-assisted treatment in which patients with opioid use disorder receive medications (methadone, buprenorphine, or naloxone) in conjunction with psychosocial support, is effective. However, only a small proportion of patients are retained in treatment for long-term recovery. NIH will increase significantly its research investment in treatments for substance use disorders, and work with private-sector partners to develop new formulations and combinations of medications to treat opioid use disorders and prevent and reverse overdose, with the goal of making a wide range of therapeutic options accessible to those who need them as quickly as possible.

Much of the opioid epidemic has struck patients seeking relief from very real sources of pain. The development of new pain treatments that lack the addictive properties of many of today's pain medications could prevent many patients from developing opioid use disorder. NIH will work with the Food and Drug Administration and pharmaceutical partners to build a public-private partnership to accelerate the development of new non-addictive pain therapies and make these widely available to patients in need.

Finally, NIH will work with other federal partners to incentivize development of new therapies and to develop and evaluate metrics for high-quality treatment.

Theme 4: Fostering an Inclusive and Talented Biomedical Research Workforce for Today and Tomorrow

A sustainable and inclusive biomedical research workforce, comprising all levels of researchers, is necessary for ensuring innovation in the biomedical and behavioral sciences. For NIH to achieve its mission, inquisitive and talented people such as established scientists, postdoctoral researchers, students, and clinicians are essential. NIH remains committed to the development, support, and retention of a motivated workforce that includes varied backgrounds and experiences as well as a broad range of expertise. NIH cultivates the human capital needed to fulfill its mission by investing in outstanding researchers with high potential, strengthening an inclusive biomedical research community, and by investing in clinician-scientists.

Supporting Early-Stage and Mid-Career Investigators

Attracting and retaining creative individuals in the biomedical research workforce requires a stable environment and opportunities for career growth. At a time where the number of applications received by NIH has risen at a rate faster than that of its budget, the biomedical workforce has grown increasingly concerned about the long-term stability of the biomedical research enterprise. In what has become an increasingly hypercompetitive environment, an investigator must spend more time seeking funds and consequently less time conducting science. This is especially challenging to those just starting their career and to recently-established independent investigators who, faced by the prospect of struggling for funding, may turn away from a career in science. This disincentive threatens the future of biomedical research.

To help create a stable path for the next generation workforce and ensure the best and brightest scientists remain in research, NIH launched the Next Generation Researchers Initiative (NGRI) in August 2017.[16] The 21st Century Cures Act encouraged NIH to develop policies that will promote earlier independence and increased rates of funding for early career investigators through the creation of the NGRI, which seeks to address challenges faced by researchers trying to embark upon and sustain independent research careers. To achieve this aim, all NIH Institutes and Centers (ICs) are committing to prioritize awards that will fund promising investigators at early stages in their career, including those seeking their first independent substantive research award. For FY 2019, the Budget includes a dedicated fund of $100 million in the Office of the Director that Institutes and Centers would be able to draw on to supplement the NGRI efforts undertaken with their own appropriations.

As part of NGRI, each IC will develop evidence-based strategies to support their mission-specific workforce that consider factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce. New methods for measuring the effects of these strategies will be devised, with special attention paid to assessing the ability to enhance workforce inclusion. Using these strategies, NIH will be able to monitor closely its success in ensuring that talented early career investigators have improved opportunities to launch and sustain a successful career.

Supporting Outstanding Scientists

Another strategy to improve stability for promising scientists is to provide steady support for a longer period of time and with greater flexibility to pursue promising scientific directions. To this end, several NIH ICs have implemented new funding opportunities to support an investigator's entire program of research, rather than an individual project, so that researchers can pursue unexpected avenues of inquiry as they arise. One such award, through the National Institute of General Medical Sciences (NIGMS), is the Maximizing Investigators' Research Award (MIRA).[17] The initial pilot program for MIRA included separate funding opportunities for both established investigators and early-stage investigators. Following successful completion of the pilot, NIGMS elected to expand the eligibility criteria of the program in order to provide

[16] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html
[17] https://www.nigms.nih.gov/Research/mechanisms/MIRA/Pages/default.aspx

additional participatory opportunities for investigators. A strategy for hastening the pathway to a successful scientific career of especially promising early investigators is funded through the Common Fund's High-Risk, High-Reward Research program.[18] In FY 2017, NIH issued 86 awards for this program.[19] The Early Independence Award supports outstanding junior scientists with the intellect, scientific creativity, drive, and maturity to flourish independently by bypassing the traditional post-doctoral training period. [20] Receiving this award accelerates the entry of exceptional junior investigators into positions of independent research. Additionally, the New Innovator award supports exceptionally creative early career investigators who propose innovative, high impact projects.[21] To be eligible for this award, a researcher must be within 10 years of completing a doctoral degree or medical residency and have never received an NIH Research Project Grant or equivalent award.

Strengthening the Inclusiveness of the Workforce

Technological advances and a new understanding of the vast complexity of biological systems and their behaviors are driving biomedical research toward increasingly multidisciplinary work. Career paths outside of academia also have become increasingly common and important in sustaining a robust biomedical research enterprise. Given the changing research environment, it is vital to equip early-stage scientists with a range of skills and experiences as well as to ensure a workforce that represents the racial, cultural, demographic, and geographic richness embodied by our country.

NIH strives for a biomedical workforce that reflects the range of backgrounds of the public it serves. To foster this value, NIH's National Research Mentoring Network (NRMN)[22] was created to increase access to high-quality research mentorship and networking opportunities for individuals with disparate backgrounds by establishing a nationwide, interconnected set of skilled mentors linked to mentees from a variety of scientific disciplines. In addition to establishing mentor-mentee relationships, the program seeks to develop best practices for mentoring, provide training for mentors, as well as professional opportunities for mentees. A trio of awards and initiatives serve as premiere examples of the programs NIH designs in order to encourage individuals with varied backgrounds to participate in science. Now in its third year, the Building Infrastructure Leading to Diversity (BUILD) Initiative supports training awards designed to apply experimental approaches towards attracting and retaining an inclusive array of students into the training pipeline. BUILD awardees work with multiple partnering institutions with high concentrations of students from disadvantaged backgrounds to test and implement transformative, broad-based approaches to the training and mentoring of students to undertake biomedical research.[23] Another program, the Institutional Research and Academic Career Development Awards (IRACDA),[24] promotes consortia between research-intensive institutions and partner institutions that have a historical mission of and a demonstrated commitment to providing training, encouragement, and assistance to students from underrepresented groups.

[18] https://commonfund.nih.gov/earlyindependence
[19] https://www.nih.gov/news-events/news-releases/nih-directors-high-risk-research-awards-announced-2017
[20] https://commonfund.nih.gov/earlyindependence
[21] https://commonfund.nih.gov/newinnovator
[22] https://www.nigms.nih.gov/training/dpc/pages/nrmn.aspx
[23] https://www.nigms.nih.gov/training/dpc/pages/build.aspx
[24] https://www.nigms.nih.gov/Training/CareerDev/Pages/TWDInstRes.aspx

Similarly, the Research Initiative for Scientific Enhancement (RISE) program[25] provides support to institutions with a commitment and history of developing students from populations underrepresented in biomedical sciences.

Supporting clinician-scientists

One of the most important functions of the NIH is to foster the translation of basic biomedical research findings from the laboratory bench to the patients and communities that can benefit from advances in medicine. By recruiting and supporting clinician-scientists in the biomedical research workforce the NIH is able to both build a clinical perspective into research activities and encourage practitioners to consider the research implications of their observations and practices. Recruiting clinicians into research, however, can be challenging. The training required to be both a practicing physician, nurse, or other clinician coupled with the lengthy requirements of research degrees can discourage candidates. Based on the recommendations from three workshops held in 2016, NIH recently released a Funding Opportunity Announcement entitled Stimulating Access to Research in Residency (StARR) to provide support for institutional research in residency programs.[26] Also, NIH issued a Request for Information (RFI) to gather input on potential revisions to the Medical Scientists Training Program (MSTP), which trains students pursuing dual health profession and Ph.D. degrees. This input will be reflected in a new Funding Opportunity Announcement to be released in FY 2018. Through these and other efforts, NIH is looking to both improve the quality of clinician-researcher training and to shorten the time each individual needs to invest in training.

Advancing Data Science

In 2012, NIH established the Big Data to Knowledge (BD2K) initiative and created a new Associate Director for Data Science (ADDS) position. In the years since, NIH has established extramural Centers of Excellence, piloted a "Data Commons," and supported enhanced training of data scientists and bioinformaticians. In FY 2019, NIH would begin the next phase of its data science activities with a $30 million fund, managed by the ADDS, to build on the success of BD2K as that initiative enters its final stages.

Optimize NIH

The Optimize NIH Initiative, part of the HHS effort to implement OMB Memorandum M-17-22 (Comprehensive Plan for Reforming the Federal Government and Reducing the Federal Civilian Workforce), is intended to increase the efficiency and effectiveness of the administrative operations that advance our scientific mission. The goals of the Initiative are improving services through coordinating and optimizing comparable functions across selected functional areas, maximizing employee engagement, and enhancing stewardship of taxpayer dollars. The Initiative will consist of three phases:

[25] https://www.nigms.nih.gov/Training/RISE/Pages/default.aspx
[26] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html

1. Enterprise-wide functional cores
2. Harmonization of scientific or mission-specific functions
3. Operational service center cores

For each phase, NIH will approach this optimization effort in a data-driven, scientific manner. NIH staff will perform a review to identify, map, and analyze all the key processes within the functions and identify opportunities for improvement. After this detailed process review, an implementation plan will be developed. Information technology needs and staffing gaps or redundancies will be evaluated, and lessons learned from each phase will be applied to the other phases. We anticipate that the re-engineering of our processes will yield the single largest increase in our overall efficiency.

Initially, the Optimize NIH Initiative will focus on enterprise-wide functional cores in the following three areas: Ethics, FOIA, and Committee Management. This phase is under way, and NIH anticipates that additional enterprise-wide functional cores may be reviewed for future optimization opportunities. The second phase will focus on the harmonization of scientific or mission-specific functions, such as grants management, scientific review of grant applications, or strategic planning, that will be kept at the IC level but may benefit from adoption of best practices. In some cases, this will allow a more equitable distribution of workload across NIH. In the last phase, NIH is planning to "cluster" activities at its Institutes and Centers (ICs), and the NIH Office of the Director (OD), into 7 Operational Service Centers over the next 24-36 months. These Centers will serve as cores to harmonize and integrate a variety of administrative support functions. In addition to these phases, Federal staff hiring at NIH is being coordinated centrally for consistency with recent levels, and will continue to be coordinated with the Optimize NIH plan.

Conclusion

The Nation's investment in NIH is borne 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, but also 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. The gains made in life expectancy in the U.S. for the period of 1970 to 2000 have been estimated to have an economic value of $95 trillion, about $3.2 trillion per year. 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 approximately $50 trillion—more than three times today's GDP.[27]

[27] http://www.ucema.edu.ar/u/je49/capital_humano/Murphy_Topel_JPE.pdf

Not only does NIH research benefit the economy through improvements in health, it is also a driver of industry, spurring innovation and growth in medical technology, pharmaceutical therapies, and biotechnology. The Human Genome Project alone likely resulted in as much as $1 trillion of economic growth, a 178-fold return on investment.[28]

Continued, targeted support of NIH is an investment in the well-being of the Nation now and into the future. Working with its many partners, NIH is well prepared to address current health needs and to capitalize on emerging scientific opportunities, the benefits of which will be felt by all generations to come.

[28] http://web.ornl.gov/sci/techresources/Human_Genome/publicat/2013BattelleReportImpact-of-Genomics-on-the-US-Economy.pdf

OVERVIEW OF PERFORMANCE

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Investments in basic biomedical and behavioral research make it possible to understand the causes of disease onset and progression, design preventive interventions, develop better diagnostics, and discover new treatments and cures. Realizing the benefits of fundamental biomedical discoveries depends on 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 2019 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 RePORT) 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 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 1-3 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 ICs and 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. Each IC and OD office carries out priority setting, performance monitoring, progress reviews, and makes 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.

Research is an inherently collaborative endeavor, and partnerships are crucial to achieving scientific research outcomes. The role of the extramural research community (the scientists at universities and hospitals across the country and around the world) as NIH's partner in research is well known. However, of increasing importance are partnerships with private companies, not-for-profit institutions, non-governmental organizations, other Federal agencies, and state and international entities. Joint research and training activities and other exchanges with such groups increase the leverage of NIH resources and support vibrant partnerships to help NIH achieve its mission. Moreover, such partnerships facilitate valuable information feedback loops that

identify emerging needs, suggest important new research questions, and otherwise inform priority setting. Partnerships also provide access to populations that are essential to advancing knowledge.

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 includes the largest category of NIH-funded research, utilizes two levels of peer review. The first level consists of chartered scientific review groups composed of outside experts in particular scientific disciplines. The second level is the National Advisory Councils of the ICs. For the Intramural Research Program, the progress of individual scientists and their laboratories is evaluated once every four years by Boards of Scientific Counselors composed of external experts. These reviews enable ongoing assessments of all intramural labs and the accomplishments of the scientists who contribute to them. It is through this well-honed system of peer review that NIH maintains its focus on supporting research of the highest possible quality.

The NIH approach to performance management is undergirded by the NIH Governance Structure. That structure includes the NIH Steering Committee and seven standing Working Groups.[29, 30] 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, 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.

[29] The NIH Steering Committee is composed of the NIH Director, Deputy Director (ex-officio), the Directors of NCI, NHLBI, and NIAID, as well as a balance of Directors from the smaller and medium-sized institutes.
[30] The seven standing working groups are: Extramural Activities, Diversity, Facilities, Management and Budget, Scientific Data Council, Administrative Data Council, and Data Science Policy Council.

ALL PURPOSE TABLE

(Dollars in Thousands)[2,3]	FY 2017 Final[1]	FY 2018 Annualized CR[1]	FY 2019 President's Budget[4]	FY 2019 President's Budget +/- 2018 Annualized CR
Total, NIH Program Level	**$34,229,139**	**$34,067,456**	**$34,766,707**	**$699,251**
Less mandatory and funds allocated from different sources:				
PHS Program Evaluation	824,443	818,844	741,000	-77,844
Mandatory Type 1 Diabetes Research	139,650	150,000	0	-150,000
Patient-Centered Outcomes Research Trust Fund (PCORTF)	0	0	124,349	124,349
Energy Employees Occupational Illness Compensation Program Act (EEOICPA)	0	0	55,358	55,358
Total, NIH Discretionary Budget Authority	**$33,265,046**	**$33,098,611**	**$33,846,000**	**$747,389**
Interior Budget Authority	77,349	76,824	53,967	-22,857
Total, NIH Labor/HHS Budget Authority	**$33,187,697**	**$33,021,788**	**$33,792,033**	**$770,245**
Number of Competing RPGs [5]	*10,123*	*8,656*	*9,084*	*428*
Total Number of RPGs [5]	*36,568*	*35,920*	*35,949*	*29*
FTEs [6]	*18,018*	*18,105*	*19,456*	*1,351*

[1] Excludes Ebola-related supplemental appropriations or transfers.

[2] Includes 21st Century Cures Act funding.

[3] Numbers may not add due to rounding.

[4] Includes funding and full-time equivalents (FTE) for proposed reorganizations supporting the establishment of the National Institute for Research on Safety and Quality (NIRSQ), National Institute for Occupational Safety and Health (NIOSH), and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

[5] Annual levels exclude grants funded by NIOSH and NIDILRR.

[6] The FY 2019 total includes an estimated 18,105 FTE for existing NIH Institutes and Centers (IC). A projected 1,351 FTE are associated with new ICs established by the proposed reorganization (1,072 for NIOSH, 247 for NIRSQ---including 2 funded from the PCORTF mandatory account, and 32 for NIDILRR).

IMPACT OF BUDGET LEVEL ON PERFORMANCE

Programs and Measures (Dollars in Millions, except where noted)	**FY 2018 Annualized CR**	**FY 2019 President's Budget[3]**	**FY 2019 +/- FY 2018**
Research Project Grants	$19,066.313	$18,894.528	-0.9%
Competing Average Cost (in thousands)	$518.305	$503.245	-2.9%
Number of Competing Awards (whole number)	8,656	9,084	4.9%
Estimated Competing RPG Success Rate	15.9%	16.0%	0.6%
Research Centers	$2,483.707	$2,482.718	0.0%
Other Research	$2,241.770	$2,192.596	-2.2%
Training	$839.805	$810.586	-3.5%
Research & Development Contracts	$2,896.751	$2,931.915	1.2%
Intramural Research	$3,787.681	$3,795.544	0.2%
Research Management and Support	$1,765.098	$1,757.337	-0.4%
Common Fund (non-add)	*$678.829*	*$598.781*	*-11.8%*
Buildings & Facilities Appropriation	$127.988	$200.000	56.3%
Other Mechanisms[1]	$858.343	$1,226.649	42.9%
Consolidations (except NIRSQ)	n/a	$474.834	n/a
Total, Program Level[2]	**$34,067.456**	**$34,766.707**	**2.1%**

[1] Includes Office of the Director-Other and Superfund Research activities funded from the Interior appropriation.

[2] Includes discretionary budget authority received from Labor/HHS appropriations (ICs) and the Interior appropriation (Superfund). Also includes mandatory budget authority derived from the Special type 1 Diabetes account (FY 2018 only) as well as Program Evaluation Financing.

[3] Includes funding for NIRSQ (except where noted), NIOSH, and NIDILRR associated with the proposed FY 2019 consolidation as well as PCORTF (NIRSQ) and EEOICPA (NIDILLR) mandatory accounts.

APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, $5,226,312,000 of which up to $20,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, $3,112,032,000.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to dental and craniofacial diseases, $413,196,000.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301, section 330B, and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, 1,965,434,000, of which $150,000,000, to remain available until expended, shall be for making grants under such section 330B.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

For carrying out section 301 and title IV of the PHS Act with respect to neurological disorders and stroke, $1,781,056,000.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to allergy and infectious diseases, $4,761,948,000.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, $2,572,669,000, of which $741,000,000 shall be from funds available under section 241 of the PHS Act.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, $1,339,592,000.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, $711,015,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, $693,199,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For necessary expenses for the National Institute of Environmental Health Sciences in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9660(a)) and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, $53,967,000.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, $1,988,200,000.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to arthritis and musculoskeletal and skin diseases, $545,494,000.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

For carrying out section 301 and title IV of the PHS Act with respect to deafness and other communication disorders, $423,992,000.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, *$145,842,000.*

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

For carrying out section 301 and title IV of the PHS Act with respect to alcohol abuse and alcoholism, $469,109,000.

NATIONAL INSTITUTE ON DRUG ABUSE

*For car*rying out section 301 and title IV of the PHS Act with respect to drug abuse, *$1,137,403,000.*

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, $1,554,692,000.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, $512,979,000.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, $346,550,000.

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to complementary and integrative health, $130,717,000.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

For carrying out section 301 and title IV of the PHS Act with respect to minority health and health disparities research, $280,545,000.

JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart 2 of part E of title IV of the PHS Act), $70,084,000.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, $395,493,000: Provided, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, 2020: Provided further, That in fiscal year 2019, the National Library of Medicine may enter into personal services contracts for the provision of services in facilities owned, operated, or constructed under the jurisdiction of the National Institutes of Health (referred to in this title as "NIH").

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, $685,087,000: Provided, That up to 10 percent of the amount available under this heading shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network.

OFFICE OF THE DIRECTOR

For carrying out the responsibilities of the Office of the Director, NIH, $1,795,706,000: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: Provided further, That $586,181,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: Provided further, That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director

of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act.

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, $12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code, for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act.

BUILDINGS AND FACILITIES

*For the study of, construction or demolition of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, $200,000,000, to remain available through September 30, 2*023.

NIH INNOVATION ACCOUNT

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the National Institutes of Health in this Act, $711,000,000, to remain available until expended: Provided, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act and are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act: Provided further, That of the amount appropriated under this heading, $400,000,000 shall be transferred to the "National Cancer Institute" for the purposes described in section 1001(b)(4)(C) of such Act, $57,500,000 shall be transferred to the "National Institute of Neurological Disorders and Stroke" for the purposes described in section 1001(b)(4)(B) of such Act, and $57,500,000 shall be transferred to the "National Institute of Mental Health" for the purposes described in section 1001(b)(4)(B) of such Act: Provided further, That remaining amounts may be transferred by the Director of the National Institutes of Health to any accounts of the National Institutes of Health: Provided further, That upon a determination by the Director that funds transferred pursuant to any of the previous provisos are not necessary for the purposes provided, such amounts may be transferred back to this account: Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

NATIONAL INSTITUTE FOR RESEARCH ON SAFETY AND QUALITY

For carrying out titles III and IX of the PHS Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, $255,960,000: Provided, That section 947(c) of the PHS Act shall not apply in fiscal year 2019: Provided further, That in addition, amounts received from Freedom of Information Act fees, reimbursable and interagency agreements, and the sale of data shall be credited to this appropriation and shall remain available until expended.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

For carrying out titles II, III, and XVII of the PHS Act, sections 101, 102, 103, 201, 202, 203, 301, and 501 of the Federal Mine Safety and Health Act, section 13 of the Mine Improvement

and New Emergency Response Act, and sections 20, 21, and 22 of the Occupational Safety and Health Act, with respect to occupational safety and health, $200,000,000.

ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM

For necessary expenses to administer the Energy Employees Occupational Illness Compensation Program Act, $55,358,000, to remain available until expended: Provided, That this amount shall be available consistent with the provision regarding administrative expenses in section 151(b) of division B, title I of Public Law 106-554.

NATIONAL INSTITUTE ON DISABILITY, INDEPENDENT LIVING, AND REHABILITATION RESEARCH

For carrying out title II (and section 14 with respect to such title) of the Rehabilitation Act of 1973, $95,127,000.

BUDGET MECHANISM TABLE

(Dollars in Thousands)[1]	FY 2017 Final[3,4]		FY 2018 Annualized CR[3,4]		FY 2019 President's Budget[4,10]		FY 2019 +/- FY 2018	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	24,638	$12,661,301	25,468	$13,495,362	25,030	$13,291,723	-438	-$203,639
Administrative Supplements[2]	*(1,508)*	225,445	*(1,174)*	157,514	*(952)*	112,473	*(-222)*	-45,041
Competing	10,123	$5,283,732	8,656	$4,486,448	9,084	$4,571,486	428	$85,038
Subtotal, RPGs	34,761	$18,170,479	34,124	$18,139,325	34,114	$17,975,682	-10	-$163,643
SBIR/STTR	1,807	923,162	1,796	926,988	1,835	918,846	39	-8,142
Research Project Grants	36,568	$19,093,641	35,920	$19,066,313	35,949	$18,894,528	29	-$171,785
Research Centers:								
Specialized/Comprehensive	1,004	$1,766,720	979	$1,706,013	1,082	$1,709,109	103	$3,096
Clinical Research	67	402,112	71	418,602	85	405,881	14	-12,721
Biotechnology	105	187,352	101	175,897	123	180,243	22	4,346
Comparative Medicine	48	121,663	47	118,807	51	127,634	4	8,827
Research Centers in Minority Institutions	24	58,462	24	64,388	22	59,851	-2	-4,537
Research Centers	1,248	$2,536,309	1,222	$2,483,707	1,363	$2,482,718	141	-$989
Other Research:								
Research Careers	3,712	$672,622	3,792	$688,038	4,226	$752,342	434	$64,304
Cancer Education	83	23,629	85	24,147	94	26,492	9	2,345
Cooperative Clinical Research	329	403,274	265	377,633	291	400,779	26	23,146
Biomedical Research Support	109	69,962	109	68,778	63	39,703	-46	-29,075
Minority Biomedical Research Support	281	104,119	281	103,454	357	110,179	76	6,725
Other	1,863	907,363	1,954	979,720	2,088	863,101	134	-116,619
Other Research	6,377	$2,180,970	6,486	$2,241,770	7,119	$2,192,596	633	-$49,174
Total Research Grants	44,193	$23,810,919	43,628	$23,791,790	44,431	$23,569,842	803	-$221,948
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,599	$157,826	3,554	$159,393	3,488	$157,910	-66	-$1,483
Institutional Awards	12,419	669,571	12,471	680,412	12,282	652,676	-189	-27,736
Total Research Training	16,018	$827,397	16,025	$839,805	15,770	$810,586	-255	-$29,219
Research & Develop. Contracts	2,028	$3,070,430	2,018	$2,896,751	2,003	$2,931,915	-15	$35,164
(SBIR/STTR) (non-add)[2]	*(88)*	*(57,569)*	*(78)*	*(60,086)*	*(98)*	*(61,241)*	*(20)*	*(1,155)*
Intramural Research		$3,782,692		$3,787,681		$3,795,544		$7,863
Res. Management & Support		1,747,769		1,765,098		1,757,337		-7,761
Res. Management & Support (SBIR Admin) (non-add)[2,11]		*(5,695)*		*(0)*		*(0)*		*(0)*
Office of the Director - Appropriation[2,5]		*(1,728,603)*		*(1,706,132)*		*(2,004,306)*		*(298,174)*
Office of the Director - Other		754,016		751,723		1,152,682		400,959
ORIP (non-add)[2,5]		*(279,131)*		*(275,580)*		*(252,843)*		*(-22,737)*
Common Fund (non-add)[2,5]		*(695,456)*		*(678,829)*		*(598,781)*		*(-80,048)*
Buildings and Facilities[6]		158,567		157,784		220,000		62,216
Appropriation		*(128,567)*		*(127,988)*		*(200,000)*		*(72,012)*
National Institute for Occupational Safety and Health[9]		---		---		200,000		200,000
National Institute on Disability, Independent Living, and Rehabilitation Research[9]		---		---		95,127		95,127
Special type 1 Diabetes[7]		-139,650		-150,000				150,000
Program Evaluation Financing[8]		-824,443		-818,844		-741,000		77,844
Subtotal, Labor/HHS Budget Authority		**$33,187,697**		**$33,021,788**		**$33,792,033**		**$770,245**
Interior Appropriation for Superfund Research		77,349		76,824		53,967		-22,857
Total, NIH Discretionary BA		**$33,265,046**		**$33,098,611**		**$33,846,000**		**$747,389**
Special type 1 Diabetes		139,650		150,000		0		-150,000
Patient-Centered Outcomes Research Trust Fund (PCORTF)						124,349		124,349
Energy Employees Occupational Illness Compensation Program Act (EEOICPA)						55,358		55,358
Total, NIH Budget Authority		**$33,404,696**		**$33,248,611**		**$34,025,707**		**$777,096**
Program Evaluation Financing		824,443		818,844		741,000		-77,844
Total, Program Level		**$34,229,139**		**$34,067,456**		**$34,766,707**		**$699,251**

1 All Subtotal and Total numbers may not add due to rounding.
2 All numbers in italics and brackets are non-add.
3 Excludes Ebola-related supplemental appropriations.
4 Includes 21st Century Cures Act funding.
5 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as a non-add; The Office of the Director - Appropriations also is noted as a non-add because the remaining funds are accounted for under OD - Other.
6 Includes the Building & Facilities appropriation as well as funds identified for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
7 In FY 2017 and FY 2018 the number of grants and dollars for mandatory Special type I Diabetes Research account are distributed by mechanism above; therefore, type I Diabetes amounts are deducted to provide subtotals that align to the Labor/ HHS Budget Authority levels. In FY 2019, resources for Special type 1 Diabetes are incorporated in discretionary appropriations.
8 Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals that align to the Labor/HHS Budget Authority levels.
9 National Institute for Occupational Safety and Health (NIOSH) and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) included in FY 2019 only and are not distributed by mechanism.
10 Includes funding for the National Institute for Research on Safety and Quality (formerly the Agency for Healthcare Research and Quality), NIOSH, and NIDILRR.
11 SBIR administrative funds pilot program expired on September 30, 2017.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
National Institutes of Health:			
Section 301 and Title IV of the PHS Act	$33,265,046		
Section 1001 (b)(3)(A) of the 21st Century Cures Act	$352,000	$496,000	$711,000
Section 402A(a)(1) of the PHS Act	$34,229,139	$34,851,000	$35,585,871
Public Law 114-10, Medicare Access and CHIP Reauthorization Act of 2015.	$139,650		
Public Law 115-123, Bipartisan Budget Act of 2018		$150,000,000	
Section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and Section 126(g) of the Superfund Amendments and Reauthorization Act of 1986	$77,349	$76,824	$53,967
Title II of the Rehabilitation Act of 1973, as amended			$119,608
Titles III and Title IX and Section 947(c) of the Public Health Service Act, as amended and Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003			$255,960
Titles II, III, and XVII of the Public Health Service Act, sections 101, 102, 103, 201, 202, 203, 301, and 501 of the Federal Mine Safety and Health Act, section 13 of the Mine Improvement and New Emergency Response Act, and sections 20, 21, and 22 of the Occupational Safety and Health Act			$200,000

APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2010	$30,988,000,000	$31,488,000,000	$30,988,000,000	$30,934,413,000 [2]
FY 2011	$32,136,209,000		$31,989,000,000	$30,935,000,000 [3]
FY 2012	$31,979,000,000		$30,630,423,000	$30,852,187,000 [4]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [5]
Sequestration				-1,552,593,211
Subtotal	$30,852,187,000		$30,810,387,000	$29,377,383,789
FY 2014	$31,323,187,000		$31,176,187,000	$30,142,653,000
FY 2015	$30,353,453,000		$30,084,304,000	$30,311,349,000 [6]
FY 2016	$31,311,349,000 [7]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [8]
FY 2017	$33,136,349,000 [9]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [10]
FY 2018	$26,919,710,000 [11]	$35,184,000,000	$36,084,000,000	$34,067,456,000 [12]
FY 2019 PB	$34,766,707,000 [13,14]			

[1] Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special type 1 Diabetes Research mandatory funding included except for FY 2019.

[2] Reflects Labor/HHS appropriation of $30,705,201,000; transfer of $300,000,000 to Global AIDS funds; $1,000,000 transfer from HHS for the Interagency Autism Coordinating Committee and Secretary's 1 percent transfer to HHS of $4,587,000.

[3] Reflects: $3,059,277,000 appropriated to the ICs for HIV research; $998,000 transfer from HHS to the Interagency Autism Coordinating Committee.

[4] Reflects: $3,074,921,000 appropriated to the ICs for HIV research; Omnibus across-the-board rescission of $58,130,567 and the Secretary's transfer of $8,726,791.

[5] Reflects: Full-year continuing resolution base. Does not include Section 3004 OMB 0.2 percent across-the-board rescission.

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

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

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

[9] Includes Program Evaluation Financing of $847,489,000. Includes mandatory financing.

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

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

[12] Includes Program Evaluation Financing of $818,844,000.

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

[14] Includes funding for NIRSQ, NIOSH, and NIDILRR associated with the proposed FY 2019 consolidation as well as PCORTF (NIRSQ) and EEOICPA (NIDILLR) mandatory accounts.

APPROPRIATIONS NOT AUTHORIZED BY LAW

Program	Last Year of Authorization	Authorization Level in Last Year of Authorization	Appropriations in Last Year of Authorization	Appropriations in FY 2018
Research on Health Costs, Quality, and Outcomes……..	FY 2005	Such Sums As Necessary	$260,695,000	$321,800,000

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 President's Budget +/- FY 2018 Annualized CR
Program Level[1,2]	$34,229,139	$34,067,456	$34,766,707	$699,251
FTE[3]	18,018	18,105	19,456	1,351

[1] Excludes Ebola-related supplemental appropriations or transfers.

[2] Includes Interior appropriation's Superfund Research allocation (all years) and the Special type 1 Diabetes account resources-- mandatory through FY 2018 and discretionary in FY 2019. Also included is NIGMS Program Evaluation funding in FY 2017 ($824 million), FY 2018 ($819 million), and FY 2019 ($741 million) as well as PCORTF ($124 million) and EEOICPA ($55 million) mandatory accounts associated with the proposed FY 2019 consolidation.

[3] FTE in FY 2019 include staff consolidated from NIRSQ, NIOSH, and NIDILRR.

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

Allocation Methods: Competitive Grants; Contract; Intramural; Other.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

NIH Research Contributes to Improvements in Human Health: Selected Examples

NIH has supported biomedical research to enhance health, lengthen life, and reduce illness and disability for more than 100 years. Between 1970 and 2015, the life expectancy of the average American increased by nearly nine years.[31] Further, the yearly death rate for Americans from all causes dropped by 43 percent from 1969 to 2015.[32] Older Americans are not just living longer; they are staying healthy and active longer. Rates of reported risk factors for chronic disease (uncontrolled cholesterol or high blood pressure, smoking, etc.) have dropped by more than ten percent since 1999. At age 65, Americans today can expect to live 19.4 more years, nearly 40 percent longer than in 1950.[33] We can attribute these remarkable improvements, in part, to NIH research advances that have helped us understand how to prevent disease or in some cases offered new treatments to cure it. NIH-funded projects have made numerous contributions that have advanced health care and improved human health, with the following as some selected examples.

Heart Disease

At the outset of the 20th Century, the three leading causes of death in the United States were pneumonia, tuberculosis, and infectious diarrhea, but by 1950, heart disease had surpassed all other maladies to become the leading cause of death. Through research advances supported in large part by NIH, deaths from heart disease decreased by approximately 67 percent between 1969 and 2015.[34] [35] The Framingham Heart Study, one of the first studies that followed a large cohort of individuals over time and begun by NIH in 1947, introduced the concept of risk factors, identifying factors that lead to heart disease, such as smoking, high blood pressure, and high cholesterol, and generating research findings that have led to more than 3,200 publications. NIH-supported clinical trials spurred the development of effective pharmacological and behavioral interventions and prevention strategies, including safe and effective surgical and catheter-based procedures to open clogged coronary arteries. While death rates have decreased in recent decades, heart disease remains the leading cause of death in the US, and so more work is required to capitalize on these advances and discover new approaches to detecting, preventing, and treating heart disease.

Diabetes

In the recent past, adults diagnosed with diabetes during middle age lived on average 10 years less than adults without diabetes. Thanks to the development of early screening methods and treatments that enable better control of diabetes-related complications, adults with diabetes are now living longer and healthier lives. Between 1969 and 2015, the death rate among adults with

[31] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[32] Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. https://www.cdc.gov/nchs/products/databriefs/db267.htm
[33] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[34] Ma J, Ward EM, Siegel RL, Jemal A. Temporal Trends in Mortality in the United States, 1969-2013. *JAMA J* …. 2015;314(16):1731-1739. doi:10.1001/jama.2015.12319. http://jamanetwork.com/journals/jama/fullarticle/2466136
[35] K Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. https://www.cdc.gov/nchs/products/databriefs/db267.htm

diabetes declined by 15.8 percent,[36] [37] and from 1990 to 2010 the rates of major diabetes complications dropped dramatically, particularly for heart attacks related to diabetes, which declined by 68 percent, and stroke related to diabetes, which declined by 53 percent.[38] These remarkable improvements are due largely to clinical trials supported by NIH. In addition, basic science research, including a recent international "big data" study that NIH helped support,[39] has unveiled genes that may be involved in the development and progression of diabetes. NIH research also is generating important insights into the prevention and management of diabetes, highlighting the importance of family support. Studies funded through the Diabetes Prevention Program also have shown that lifestyle changes, such as diet and physical activity, can lower the risk of developing type 2 diabetes by 58 percent in adults at high risk for the disease. Further research is investigating potential approaches to reversing type 2 diabetes, including remission after bariatric surgery. For individuals with type 1 diabetes, islet cell transplantation trials and progress toward the development of a fully reliable artificial pancreas provide hope for an end to the daily routine of finger sticks and insulin injections (see later section on Promising New Treatments for Type 1 Diabetes).

Stroke

Fewer people are dying of stroke today—the age-adjusted stroke mortality rate has decreased by 76 percent since 1969,[40] due to treatment and prevention strategies based on NIH-funded research. While much of this decrease is due to improvements in stroke diagnosis and prevention, NIH has also contributed to advances in stroke treatment. In 1995, an NIH-funded clinical trial established the first and only FDA-approved treatment for acute ischemic stroke, which makes up 87% of strokes in the U.S.[41] The drug tissue plasminogen activator (tPA) reduces the risk of disability and maximizes the potential for patient recovery. However, tPA must be administered quickly after the onset of symptoms. Current estimates suggest that fewer than ten percent of stroke patients are treated with the drug. A recent analysis estimated that tPA can provide considerable cost savings—nearly $74 million annually for the first post-stroke year alone—if used in just 20 percent of all ischemic stroke patients in the United States. Recent NIH-funded research has led to the revision of tPA administration guidelines to extend the timing from three hours to four and a half hours in some cases.[42,43] NIH researchers are currently working to improve public awareness of stroke and to educate high risk populations on the importance of seeking immediate medical attention in order to increase the number of those receiving this life-saving and disability-reducing treatment.

---

[36] Ma J, et al. *JAMA* 2015; 314(16):1731-1739. PMID: 26505597 http://jama.jamanetwork.com/article.aspx?articleid=2466136&linkid=18099832

[37] Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. https://www.cdc.gov/nchs/products/databriefs/db267.htm

[38] Gregg EW, et al. *N Engl J Med* 2014; 370(16):1514-23. PMID: 24738668 http://www.ncbi.nlm.nih.gov/pubmed/24738668

[39] Fuchsberger C, et al. *Nature* 2016; epub ahead of print. PMID: 27398621 http://www.nature.com/nature/journal/vaop/ncurrent/full/nature18642.html

[40] Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. https://www.cdc.gov/nchs/products/databriefs/db267.htm

[41] https://www.cdc.gov/stroke/types_of_stroke.htm

[42] Jauch EC, et al. *Stroke* 2013; 44(3):870-947 PMID: 23370205 http://www.ncbi.nlm.nih.gov/pubmed/23370205

[43] http://www.medpagetoday.com/Cardiology/Strokes/41156

Lung Cancer

Lung cancer is the second most common cancer and is the primary cause of cancer-related death in both men and women in the United States. However, both incidence rates and mortality rates continue to decline for men and women. NIH-funded research has contributed to the decrease in mortality, lowering the death rate by 43 percent in men and 17 percent in women from 2002 to 2014.[44] Much of this decrease is due to prevention efforts targeting smoking, which has been estimated to cause 80% of deaths from lung cancer.[45] Many of these efforts to reduce smoking were developed and tested using NIH funding. The recent development of targeted cancer therapies, such as erlotinib and crizotinib, has led to dramatic responses in individuals whose lung cancers harbor particular genetic mutations. Advances in genetic screening techniques have helped NIH-funded researchers identify genes that may influence the risk for lung cancer development and genetic errors that cause lung cancer, and new precision medicine clinical trials are targeting some types of this disease.

HIV/AIDS

HIV, the virus that causes AIDS, was first recognized more than 30 years ago. In that time, NIH has established the world's leading AIDS research program. Each year, close to 40,000 people in the United States are still diagnosed with HIV. [46] Currently, there are more than one million people in the United States, and over 35 million people globally, who are living with HIV infection. In the early 1980s when the HIV/AIDS epidemic began, those infected with the virus were not likely to live longer than a few years. Now, thanks to research funded in large part by NIH, there are powerful treatments that can suppress the virus to undetectable levels, allowing those infected with HIV to live for many years. As a result, death rates dropped more than 80 percent between 1990 and 2015,[47] and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s.[48] NIH research also has informed the implementation of HIV testing and preventive interventions that have reduced the rate of mother-to-child infection by more than 90 percent in the United States.[49] Ongoing efforts seek to develop new and even more effective treatment approaches, including new research in primates that could prove useful in suppressing HIV in humans.[50] These treatments, combined with encouraging advances toward the development of an HIV vaccine and research to find a cure, mean that a future AIDS-free generation is possible with sustained effort.

[44] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2017. *CA Cancer J Clin*. January 2017:n/a - n/a. 10.3322/caac.21387. https://www.ncbi.nlm.nih.gov/pubmed/26742998
[45] Siegel RL, et al. JAMA Intern Med. 2015;175:1574-1576. https://www.ncbi.nlm.nih.gov/pubmed/26076120
[46] https://www.cdc.gov/nchs/data/hus/2016/034.pdf
[47] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[48] Samji H, et al. *PLoS One* 2013; Dec 18;8(12):e81355 PMID: 24367482 http://www.ncbi.nlm.nih.gov/pubmed/24367482
[49] http://www.niaid.nih.gov/topics/HIVAIDS/Understanding/Prevention/Pages/perinatal.aspx
[50] https://www.nih.gov/news-events/nih-research-matters/dual-antibody-treatment-suppresses-hiv-virus-monkeys

Breast Cancer

Primarily because of NIH-supported research, multiple breast cancer susceptibility genes have been identified, including BRCA1, BRCA2, TP53, and PTEN/MMAC1. Genetic testing now allows for tailored, safer, and more efficient treatments. Recent studies identified 55 genes linked to a tumor suppressor gene that can predict breast cancer survival as well as a natural compound that can attack human epidermal growth factor receptor 2 (HER2) positive breast cancer cells. Scientists also conducted studies in mice in which they found a protein that reduces the risk that breast cancer will spread. In addition, a new imaging technique to improve diagnosis in women with dense breast tissue has been developed. As a result of these and many other advances, breast cancer death rates for women declined by about 38 percent from 1989 to 2015,[51] and the relative 5-year survival from breast cancer in women has increased from 74.8 percent in 1980 to greater than 91 percent, as of a 2015 CDC report.[52]

Prostate Cancer

Prostate cancer is one of the most common cancers and the second leading cause of cancer-related death for men in the United States. NIH-supported research on the treatment of prostate cancer has improved surgical approaches as well as radio-, chemo-, and hormonal therapies. NIH has also supported research to help understand genetic risk factors for the disease, and to develop and improve early screening for at-risk populations. The success of these advances has contributed to the significant decline in the death rate. Between 1993 and 2014, the prostate cancer death rate dropped by 51 percent,[53] with a 5-year survival rate approaching 99 percent.[54] Current research focuses on increasing understanding of the epidemiology and genetics of prostate cancer and improving treatment and diagnostic options.

Infant Health

In 1960, 26 of every 1,000 babies born in the United States died before their first birthday. By 2014, the infant mortality rate was below 6 per 1,000 births, considerably less than a generation before.[55] A sustained, long-term effort, informed in large part by NIH research to reduce preterm births, neonatal mortality, and other complications that increase the risk of infant death, contributed to these substantial improvements in the survival rates of infants born preterm and to advances in care for all newborns. For example, rates of Sudden Infant Death Syndrome have declined considerably, with the mortality rate in 2014 being one-third the rate of 1990,[56] and the

[51] Samji H, Cescon A, Hogg RS, et al. Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada. Okulicz JF, ed. *PLoS One*. 2013;8(12):e81355. doi:10.1371/journal.pone.0081355. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3867319/
[52] https://www.cdc.gov/nchs/data/hus/hus15.pdf , Table 37
[53] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2017. *CA Cancer J Clin*. January 2017:n/a - n/a. 10.3322/caac.21387. https://www.ncbi.nlm.nih.gov/pubmed/26742998
[54] Cancer of the Prostate - SEER Stat Fact Sheets. http://seer.cancer.gov/statfacts/html/prost.html
[55] https://www.cdc.gov/nchs/nvss/deaths.htm
[56] https://www.cdc.gov/sids/data.htm

death rate from Respiratory Distress Syndrome in infants has dropped 95%, from 2.2 deaths per 100,000 in 1980 to only 0.1 in 2015.[57]

Burns and Traumatic Injury

NIH-funded research on fluid resuscitation, wound cleaning, skin replacement, infection control, and nutritional support has improved greatly the chances of surviving catastrophic burns and traumatic injuries. In the mid-1970s, burns that covered even 25 percent of the body were almost always fatal. Today, people with burns covering 90 percent of their bodies can survive, although often with some impairments. From 1990 to 2015, the death rate per 100,000 people from motor vehicle traffic injury decreased from 18.5 to 11.5, [58] and firearm fatalities dropped from 14.6 to 11.1.[59] These dramatic increases in survival rates, as well as increased health, functioning, and quality of life of survivors, are due in large part to research findings that have transformed clinical practice.

Science Advances from NIH Research:

NIH-funded scientists report thousands of new findings every year across the spectrum of biomedical science, from basic, translational, and clinical research studies. A few of the many recent NIH-funded research accomplishments are listed below.

CRISPR Used in Wide-Ranging Applications

Hailed as the 2015 Breakthrough of the Year by Science magazine, the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) system continues to facilitate groundbreaking scientific research. The system, which allows relatively easy and precise genome editing, has promise for use in a range of applications, from studying gene function to treating genetic diseases and developing therapeutics for clinical trials. In one study, NIH-funded researchers used CRISPR to stop the production of a particular protein in mouse models of Huntington's disease, reversing the disease process.[60] In another project, NIH-funded scientists isolated cells with two copies of the mutation that causes sickle cell disease and used CRISPR to remove one copy of the mutation. With only one copy of the gene, the cultured cells went on to produce healthy hemoglobin at a frequency that might be able to help patients.[61] Early proof-of-concept studies have even shown the potential of CRISPR for such diverse applications as disrupting genes that cause high cholesterol, or removing HIV viral DNA from the genomes of infected cells.[62,63] Researchers are also working to improve gene editing technology itself, including expanding its capabilities to target RNA, the intermediate step between DNA and the creation of

[57] CDC WONDER Mortality Database, https://wonder.cdc.gov/
[58] https://www.cdc.gov/nchs/data/hus/2016/017.pdf
[59] https://www.cdc.gov/nchs/data/hus/2016/031.pdf
[60] Yang S, *et al*. *J Clin Invest* 2017 Jun 30; 127(7):2719-2724. PMID: 28628038 https://www.ncbi.nlm.nih.gov/pubmed/28628038
[61] DeWitt MA et al. Sci Transl Med. 2016 Oct 12;8(360):360ra134. PMID: 27733558 https://www.ncbi.nlm.nih.gov/pubmed/27733558
[62] Yin H et al. Nat Biotech 2017 6 Nov 13. PMID: 29131148 https://www.ncbi.nlm.nih.gov/pubmed/29131148
[63] Kaminski R. et al. Gene Ther. 2016 Aug 23. PMID: 27194423 https://www.ncbi.nlm.nih.gov/pubmed/27194423

functional proteins.[64,65] In one such study, researchers used novel RNA-targeted gene editing tools to eliminate RNA that leads to toxic proteins in a model of the degenerative disease myotonic dystrophy, providing a potential use for such expanded tools in humans.[66] In the future, this technology could potentially be applied to treat people affected by a variety of devastating diseases, many of which currently have no approved therapies.

Precision Oncology Leads to Targeted Therapies

In the field of oncology, immunotherapy has been used to enlist a patient's own immune system to fight, and sometimes cure, cancer. However, immunotherapy does not work for all patients or types of cancer. Precision medicine has enormous potential to allow doctors and researchers to treat and prevent disease using strategies targeted for a patient's individual biology, lifestyle, and environment. Such approaches can lead to the development and application of targeted drugs which address the specific genetic alterations in a patient's cancer cells, and can also provide clues to which patients will respond better to immunotherapy, ensuring that the right patient gets the right drug (or combination of drugs) with the best chance of treating their cancer. In May 2017, the Food and Drug Administration (FDA) approved the use of the cancer immunotherapy pembrolizumab[67] to treat patients with any solid tumor with a particular genetic defect, regardless of location, making it the first treatment ever approved to treat cancer based on a specific genetic feature rather than the tumor's location in the body. In addition, new breakthroughs are allowing doctors to re-engineer a patient's own immune cells as a "living drug" that can target cancerous cells based on a tumor's unique molecular signature. In August 2017, the FDA approved the first cell-based immunotherapy, Kymriah (tisagenlecleucel), to treat a type of leukemia that is the most common childhood cancer in the United States.[68] Kymriah, which is part of a broader family of cell-based immunotherapies called CAR-T, was developed in part based on NIH-supported research, ranging from pioneering research in the 80's to more recent improvements of the methodology that make the treatment more effective. Breakthroughs like this allow for more informed and effective health care and will benefit many cancer patients who lack other treatment options.

Combating the Opioid Crisis and Designing More Safe and Effective Opioids

Opioids are powerful drugs that can relieve severe pain through the activation of opioid receptors on nerve cells throughout the body. While opioids generally are safe when used as directed, they have the potential for misuse which can result in addiction and dangerous side effects that include lethal overdoses. The Nation is currently facing an unprecedented crisis in opioid addiction. NIH and its many partners are working to address this crisis on several fronts, including making safer, non-addictive painkillers and understanding how to treat individuals suffering from opioid addiction. NIH-funded researchers found that providing the drug naltrexone, which is used to treat opioid addiction, can reduce the incidence of opioid-related

[64] Cox DBT, et al. Science. 2017 Oct 25. pii: eaaq0180. doi: 10.1126/science.aaq0180. PMID: 29070703. https://www.ncbi.nlm.nih.gov/pubmed/29070703
[65] Abudayyeh OO, et al. Science. 2016 Aug 5 PMID: 27256883 https://www.ncbi.nlm.nih.gov/pubmed/27256883
[66] Batra R, et al. Cell 2017 Aug 24. PMIDD" 28803727 https://www.ncbi.nlm.nih.gov/pubmed/28803727
[67] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm560167.htm
[68] https://directorsblog.nih.gov/2017/08/30/fda-approves-first-car-t-cell-therapy-for-pediatric-acute-lymphoblastic-leukemia/

emergencies when prescribed to chronic pain patients alongside opioid drugs for their pain.[69] Another group of researchers found that a similar treatment for opioid addiction, buprenorphine, can safely and effectively treat the withdrawal symptoms of newborn infants exposed to opioids during pregnancy.[70] NIH is also working to find alternative ways to provide pain relief to those in need. In pre-clinical studies using mouse models, several NIH-funded researchers have found opioid-related compounds which act on more specific subsets of the signaling pathways used by conventional opioids, allowing for effective pain relief without dangerous side effects like addiction, or slowed breathing and heart rate, including two compounds called PZM21[71] and BU08028.[72] Mice treated with these compounds experience less pain, but do not display drug-seeking behavior or dangerous cardiovascular side effects, suggesting that such compounds may be a safer alternative to current drugs. NIH-funded researchers have also developed new ways to molecularly characterize the mechanism of action for a given opioid drug, allowing them to tease apart the effects on pain relief and effects on breathing to design effective pain therapies that avoid dangerous side effects.[73] Such studies have the potential to both treat existing cases of opioid addiction, and provide new therapies for pain relief that can prevent people from getting addicted in the first place.

Informing Prevention of Heart Disease and Stroke

Heart disease and stroke are both among the leading causes of death in Americans, and having high blood pressure is a strong risk factor for both.[74] A major NIH-funded trial, the Systolic Blood Pressure Intervention Trial (SPRINT), provided key evidence that treating high blood pressure earlier could save lives, and prevent cardiovascular and kidney diseases. The SPRINT trial included more than 9,300 participants recruited from around 100 medical centers and clinical practices around the country, the largest study of its kind to date, examining how maintaining blood pressure at a lower level than previously recommended impacts both cardiovascular and kidney diseases. The study found that aiming for a lower target blood pressure could significantly reduce the rate of death from cardiovascular causes by 43%, and reduce the rate of an initial cardiovascular event, such as a stroke or heart attack, by 25%.[75] This evidence was cited as a key factor for new guidelines released by the American Heart Association (AHA) and the American College of Cardiology (ACC) in November 2017, which urge doctors to aim for a lower target blood pressure in at-risk patients, using both lifestyle changes, and in some cases, medication.[76] Successfully implementing these new guidelines will improve the cardiovascular health of the nation, and save lives, reducing the risks for heart disease and stroke.

---

[69] Lee JD, et al. *NEJM* 2016 Mar 31;374(13):1232-42. PMID: 27028913 https://www.ncbi.nlm.nih.gov/pubmed/27028913
[70] Kraft WK, et al. *NEJM* 2017 Jun 15;376(24):2341-2348. PMID: 28468518 https://www.ncbi.nlm.nih.gov/pubmed/28468518
[71] Manglik A, et al. *Nature* 2016 Sep 8;537(7619):185-190. PMID: 27533032 https://www.ncbi.nlm.nih.gov/pubmed/27533032
[72] Ding H., et al. *PNAS* 2016 Sep 13;113(37): E5511-8. PMID: 27573832 https://www.ncbi.nlm.nih.gov/pubmed/27573832
[73] Schmid, et al. Cell. November 16, 2017.
[74] https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm
[75] The SPRINT Research Group. NEJM 2015 Nov 26. https://www.ncbi.nlm.nih.gov/pubmed/29262284
[76] https://www.nih.gov/news-events/news-releases/data-landmark-nih-blood-pressure-study-supports-important-part-new-aha-acc-hypertension-guidelines

All of Us Research Program

Spearheading a precision medicine approach for disease prevention and treatment, which takes into account individual differences in lifestyle, environment, and biology (e.g., genetics), NIH's *All of Us* Research Program is an ambitious effort to gather data on the biological, environmental, and behavioral influences on health and disease over many years from one million or more people living in the US. Already, several key implementation milestones have been reached, including study protocol approval, establishing a state-of-the-art biobank to process and store biological samples from patients, and building a big data IT system to store data for research use. Working together with federal, academic, and industry partners, *All of Us* began participant enrollment for its beta testing phase in May 2017, and, as of mid-January 2018, more than 19,000 participants were enrolled, of whom more than 12,000 have completed the full protocol. This phase will pave the way for a planned full-scale launch at more than 200 sites in the spring of 2018. Already the program is breaking new ground, recently growing the network of medical center partners that will expand the geographic reach of the program and facilitate enrollment of underserved communities. New community partners also are on board to begin building a national network of trusted leaders to motivate a variety of communities to join *All of Us*. As enrollment increases, *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions and enabling individualized prevention and treatment options for patients.

Wearable Devices Provide Useful Physiological Data, Detect Early Signs of Disease

For many scientists studying large cohorts of research participants, one of the biggest challenges is collecting data about what happens outside the lab or clinic. The brief period in which a participant provides samples or answers interview questions is just a small slice of a much larger set of both physiological states and lifestyle behaviors. With the advent of wearable technologies that can track a user's heart rate, blood oxygenation, physical activity, sleep, and more, it is now possible to provide study participants with devices that can generate a stream of data—as many as 250,000 measurements per person per day. A recent NIH-funded study evaluated many of these wearable technologies in a real-world setting, and found that they can provide useful, health-relevant information about an individual's physiology, detecting changes related to fatigue, inflammation, Lyme disease, and insulin resistance.[77] As researchers continue to validate wearable technologies, they will provide promising opportunities for gathering useful, real-world data for clinical research, including integration into larger studies like the *All of Us* research program.

Discovering the Brain's Lymphatic System

The lymphatic system is a key part of the circulatory system, acting as a highway that allows important immune cells to move through the body, and providing a route for waste products to be carried away from the tissues and into the blood. For a long time, the brain was thought to be a notable exception to this system, kept apart from immune cells and the highways they use except in cases of damage or dysfunction. Recent discoveries, however, are challenging this view. First, in 2015, NIH-funded researchers used cutting-edge, high-powered microscopy

[77] Li,X, et al. PLoS Bio 2017 Jan 12;15(1):e2001402 PMID 28081144 https://www.ncbi.nlm.nih.gov/pubmed/28081144

techniques to visualize lymphatic vessels in the layers of protective tissue that surround the mouse brain.[78] In October 2017, those same researchers collaborated with a group with expertise in non-invasive MRI imaging to demonstrate that these same vessels exist in the human brain.[79] . Since the lymphatic system plays a vital role in immune response, these surprising discoveries open up entirely new areas for research which have potential to shed light on how the brain and immune system interact in disease states. Studying the brain's lymphatic system could lead to new insights for understanding, treating, and preventing brain disorders involving immune-related inflammation, including multiple sclerosis, stoke, Alzheimer's disease, or Parkinson's disease.

Targeted Use of Antibiotics

Antibiotics are ineffective against viruses, but doctors often have no way of quickly determining whether an illness is viral or bacterial, which can lead to inappropriate use of antibiotics in patients who will not benefit from them. In addition to wasting medical resources, this behavior also can accelerate the development of antibiotic-resistant bacterial strains. To meet the need of rapid diagnostics, NIH-funded researchers have developed quicker, more accurate blood tests that can help distinguish between bacterial and viral infections.[80] Treating infections caused by antibiotic-resistant bacteria can be challenging or even impossible. Another NIH-funded team is working to modify existing antibiotics to be more effective against these types of bacteria. In recent lab tests, one new compound was 10,000 times more effective than current treatments.[81] These advances will help clinicians to use the most effective treatments for patients and avoid unnecessary use of antibiotics.

Developing New Tools for Delivering Anti-Obesity Drugs

Metabolic disorders like obesity and diabetes impact many Americans, and understanding fat cell behavior can provide insight into these disorders and potential methods of treatment. There are two main types of fat cells in the human body: white fat cells, which store calories and are associated with obesity when overabundant, and brown fat cells, which burn calories to generate heat and regulate body temperature. Several clinically-available drugs have been shown to promote a fat cell process known as "browning," which transitions white fat cells into a calorie-burning variety cell called "beige fat." However, when these drugs are taken as pills or injections, they can have unpleasant side effects on parts of the body outside of fatty tissue. NIH-funded researchers are working to get around these side effects on other parts of the body by delivering the drug directly into fatty tissue.[82,83] Recent efforts have created an on-skin patch

[78] Absinta M, et al. Elife. 2017 Oct 3. https://www.ncbi.nlm.nih.gov/pubmed/26030524
[79] Louveau Et al. Nature. 2015 Jul 16 https://www.ncbi.nlm.nih.gov/pubmed/28971799
[80] Sweeney TE, et al. *Sci Transl Med* 2016; 8(346):346ra91. PMID: 27384347
http://www.ncbi.nlm.nih.gov/pubmed/27384347
Tsalik EL, et al. *Sci Transl Med* 2016; 8(322):322ra11. PMID: 26791949
http://www.ncbi.nlm.nih.gov/pubmed/26791949
[81] Okano A, et al. *Proc Natl Acad Sci USA* 2017; 114(26). PMID: 28559345
https://www.ncbi.nlm.nih.gov/pubmed/28559345
[82] https://www.nih.gov/news-events/nih-research-matters/nanoparticles-target-transform-fat-tissue
[83] https://www.nih.gov/news-events/nih-research-matters/microneedle-patch-shrinks-fat-tissue-mice

which uses microscopic needles to deliver highly localized treatment.[84] Mice treated with the patch developed beige fat cells and reduced the size of their white fat cells, and treatment had beneficial effects on the metabolisms of obese mice as well. While such patch-based treatments have not yet been attempted in humans, these mouse-model results indicate a promising area for potential future clinical trials.

New Therapies for Cystic Fibrosis

Roughly 30,000 Americans currently suffer from cystic fibrosis (CF), an inherited disease in which malfunctioning secretory glands cause the accumulation of organ-damaging mucus that can lead to respiratory failure. Twenty-five years ago, when NIH-funded researchers discovered the first of several genetic mutations that cause CF[85], the disease was still considered fatal in childhood. Today, thanks to years of hard work supported by NIH and the Cystic Fibrosis Foundation, the outlook for patients with CF is much brighter. Over time, researchers have uncovered several different mutations that cause CF and have shed light on how those mutations lead to the buildup of mucus. Currently, there are FDA-approved targeted treatments for approximately 40 percent of CF patients, based on their particular mutation. That number may be rising in the near future, as Vertex Pharmaceuticals Inc. recently announced that promising results have been found in Phase 1 and 2 clinical trials of three new triple-drug CF treatments.[86] Patients were already able to breathe better after 2-4 weeks of treatment, including patients with notoriously difficult-to-treat variants of CF. Assuming Phase 3 clinical trials are successful and the triple-drug formula is approved, doctors may soon be able to treat up to 90 percent of people with CF.[87]

Catalyzing Progress Towards a Universal Flu Vaccine

The flu (influenza) virus is a costly and dangerous pathogen, and seasonal flu places a substantial burden on the US population that encompasses both health and economic losses. While vaccination is the most effective way to reduce both morbidity and mortality caused by the flu, seasonal flu vaccines currently rely on predictions, often made a year in advance, about which individual virus strains will be in circulation. Since these predictions limit the effectiveness of a seasonal vaccine, a single, universal flu vaccine would allow for substantial improvement in the burden of flu, providing safe, effective, long-lasting immunity. On June 28-29, 2017, NIH convened a conference entitled "Pathway to a Universal Influenza Vaccine", catalyzing the field around a series of unmet needs and knowledge gaps, including understanding the immune response to influenza, developing vaccine platforms, diagnostics for assessing mechanisms of immune protection, and both animal and human models for influenza research. NIH-funded researchers continue to make progress toward this goal by targeting a particular protein on the surface of the flu virus, several versions of which are being evaluated for further clinical study. In addition, Phase 1/2 clinical trials already are underway for an alternative approach involving a

[84] Zhang, Y. et al. *ACS Nano* 2017; 11(9):9223-9230. PMID: 28914527 http://pubs.acs.org/doi/10.1021/acsnano.7b04348
[85] Rommens JM, *et al. Science*. 1989 Sept 8;245(4922): 1059-1065. PMID: 2772657 https://www.ncbi.nlm.nih.gov/pubmed/2772657
[86] http://investors.vrtx.com/releasedetail.cfm?ReleaseID=1033559
[87] https://directorsblog.nih.gov/2017/07/20/another-milestone-in-the-cystic-fibrosis-journey/

DNA-based vaccine and a seasonal booster. Continued investment in this research will enable the fastest possible vaccine development to protect millions of people from infection.

Addressing the Threat of Zika Virus

The recent outbreak of Zika virus, beginning in South America in spring 2015, now has infected more than one million Brazilians, includes documented cases in the continental U.S. and Puerto Rico[88], and is linked to a steep increase in the number of babies born with microcephaly, a very serious condition characterized by a small head and brain. In response to this emerging threat, NIH has stepped up its efforts to develop innovative approaches against the virus. Three NIH-funded studies[89,90,91] conducted foundational basic research on the Zika virus, paving the way for future research on Zika prevention and treatment. In August 2016, NIH built on these results and launched the first clinical trial that demonstrated safety and efficacy of one vaccine candidate, leading to a Phase 2/2b trial that began in March 2017 to obtain additional evidence on whether the vaccine is safe and effective against natural Zika infection.[92,93] NIH research also has found that experimental Zika vaccines administered to female and male mice restricted transmission from mother to fetus as well as prevented infection in the testis, an important discovery given Zika's impact on fetal and infant development and the persistence of Zika virus in the male reproductive system.[94,95] Furthermore, NIAID-supported researchers developed a novel vaccine approach that may be safe and effective to administer during pregnancy to protect both the mother and the fetus. This new vaccine candidate protected nonhuman primates from infection, and the researchers are pursuing studies in people.[96,97] To help speed up possible treatments for Zika NIH has been working to identify compounds, including FDA-approved drugs, that potentially can be used to inhibit Zika virus replication and reduce its ability to kill brain cells. Recently NIH identified two such compounds, providing new paths for research into combating the virus.[98]

Human Microbiome Project

In the past, disease-causing germs such as bacteria and microbes have been thought to be invaders, causing negative effects on human health. However, recent research has discovered

[88] https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika
[89] Sirohi D, et al. *Science* 2016; 352(6284):467-70. PMID: 27033547 http://www.ncbi.nlm.nih.gov/pubmed/27033547
[90]Tang H, et al. *Cell Stem Cell* 2016; 18(5):587-90. PMID: 26952870 http://www.ncbi.nlm.nih.gov/pubmed/26952870
[91] Nowakowski TJ, et al. *Cell Stem Cell* 2016; 18(5):591-6. PMID: 27038591 http://www.ncbi.nlm.nih.gov/pubmed/27038591
[92] Gaudinski MR, et al. *Lancet* 2017; S0140-6736(17)33105-7. PMID: 29217376 https://www.ncbi.nlm.nih.gov/pubmed/29217376
[93] https://www.nih.gov/news-events/news-releases/gene-based-zika-vaccine-safe-immunogenic-healthy-adults
[94] https://www.nih.gov/news-events/news-releases/experimental-zika-virus-vaccines-restrict-utero-virus-transmission-mice
[95] https://www.niaid.nih.gov/news-events/single-dose-investigational-zika-vaccine-protects-mice-monkeys
[96] Magnani, DM, et al. *Sci Transl Med* 2017; 9(410). pii: eaan8184 https://www.ncbi.nlm.nih.gov/pubmed/28978754
[97] https://www.nih.gov/news-events/news-releases/monoclonal-antibodies-against-zika-show-promise-monkey-study
[98] https://www.nih.gov/news-events/news-releases/nih-collaboration-helps-advance-potential-zika-treatments

that there is a population of microbes both inside and on the surface of the human body, called the microbiome, that normally work together with the human body. Over the last decade, NIH's Human Microbiome Project (HMP) has expanded our view of the importance of microorganisms, collecting all of the genes of all the microorganisms that live on or in a specific location on the body such as the mouth, a sample known as a metagenome. In a healthy human adult, bacterial cells outnumber human cells, in vast numbers that researchers cannot comprehensively count. In the last 5 years, the HMP has provided new data that includes an additional 1,631 metagenomes taken from 265 volunteers, tripling the discovery of microbes in our bodies.[99] These studies have led to the surprising discovery that, in perfectly healthy people, the microbes present in the mouth, gut, nose, and several other parts of the body also include fungi, and even several viruses.[100] Thanks to the HMP, NIH-funded researchers have discovered that these large numbers of microbes have helped us adapt to life as we know it. For example, microbes found in the mouth modify chemical processes whose products are linked to blood pressure regulation and prevention of migraines, among other health conditions. The study also was able to begin to delve into the difference between the microbes that live on or in people across different regions of the country, allowing researchers to understand how the environment an individual lives in can affect their microbiome. In the future, research from the HMP could help to further characterize of the human microbiome and the role of these microbes in human health and disease, potentially allowing researchers to target them as a new form of treatment.

Promising New Treatments for Type 1 Diabetes

Type 1 diabetes, usually diagnosed in childhood, is a serious, chronic condition in which the pancreas does not produce sufficient insulin to maintain healthy blood sugar levels. This form of diabetes appears to be an autoimmune disorder, with the immune system attacking the insulin-producing islet cells of the pancreas. Individuals with type 1 diabetes currently manage their disease with multiple daily injections of insulin or a pump that delivers insulin through a catheter placed under the skin. Recent NIH-funded research is providing hope for better treatment options. In one recent trial, islet cell transplantation combined with immunosuppression provided near-normal control of blood sugar levels in 88 percent of participants for the first year, and in 71 percent for the second year.[101] A large-scale, long-term study on an artificial pancreas that uses a glucose monitor implant and an adaptive smartphone application to automate insulin pump use and eliminate the need for manual finger sticks is currently underway. This study, along with three others that are slated to start in 2017 and 2018, is potentially the last step before requesting regulatory approval for permanent use of these fully automated devices and [102, 103] greatly improving the quality of life for people with this debilitating disease.

[99] Strains, functions, and dynamics in the expanded Human Microbiome Project. Nature. 2017 Sept 20.
[100] Structure, function and diversity of the healthy human microbiome. Human Microbiome Project Consortium. Nature. 2012 Jun 13;486(7402):207-14.
[101] Hering BJ, et al. *Diabetes Care* 2016; 39(7):1230-40. PMID: 27208344 http://www.ncbi.nlm.nih.gov/pubmed/27208344
[102] http://news.harvard.edu/gazette/story/2016/01/artificial-pancreas-system-aimed-at-type-1-diabetes-mellitus/
[103] https://www.nih.gov/news-events/news-releases/four-pivotal-nih-funded-artificial-pancreas-research-efforts-begin

Cell-Free Liquid Biopsy

After cells die, fragments of their DNA leak into the bloodstream. Researchers have been trying to detect these free-floating pieces of genetic material to inform clinical care, allowing clinicians and researchers to learn more about an individual's physiology without more invasive procedures. These "liquid biopsy" techniques have been utilized to test maternal blood for DNA from a fetus; test a cancer patient's blood for specific mutations or possible relapse; or test an organ transplant recipient for signs of organ rejection, and could one day test healthy individuals for early signs of future health problems.[104] NIH funded research has even developed a version of the technology that can trace free-floating DNA back to their cellular sources, allowing researchers to quickly pinpoint the location or tissue type of a potential tumor.[105] Using this technology, several NIH-funded researchers have developed blood tests that can detect genetic mutations in DNA released from cancer cells, and use that information to estimate the stage of cancer and the likelihood of cancer returning after surgery.[106,107,108] Further development and use of the test will transform how those with cancer are treated and monitored.

[104] https://directorsblog.nih.gov/2016/02/16/a-new-tool-in-the-toolbox-new-method-traces-free-floating-dna-back-to-its-source/
[105] Snyder MW, et al. *Cell* 2016;164(1-2):57-68. PMID 26771485, http://www.ncbi.nlm.nih.gov/pubmed/26771485
[106] http://www.sciencedirect.com/science/article/pii/S1525157817300107
[107] https://www.eurekalert.org/pub_releases/2017-08/e-nbt081117.php
[108] Phallen J, et al. Sci Transl Med. 2017 Aug 16;9(403). https://www.ncbi.nlm.nih.gov/pubmed/28814544

FUNDING HISTORY

Fiscal Year	Amount[1]
2015 [2]	$30,311,349,000
2016 [2]	$32,311,349,000
2017 [3,4]	$34,229,139,000
2018 Annualized CR[4]	$34,067,456,000
2019 Budget Request[4,5]	$34,766,707,000

[1] Appropriated amounts include discretionary budget authority received from both Labor/HHS appropriations that fund ICs as well as the Interior, Environment & Related Agencies appropriation that supports NIH Superfund Research activities. Also includes mandatory budget authority derived from the Special type 1 Diabetes account (through FY 2018), and NIGMS Program Evaluation financing of $715 million in FY 2015, $780 million in FY 2016, $824 million in FY 2017, $819 million in FY 2018 and $741 million in FY 2019.

[2] Excludes Ebola-related and Zika-related supplemental appropriations or transfers.

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

[4] Includes funding authorized by the 21st Century Cures Act.

[5] Includes funding for NIRSQ, NIOSH, and NIDILRR associated with the proposed FY 2019 consolidation as well as PCORTF (NIRSQ) and EEOICPA (NIDILLR) mandatory accounts.

SUMMARY OF REQUEST NARRATIVE

The FY 2019 President's Budget request would provide $34.8 billion to NIH, which is $0.7 billion above the FY 2018 Annualized CR level.

The following summary references program level funding, which includes discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriation and in the Department of the Interior, Environment, and Related Agencies appropriation (dedicated to the Superfund Research program), and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act.

This level also includes the consolidation into NIH of the Agency for Healthcare Research and Quality (AHRQ) as the National Institute for Research on Safety and Quality (NIRSQ), the National Institute for Occupational Safety and Health (NIOSH) from the Centers for Disease Control and Prevention (CDC), and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Administration for Community Living (ACL). Both NIRSQ and NIOSH have mandatory funding as well as discretionary.

Many elements of the NIH submission supporting the FY 2019 request were developed prior to announcement of the February 12, 2018 addendum to the President's Budget. Therefore, exhibits reflecting pre-addendum levels were excluded from the NIH budget justification.

The primary budget mechanisms discussed below include mechanism allocations of Program Evaluation Financing, discretionary budget authority of the National Institute for Research on Safety and Quality, and Special type 1 Diabetes funds.

Research Project Grants (RPGs)

The FY 2019 President's Budget would provide $18.9 billion for RPGs, which is $0.2 billion less than the FY 2018 Annualized CR level estimate. This amount would fund 9,084 Competing RPGs, or 428 more than estimated for the FY 2018 Annualized CR. It also supports 25,030 Noncompeting RPGs, 438 fewer than the FY Annualized CR level. In addition, the projected Competing RPGs average cost of approximately $503,245 would be 2.9% below the FY 2018 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2019 President's Budget would provide $919 million for SBIR/STTR program grants, which is $8 million below the FY 2018 Annualized CR level. The minimum set-aside requirement is 3.65% in FY 2019.

Research Centers

The FY 2019 President's Budget would provide $2.5 billion for Research Centers, which is $1 million less than the FY 2018 Annualized CR level. It would fund 1,363 grants, 141 more than the FY 2018 Annualized CR level.

Other Research
The FY 2019 President's Budget would provide $2.2 billion for this mechanism, which is $49 million less than the FY 2018 Annualized CR level. It would fund 7,119 grants, which is 633 more than the FY 2018 Annualized CR level.

Training
The FY 2019 President's Budget would provide $811 million for training, which is $29 million below the FY 2018 Annualized CR level. It would fund 15,770 Full-Time Trainee Positions (FTTPs), which is 255 fewer than the FY 2018 Annualized CR level.

Research & Development (R&D) Contracts
The FY 2019 President's Budget would provide $2.9 billion for R&D contracts, which is $35 million more than the FY 2018 Annualized CR level. It would fund an estimated 2,003 contracts, which are 15 fewer than the FY 2018 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2019 President's Budget includes a $61 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement is 3.65% in FY 2019.

Intramural Research (IR)
The FY 2019 President's Budget would provide $3.8 billion for IR, which is $8 million more than the FY 2018 Annualized CR level.

Research Management and Support (RMS)
The FY 2019 President's Budget would provide $1.8 billion for RMS, which is $8 million less the FY 2018 Annualized CR level.

Office of the Director (OD)
The FY 2019 President's Budget would provide $2.0 billion for OD, which is $298 million more than the FY 2018 Annualized CR level.

- **Other than Common Fund**
  The $1.2 billion allocated for OD elements other than the Common Fund or the Office of Research Infrastructure Programs is a net increase of $400 million above the FY 2018 Annualized CR level. This is due, in part, to an increase in funding authorized by the 21st Century Cures Act managed by OD, from $52 million to $196 million.

- **Common Fund (CF)**
  Approximately $599 million is allocated for CF-supported programs. This amount is $80 million below the FY 2018 Annualized CR level.

Buildings & Facilities (B&F)
The FY 2019 President's Budget provides $220 million for infrastructure sustainment projects associated with the B&F program, which is $62 million above the FY 2018 Annualized CR

level. This amount includes $20 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Consolidation
The FY 2019 President's Budget provides $200 million for NIOSH and $95.1 million for NIDILRR, in addition to the NIRSQ funding in the mechanisms above.

Superfund Research Program
The FY 2019 President's Budget would provide $54 million, which is $23 million less than the FY 2018 Annualized CR level.

Patient-Centered Outcomes Research Trust Fund (PCORTF)
The FY 2019 President's Budget would provide $124 million in mandatory funding; PCORTF is proposed within NIH to accompany the National Institute for Research on Safety and Quality.

Energy Employees Occupational Illness Compensation Program Act (EEOICPA)
The FY 2019 President's Budget would provide $55.4 million for EEOICPA.

Program Evaluation Financing
The FY 2019 President's Budget would provide $741 million for Program Evaluation Financing purposes, which is $78 million less than the FY 2018 Annualized CR level.

OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-1.3 By 2017, complete testing of the hypothesized mechanism of treatment effect of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (e.g., pilot studies or efficacy trials). (Output)	FY 2017: Initiated testing of 45 hypothesized mechanisms of treatment effect of novel interventions; completed testing of 16. Of the 16, 13 progressed to pilot studies of clinical effect. Target: Complete testing of the hypothesized mechanism of treatment of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (pilot study or efficacy trial). (Target Exceeded)	N/A	N/A	N/A
SRO-1.5 By 2020, increase our understanding of cancer trends and outcomes in the context of disparities and population subgroups through expansion of coverage and representation of the US population in the Surveillance, Epidemiology and End Results (SEER) Program registries. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population. (In Progress)	Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population.	Expand SEER to include links with 1-2 outside sources such as biospecimen acquisition, genomics and molecular profile data.	N/A
SRO-1.6 By 2020, determine the effectiveness of an evidence-based, patient-centered multicomponent fall injury prevention strategy in adults 75 years of age and older. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy. (In Progress)	Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy.	Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy and analyze trial data.	N/A
SRO-2.1 By 2023, develop, optimize, and evaluate the effectiveness of nano-enabled	FY 2018: Result Expected Dec 31, 2018 Target: Optimize properties of 3	Optimize properties of 3 nanoformulations for effective	Further optimize top 2 candidate nanoformulations for co-delivery of	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
immunotherapy (nano-immunotherapy) for one cancer type. (Output)	nanoformulations for effective delivery and antigen-specific response in immune cells. (In Progress)	delivery and antigen-specific response in immune cells.	multiple antigens to enhance anti-tumor response in one animal model.	
SRO-2.2 By 2018, assess the efficacy of one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	FY 2017: Follow-up visits of enrolled subjects and final analysis report were completed. Target: Conduct follow-up visits of enrolled subjects. (Target Met)	Complete study and publish manuscript.	N/A	N/A
SRO-2.3 By 2019, evaluate the impact of two community-level combination prevention packages (which include universal HIV testing and intensified provision of HIV antiretroviral therapy and care) on population-level HIV incidence in the developing world. (Outcome)	FY 2017: Enrollment, tracking and follow-up with participants has proven difficult, in part because of greater than expected rates of mobility and migration. Therefore, to ensure that there are sufficient data to meet the primary study objective, the Data and Safety Monitoring Board extended the period of follow-up through June 2018. Target: Complete additional annual follow-up visits of all participants and HIV incidence evaluations. (Target Not Met)	Finish conducting follow-up visits and begin data analysis.	Complete data analyses to evaluate the impact of two community-level combination prevention packages on population-level HIV incidence.	N/A
SRO-2.4 By 2020, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding one new treatment option per year. (Outcome)	FY 2017: NIH-supported scientists completed a phase I clinical trial of a hearing system to treat hearing loss. Individuals using the Earlens light-driven contact hearing aid demonstrated significant improvement in word recognition. Target: Initiate testing one new potential treatment option for a hearing disorder. (Target Met)	Initiate testing one new potential treatment option for a speech and language disorder.	Initiate testing one new potential treatment option for a hearing disorder.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Develop prototypes for four imaging technologies based on adaptive optics in animal models. (In Progress)	Develop prototypes for four imaging technologies based on adaptive optics in animal models.	Integrate measurements of cell function with anatomical imaging.	N/A
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these changes can be inherited. (Output)	FY 2017: Seven environmental chemicals that altered epigenetic processes in animal models were analyzed. Target: Analyze the impact of how 2-6 distinct/individual environmental exposures alter epigenetic processes in animal models. (Target Exceeded)	Through the use of epigenetic signatures, evaluate if 3 different environmentally induced changes in 3 different tissues or cells obtained noninvasively are similar in major organs or tissues.	Determine and identify, if present, sex differences in three environmentally induced epigenomic signatures in three different mouse tissues.	N/A
SRO-2.7 By 2022, file Phase II Investigational New Drug (IND) application with the FDA for a therapy to treat geographic atrophy in age-related macular degeneration using patient-derived stem cells. (Outcome)	FY 2017: Clinical grade retinal tissue patch derived from AMD patients was safe and effective in rescuing retinal degeneration in rodent and pig models. Target: Complete preclinical work to test safety and efficacy of the clinical product in animal models. (Target Met)	Submit IND application with the FDA to launch phase I clinical trial upon approval.	Recruit 3 AMD patients into Phase I clinical trial.	N/A
SRO-2.8 By 2023, advance the development of three novel drug or biologic therapeutic candidates for Alzheimer's disease (AD) or related dementias toward the point of entry into Phase I human studies. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets. (In Progress)	Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets.	For each of the novel therapeutic targets, select 3-5 candidate therapeutic agents for entry into preclinical optimization studies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	FY 2017: Enrollment of participants continued for both studies. Target: Strategy 1: Continue enrolling participants into two studies to test the safety, tolerability, and effectiveness of VRC01 as an intravenous prevention strategy. (Target Met)	Strategy 2: Analyze primary results of a Phase 2a study examining the long-acting injectable, cabotegravir, for the prevention of HIV.	Strategy 3: Complete final analysis of an open-label extension study that builds on the findings of an earlier trial and aims to assess the continued safety of the dapivirine vaginal ring in a more real-world context and study participants' adherence.	N/A
SRO-2.10 By 2021, develop methods for the regeneration of functional tissues of the human dental, oral, and craniofacial complex to enable initiation of human Phase I clinical trials. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Establish a centralized Resource Center that is fully operational to develop, optimize, and validate tools and strategies for dental, oral, and craniofacial tissue regeneration. (In Progress)	Establish a centralized Resource Center that is fully operational to develop, optimize, and validate tools and strategies for dental, oral, and craniofacial tissue regeneration.	Submit an Investigational New Drug (IND) application for an FDA-approved tissue regeneration combination product.	N/A
SRO-2.12 By 2021, develop, validate, and/or disseminate 3-5 new research tools or technologies that enable better understanding of brain function at the cellular and/or circuit level. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level. (In Progress)	Develop four novel neurotechnologies for stimulating/ recording in the brain to enable basic studies of neural activity at the cellular level.	Test new and/or existing brain stimulation devices for 2 new therapeutic indications in humans through the BRAIN Public Private Partnership.	N/A
SRO-2.13 By 2023, advance the development of 1-2 new drugs and/or other therapeutic candidates for neurological diseases from lead optimization or device development toward the point of preparedness for	FY 2018: Result Expected Dec 31, 2018 Target: Initiate lead optimization studies to identify a pre-clinical candidate for 4-7 therapeutic or device candidates.	Initiate lead optimization studies to identify a pre-clinical candidate for 4-7 therapeutic or device candidates.	Identify and characterize 2-4 therapeutic or device candidates in preparation for animal toxicology studies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
first-in-human studies. (Output)	(In Progress)			
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development. (In Progress)	Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development.	Continue to evaluate the impact of adolescent alcohol or other substance use on brain development.	N/A
SRO-3.2 By 2023, establish the feasibility of using one emerging technology to safely and non-invasively obtain real time data on human placenta development and function during pregnancy. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Implement 3 research studies designed to evaluate the potential use of imaging technologies to obtain data on the placenta in humans and/or animal models. (In Progress)	Implement 3 research studies designed to evaluate the potential use of imaging technologies to obtain data on the placenta in humans and/or animal models.	Develop specifications for a curated dataset to serve as a resource for placental research, including identifying research gaps and discovering potential biomarkers and therapeutic targets for drug delivery.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2017: Researchers have designed a compassionate use study to evaluate treatment with Janus Kinase (JAK) inhibitors in juvenile dermatomyositis (JDM). Target: Design a clinical study testing an agent for a disorder of the immune system that affects children. (Target Met)	Initiate an interventional clinical study of a molecularly-targeted therapy in a cohort of patients with a disorder of the immune system that affects children.	Complete an interventional clinical study of a molecularly targeted therapy for a disorder of the immune system that affects children.	N/A
SRO-3.10 By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY 2017: NIH-supported researchers conducted a human laboratory study to investigate the role of varenicline, a smoking cessation medication, on alcohol craving. Target: Conduct one human	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	laboratory study on a candidate compound. (Target Met)			
SRO-3.11 By 2017, advance the discovery of high need cures through innovations in the therapeutics discovery and development process, by developing 3-D human tissue chips that accurately model the structure and function of human organs. (Outcome)	FY 2017: NIH-funded scientists continued to collaborate to integrate tissue chips into linked systems to mimic complex human organ interactions. Scientists investigated sequential metabolism of drugs through four organ systems (gut, liver, blood-brain barrier, kidney) and investigated off-target side-effects of drugs and metabolites on skeletal muscle. Target: Demonstrate that integrated organ chip systems model the structure and function of human organs. (Target Met)	N/A	N/A	N/A
SRO-4.1 By 2020, enable 1-3 Bridging Interventional Development Gaps (BrIDGs) projects to have sufficient pre-clinical data for therapeutic agents in order to apply for Investigational New Drug (IND) approval from the FDA. (Output)	FY 2017: The BrIDGs program acquired GMP-compliant drug material for one project. However, due to factors outside of BrIDGs' control (deficiency in required drug materials provided by the collaborator), formal GLP toxicology studies could not be conducted. Target: Acquire Good Manufacturing Practice (GMP)-compliant drug material and conduct formal Good Laboratory Practice (GLP) toxicology studies for 1-3 projects. (Target Not Met)	Acquire GMP-compliant drug material for 1-3 projects.	Initiate formal GLP toxicology studies for 1-3 projects.	N/A
SRO-4.2 By 2017, develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in	FY 2017: NIH-supported research examined data related to effective smoking cessation rates in NA communities.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
Native American (NA) populations that are culturally appropriate and promote the adoption of healthy lifestyles. (Outcome)	Target: Continue to develop, adapt, and test the effectiveness of culturally appropriate health promotion and disease prevention interventions in NA populations. Begin analyzing preliminary data from testing interventions in NA communities, and adapt community interventions based on initial finding. (Target Met)			
SRO-4.3 By 2020, advance our characterization and understanding of the cellular and genetic components that make up the diverse composition of most tumors. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Identify the cellular/genetic components of 3 common cancer types. (In Progress)	Identify the cellular/genetic components of 3 common cancer types.	Identify the role various cellular components play in the phenotype of the 3 cancers.	N/A
SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)	FY 2017: The molecular bases of 32 rare diseases were discovered. Target: Discover the molecular bases of an additional 10 rare diseases. (Target Exceeded)	Discover the molecular bases of an additional 10 rare diseases.	Discover the molecular bases of an additional 10 rare diseases.	N/A
SRO-4.8 By 2019, establish a sharable collection of positive Zika virus (ZIKV) biospecimens to increase knowledge of viral infection and associated host immune response to help evaluate potential strategies to ensure the safety of the blood supply. (Output)	FY 2017: The main Brazil transfusion recipient study in Sao Paulo to identify cases of probable transfusion-transmitted arboviral infections was launched in January 2017 and successfully enrolled 946 recipients before enrollment was halted based on a lack of a significant evolving epidemic. Target: Launch the main Brazil transfusion recipient study in Sao Paulo to identify cases of probable transfusion-transmitted ZIKV, chikungunya virus (CHIKV), and dengue virus	Establish a sharable repository of biospecimens from blood donors with ZIKV infection and analyze data from a US natural history of blood donors infected with ZIKV.	Complete the establishment of a shareable repository of Zika bio specimens, analyze data from a US Zika database, establish utility of blood screening for Zika virus, and assess Zika transfusion-transmission risks in animal models.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(DENV). (Target Met)			
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment. (In Progress)	Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment.	Conduct 1 preclinical study and 1 clinical trial to develop non-opioid based medications to treat OUD that may avoid the risks of opioid dependence and overdose.	N/A
SRO-4.10 By 2020, design and develop novel dental composite resins that demonstrate superiority over the currently used restorative materials. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials. (In Progress)	Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials.	Implement regulatory feedback received by the FDA to demonstrate safety and effectiveness.	N/A
SRO-4.11 By 2020, create a model system that recreates key features of human type 1 diabetes (T1D) autoimmunity for use in therapeutics development and testing. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D. (In Progress)	Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D.	Develop a system for rapid and high fidelity insertion of 2 T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line.	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic outcomes in response to treatment of adolescents with severe obesity. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: By 2018, assess the extent and durability of improvements in diabetes and its comorbid conditions in response to one treatment modality in adolescents with severe obesity and type 2 diabetes.	By 2018, assess the extent and durability of improvements in diabetes and its comorbid conditions in response to one treatment modality in adolescents with	By 2019, evaluate the impact of bariatric surgery for severe obesity during adolescence on weight-related and psychosocial and behavioral outcomes.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(In Progress)	severe obesity and type 2 diabetes.		
SRO-4.13 By 2020, complete analysis from the oral insulin trial for the prevention of type 1 diabetes in relatives at risk for the disease. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Begin final outcomes assessment for the oral insulin trial. (In Progress)	Begin final outcomes assessment for the oral insulin trial.	Complete final outcomes assessment for 450 participants in the oral insulin trial.	N/A
SRO-4.14 By 2020, identify a total of three effective strategies to reduce modifiable health risk factors associated with premature mortality in people with serious mental illness (SMI) and adolescents and youths with serious emotional disturbance (SED). (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI. (In Progress)	Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI.	Conduct testing of 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	N/A
SRO-5.1 By 2020, develop and test the effectiveness of two strategies for translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	FY 2017: Several U54 PACHE Partnerships have developed and/or validated evidence-based interventions and tools to help reduce the burden of cancer disparities in underserved communities across the United States. They are working with various community-based organizations (including faith-based organizations and community-based clinical practices and organizations) to disseminate/translate the interventions and tools in the diverse communities. Target: Develop 2 strategies for translating validated basic knowledge, clinical interventions, or behavioral interventions to diverse communities and clinical practice through establishing the Partnerships to Advance Cancer	Develop and support 2 partnerships to test validated basic cancer knowledge, clinical or behavioral interventions to diverse communities in clinical practice.	Finalize testing and validating the strategies to translate basic cancer knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Health Equity (PACHE) program between Minority Serving Institutions (MSI) and NCI-designated Cancer Centers (CC). (Target Met)			
SRO-5.2 By 2018, (a) identify genetic factors that enhance or reduce the risk of development and progression of chronic obstructive pulmonary disease (COPD) and (b) validate new genetic and clinical criteria that may be added to COPD classification and contribute to better and/or earlier diagnosis or prognosis of the disease. (Output)	FY 2017: Target of completing exome genotyping of 10,171 COPDGENE subjects was not met, due to a shift to whole genome sequencing in response to being awarded the TOPMed X01 announcement. This superior genome sequencing has been completed for 500 cases and 500 controls. Target: Complete exome chip genotyping of 10,171 COPDGene subjects and identify 1 to 5 new rare and common genetic determinants of COPD. (Target Not Met but Improved)	Identify 1-5 genomic loci that correlate with specific lung patterns of emphysema.	N/A	N/A
SRO-5.3 By 2020, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease. (Output)	FY 2017: NIH met its target of confirming genomic regions of interest in the Discovery and Replication phase data sets and continues to harmonize the Discovery Phase and Replication Phase data sets. Target: Continue confirmation of genomic regions of interest in the Discovery and Replication phase datasets. Continue harmonization of Discovery Phase and Replication Phase datasets. (Target Met)	Continue confirmation of genomic regions of interest in the Discovery using samples from the Replication phase. Continue harmonization of Discovery Phase and Replication Phase datasets. Begin analysis of genomic regions of interest in the genomes of minority cohorts.	Begin analysis of genomic regions of interest in the ADSP Discovery Follow-Up Phase using whole genome sequence data from ethnically diverse cohorts. Continue confirmation of genomic regions of interest in the Discovery Phase using samples from the Follow-Up phase. Continue harmonization of Discovery Phase and Follow-Up Phase datasets.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-5.4 By 2017, address the growing public health problem of antimicrobial resistance by discovering four to six new therapeutic candidates and assessing two novel approaches/regimens designed to preserve existing antimicrobials. (Output)	FY 2017: Three novel approaches/regimens designed to preserve existing antimicrobials were assessed. Target: Assess two novel approaches/regimens designed to preserve existing antimicrobials. (Target Exceeded)	N/A	N/A	N/A
SRO-5.5 By 2018, complete pre-commercial development of a point-of-care technology targeted for use in primary care setting. (Output)	FY 2017: Several point-of-care projects focused on development of technology for use in primary care have continued to progress along the device development pipeline, namely initiating the regulatory process through meetings or discussions with the FDA, or preliminary applications for FDA approval or clearance. Target: Support research on continued development of one or two prototype devices that will begin to initiate the regulatory process. (Target Met)	Support research on refinement of one or two devices for use in primary care that includes end-user feedback.	N/A	N/A
SRO-5.6 By 2017, develop, evaluate, refine, and/or promote strategies for preventing prescription drug abuse and its consequences. (Output)	FY 2017: Basic research explored two different targets related to the endocannabinoid system for the development of treatments for chronic pain that are not associated with development of tolerance or dependence. Three different studies were released with findings that can inform the development of treatment strategies for individuals with co-morbid opioid addiction and chronic pain that can later be tested in clinical research. Translational research exploring the impact of prescription monitoring	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	programs was disseminated in four publications. Target: In basic research: identify new targets or refine existing ones in the endocannabinoid system for the development of treatments of chronic pain without development of tolerance or dependence. In clinical research: develop, evaluate, and/or refine two to four treatment strategies that target co-morbid opioid addiction and chronic pain. In translation research identify the impact of state level prescription monitoring programs (PMP) on prescriber behavior and patient outcomes. (Target Met)			
SRO-5.8 By 2022, obtain pre-clinical and clinical data from newly initiated and current studies to evaluate 1-2 HIV vaccine candidate(s). (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population. (In Progress)	Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population.	Evaluate 1-2 alternative HIV vaccine candidates' suitability for human testing.	N/A
SRO-5.9 By 2017, determine the potential contributions of infectious agents to the underlying etiology of urologic chronic pelvic pain syndromes (UCPPS). (Outcome)	FY 2017: The potential contributions of the urinary tract microbial community to the underlying etiology and symptom profiles for urologic chronic pelvic pain syndrome was determined. Target: Determine the potential contributions of infectious agents to the underlying etiology and symptom profiles for urologic chronic pelvic pain syndromes in males and females.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
SRO-5.10 By 2020, assess the effectiveness of five to seven interventions that focus on eliminating health disparities by utilizing community partnerships to conduct intervention research that will foster sustainable efforts at the community level that will impact disparate conditions. (Output)	FY 2017: Phase II intervention research projects have recruited 60 percent of participants and have begun collection of second year assessment variables. Target: Assess intervention progress and collect second year assessment variables. (Target Met)	Assess intervention progress and collect third year assessment variables.	Assess intervention progress and collect fourth year assessment variables.	N/A
SRO-5.11 By 2018, develop and test three to five strategies for symptom management that reduce the effects of acute and chronic illness. (Output)	FY 2017: A smart phone app was developed for lung transplant recipients to facilitate daily self-reporting of clinical signs and symptoms to their clinicians, helping to quickly identify critical changes in health. Target: Assess the efficacy of one strategy that improves health outcomes through symptom self-management. (Target Met)	Test three strategies for symptom management that improve health outcomes across multiple illness trajectories.	N/A	N/A
SRO-5.12 By 2020, develop and/or characterize 3 mouse models for investigation of properties and functions of skin stem cells that can be used to advance research on wound healing, tissue engineering, or skin cancer. (Outcome)	FY 2017: Researchers used mouse models to identify environments that control skin stem cells, demonstrate how other cells affect stem cell behavior, and clarify the function of receptors on stem cell surfaces. Target: Develop and/or characterize a mouse model that can be used to improve understanding of the in vivo conditions required for skin stem cell maintenance. (Target Met)	Develop and/or characterize a mouse model in which skin stem cell life-span is shortened, to determine whether alterations in stem cell life-span modulate wound healing.	Develop and/or characterize a mouse model in which skin stem cell participation in wound repair is impaired.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment. (In Progress)	Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment.	Initiate research to test and refine one new or improved technology that uses acoustic, optical or electromagnetic waves to manipulate cells for treatment of illness.	N/A
SRO-5.14 By 2020, evaluate the effectiveness of one intervention to reduce death and/or neurodisability in pre-term or in full term infants with life-threatening conditions. (Outcome)	FY 2017: Completed follow-up on 168 subjects enrolled in study of newborn infants with brain injury due to low oxygenation. Target: Complete follow-up on 168 subjects enrolled in a study of term or late preterm infants with brain injury due to low oxygenation. (Target Met)	Complete enrollment in study of preterm infants undergoing incubator treatment.	Complete enrollment in transfusion study.	N/A
SRO-5.15 By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations. (Outcome)	FY 2017: NIH promoted and disseminated *CollegeAIM* and initiated efforts to update *CollegeAIM* to reflect the latest evidence-based alcohol interventions. Target: Continue to promote the College Alcohol Intervention Matrix (CollegeAIM). (Target Met)	Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native).	N/A	N/A
SRO-5.16 By 2021, conduct research to support pharmaceutical labeling changes for 5 drugs, to reflect safe and appropriate dosing and use specifically in children. (Outcome)	FY 2017: A proposed label change on acyclovir was submitted to the FDA. Target: Submit one proposed label change to FDA. (Target Met)	Complete one Phase I/II clinical trial on a prioritized drug.	Begin one Phase III clinical trial for drug development.	N/A
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-	FY 2018: Result Expected Dec 31, 2018 Target: Initiate development of	Initiate development of new strategies for patient- and	Test at least one novel strategy for improving care for patients with	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
of-life and palliative care. (Outcome)	new strategies for patient- and caregiver-centered decision-making in end-of-life and palliative care. (In Progress)	caregiver-centered decision-making in end-of-life and palliative care.	advanced illness through shared decision-making.	
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2017: Enrollment has been completed for two of the three Restoring Insulin Secretion studies. Target: Complete enrollment for at least one Restore Insulin Secretion protocol. (Target Met)	Complete at least one Restoring Insulin Secretion protocol.	Analyze the baseline data from the three Restoring Insulin Secretion protocols to understand differences between adult and pediatric individuals with pre-diabetes or newly diagnosed type 2 diabetes.	N/A
SRO-6.2 By 2025, advance 1-2 new or repurposed compounds that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Conduct at least 1 study with an animal model to evaluate the effect of a novel or repurposed compound on a neurobiological target involved in alcohol or other substance use disorders. (In Progress)	Conduct at least 1 study with an animal model to evaluate the effect of a novel or repurposed compound on a neurobiological target involved in alcohol or other substance use disorders.	Conduct at least 1 human laboratory study to evaluate the safety and efficacy of candidate compounds for treating alcohol or other substance use disorders.	N/A
SRO-7.2 By 2018, develop an evidence-based, online resource to help people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	FY 2017: In collaboration with Consumer Reports, NIH-supported investigators produced a web-based calculator that provides personalized estimates of treatment benefits and harms. Target: Integrate the individualized outcome models into an outcomes calculator and assess its use in a web-based environment (Target Met)	Develop an evidence-based, online resource to help people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-7.3 By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery or adherence for substance use disorders and related health consequences. (Output)	FY 2017: Research testing the feasibility and efficacy of 3 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including research in 2 different care delivery settings. Target: Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings. (Target Met)	Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities.	Develop and/or evaluate 2 HIT based interventions to prevent or treat substance use disorders or to improve medication adherence.	N/A
SRO-8.2 By 2017, identify circuits within the brain that mediate reward for 1) drugs, 2) non-drug rewards such as food or palatable substances, and 3) aversion to drug effects, and 4) determine the degree of overlap between these circuits. (Output)	FY 2017: Research disseminated through six studies has made significant advances in identifying the structural and functional plasticity of dendritic spines of neurons due to the use of drugs of abuse, withdrawal from chronic use, and relapse. Research shows that exposure to different drugs of abuse can alter dendritic spine morphology, and that drug-induced altered spine morphology occurs in several brain regions and can vary depending on the distance from the cell body. The biological mechanisms that contribute to these changes in dendritic spines are being studied. Target: Identify morphological and functional neuroplastic modifications due to drugs at the level of dendritic spines and electrophysiological indices and their persistence during the development of drug dependence (or during repeated	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	intermittent drug administration). (Target Met)			
SRO-8.7 By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems. (Outcome)	FY 2017: NIH researchers tested research-to-practice partnerships that were designed to enhance dissemination and implementation evidence-based practices. Three research projects focused on testing the development of organizational structures among research faculty, mental health treatment providers and agency stakeholders in rural primary care. Findings suggest that shared decision-making, written protocols, ongoing collaborative assessments and the implementation of warm hand-offs contributed to increased access to treatment among patients with mental health needs. Target: Establish one research-practice partnerships to improve dissemination, implementation, and continuous improvement of evidence-based mental health care services. (Target Exceeded)	Identify three implementation strategies that improve the sustainability and uptake of evidence-based practices in large public services settings, such as child welfare and mental health agencies.	N/A	N/A
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/intervention programs in minority communities. (Outcome)	FY 2017: The Shake, Rattle and Roll trial demonstrated efficacy of a blood pressure management intervention to reduce racial disparities in blood pressure control, a major contributor to stroke disparities. Target: Complete data analysis for a study that tested culturally tailored interventions to address major contributors to stroke disparities in racial/ethnic minority populations.	Initiate dissemination and implementation (D&I) data analyses to identify scalable components of successful disparities intervention programs.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2017: Award rate to comparison group reached 12%. Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2017: Award rate to comparison group reached 15% and exceeded the target by 5%. Target: N ≥ 10% (Target Exceeded)	N ≥ 10%	N ≥ 10%	N/A
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (Output)	FY 2017: NBS developed the Oracle Managed Cloud Services Performance Work Statement to define the necessary OMCS capacity and capabilities. NBS submitted the PWS to Vendor. Target: (Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud (Target Met)	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud	(Development [Dev]) Continue development of remediation activities to comply with HHS Accounting Treatment Manual (ATM) and other Treasure Mandates to increase accuracy and functionality of the NIH Business System.	N/A
CBRR-4 By 2021, produce and phenotype 2500 knockout (KO) mouse strains to enhance the capacity of researchers to investigate the in vivo function of mammalian genes and identify new models of human disease. (Outcome)	FY 2017: 413 juvenile lines of genetically modified mice were phenotyped. The mouse production and phenotyping is reported to a central database, and the information is disseminated at www.impc.org. Target: Deliver phenotyping on 300 knockout (KO) juvenile lines of genetically modified mice.	Deliver phenotyping on 500 knockout (KO) juvenile lines.	Deliver phenotyping on 600 knockout (KO) juvenile lines.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CBRR-5 By 2019, enhance the Clinical and Translational Science Awards (CTSA) Program by establishing resources, processes and guidelines to streamline and accelerate the implementation of multisite clinical trials. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and Recruitment Innovation Centers. (In Progress)	Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and Recruitment Innovation Centers.	Launch at least two multi-site clinical trials within the CTSA trial innovation network.	N/A
CBRR-6 By 2019, launch and establish a Biomedical Citizen Science Hub to serve as an online collaboration space for biomedical citizen science research efforts in cancer biology. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Complete development & launch the Biomedical Citizen Science Hub. (In Progress)	Complete development & launch the Biomedical Citizen Science Hub.	Establish 200-300 registered users of the site and 5 subgroups for the Biomedical Citizen Science Hub.	N/A
CBRR-7 By 2017, expand the scope and reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENE®), a national genetics research resource for rare inherited ocular diseases, by adding new patient records to the database, augmenting and refining the phenotypic data collected, and by increasing the number of registered researchers to 900. (Output)	FY 2017: With 6,450 participants (including 3,000 detailed phenotypes), eyeGENE is now an ocular genetics resource with 1,043 registered users in 5 countries and has been cited in 129 research publications. Target: Increase the number of registered eyeGene users to 900. (Target Exceeded)	N/A	N/A	N/A
CBRR-8 By 2017, characterize the three-dimensional atomic structure of 400 proteins of biomedical interest related to infectious agents. (Output)	FY 2017: 205 three-dimensional structures were characterized to enhance the biomedical research community's understanding of these proteins and to assist with the development of structure-based vaccines, diagnostics, and therapeutics.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Target: Characterize the three-dimensional structure of an additional 100 protein targets or other molecules of biomedical interest with regard to bacterial, viral, and eukaryotic pathogens. (Target Exceeded)			
CBRR-9 By 2020, enroll a total of 2,352 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	FY 2017: A cumulative 1,302 participants were enrolled in GenomeConnect. Target: Enroll 1,046 cumulative participants in GenomeConnect. (Target Exceeded)	Enroll 1,652 cumulative participants in GenomeConnect.	Enroll 2,002 cumulative participants in GenomeConnect.	N/A
CBRR-10 By 2020, enroll 180 children into the Pediatric Heart Network (PHN) to support a research resource for investigators conducting research in congenital heart disease across the age spectrum. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Enroll 50 children with complex congenital heart disease in a clinical research study. (In Progress)	Enroll 50 children with complex congenital heart disease in a clinical research study.	Enroll 50 children with complex congenital heart disease in a clinical research study.	N/A
CBRR-12 By 2017, produce x-ray diffraction data for new protein structures that will enhance an existing x-ray resource for understanding basic biological processes. (Output)	FY 2017: X-ray crystallographic data for 176 new structures of biomedical relevance provided to researchers worldwide. Target: Provide x-ray crystallographic data for 170 new structures of macromolecules of biomedical relevance to researchers worldwide. (Target Met)	N/A	N/A	N/A
CBRR-13 By 2017, archive and annotate new protein structures to support research in human health and disease and drug development. (Output)	FY 2017: In FY 2017, 9,691 structures were archived and annotated at the Protein Data Bank and made available to the community, exceeding the target. Target: Annotate and archive	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	9,200 new protein structures. (Target Exceeded)			
CBRR-14 By 2018, establish and utilize a national clinical network to conduct five stroke clinical trials using shared infrastructure and efficient processes. (Output)	FY 2017: A new prevention trial for the NIH StrokeNet – Atrial Cardiomyopathy and Antithrombotic Drugs in Prevention After Cryptogenic Stroke (ARCADIA) – was initiated. Target: To broaden the network's scope across stroke research, initiate one new trial in stroke prevention or stroke treatment within the stroke network. (Target Met)	Complete enrollment in 1 to 3 trials being conducted within the stroke network.	N/A	N/A
CBRR-17 By 2017, take steps to improve the quality and availability of information to inform decisions about the size of the NIH training programs and the number of people in training to address future needs for the nation's biomedical research workforce. (Output)	FY 2017: NIH has developed and released the xTRACT system, which allows NIH applicants to create data tables for training grant applications electronically and NIH to capture the resulting trainee outcome data. Target: Adopt a system for reporting training grant data and trainee outcomes electronically. (Target Met)	N/A	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample. (In Progress)	Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample.	Review results from the assessment protocol as deployed in the US in 2016-2017 and in other countries in 2017 and 2018. Refine protocol as needed to increase sensitivity and specificity.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
CBRR-19 By 2019, identify and characterize 1900 immune epitopes from infectious pathogens and allergens for deposit into the Immune Epitope Database (www.iedb.org) to accelerate development of more effective vaccines and immune-based therapeutics. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Identify and characterize 600 T cell and 200 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics. (In Progress)	Identify and characterize 600 T cell and 200 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics.	Identify and characterize 650 T cell and 250 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics.	N/A
CBRR-20 By 2020, advance the preclinical development of ten candidate products (e.g., vaccines, therapeutics) to combat infectious diseases. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Advance the preclinical development of three vaccine and/or therapeutic candidate products. (In Progress)	Advance the preclinical development of three vaccine and/or therapeutic candidate products.	Advance the preclinical development of three vaccine and/or therapeutic candidate products.	N/A
CBRR-21 By 2020, establish and implement a national collaborative Pilot and Feasibility (P&F) program that utilizes specialized equipment, and expertise in nonmalignant hematology that are available through the Cooperative Centers of Excellence in Hematology (CCEH). (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions. (In Progress)	Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions.	Support 2 P&F projects involving collaboration outside the hematology Centers.	N/A
CBRR-22 By 2020, establish a reference map that will serve as the framework to understand the development of the human urinary tract. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate. (In Progress)	Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate.	Identify and map at least 5 specific cell types or subtypes within the kidney, urinary outflow tract, and/or prostate.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
CBRR-23 By 2019, provide access to laboratory and data analytical services and a data repository that will allow the NIH extramural research community the capability to add or expand the inclusion of environmental exposure analysis in children's health research. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Support at least 20-40 studies (or about 20,000 sample analyses) in a project management pipeline from application development and review to laboratory and data analysis. (In Progress)	Support at least 20-40 studies (or about 20,000 sample analyses) in a project management pipeline from application development and review to laboratory and data analysis.	Support analysis for at least 10 additional studies (or about 10,000 sample analyses) and make the results from about 10 studies or 10,000 sample analyses available to the broader scientific community.	N/A
CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5% above baseline. (In Progress)	Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5% above baseline.	Expand by 5% the proportion of NIGMS-supported investigators funded by active R01-equivalent awards who are MIRA recipients.	N/A
CBRR-25 Increase the total number of mentored research career development experiences for trainees from underrepresented backgrounds to promote individual development and to prepare them for a range of research-related careers. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: 3505 career experiences across all career stages. (In Progress)	3505 career experiences across all career stages.	3522 career experiences across all career stages.	N/A
CBRR-26 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA Networks of Biomedical Research Excellence (INBRE) program in order to sustain a pipeline of undergraduate students	FY 2018: Result Expected Dec 31, 2018 Target: Sustain the number of undergraduate mentored research experiences from 2017 level. (In Progress)	Sustain the number of undergraduate mentored research experiences from 2017 level.	Sustain the number of undergraduate mentored research experiences from 2018 level.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
who will pursue health research careers. (Output)				
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Expand the validation of assessment methods for risk of suicide among at least one subgroup (e.g., youth, adults; persons who have experienced trauma) seen in emergency department. (In Progress)	Expand the validation of assessment methods for risk of suicide among at least one subgroup (e.g., youth, adults; persons who have experienced trauma) seen in emergency department.	Validate risk stratification approaches in emergency care settings for youth who are at risk for suicide.	N/A
CBRR-28 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting research on brain and behavior. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Collect brain tissue from 70 new donors and distribute tissue samples or data derived from tissue to 25 researchers studying mental or neurological disorders. (In Progress)	Collect brain tissue from 70 new donors and distribute tissue samples or data derived from tissue to 25 researchers studying mental or neurological disorders.	Collect brain tissue from an additional 70 new donors and distribute tissue samples or data derived from tissue to 30 researchers studying mental or neurological disorders.	N/A
CBRR-29 By 2020, establish an interactive consortium to facilitate efficient data collection and sharing for biomarker studies of vascular contribution to cognitive impairment and dementia (VCID). (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations. (In Progress)	Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations.	Initiate multi-site validation studies for one candidate biomarker.	N/A
CTR-1 By 2018, increase the number of SBIR/STTR outreach events that are targeted to groups that are currently underrepresented in the NIH SBIR/STTR portfolio. (Output)	FY 2017: Three outreach events to women-targeted or minority-targeted organizations were completed. Target: Complete three outreach events with either a minority-targeted organization or program, or a women-targeted organization or program.	Complete four outreach events with either a minority-targeted organization or program, or a women-targeted organization or program.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CTR-2 By 2017, reach 500,000 visits to the website Genome: Unlocking Life's Code. (Outcome)	FY 2017: As of November 19, 2017, ULC reached 490,456 visits and 1,676,887 page views. The target of 2.5 million pages was not met; however, the 1.68 million pages represents a continuing upward trend from previous years. Target: By 2017, reach 2.5 million total page views. (Target Not Met but Improved)	N/A	N/A	N/A
CTR-4 By 2017, expand and implement the broad use of Common Data Elements for 17 neurological disorders among investigators conducting clinical research. (Output)	FY 2017: NIH institutes/centers collaborated to develop a new CDE library and to provide centralized access to CDE resources for the clinical research community. Target: Develop collaborative model to enable implementation of the CDE project as a long-term sustainable resource for the clinical research community. (Target Met)	N/A	N/A	N/A
CTR-5 By 2018, increase the number of computer-indexed MEDLINE journals by 469 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	FY 2017: The number of computer-indexed MEDLINE journals was increased by 100 titles, thereby increasing indexing efficiency for MEDLINE. Target: Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year. (Target Exceeded)	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 60 titles over the previous year.	N/A	N/A
CTR-6 By 2018, improve NIH's ability to identify outcomes that result from	FY 2017: The Final Research Performance Progress Report is one of three final reports that	By 2018, implement system improvements to	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
NIH funded research projects and reports to the public on research outcomes. (Outcome)	allow NIH to closeout grant awards. The F-RPPR includes a Project Outcomes section that allows recipients to summarize the cumulative outcomes or findings of the project. This section is written in laymen's terms for the general public and will be made public in NIH RePORTER. Target: By 2017, establish an electronic closeout process for NIH research grants which includes a Project Outcomes Report for the general public summarizing the project outcomes or findings that expand fundamental knowledge, enhance health, lengthen life, reduce illness and disability, and otherwise fulfill the programmatic goals of the research activity. (Target Met)	collect inclusion data (i.e., race, gender, etc.) at award closeout in a structured format.		
CTR-7 By 2022, engage a national community in the development, dissemination, and implementation of a comprehensive national strategy to address the burden of Chronic Obstructive Pulmonary Disease (COPD) in the US. (Output)	FY 2017: The COPD National Action Plan was launched on May 22, 2017 at the American Thoracic Society annual meeting in Washington, DC with a press conference and expert panel. Target: Complete development and begin dissemination of a national COPD action plan. (Target Met)	Conduct annual implementation progress webinars/meetings with stakeholders.	Analyze completed webinars and meeting, and brief stakeholders on Action Plan progress.	N/A
CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform agency funding decisions, and promote transparency	FY 2018: Result Expected Dec 31, 2018 Target: By 2018, develop a metric that captures the unique number of individuals who apply for and receive NIH funding over a five-year time period.	By 2018, develop a metric that captures the unique number of individuals who apply for and receive NIH funding over a five-year time period.	By 2019, develop a central public report displaying NIH Institute/Center-specific award data on investigator-initiated R01/R37 grants.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
regarding the agency's funding strategies. (Output)	(In Progress)			
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Output)	FY 2017: NIH's leadership development programs incorporated technology to increase engagement and access for remote employees. While students were open to technological tools, participants tend to prefer face-to-face interactions. Target: Assess [AS] results of implementation *Assess best practices and review the literature regarding incorporating the latest technologies into leadership development programs to determine which are most effective and practicable to create efficiencies and/or enhance learning [EX 2015 /AS 2017] (Target Met) FY 2017: Recommendations from a prior evaluation were implemented to ensure that the Executive Leadership Program (ExLP) meets participant expectations and organizational requirements. Target: Implement [IM] recommendation from prior year assessments *NIH will implement the recommendations from prior year assessments of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/ AS 2018] (Target Met)	Examine [EX] key area to enhance leadership skills *NIH workforce trends to target junior-level programs to job series with the largest anticipated risk in filling future leadership positions. [IM 2019/ AS 2020] Implement [IM] recommendation from prior year assessments *NIH will implement best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019] Assess [AS] results of implementation *NIH will assess the outcomes of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its	Examine [EX] key area to enhance leadership skills Examine the Management Seminar Series as a method for engaging and encouraging leadership in high-performing NIH employees.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	FY 2017: The NIH Office of Human Resources found that supervisors need targeted guidance and support on topics specific to supervision and leadership. In addition, hiring managers need to have additional resources to better prepare for onboarding employees. Target: Examine [EX] key area to enhance leadership skills *NIH will examine best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019] (Target Met)	current content [IM 2017/ AS 2018]		
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Output)	FY 2017: NIH/OHR successfully increased the use of Global Recruitments as it relates to select positions at the NIH that have Direct Hire Authority as a result of a critical need. As a result, there is a quarterly coordinated and consolidated approach to announcing for Contract Specialist and Medical Officer positions reducing the number of resources across 27 Institutes and Centers and OD Offices for hiring within these positions. Target: Assess [AS] results of implementation *Assess the results of implementation on the Increase use of Global Recruitments. [AS 2017] (Target Met) FY 2017: NIH/OHR managerial	Examine [EX] key area to enhance recruitment *NIH will examine HR CARDS to determine whether it is effective in meeting program goals and streamlining the efficient use of standard HR packages. [IM 2019/AS 2020] Implement [IM] key area to enhance recruitment *Implement the creation of a program that incorporates SMEs during the recruitment process, as	Examine [EX] key area to enhance recruitment Examine recruitment activities to identify the most opportune times throughout the year for NIH to recruit NIH for varying occupations.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	staff were all interviewed regarding skill gaps and organizational needs. All eligible OHR Interns have been converted into the CSD organization to ensure a pipeline of staff. Also, OHR launched the group working on managing training internally to ensure new staff is trained and functioning quickly. Target: Assess [AS] results of implementation *Assess the results of launching a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [AS 2017] (Target Met) FY 2017: NIH Pathway's Program expanded to include targeted announcements for NIH Student Trainee Bio Science Lab Tech, Health Specialist and Student Trainee Engineering positions. In addition, the NIH continued the Presidential Management Fellow's track of Health Specialist and Public Health Analyst/Advisor. Target: Implement [IM] key area to enhance recruitment *Implement an expansion of the Pathways Program to STEM career path for focused students and supporting of succession planning efforts. [IM 2017] [AS 2018] (Target Met) FY 2017: NIH/OHR created an analysis by reviewing all resumes of two recruitments to study the impact of SME incorporation in the recruitment process.	appropriate. [IM 2018] [AS 2019] Assess [AS] results of implementation *Assess the expansion of the Pathways Program to STEM career path for focused students and in support of succession planning efforts. [IM 2017] [AS 2018]		

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Target: Examine [EX] key area to enhance recruitment *Examine a way to create a comprehensive program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019] (Target Met)			
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2017: 25% of Principal Investigators were reviewed resulting in 25% of resources recommended to be reallocated. Target: Conduct BSC reviews of 25% of Principal Investigators to access quality of science in order to prioritize resources. (Target Met)	Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.	Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.	N/A
MPO-5 Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa=85). (Output and Efficiency)	FY 2017: The condition of the facilities portfolio reached a CIwa of 83.08. Target: CIwa = 78.40 (Target Exceeded)	CIwa=80.86	CIwa=80.94	N/A
MPO-6 By 2017, maintain the annual condition of buildings and facilities portfolio so that no less than 95% of occupied gross square feet (GSF) will have a CI greater than 65. (Output and Efficiency)	FY 2017: 87.85% of the occupied gross square feet (GSF) reached a CI greater than 65. Target: Target = 85.68% (Target Exceeded)	N/A	N/A	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final approved project cost. (Output)	FY 2017: The sixteen (16) active funded projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100% of the final approved project cost.	15 Active Projects	18 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Target: 16 Active Projects (Target Met)			
MPO-8 Manage design and construction of capital facility projects funded by B&F so that no more than 10% of the projects may incorporate plus or minus 10% adjustments of the approved scope. (Output)	FY 2017: The design and construction for thirteen (13) of the sixteen (16) active funded projects in the portfolio were managed effectively under this target that focused on ensuring that no more than 10% of the portfolio incorporated a plus or minus 10% adjustment of the approved scope. (target Not Met) Target: 16 Active Projects (Target Not Met)	15 Active Projects	18 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (Output)	FY 2017: Obligated 47% of eligible service contracting dollars to PBC. Target: Obligate the FY 2017 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2018 goal of eligible service contracting dollars to PBC.	Obligate the FY 2019 goal of eligible service contracting dollars to PBC.	N/A
MPO-10 Conduct systematic evaluations and pilot studies to identify strategies and future needs for enhancing the quality of peer review and improving efficiency. (Output)	FY 2017: Historical measures of peer review quality and efficiency were identified in 11 studies conducted by CSR. This input was utilized in the planning and implementation of 8 original research and evaluation studies in 2017. Measures to assess peer review quality include those of structure, process, or outcome. Target: Identify historical measures of peer review quality and efficiency. (Target Exceeded)	Design and test measures of peer review quality and efficiency.	Refine and test measures of peer review quality and efficiency.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
MPO-11 Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: 70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award. (In Progress)	70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	75% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	N/A
MPO-12 By 2020, enhance the management, oversight, and transparency of NIH-funded clinical trials through reforms to clinical trials grant applications, peer review, and tracking of awards. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Improve the quality and strengthen peer review of clinical trial applications by 1) requiring that all clinical trial applications be submitted to clinical trial-specific funding opportunity announcements (FOAs) and 2) introducing new clinical trials-specific review criteria to enhance peer review. (In Progress)	Improve the quality and strengthen peer review of clinical trial applications by 1) requiring that all clinical trial applications be submitted to clinical trial-specific funding opportunity announcements (FOAs) and 2) introducing new clinical trials-specific review criteria to enhance peer review.	Enhance transparency of NIH-funded clinical trials by establishing an NIH policy that expects all NIH-funded clinical trials to register and submit results to ClinicalTrials.gov and by creating a more robust process for assuring compliance with the policy.	N/A

GRANT AWARDS TABLE

	FY 2017 Final[3]	FY 2018 Annualized CR[3]	FY 2019 President's Budget[3,4]
Number of Awards	44,193	43,628	44,431
Average Award (in Whole $s)	$538,794	$545,333	$530,482
Range of Awards (in Whole $s)[1,2]	$1,000 to $47,653,075	$1,000 to $34,196,739	$1,000 to $33,205,852

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

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

[3] Includes 21st Century Cures Act funding.

[4] Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF, and EEOICPA.

BUDGET REQUEST BY IC (SUMMARY TABLE)

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
NCI	$5,659,955	$5,650,693	$5,626,312
NHLBI	$3,209,929	$3,184,813	$3,112,032
NIDCR	$424,797	$422,860	$413,196
NIDDK[1]	$2,009,504	$2,007,892	$1,965,434
NINDS	$1,778,688	$1,771,541	$1,838,556
NIAID	$4,905,718	$4,873,317	$4,761,948
NIGMS[2]	$2,646,152	$2,632,836	$2,572,669
NICHD	$1,376,608	$1,370,921	$1,339,592
NEI	$731,212	$727,643	$711,015
NIEHS[3]	$790,018	$786,234	$747,166
NIA	$2,048,814	$2,034,698	$1,988,200
NIAMS	$556,606	$554,063	$545,494
NIDCD	$435,904	$433,908	$423,992
NIMH	$1,604,658	$1,591,052	$1,612,192
NIDA	$1,070,846	$1,083,445	$1,137,403
NIAAA	$482,451	$480,080	$469,109
NINR	$149,937	$149,252	$145,842
NHGRI	$528,346	$524,977	$512,979
NIBIB	$356,981	$354,655	$346,550
NIMHD	$287,670	$287,106	$280,545
NCCIH	$134,389	$133,774	$130,717
NCATS	$704,330	$701,109	$685,087
FIC	$71,852	$71,723	$70,084
NLM	$406,604	$404,743	$395,493
B&F	$128,567	$127,988	$200,000
OD	$1,728,603	$1,706,132	$2,004,306
NIRSQ	---	---	$255,960
NIOSH	---	---	$200,000
NIDILRR	---	---	$95,127
PCORTF (NIRSQ)	---	---	$124,349
EEOICPA (NIOSH)	---	---	$55,358
TOTAL, NIH Program Level	**$34,229,139**	**$34,067,456**	**$34,766,707**
Special type 1 Diabetes Research	-$139,650	-$150,000	---
PCORTF	---	---	-$124,349
EEOICPA	---	---	-$55,358
PHS Program Evaluation	-$824,443	-$818,844	-$741,000
Interior Approp. (Superfund Research)	-$77,349	-$76,824	-$53,967
Total, NIH Labor/HHS Budget Authority	**$33,187,697**	**$33,021,788**	**$33,792,033**

[1] Includes Special type 1 Diabetes Research mandatory funding in FY 2017 ($139.65 million) and FY 2018 ($150 million) and discretionary funding in FY 2019 ($150 million).

[2] Includes Program Evaluation financing of $824 million in FY 2017, $818 million in FY 2018, and $741 million in FY 2019.

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

APPROPRIATIONS ADJUSTMENT TABLES

(Dollars in Thousands)	FY 2017 Enacted	Permissive Transfer (NIH Innovation Account)[4]	Permissive Transfer (Secretary 1% Authority)[5]	HIV/AIDS Transfer	Sequestration	FY 2017 Operating Level
NCI	$5,389,329	$300,000	-$11,971	-$17,403		$5,659,955
NHLBI	$3,206,589		-$7,152	$10,492		$3,209,929
NIDCR	$425,751		-$954	---		$424,797
NIDDK[1,2]	$2,020,595		-$4,174	$3,433	-$10,350	$2,009,504
NINDS	$1,783,654		-$3,894	-$1,072		$1,778,688
NIAID	$4,906,638		-$10,628	$9,708		$4,905,718
NIGMS	$2,650,838		-$3,976	-$710		$2,646,152
NICHD	$1,380,295		-$3,076	-$611		$1,376,608
NEI	$732,618		-$1,643	$237		$731,212
NIEHS[3]	$791,610		-$1,592	---		$790,018
NIA	$2,048,610		-$3,673	$3,877		$2,048,814
NIAMS	$557,851		-$1,245	---		$556,606
NIDCD	$436,875		-$971	---		$435,904
NIMH	$1,601,931		-$3,554	$6,281		$1,604,658
NIDA	$1,090,853		-$2,474	-$17,533		$1,070,846
NIAAA	$483,363		-$1,074	$162		$482,451
NINR	$150,273		-$336	---		$149,937
NHGRI	$528,566		-$1,191	$971		$528,346
NIBIB	$357,080		-$796	$697		$356,981
NIMHD	$289,069		-$642	-$757		$287,670
NCCIH	$134,689		-$300	---		$134,389
NCATS	$705,903		-$1,573	---		$704,330
FIC	$72,213		-$162	-$199		$71,852
NLM	$407,510		-$906	---		$406,604
OD	$2,029,783	-$300,000	-$3,607	$2,427		$1,728,603
B&F	$128,863		-$296	---		$128,567
Total, NIH Program Level	**$34,311,349**	**---**	**-$71,860**	**---**	**-$10,350**	**$34,229,139**
Less funds allocated from different sources:						
Mandatory Type 1 Diabetes Research	-$150,000	---	---	---	-$10,350	-$139,650
PHS Program Evaluation	-$824,443	---	---	---	---	-$824,443
Total, NIH Discretionary Budget Authority	**$33,336,906**	**---**	-$71,860	**---**	**---**	**$33,265,046**
Interior Budget Authority	-$77,349	---	---	---	---	-$77,349
Total, NIH Labor/HHS Budget Authority	**$33,259,557**	**---**	**-$71,860**	**---**	**---**	**$33,187,697**

[1] Includes funding for mandatory Special type 1 Diabetes Research account as authorized under Section 213(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10).

[2] Includes a sequestration adjustment for the Special type 1 Diabetes Research mandatory account.

[3] Includes the Superfund Research allocation as provided by the Interior & Environment section (Division G) of the Consolidated Appropriations Act of 2017 (P.L. 115-31).

[4] Reflects redistribution of NIH Innovation account for the 21st Century Cures Act (P.L. 114-255).

[5] Identifies amounts transferred to HHS consistent with the Secretary's 1% transfer authority consistent with Section 205 (Division H) of P.L. 115-31.

BUDGET MECHANISM TABLE

(Dollars in Thousands)[1]	FY 2017 Final[3,4]		FY 2018 Annualized CR[3,4]		FY 2019 President's Budget[4, 10]		FY 2019 +/- FY 2018	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	24,638	$12,661,301	25,468	$13,495,362	25,030	$13,291,723	-438	-$203,639
Administrative Supplements[2]	*(1,508)*	225,445	*(1,174)*	157,514	*(952)*	112,473	*(-222)*	-45,041
Competing	10,123	$5,283,732	8,656	$4,486,448	9,084	$4,571,486	428	$85,038
Subtotal, RPGs	34,761	$18,170,479	34,124	$18,139,325	34,114	$17,975,682	-10	-$163,643
SBIR/STTR	1,807	923,162	1,796	926,988	1,835	918,846	39	-8,142
Research Project Grants	36,568	$19,093,641	35,920	$19,066,313	35,949	$18,894,528	29	-$171,785
Research Centers:								
Specialized/Comprehensive	1,004	$1,766,720	979	$1,706,013	1,082	$1,709,109	103	$3,096
Clinical Research	67	402,112	71	418,602	85	405,881	14	-12,721
Biotechnology	105	187,352	101	175,897	123	180,243	22	4,346
Comparative Medicine	48	121,663	47	118,807	51	127,634	4	8,827
Research Centers in Minority Institutions	24	58,462	24	64,388	22	59,851	-2	-4,537
Research Centers	1,248	$2,536,309	1,222	$2,483,707	1,363	$2,482,718	141	-$989
Other Research:								
Research Careers	3,712	$672,622	3,792	$688,038	4,226	$752,342	434	$64,304
Cancer Education	83	23,629	85	24,147	94	26,492	9	2,345
Cooperative Clinical Research	329	403,274	265	377,633	291	400,779	26	23,146
Biomedical Research Support	109	69,962	109	68,778	63	39,703	-46	-29,075
Minority Biomedical Research Support	281	104,119	281	103,454	357	110,179	76	6,725
Other	1,863	907,363	1,954	979,720	2,088	863,101	134	-116,619
Other Research	6,377	$2,180,970	6,486	$2,241,770	7,119	$2,192,596	633	-$49,174
Total Research Grants	44,193	$23,810,919	43,628	$23,791,790	44,431	$23,569,842	803	-$221,948
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,599	$157,826	3,554	$159,393	3,488	$157,910	-66	-$1,483
Institutional Awards	12,419	669,571	12,471	680,412	12,282	652,676	-189	-27,736
Total Research Training	16,018	$827,397	16,025	$839,805	15,770	$810,586	-255	-$29,219
Research & Develop. Contracts	2,028	$3,070,430	2,018	$2,896,751	2,003	$2,931,915	-15	$35,164
(SBIR/STTR) (non-add)[2]	*(88)*	*(57,569)*	*(78)*	*(60,086)*	*(98)*	*(61,241)*	*(20)*	*(1,155)*
Intramural Research		$3,782,692		$3,787,681		$3,795,544		$7,863
Res. Management & Support		1,747,769		1,765,098		1,757,337		-7,761
Res. Management & Support (SBIR Admin) (non-add)[2,11]		*(5,695)*		*(0)*		*(0)*		*(0)*
Office of the Director - Appropriation[2,5]		*(1,728,603)*		*(1,706,132)*		*(2,004,306)*		*(298,174)*
Office of the Director - Other		754,016		751,723		1,152,682		400,959
ORIP (non-add)[2,5]		*(279,131)*		*(275,580)*		*(252,843)*		*(-22,737)*
Common Fund (non-add)[2,5]		*(695,456)*		*(678,829)*		*(598,781)*		*(-80,048)*
Buildings and Facilities[6]		158,567		157,784		220,000		62,216
Appropriation		*(128,567)*		*(127,988)*		*(200,000)*		*(72,012)*
National Institute for Occupational Safety and Health[9]		---		---		200,000		200,000
National Institute on Disability, Independent Living, and Rehabilitation Research[9]		---		---		95,127		95,127
Special type 1 Diabetes[7]		-139,650		-150,000				150,000
Program Evaluation Financing[8]		-824,443		-818,844		-741,000		77,844
Subtotal, Labor/HHS Budget Authority		**$33,187,697**		**$33,021,788**		**$33,792,033**		**$770,245**
Interior Appropriation for Superfund Research		77,349		76,824		53,967		-22,857
Total, NIH Discretionary BA		**$33,265,046**		**$33,098,611**		**$33,846,000**		**$747,389**
Special type 1 Diabetes		139,650		150,000		0		-150,000
Patient-Centered Outcomes Research Trust Fund (PCORTF)						124,349		124,349
Energy Employees Occupational Illness Compensation Program Act (EEOICPA)						55,358		55,358
Total, NIH Budget Authority		**$33,404,696**		**$33,248,611**		**$34,025,707**		**$777,096**
Program Evaluation Financing		824,443		818,844		741,000		-77,844
Total, Program Level		**$34,229,139**		**$34,067,456**		**$34,766,707**		**$699,251**

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

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

3 Excludes Ebola-related supplemental appropriations.

4 Includes 21st Century Cures Act funding.

5 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as a non-add; The Office of the Director - Appropriations also is noted as a non-add because the remaining funds are accounted for under OD - Other.

6 Includes the Building & Facilities appropriation as well as funds identified for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

7 In FY 2017 and FY 2018 the number of grants and dollars for mandatory Special type I Diabetes Research account are distributed by mechanism above; therefore, type I Diabetes amounts are deducted to provide subtotals that align to the Labor/ HHS Budget Authority levels. In FY 2019, resources for Special type 1 Diabetes are incorporated in discretionary appropriations.

8 Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals that align to the Labor/HHS Budget Authority levels.

9 National Institute for Occupational Safety and Health (NIOSH) and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) included in FY 2019 only and are not distributed by mechanism.

10 Includes funding for the National Institute for Research on Safety and Quality (formerly the Agency for Healthcare Research and Quality), NIOSH, and NIDILRR.

11 SBIR administrative funds pilot program expired on September 30, 2017.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING TYPE 1 DIABETES

(Dollars in Thousands)[1]

Object Classes	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 Revised +/- FY 2018
Personnel Compensation			
Full-Time Permanent (11.1)	$1,005,750	$1,044,655	$38,904
Other Than Full-Time Permanent (11.3)	529,051	534,339	5,288
Other Personnel Compensation (11.5)	46,458	45,327	-1,132
Military Personnel (11.7)	18,543	19,658	1,115
Special Personnel Services Payments (11.8)	177,354	157,705	-19,649
Subtotal Personnel Compensation (11.9)	**$1,777,158**	**$1,801,684**	**$24,527**
Civilian Personnel Benefits (12.1)	517,577	535,167	17,590
Military Personnel Benefits (12.2)	12,490	13,100	610
Benefits to Former Personnel (13.0)	0	1,401	1,401
Total Pay Costs	**$2,307,225**	**$2,351,353**	**$44,128**
Travel & Transportation of Persons (21.0)	50,395	52,272	1,877
Transportation of Things (22.0)	5,205	5,328	123
Rental Payments to GSA (23.1)	23,583	24,398	814
Rental Payments to Others (23.2)	1,312	1,618	306
Communications, Utilities & Misc. Charges (23.3)	30,808	31,571	763
Printing & Reproduction (24.0)	536	563	26
Consultant Services (25.1)	199,844	205,320	5,476
Other Services (25.2)	1,187,625	1,244,511	56,885
Purchase of goods and services from government accounts (25.3)	3,185,009	3,396,595	211,586
Operation & Maintenance of Facilities (25.4)	207,649	236,105	28,456
R&D Contracts (25.5)	1,402,484	1,432,723	30,239
Medical Care (25.6)	24,851	26,718	1,867
Operation & Maintenance of Equipment (25.7)	120,524	124,788	4,264
Subsistence & Support of Persons (25.8)	1,565	2,218	653
Subtotal Other Contractual Services (25.0)	**$6,329,550**	**$6,668,977**	**$339,427**
Supplies & Materials (26.0)	219,034	223,773	4,739
Equipment (31.0)	147,083	82,204	-64,879
Land and Structures (32.0)	0	0	0
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	24,057,027	24,054,822	-2,205
Insurance Claims & Indemnities (42.0)	1	0	-1
Interest & Dividends (43.0)	27	27	0
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$30,864,563**	**$31,145,553**	**$280,990**
Total Budget Authority	**$33,171,788**	**$33,496,906**	**$325,118**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related supplemental appropriations, and Program Evaluation financing (all years). Includes mandatory Special type 1 Diabetes Research account for FY 2018 only. Excludes budgetary resources associated with NIOSH, NIDILRR, PCORTF, and EEOICPA for FY 2019 only.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING SSF AND MF

(Dollars in Thousands)

Object Classes	FY 2018 Annualized CR[1]	FY 2019 President's Budget	FY 2019 Revised +/- FY 2018
Personnel Compensation			
Full-Time Permanent (11.1)	$1,383,943	$1,424,663	$40,720
Other Than Full-Time Permanent (11.3)	592,957	598,551	5,595
Other Personnel Compensation (11.5)	73,834	72,834	-1,000
Military Personnel (11.7)	27,118	28,413	1,295
Special Personnel Services Payments (11.8)	182,506	162,882	-19,624
Subtotal Personnel Compensation (11.9)	**$2,260,358**	**$2,287,343**	**$26,985**
Civilian Personnel Benefits (12.1)	668,642	688,091	19,449
Military Personnel Benefits (12.2)	18,349	19,082	733
Benefits to Former Personnel (13.0)	1,160	2,573	1,413
Total Pay Costs	**$2,948,509**	**$2,997,088**	**$48,579**
Travel & Transportation of Persons (21.0)	53,451	55,328	1,877
Transportation of Things (22.0)	7,187	7,311	123
Rental Payments to GSA (23.1)	82,443	83,257	814
Rental Payments to Others (23.2)	87,605	87,911	306
Communications, Utilities & Misc. Charges (23.3)	167,135	167,898	763
Printing & Reproduction (24.0)	547	573	26
Consultant Services (25.1)	226,121	230,097	3,976
Other Services (25.2)	1,758,432	1,795,318	36,885
Purchase of goods and services from government accounts (25.3)	1,157,674	1,330,823	173,150
Operation & Maintenance of Facilities (25.4)	367,474	395,931	28,456
R&D Contracts (25.5)	1,402,724	1,432,963	30,239
Medical Care (25.6)	30,478	32,345	1,867
Operation & Maintenance of Equipment (25.7)	285,250	278,499	-6,751
Subsistence & Support of Persons (25.8)	6,505	7,158	653
Subtotal Other Contractual Services (25.0)	**$5,234,658**	**$5,503,134**	**$268,476**
Supplies & Materials (26.0)	328,719	331,958	3,239
Equipment (31.0)	204,349	207,470	3,121
Land and Structures (32.0)	0	0	0
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	24,057,040	24,054,835	-2,205
Insurance Claims & Indemnities (42.0)	3	2	-1
Interest & Dividends (43.0)	141	141	0
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$30,223,279**	**$30,499,818**	**$276,539**
Total Budget Authority	**$33,171,788**	**$33,496,906**	**$325,118**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related supplemental appropriations, and Program Evaluation financing (all years). Includes mandatory Special type 1 Diabetes Research account for FY 2018 only. Excludes budgetary resources associated with NIOSH, NIDILRR, PCORTF, and EEOICPA for FY 2019 only.

SALARIES AND EXPENSES

(Dollars in Thousands)[1]

Object Classes	FY 2018 Annualized CR	FY 2019 President's Budget[2]	FY 2019 Rev +/- FY 2018
Personnel Compensation			
Full-Time Permanent (11.1)	$1,005,750	$1,044,655	38,904
Other Than Full-Time Permanent (11.3)	529,051	534,339	5,288
Other Personnel Compensation (11.5)	46,458	45,327	-1,132
Military Personnel (11.7)	18,543	19,658	1,115
Special Personnel Services Payments (11.8)	177,354	157,705	-19,649
Subtotal Personnel Compensation (11.9)	**$1,777,158**	**$1,801,684**	**$24,527**
Civilian Personnel Benefits (12.1)	517,577	535,167	17,590
Military Personnel Benefits (12.2)	12,490	13,100	610
Benefits to Former Personnel (13.0)	0	1,401	1,401
Total Pay Costs	**$2,307,225**	**$2,351,353**	**$44,128**
Travel & Transportation of Persons (21.0)	50,395	52,272	1,877
Transportation of Things (22.0)	5,205	5,328	123
Rental Payments to Others (23.2)	1,312	1,618	306
Communications, Utilities & Misc. Charges (23.3)	30,808	31,571	763
Printing & Reproduction (24.0)	536	563	26
Other Contractual Services:			
Consultant Services (25.1)	163,999	168,493	4,494
Other Services (25.2)	1,187,625	1,244,511	56,885
Purchase of goods and services from government accounts (25.3)[3]	2,324,576	2,479,001	154,426
Operation & Maintenance of Facilities (25.4)	202,465	230,211	27,746
Operation & Maintenance of Equipment (25.7)	120,524	124,788	4,264
Subsistence & Support of Persons (25.8)	1,565	2,218	653
Subtotal Other Contractual Services	**$4,000,753**	**$4,249,222**	**$248,468**
Supplies & Materials (26.0)	219,034	223,773	4,739
Subtotal Non-Pay Costs	**$4,308,045**	**$4,564,347**	**$256,303**
Total Salaries and Expense / Administrative Costs	**$6,615,270**	**$6,915,701**	**$300,431**

1 Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related supplemental appropriations, and Program Evaluation Financing.

2 Does not include PCORTF, NIOSH, NIDILRR, and EEOICPA funds.

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

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE)

Institutes and Centers	FY 2017 Actual	FY 2018 Estimate	FY 2019 Estimate
NCI*	3,029	3,047	3,036
NHLBI	955	962	962
NIDCR	235	235	235
NIDDK	655	663	663
NINDS	525	532	532
NIAID	1,959	1,963	1,963
NIGMS	182	184	184
NICHD	553	557	557
NEI	272	273	273
NIEHS	658	662	662
NIA	430	434	434
NIAMS*	227	227	238
NIDCD	138	140	140
NIMH	560	563	563
NIDA	380	382	382
NIAAA	236	238	238
NINR	95	96	96
NHGRI	346	349	349
NIBIB	103	102	102
NCATS	166	167	167
NCCIH	71	73	73
NIMHD	68	68	68
FIC	61	61	61
NLM	733	741	741
OD	785	781	781
NIRSQ**	---	---	247
NIOSH	---	---	1,072
NIDILRR	---	---	32
OD - CS	829	841	841
CC	1,851	1,844	1,844
CSR	417	417	417
CIT	252	257	257
ORS	533	539	539
ORF	714	707	707
Central Services[1]	4,596	4,605	4,605
Total	**18,018**	**18,105**	**19,456**
PHS Trust Fund (non-add)[2]	*4*	*4*	*4*
CRADA (non-add)[3]	*5*	*5*	*5*
Grand Total	**18,018**	**18,105**	**19,456**

* Reflects move of Dermatology Section from NCI to NIAMS in FY 2019.

** Includes two Reimbursable FTEs.

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

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

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

HISTORY OF OBLIGATIONS BY IC

(Dollars in Thousands)	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015[1]	FY 2016[1]	FY 2017 Actual [1,6]	FY 2018 Annualized CR [1,6,7]	FY 2019 President's Budget [6,7]
NCI	$5,098,147	$5,058,105	$5,062,763	$4,789,014	$4,932,368	$4,953,028	$5,206,169	$5,636,393	$5,650,693	$5,626,312
NHLBI	$3,093,501	$3,069,550	$3,073,302	$2,903,768	$2,988,415	$2,995,865	$3,109,062	$3,209,843	$3,184,813	$3,112,032
NIDCR	$412,527	$409,549	$409,947	$387,309	$397,833	$397,700	$412,788	$424,782	$422,860	$413,196
NIDDK[2]	$1,958,905	$1,942,155	$1,943,706	$1,837,027	$1,884,377	$1,899,140	$1,963,738	$2,009,448	$2,007,892	$1,965,434
NINDS	$1,633,568	$1,622,001	$1,623,344	$1,533,793	$1,588,899	$1,604,607	$1,692,830	$1,778,684	$1,771,541	$1,838,556
NIAID	$4,515,426	$4,478,595	$4,482,369	$4,235,094	$4,401,185	$4,417,558	$4,749,884	$4,905,708	$4,873,317	$4,761,948
NIGMS[3]	$2,048,112	$2,033,663	$2,425,522	$2,293,044	$2,366,429	$2,372,301	$2,508,868	$2,646,059	$2,632,836	$2,572,669
NICHD	$1,327,349	$1,317,682	$1,318,943	$1,246,140	$1,283,314	$1,286,869	$1,338,280	$1,376,541	$1,370,921	$1,339,592
NEI	$705,792	$700,781	$701,407	$657,055	$675,551	$676,764	$707,002	$731,203	$727,643	$711,015
NIEHS[4]	$774,008	$762,602	$763,225	$721,331	$743,002	$744,682	$769,730	$789,860	$786,234	$747,166
NIA	$1,108,208	$1,100,445	$1,120,391	$1,040,565	$1,171,656	$1,197,523	$1,596,005	$2,048,792	$2,034,698	$1,988,200
NIAMS	$538,028	$534,260	$534,791	$505,206	$520,314	$521,528	$540,874	$556,568	$554,063	$545,494
NIDCD	$418,001	$415,104	$415,500	$392,540	$404,237	$405,207	$422,311	$435,877	$433,908	$423,992
NIMH	$1,493,510	$1,477,257	$1,477,516	$1,396,006	$1,419,632	$1,433,651	$1,516,325	$1,604,624	$1,591,052	$1,612,192
NIDA	$1,066,909	$1,050,519	$1,051,410	$993,404	$1,017,957	$1,015,705	$1,048,971	$1,070,813	$1,083,445	$1,137,403
NIAAA	$461,544	$458,257	$458,665	$433,247	$446,282	$447,153	$466,713	$482,449	$480,080	$469,109
NINR	$145,420	$144,369	$144,500	$136,516	$140,553	$140,852	$145,701	$149,930	$149,252	$145,842
NHGRI	$524,131	$511,469	$512,258	$483,650	$498,076	$498,677	$512,486	$528,316	$524,977	$512,979
NIBIB	$316,028	$313,787	$337,728	$319,062	$326,989	$327,243	$342,997	$356,971	$354,655	$346,550
NIMHD	$211,194	$209,693	$275,927	$260,671	$268,439	$270,969	$280,264	$287,640	$287,106	$280,545
NCRR	$1,267,021	$1,257,641	---	---	---	---	---	---	---	---
NCCAM	$128,615	$127,706	$127,820	$120,767	$124,368	$124,062	$129,760	$134,373	$133,774	$130,717
NCATS	---	---	$574,297	$542,598	$633,571	$632,710	$684,366	$704,248	$701,109	$685,087
FIC	$69,957	$69,413	$69,493	$65,627	$67,575	$67,634	$69,996	$71,813	$71,723	$70,084
NLM[5]	$348,467	$344,860	$373,087	$325,088	$334,383	$337,324	$393,074	$406,250	$404,743	$395,493
ORIP	---	---	$303,525	$290,042	$294,486	$294,665	$295,783	$279,130	$275,580	$252,843
Common Fund	$544,028	$543,017	$544,930	$513,461	$531,146	$545,639	$675,628	$695,430	$678,829	$598,781
OD - Other	$632,966	$623,887	$608,713	$608,584	$477,293	$573,430	$599,263	$714,058	$751,723	$1,152,682
B&F	$203,056	$62,161	$125,308	$106,676	$88,880	$128,863	$79,883	$113,415	$127,988	$200,000
NIRSQ	---	---	---	---	---	---	---	---	---	$255,960
NIOSH	---	---	---	---	---	---	---	---	---	$200,000
NIDILRR	---	---	---	---	---	---	---	---	---	$95,127
PCORTF (NIRSQ)	---	---	---	---	---	---	---	---	---	$124,349
EEOICPA (NIDILRR)	---	---	---	---	---	---	---	---	---	$55,358
Total, NIH Program Level	**$31,044,418**	**$30,638,528**	**$30,860,387**	**$29,137,284**	**$30,027,205**	**$30,311,349**	**$32,258,751**	**$34,149,217**	**$34,067,456**	**$34,766,707**
Less funds allocated from different sources:										
Mandatory - Special type 1 Diabetes Research	-$150,000	-$150,000	-$150,000	-$142,350	-$139,200	-$150,000	-$150,000	-$139,650	-$150,000	---
Mandatory - PCORTF and EEOICPA	---	---	---	---	---	---	---	---	---	-$179,707
PHS Program Evaluation	-$8,200	-$8,200	-$8,200	-$8,200	-$8,200	-$715,000	-$780,000	-$824,443	-$818,844	-$741,000
Total, NIH Discretionary Budget Authority	**$30,886,218**	**$30,480,328**	**$30,702,187**	**$28,986,734**	**$29,879,805**	**$29,446,349**	**$31,328,751**	**$33,185,124**	**$33,098,611**	**$33,846,000**
Interior Budget Authority	-$79,201	-$79,045	-$78,928	-$74,864	-$77,345	-$77,349	-$77,252	-$77,337	-$76,824	-$53,967
Total, NIH Labor/HHS Budget Authority	**$30,807,017**	**$30,401,283**	**$30,623,259**	**$28,911,870**	**$29,802,460**	**$29,369,000**	**$31,251,499**	**$33,107,787**	**$33,021,788**	**$33,792,033**

[1] Excludes Ebola and/or Zika supplemental-related funding or transfers.

[2] Includes Special type 1 Diabetes Research mandatory account funding (through FY 2018).

[3] Includes PHS Program Evaluation financing of $715 million in FY 2015, and $780 million in FY 2016, $824 million in FY 2017, $818 million in FY 2018, and $741 million in FY 2019.

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

[5] Includes PHS Program Evaluation financing of $8.2 million for years before FY 2015.

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

[7] Values represent estimated or requested budget authority as opposed to obligations displayed in historic years.

HISTORY OF OBLIGATIONS BY TOTAL MECHANISM

(Dollars in Thousands)[1]	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual[3]	FY 2016 Actual[3]	FY 2017 Actual[3]	FY 2018 Annualized CR[3]	FY 2019 President's Budget[3]
Research Project Grants	$16,501,300	$16,428,047	$16,550,486	$15,445,463	$16,168,246	$16,441,843	$17,836,992	$19,105,304	$19,066,313	$18,894,528
Research Centers	$3,082,914	$3,009,480	$3,040,375	$2,708,744	$2,723,203	$2,663,064	$2,575,314	$2,536,308	$2,483,707	$2,482,718
Other Research	$1,794,148	$1,802,937	$1,808,138	$1,783,481	$1,846,841	$1,802,719	$2,019,519	$2,181,261	$2,241,770	$2,192,596
Subtotal, Research Grants	$21,378,362	$21,240,464	$21,398,999	$19,937,688	$20,738,290	$20,907,625	$22,431,826	$23,822,873	$23,791,790	$23,569,842
Research Training	$775,186	$771,766	$761,934	$733,524	$738,429	$758,017	$804,466	$827,397	$839,805	$810,586
R & D Contracts	$3,143,929	$2,996,640	$2,937,188	$2,927,077	$2,990,037	$2,826,971	$2,915,277	$3,046,759	$2,896,751	$2,931,915
Intramural Research	$3,306,312	$3,330,815	$3,401,506	$3,247,193	$3,373,601	$3,409,362	$3,684,875	$3,780,181	$3,787,681	$3,795,544
Res. Mgt. & Support	$1,509,287	$1,517,630	$1,530,874	$1,485,575	$1,527,131	$1,619,784	$1,653,326	$1,747,406	$1,765,098	$1,757,337
Office of the Director	$632,966	$623,887	$609,530	$608,584	$477,293	$573,328	$599,368	$701,864	$751,723	$1,152,682
Subtotal	**$30,746,042**	**$30,481,202**	**$30,640,031**	**$28,939,641**	**$29,844,781**	**$30,095,088**	**$32,089,138**	**$33,928,465**	**$33,832,848**	**$34,017,906**
Buildings & Facilities[2]	$210,975	$70,081	$133,228	$114,580	$96,880	$123,464	$144,863	$143,415	$157,784	$220,000
Interior- Superfund	$79,201	$79,045	$78,928	$74,864	$77,345	$77,332	$77,349	$77,337	$76,824	$53,967
NIOSH	---	---	---	---	---	---	---	---	---	$200,000
NIDILRR	---	---	---	---	---	---	---	---	---	$95,127
PCORTF (NIRSQ)[4]	---	---	---	---	---	---	---	---	---	$124,349
EEOICCPA (NIDILRR)[4]	---	---	---	---	---	---	---	---	---	$55,358
Total	**$31,036,218**	**$30,630,328**	**$30,852,187**	**$29,129,085**	**$30,019,005**	**$30,295,884**	**$32,311,350**	**$34,149,217**	**$34,067,456**	**$34,766,707**

[1] Obligations for actual years exclude lapse. Amounts for all years include Special type 1 Diabetes, except for FY 2019.

[2] Building & Facilities (B&F) mechanism amounts include the B&F appropriation plus funding associated with repair and improvement (R&I) related construction for the Frederick, Maryland facility appropriated to NCI.

[3] Includes Program Evaluation Financing resources of $715 million in FY 2015, $780 million in FY 2016, $824 million in FY 2017, $818 million in FY 2018, and $741 million in FY 2019.

[4] Identifies mandatory accounts related to proposed FY 2019 consolidation (and associated administrative organization).

PHYSICIAN'S COMPARABILITY ALLOWANCE WORKSHEET

		FY 2016 Actual	FY 2017 Actual	FY 2018 Estimate	FY 2019 Estimate
1) Number of Physicians Receiving PCAs		161	150	128	128
2) Number of Physicians with One-Year PCA		23	20	17	17
3) Number of Physicians with Multi-Year PCA		138	130	111	111
4) Average Annual Physician Pay (without PCA payment)		$153,267	$159,133	$161,900	$163,000
5) Average Annual PCA Payment		$18,311	$17,991	$20,176	$20,570
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position				
	Category II Research Position	158	148	126	126
	Category III Occupational Health				
	Category IV-A Disability Evaluation				
	Category IV-B Health and Medical Admin.	3	2	2	2

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

Maximum annual PCA amount for category II and IV-B vary based on grade level, amount of federal service and length of the PCA agreement. The monetary range is between $10,000 and $30,000. These flexible amounts are necessary to recruit and retain the caliber of physician needed to carry out the NIH mission which directly impacts the health of the nation.

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

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

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

In FY 2017, there were a total of 150 PCA recipients across NIH. In FY 2018 and beyond, there may continue to be a slight decrease due to hiring restriction , but still the critical need continues to exist for highly qualified, specialized physicians to support the NIH mission and NIH may effectively utilize compensation flexibilities such as PCA to attract and retain qualified physicians.

STATISTICAL DATA: DIRECT AND INDIRECT COSTS AWARDED

(Dollars in Thousands)	Direct Cost Awarded	Indirect Cost Awarded	Percent of Total		Percent Change	
			Direct Cost Awarded	Indirect Cost Awarded	Direct Cost Awarded	Indirect Cost Awarded
FY 2007	$15,387,745	$5,876,060	72.4%	27.6%	1.1%	1.6%
FY 2008	$15,295,950	$5,903,730	72.2%	27.9%	-0.6%	0.5%
FY 2009	$15,683,872	$6,027,543	72.2%	27.8%	2.5%	2.1%
FY 2010	$16,040,991	$6,193,567	72.1%	27.9%	2.3%	2.8%
FY 2011	$15,849,082	$6,173,769	72.0%	28.0%	-1.2%	-0.3%
FY 2012	$15,978,032	$6,182,900	72.1%	27.9%	0.8%	0.2%
FY 2013	$14,915,599	$5,755,617	72.2%	27.8%	-6.7%	-6.9%
FY 2014	$15,568,553	$5,908,275	72.5%	27.5%	4.4%	2.7%
FY 2015	$15,645,282	$6,020,843	72.2%	27.8%	0.5%	1.9%
FY 2016	$16,791,158	$6,445,133	72.3%	27.7%	7.3%	7.1%
FY 2017 Final[2]	$17,799,515	$6,838,801	72.2%	27.8%	6.0%	6.1%
FY 2018 Annualized CR[1,2]	$17,815,418	$6,816,177	72.3%	27.7%	0.1%	-0.3%
FY 2019 President's Budget[1,2,3]	$17,623,855	$6,756,573	72.3%	27.7%	-1.1%	-0.9%

[1] FY 2018 and FY 2019 data represent estimates and will change as actual data is received.

[2] Includes 21st Century Cures Act funding.

[3] Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF and EEOICPA.

RESEARCH PROJECT GRANTS – TOTAL NUMBER OF AWARDS AND FUNDING

(Dollars in Thousands)	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017 Final[3]	FY 2018 Annualized CR[3]	FY 2019 President's Budget[3,4]
No. of Awards:										
Competing	9,386	8,706	8,986	8,234	9,168	9,540	10,364	10,123	8,656	9,084
Noncompeting	25,738	26,166	25,631	25,140	23,504	23,261	23,528	24,638	25,468	25,030
Subtotal	35,124	34,872	34,617	33,374	32,672	32,801	33,892	34,761	34,124	34,114
SBIR/STTR	1,685	1,494	1,642	1,466	1,660	1,578	1,689	1,807	1,796	1,835
Total	**36,809**	**36,366**	**36,259**	**34,840**	**34,332**	**34,379**	**35,581**	**36,568**	**35,920**	**35,949**
Average Annual Cost:										
Competing	$417	$427	$421	$418	$489	$452	$484	$522	$518	$503
Total RPGs[1]	$450	$453	$459	$444	$474	$479	$502	$523	$532	$527
Percent Change over prior year[2]										
Average Costs:										
Competing RPGs	-2.4%	2.5%	-1.5%	-0.8%	17.0%	-7.5%	7.2%	7.8%	-0.7%	-2.9%
Total RPGs[1]	3.0%	0.5%	1.4%	-3.3%	6.7%	1.2%	4.8%	4.0%	1.7%	-0.9%
Average Length of Award in Years	**3.8**	**3.7**	**3.5**	**3.5**	**3.5**	**3.5**	**3.6**	**3.6**	**3.6**	**3.6**

NOTE: Includes awards supported by the Common Fund program (for all years) and the Type 1 Diabetes mandatory account (through FY 2018).

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

[2] Based on average costs in whole dollars.

[3] Includes 21st Century Cures Act funding.

[4] Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF and EEOICPA.

RESEARCH PROJECT GRANTS – SUCCESS RATES

INSTITUTES & CENTERS [1,2]	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017 Final[9]	FY 2018 Annualized CR[8,9]	FY 2019 President's Budget[8,9,10]
NCI	17.1%	13.8%	13.6%	13.7%	14.1%	13.0%	12.0%	11.7%	10.8%	
NHLBI	19.9%	17.4%	14.7%	16.9%	18.2%	21.9%	24.2%	23.5%	21.9%	
NIDCR	22.2%	22.5%	21.2%	19.9%	21.5%	22.0%	19.9%	17.8%	14.5%	
NIDDK	25.9%	20.7%	19.8%	21.0%	22.9%	20.3%	20.1%	17.8%	15.8%	
NINDS	22.6%	21.1%	19.5%	19.8%	18.7%	20.5%	19.8%	17.7%	14.3%	
NIAID	23.9%	20.2%	23.2%	18.8%	22.0%	21.5%	23.8%	19.1%	16.4%	
NIGMS	26.9%	23.1%	24.4%	19.9%	24.8%	29.6%	29.6%	30.6%	22.5%	
NICHD	15.2%	12.4%	12.5%	10.8%	12.5%	11.5%	13.2%	16.1%	12.3%	
NEI	26.9%	28.8%	29.8%	23.7%	26.7%	21.4%	25.7%	24.9%	21.0%	
NIEHS	25.1%	14.7%	14.3%	15.3%	15.0%	14.7%	14.2%	15.0%	12.9%	
NIA	14.5%	16.1%	15.5%	13.6%	15.9%	17.7%	22.8%	26.6%	30.7%	
NIAMS	21.4%	14.9%	15.6%	15.9%	18.1%	16.7%	16.0%	17.0%	11.6%	
NIDCD	30.2%	27.5%	26.6%	22.5%	25.8%	24.9%	26.7%	24.4%	21.2%	
NIMH	22.1%	17.1%	21.6%	18.7%	19.4%	20.4%	22.9%	20.9%	17.5%	
NIDA	19.8%	18.2%	21.2%	19.5%	18.0%	19.6%	15.4%	19.7%	13.3%	
NIAAA	26.5%	18.6%	18.4%	19.5%	19.2%	16.4%	18.8%	22.0%	17.9%	
NINR	13.2%	8.5%	13.0%	9.1%	11.6%	8.0%	9.0%	8.9%	8.6%	
NHGRI	33.6%	27.4%	23.9%	20.5%	17.7%	18.8%	25.6%	23.9%	14.4%	
NIBIB	16.0%	12.9%	12.1%	13.7%	13.1%	12.0%	14.6%	13.0%	14.4%	
NIMHD	8.0%	11.9%	9.9%	4.3%	11.9%	13.7%	19.3%	21.5%	5.5%	
NCCIH[3]	11.0%	9.1%	9.5%	11.6%	8.7%	10.8%	13.9%	16.7%	9.4%	
NCATS[4]	N/A	N/A	0.0%	0.0%	16.7%	66.7%	27.7%	21.8%	6.7%	
FIC	26.1%	11.9%	16.0%	14.6%	9.1%	9.7%	29.5%	10.8%	12.3%	
NLM	21.1%	16.1%	12.8%	12.3%	19.4%	19.8%	13.0%	14.9%	9.6%	
ORIP & SEPA[5,6,7]	22.0%	21.3%	18.6%	20.0%	19.6%	21.5%	18.8%	16.5%	9.8%	
Common Fund	11.1%	11.3%	8.0%	9.2%	10.0%	12.1%	12.6%	11.8%	12.6%	
NIRSQ	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	25.0%
NIH [7]	**21.0%**	**20.5%**	**17.5%**	**16.7%**	**18.0%**	**18.3%**	**19.1%**	**18.7%**	**15.9%**	**16.0%**

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

[2] Includes Special type 1 Diabetes Research program administered by NIDDK (except for FY 2019). Excludes NIEHS Superfund Research account administered by NIEHS.

[3] The National Center for Complementary and Alternative Medicine (NCCAM) was renamed in December 2014 to the National Center for Complementary and Integrative Health (NCCIH) consistent with enactment of the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235).

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

[5] Success rate data associated with grants funded from the OD appropriation unrelated to the Common Fund or ORIP & SEPA is not included. Collection of this information was initiated in FY 2012.

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

[7] NIH success rate excludes application and grant data from OD Non-Common Fund and OD Non-ORIP & SEPA accounts.

[8] Success Rates identified in FY 2018 and FY 2019 are estimates, and will change as applications are received and selected for funding.

[9] Includes 21st Century Cures Act funding.

[10] Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF and EEOICPA.

TOTAL R01 EQUIVALENT DATA FOR FIRST TIME AND ESTABLISHED INVESTIGATORS

R01 Equivalent Grants[1,2,3]	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget[4]
Applications			
Received	31,065	31,096	32,386
Funded	6,041	5,117	5,389
Total Investigators			
Received	27,537	27,324	28,371
Funded	6,578	5,623	5,965
Established Investigators			
Received	17,443	17,482	18,211
Funded	4,674	3,996	4,237
First-time Investigators			
Received	10,094	9,842	10,160
Funded	1,904	1,627	1,728

[1] In the out years, values for R01 equivalent grants are based on linear extrapolation of five years of latest actual

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

[3] Estimates for received applications reflect consolidations of Institute/Center validated refinements to linear extrapolation of five years of latest actual data.

[4] Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF, and EEOICPA.

COMPETING RPGS BY LENGTH OF AWARD

(Dollars in Thousands)	FY 2017 Final		FY 2018 Annualized CR		FY 2019 President's Budget[2]	
	No.	Amount	No.	Amount	No.	Amount
Competing RPGs:[1]						
One-Year Awards	880	$1,020,401	755	$734,179	792	$748,095
Two-Year Awards	2,408	$512,038	2,192	$504,193	2,301	$513,750
Three-Year Awards	530	$260,296	501	$259,385	526	$264,302
Four-Year Awards	2,037	$1,052,828	1,739	$915,844	1,825	$933,203
Five or More Year Awards	4,268	$2,438,169	3,469	$2,072,847	3,640	$2,112,136
Total Competing RPGs	10,123	$5,283,732	8,656	$4,486,448	9,084	$4,571,486

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

[2] Includes NIRSQ, and excludes NIOSH, NIDILRR, PCORTF, and EEOICPA.

NON-COMPETING COMMITMENTS

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget[4]
Research Project Grants (RPGs)			
Noncompeting:			
Number	24,638	25,468	25,030
Amount	$12,661,301	$13,495,362	$13,291,723
Administrative Supp	$225,445	$157,514	$112,473
Competing:			
Number	10,123	8,656	9,084
Amount	$5,283,732	$4,486,448	$4,571,486
SBIR/STTR:			
Number	1,807	1,796	1,835
Noncompeting	792	785	802
Amount[1]	$923,162	$926,988	$918,846
Noncompeting	$404,652	$405,323	$401,763
Subtotal, RPGs			
Number	36,568	35,920	35,949
Amount	$19,093,640	$19,066,312	$18,894,528
Research Centers:			
Number	1,248	1,222	1,363
Noncompeting	938	882	984
Amount	$2,536,309	$2,483,707	$2,482,718
Noncompeting	$1,906,190	$1,792,371	$1,791,657
Other Research:			
Number	6,377	6,486	7,119
Noncompeting	4,140	4,367	4,793
Amount	$2,180,970	$2,241,770	$2,192,596
Noncompeting	$1,415,941	$1,509,396	$1,476,287
Training:			
FTTPs:	16,018	16,025	15,770
Noncompeting	11,756	11,677	11,475
Amount	$827,397	$839,805	$810,586
Noncompeting	$607,247	$611,941	$589,816
Total Extramural Research:[2]	**$24,638,316**	**$24,631,594**	**$24,380,428**
Noncompeting Number/FTTPs	42,264	43,179	43,084
Competing Number/FTTPs	17,947	16,474	17,117
Noncompeting Amount	$17,220,776	$17,971,907	$17,663,719
Competing Amount	$7,417,540	$6,659,687	$6,716,709
Total % Change	**6.0%**	**0.0%**	**-1.0%**
Total Discretionary Budget Authority[3]	**$34,089,489**	**$33,917,456**	**$34,587,000**
% Change	**6.0%**	**-0.5%**	**2.0%**

[1] The 3.65% combined SBIR/STTR program threshold is achieved in FY 2017 and sustained in subsequent years.

[2] Includes both grants and FTTPs for Noncompeting Number and Competing Number and excludes resources related to R&D Contracts.

[3] Includes Labor/HHS appropriations, the Interior Superfund Research account, 21st Cures Act allocations, as well as Program Evaluation financing resources. Excludes Type 1 Diabetes mandatory funds in FY 2017 and FY 2018.

[4] The grant awards section includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF, and EEOICPA. The Total Discretionary BA includes NIRSQ, NIOSH and NIDILRR and excludes mandatory resources related to PCORTF and EEOICPA.

MANAGEMENT FUND GENERAL STATEMENT

General Statement

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

MANAGEMENT FUND BUDGET AUTHORITY BY ACTIVITY

Budget Authority by Activity
(Dollars in thousands)

	FY 2017 Final		FY 2018 Annualized CR		FY 2019 President's Budget		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:								
Clinical Center	1,850	$478,021	1,843	$495,229	1,843	$495,229	0	$0
Center for Scientific Review	417	135,838	417	140,728	417	140,728	0	0
Office of Research Services, Development & Operations and Administrative services	533	77,415	539	80,202	539	80,202	0	0
TOTAL	**2,800**	**$691,274**	**2,799**	**$716,159**	**2,799**	**$716,159**	0	$0

MANAGEMENT FUND BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in thousands)

		FY 2018 Annualized CR	FY 2019 President's Budget	Increase or Decrease	Percent Change
Total compensable workyears:					
	Full-time employment	2,799	2,799	0	0.0%
	Full-time equivalent of overtime and holiday hours	0	0	0	0.0%
	Average ES salary	$191	$192	1	0.5%
	Average GM/GS grade	11.2	11.2	0	0.0%
	Average GM/GS salary	$97	$98	1	1.0%
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$91	$92	1	1.1%
	Average salary of ungraded positions	132	133	1	0.8%
	OBJECT CLASSES	**FY 2018 Enacted**	**FY 2019 Estimate**	**Increase or Decrease**	**Percent Change**
	Personnel Compensation:				
11.1	Full-time permanent	$183,857	$184,739	$882	0.5%
11.3	Other than full-time permanent	54,501	54,763	262	0.5%
11.5	Other personnel compensation	17,014	17,096	82	0.5%
11.7	Military personnel	6,293	6,425	132	2.1%
11.8	Special personnel services payments	5,095	5,120	25	0.5%
	Total, Personnel Compensation	**266,760**	**268,143**	**1,383**	0.5%
12.0	Personnel benefits	78,968	79,939	971	1.2%
12.2	Military personnel benefits	4,733	4,832	99	2.1%
13.0	Benefits for former personnel	0	0	0	-
	Subtotal, Pay Costs	**350,461**	**352,914**	**2,453**	0.7%
21.0	Travel and transportation of persons	2,112	2,112	0	0.0%
22.0	Transportation of things	923	923	0	0.0%
23.1	Rental payments to GSA	5	5	0	0.0%
23.2	Rental payments to others	21	21	0	0.0%
23.3	Communications, utilities and miscellaneous charges	7,328 0	7,328 0	0 0	0.0% -
24.0	Printing and reproduction	9	9	0	0.0%
25.1	Consulting services	16,042	16,042	0	0.0%
25.2	Other services	102,506	101,553	(953)	-0.9%
25.3	Purchase of goods and services from government accounts	145,378	143,878	(1,500)	-1.0%
25.4	Operation and maintenance of facilities	8,300	8,300	0	0.0%
25.5	Research and development contracts	0	0	0	-
25.6	Medical care	4,868	4,868	0	0.0%
25.7	Operation and maintenance of equipment	18,577	18,577	0	0.0%
25.8	Subsistence and support of persons	2,323	2,323	0	0.0%
25.0	**Subtotal, Other Contractual Services**	**297,994**	**295,541**	**(2,453)**	-0.8%
26.0	Supplies and materials	32,000	32,000	0	0.0%
31.0	Equipment	25,274	25,274	0	0.0%
32.0	Land and structures	0	0	0	-
33.0	Investments and loans	0	0	0	-
41.0	Grants, subsidies and contributions	12	12	0	0.0%
42.0	Insurance claims and indemnities	0	0	0	-
43.0	Interest and dividends	19	19	0	0.0%
44.0	Refunds	0	0	0	-
	Subtotal, Non-Pay Costs	**365,697**	**363,244**	**(2,453)**	-0.7%
	Total Budget Authority by Object	**$716,159**	**$716,159**	**0**	0.0%

MANAGEMENT FUND DETAIL OF POSITIONS

GRADE	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Total, ES Positions	2	3	3
Total, ES Salary	$372,100	$571,883	$574,629
GM/GS-15	115	119	119
GM/GS-14	309	338	338
GM/GS-13	403	437	437
GS-12	497	523	523
GS-11	495	532	532
GS-10	30	30	30
GS-9	155	165	165
GS-8	112	120	120
GS-7	222	246	246
GS-6	46	46	46
GS-5	26	31	31
GS-4	15	15	15
GS-3	11	11	11
GS-2	8	8	8
GS-1	1	1	1
Subtotal	2,445	2,622	2,622
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	15	15	15
Senior Grade	20	20	20
Full Grade	21	21	21
Senior Assistant Grade	18	18	18
Assistant Grade	1	1	1
Subtotal	75	75	75
Ungraded	441	447	447
Total permanent positions	2,343	2,630	2,631
Total positions, end of year	2,993	3,147	3,147
Total full-time equivalent (FTE) employment, end of year	2,800	2,799	2,799
Average ES salary	186,050	190,628	191,543
Average GM/GS grade	10.2	11.2	11.2
Average GM/GS salary	95,449	97,021	97,565

SERVICE AND SUPPLY FUND GENERAL STATEMENT

General Statement

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

SERVICE AND SUPPLY FUND BUDGET AUTHORITY BY ACTIVITY

Budget Authority by Activity
(Dollars in thousands)

	FY 2017 Final		FY 2018 Annualized CR		FY 2019 President's Budget		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:								
Research Support and Administrative	829	$964,058	841	$998,764	841	$998,764	0	$0
Office of Research Facilities Development & Operations	714	566,830	707	587,236	707	587,236	0	0
Information Technology	252	365,195	257	378,342	257	378,342	0	0
Clinical Center	1	134	1	139	1	139	0	0
TOTAL	**1,796**	**$1,896,217**	**1,806**	**$1,964,481**	**1,806**	**$1,964,481**	0	$0

SERVICE AND SUPPLY FUND BUDGET AUTHORITY BY OBJECT

(Dollars in Thousands)

		FY 2018 Annualized CR	FY 2019 President's Budget	Increase or Decrease	Percent Change
Total compensable workyears:					
	Full-time employment	1,806	1,806	0.0	0.0%
	Full-time equivalent of overtime and holiday hours	0	0	0	0.0%
	Average ES salary	$183	$184	$1	0.5%
	Average GM/GS grade	11.8	11.8	0.0	0.0%
	Average GM/GS salary	$103	$103	$0	0.0%
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$107	$108	$1	0.9%
	Average salary of ungraded positions	130	131	1	0.8%
	OBJECT CLASSES	**FY 2018 Enacted**	**FY 2019 Estimate**	**Increase or Decrease**	**Percent Change**
	Personnel Compensation:				
11.1	Full-time permanent	$194,336	$195,269	$933	0.5%
11.3	Other than full-time permanent	9,404	9,449	45	0.5%
11.5	Other personnel compensation	10,362	10,411	49	0.5%
11.7	Military personnel	2,282	2,330	48	2.1%
11.8	Special personnel services payments	56	57	1	1.8%
	Total, Personnel Compensation	**216,440**	**217,516**	**1,076**	0.5%
12.0	Personnel benefits	72,097	72,984	887	1.2%
12.2	Military personnel benefits	1,126	1,150	24	2.1%
13.0	Benefits for former personnel	1,160	1,172	12	1.0%
	Subtotal, Pay Costs	**290,823**	**292,822**	**1,999**	0.7%
21.0	Travel and transportation of persons	943	943	0	0.0%
22.0	Transportation of things	1,059	1,059	0	0.0%
23.1	Rental payments to GSA	58,855	58,855	0	0.0%
23.2	Rental payments to others	86,272	86,272	0	0.0%
23.3	Communications, utilities and miscellaneous charges	128,999	128,999	0	0.0% -
24.0	Printing and reproduction	2	2	0	0.0%
25.1	Consulting services	10,235	10,235	0	0.0%
25.2	Other services	468,301	467,302	(999)	-0.2%
25.3	Purchase of goods and services from government accounts	507,925	506,925	(1,000)	-0.2%
25.4	Operation and maintenance of facilities	151,526	151,526	0	0.0%
25.5	Research and development contracts	240	240	0	0.0%
25.6	Medical care	759	759	0	0.0%
25.7	Operation and maintenance of equipment	146,149	146,149	0	0.0%
25.8	Subsistence and support of persons	2,617	2,617	0	0.0%
25.0	**Subtotal, Other Contractual Services**	**1,287,752**	**1,285,753**	**(1,999)**	-0.2%
26.0	Supplies and materials	77,685	77,685	0	0.0%
31.0	Equipment	31,992	31,992	0	0.0%
32.0	Land and structures	0	0	0	-
33.0	Investments and loans	0	0	0	-
41.0	Grants, subsidies and contributions	0	0	0	-
42.0	Insurance claims and indemnities	2	2	0	0.0%
43.0	Interest and dividends	96	96	0	0.0%
44.0	Refunds	0	0	0	-
	Subtotal, Non-Pay Costs	**1,673,657**	**1,671,658**	**(1,999)**	-0.1%
	Total Budget Authority by Object	**$1,964,481**	**$1,964,481**	**0**	0.0%

SERVICE AND SUPPLY FUND DETAIL OF POSITIONS

GRADE	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Total, ES Positions	6	7	7
Total, ES Salary	$1,091,240	$1,278,731	$1,287,039
GM/GS-15	87	90	91
GM/GS-14	270	271	273
GM/GS-13	516	525	526
GS-12	262	266	267
GS-11	114	114	114
GS-10	2	2	2
GS-9	79	83	83
GS-8	25	25	25
GS-7	71	67	67
GS-6	11	11	11
GS-5	17	17	17
GS-4	10	10	10
GS-3	14	14	14
GS-2	8	8	8
GS-1	12	15	15
Subtotal	1,498	1,518	1,523
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	5	5	5
Senior Grade	2	2	2
Full Grade	6	6	6
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	14	14	14
Ungraded	326	336	336
Total permanent positions	1,741	1,743	1,743
Total positions, end of year	1,843	1,875	1,880
Total full-time equivalent (FTE) employment, end of year	1,796	1,806	1,806
Average ES salary	181,873	182,676	183,863
Average GM/GS grade	11.8	11.8	11.8
Average GM/GS salary	102,044	102,724	103,107

COMMON FUND (CF)

NATIONAL INSTITUTES OF HEALTH
Common Fund

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2017 Final		FY 2018 Annualized CR		FY 2019 President's Budget		FY 2019 +/- FY 2018 CR	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	263	$169,549	198	$131,768	223	$169,701	25	$37,933
Administrative Supplements	*(45)*	25,038	*(5)*	1,529	*(4)*	2,375	*(-1)*	846
Competing:								
Renewal	1	396	0	0	0	0	0	0
New	121	150,110	124	154,227	110	135,913	-14	-18,314
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	122	$150,506	124	$154,227	110	$135,913	-14	-$18,314
Subtotal, RPGs	385	$345,094	322	$287,524	333	$307,989	11	$20,465
SBIR/STTR	0	0	0	0	0	0	0	0
Research Project Grants	385	$345,094	322	$287,524	333	$307,989	11	$20,465
Research Centers:								
Specialized/Comprehensive	28	$38,053	27	$36,484	24	$33,189	-3	-$3,295
Clinical Research	10	16,001	14	21,658	12	18,666	-2	-2,992
Biotechnology	2	4,022	1	2,075	0	516	-1	-1,559
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	40	$58,076	42	$60,217	36	$52,371	-6	-$7,846
Other Research:								
Research Careers	19	$3,170	3	$475	3	$431	0	-$44
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	126	186,534	169	249,511	93	137,604	-76	-111,907
Other Research	145	$189,703	172	$249,986	96	$138,035	-76	-$111,951
Total Research Grants	570	$592,873	536	$597,727	465	$498,395	-71	-$99,332
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	196	23,810	176	21,826	125	15,530	-51	-6,296
Total Research Training	196	$23,810	176	$21,826	125	$15,530	-51	-$6,296
Research & Develop. Contracts	0	$27,446	0	$25,034	0	$52,000	0	$26,966
(SBIR/STTR) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Intramural Research	0	15,943	0	13,181	0	13,685	0	504
Res. Management & Support	0	35,385	0	21,061	0	19,171	0	-1,890
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, Common Fund	0	$695,456	0	$678,829	0	$598,781	0	-$80,048

[1] All items in italics and brackets are non-add entries.

Major Changes in the Fiscal Year 2019 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2019 President's Budget for the Common Fund, which is $80.048 million less than the FY 2018 Annualized Continuing Resolution Level, for a total of $598.781million. The FY 2019 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, the Common Fund will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (+$20.465 million; total $307.989 million): The Common Fund expects to support a total of 333 Research Project Grant (RPG) awards in FY 2019. Plans include 223 Noncompeting RPGs and the award of 110 Competing RPGs. In general, the $307.989 million requested for RPGs represents a 7.0 percent increase in comparison to the FY 2018 Annualized CR Level.

Research Centers (-$7.846 million; total $52.371 million): The estimated decrease in Common Fund support for Research Centers reflects a general reduction in the Common Fund budget in accordance with the FY 2019 President's Budget Request.

Other Research (-$111.951 million; total $138.035 million): The estimated decrease in Common Fund support for the Other Research mechanism reflects the transfer of the *All of Us* Research Program out of the Common Fund to a separate *All of Us* Research Program office in the Office of the Director, resulting in a reduction in the use of Other Transactions within the Common Fund. The remaining budget for Other Transactions will be used by the Stimulating Peripheral Activity to Relieve Conditions (SPARC) program, the Data Commons within the Big Data to Knowledge (BD2K) program, and the Human BioMolecular Atlas Program (HuBMAP).

Research and Development Contracts (+$26.966 million; total $52.000 million): Several activities contribute to the change in support for Research and Development Contracts. A contract within the *All of Us* Research Program is no longer supported by the Common Fund in FY 2019 as this program transfers elsewhere in the Office of the Director. Meanwhile, the Common Fund is launching a new Innovation Prize Program (described below) in FY 2019 using Research and Development Contracts.

National Institutes of Health
Common Fund by Initiative
(Dollars in Thousands)

	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
4D Nucleome	**27,940**	**27,841**	**25,085**
Technology Development, Biological Validation, Modeling and Pilot Mapping	10,169	9,982	8,965
Nucleomic, Imaging, and Computational Tool Development	10,149	10,076	9,054
4D Nucleome Coordination and Integration	7,621	7,784	7,066
Acute to Chronic Pain Signatures	**0**	**5,600**	**6,314**
All of Us Research Program	**129,994**	**129,117**	**0**
Big Data to Knowledge (BD2K)	**55,161**	**22,198**	**16,916**
Enhancing the Diversity of the NIH-Funded Workforce	**50,514**	**50,817**	**47,513**
BUILD Initiative	44,557	47,554	36,892
National Research Mentoring Network (NRMN)	1,776	1,798	9,110
Coordination and Evaluation Center (CEC)	4,181	1,465	1,511
Epigenomics	**4,003**	**78**	**0**
Extracellular RNA Communication	**28,222**	**6,912**	**5,241**
Data Management and Resource/Repository (DMRR)	2,489	2,714	54
Reference Profiles of Human Extracellular RNA	4,285	4,055	0
Extracellular RNA Biogenesis, Biodistribution, Uptake, and Effector Function	7,694	71	0
Clinical Utility of Extracellular RNAs as Biomarkers and Therapeutic Agents	13,753	71	5,187
Gabriella Miller Kids First Pediatric Research	**13,105**	**993**	**12,952**
Genotype-Tissue Expression (GTEx) Resources	**1,725**	**577**	**509**
Global Health	**15,527**	**15,837**	**13,948**
Medical Education Partnership Initiative (MEPI)	3,000	3,000	2,706
Human Heredity and Health in Africa (H3Africa)	10,179	10,491	9,126
Cookstove Initiative	2,348	2,346	2,116
Glycoscience	**23,164**	**20,345**	**17,571**
Health Care Systems Research Collaboratory	**11,835**	**5,624**	**1,579**
NIH-HMORN Coordinating Center	2,115	1,623	1,579
Expansion Activities	9,720	4,001	0
Health Economics	**3,289**	**60**	**0**
Changing Incentives for Consumers, Insurers, and Providers	146	44	0
Science of Structure, Organization, and Practice Design in the Efficient Delivery of Healthcare	1,544	0	0
Economics of Prevention	1,177	0	0
Data Infrastructure to Enable Research on Health Reform	423	17	0
High-Risk Research	**179,489**	**166,090**	**172,192**
NIH Director's Pioneer Award	24,886	34,696	39,956
NIH Director's New Innovator Award Program	115,395	88,472	86,697
Transformative Research Award	17,560	22,759	26,737
NIH Director's Early Independence Award Program	21,648	20,163	18,802
Human BioMolecular Atlas Project (HuBMAP)	**0**	**7,479**	**13,536**
Technology Development	0	2,105	3,738
Human Tissue Mapping	0	2,697	6,564
Data Coordination and Integration	0	2,676	3,233
Human Microbiome	**210**	**0**	**0**
Illuminating the Druggable Genome	**7,846**	**9,400**	**11,184**
Knowledge Management Network	560	1,574	3,264
Technology Development	15	0	0
Data and Resource Generation Centers	7,216	7,284	7,429
Dissemination and Outreach Hub	55	542	492
Knockout Mouse Phenotyping Program	**12,566**	**11,000**	**9,922**
Data Coordination	1,262	1,335	1,138
Production, Characterization, Cryopreservation, Phenotyping, and Data Release	11,304	9,665	8,784
Library of Integrated Network-Based Cellular Signatures (LINCS)	**9,964**	**10,000**	**9,020**

National Institutes of Health
Common Fund by Initiative
(Dollars in Thousands)

	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Metabolomics	**10,374**	**12,401**	**11,188**
Comprehensive Metabolomics Research Cores	6,035	0	0
Interdisciplinary Training in Metabolomics	15	0	0
Metabolomics Technology Development	30	0	0
Metabolomics Reference Standards Synthesis	1,946	0	0
Metabolomics Data Sharing and Program Coordination Core	2,347	5,350	4,828
Metabolomics Data Analysis	0	7,051	6,360
Molecular Transducers of Physical Activity	**5,587**	**24,990**	**33,166**
Study Coordination and Data Management	1,526	4,370	4,359
Molecular Transducers of Physical Activity in Humans – Clinical Study	2,130	8,920	9,463
Chemical Analysis of Biological Samples	1,809	10,262	17,945
Characterization of Human Molecular Transducers of Physical Activity in Model Systems	123	1,437	1,399
NIH Center for Regenerative Medicine (NCRM)	**7,242**	**5,600**	**6,855**
NIH Center for Regenerative Medicine (NCRM)	0	0	0
Cell Therapy Projects	1,248	600	541
Stem Cell Translation Laboratory (SCTL)	5,995	5,000	6,314
Protein Capture	**1,358**	**5**	**0**
Production of anti-TF antibodies	1,353	0	0
New Reagent Technology Development and Piloting	5	5	0
Science of Behavior Change	**8,968**	**12,445**	**11,381**
Single Cell Analysis	**47**	**0**	**0**
Pilot Studies to Evaluate Cellular Heterogeneity	22	0	0
Accelerating the Integration and Translation of Technologies to Characterize Biological Processes at the Single Cell Level	25	0	0
Single Cell Analysis Challenges	0	0	0
Somatic Cell Genome Editing	**0**	**19,370**	**35,315**
S.P.A.R.C. - Stimulating Peripheral Activity to Relieve Conditions	**41,710**	**47,068**	**41,734**
Functional and Anatomical Mapping of Five Organ Systems	23,033	19,705	18,856
Next Generation Tools	10,205	12,079	9,091
Off-Label Use of Existing Market-Approved Technology for Small Markets	3,381	9,153	8,303
Data Coordination	5,091	6,132	5,483
Strengthening the Biomedical Research Workforce	**6,566**	**2,985**	**0**
Transformative High Resolution Cryo-Electron Microscopy (CryoEM)	**0**	**26,255**	**13,440**
National Centers for Cryo-Electron Microscopy	0	25,602	12,849
Training Cryo-electron Microscopists	0	653	591
Undiagnosed Diseases Network	**31,787**	**28,900**	**26,068**
Undiagnosed Diseases Program Network	30,972	28,900	26,068
Training in the Use of Contemporary Genomic Approaches to Rare Disease Diagnostics	815	0	0
Strategic Planning Funds	7,262	6,800	6,153
Subtotal Common Fund	695,456	676,785	548,781
New Initiatives in Common Fund	0	2,044	50,000
Total Common Fund	695,456	678,829	598,781

Justification of Budget Request

Common Fund

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as Amended.

Budget Authority (BA):

	FY 2017 Final	FY 2018 Annualized Continuing Resolution level	FY 2019 President's Budget	FY 2019 +/- FY 2018
BA	$695,456,000	$678,829,325	$598,781,000	-$80,048
FTE	0	0	0	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural; and Other.

Overview

The NIH Common Fund (CF) supports research in areas of emerging scientific opportunities, rising public health challenges, and knowledge gaps that deserve special emphasis; that would benefit from strategic coordination and planning across NIH Institutes and Centers (ICs); and that are designed to address specific, high-impact goals and milestones within a 5- to 10-year timeframe.[109] Collectively, these programs represent strategic investments aimed at solving problems or building resources to affect research throughout the entire biomedical research enterprise. CF programs attempt to change the way science is conducted through the establishment of new scientific fields or paradigms, the development of new and innovative technologies that change the way scientists approach their work, or the generation of comprehensive data sets or other resources that catalyze all research and enable discovery.

Many CF programs support the NIH Director's priority themes for FY 2019:

1) Tackling Complex Challenges by Leveraging Partnerships
2) Supporting Basic Research to Drive New Understanding of Health and Disease in Living Systems
3) Investing in Translational and Clinical Research to Improve Health
4) Fostering a Diverse & Talented Biomedical Research Workforce for Today & Tomorrow

Significant efforts are being made to evaluate programs during their lifetime, and outcomes are assessed as programs end. Continuous evaluation during program implementation allows flexibility to modify program management and/or budgets in response to rapidly evolving scientific landscapes, technical challenges, or other unforeseen challenges or opportunities.

[109] https://commonfund.nih.gov/

Funds will be available in FY 2019 for new challenges and opportunities as programs end, move to other sources of support, or require decreased support as indicated by evaluative data.

Overall Budget Policy: The FY 2019 President's Budget Request for the CF is $598.781million, a decrease of $80.048 million or 11.8 percent compared to the FY 2018 Annualized Continuing Resolution level. This decrease reflects the transition of the *All of Us* Research Program out of the CF but still within the Office of the Director, and also allows for the launch of a new $50 million Innovation Prize Program in FY 2019. The CF will continue to support high-priority research with trans-NIH relevance in FY 2019. As mature programs transition out of the CF, new programs are being established through strategic planning activities that identify potentially transformative areas of research where limited-term investment can have a catalytic impact

Selected Program Descriptions and Accomplishments

CF supports approximately 30 programs, most of which consist of a series of integrated initiatives that collectively address a set of goals aiming to transform the way research is conducted, the way that health and disease are understood, and/or the way that diseases are diagnosed or treated. These programs span a wide range of biomedical research fields, and encompass basic, translational, and clinical research. The paragraphs below focus on new programs for FY 2019, programs requesting a second stage of support, and/or those in which the budget is changed by $5 million or more from the FY 2018 Annualized Continuing Resolution level. One CF program, Strengthening the Biomedical Research Workforce, will receive its final year of support in FY 2018; funds are therefore not requested in FY 2019. Information on this program and its accomplishments can be found on the program website.[110]

Program Portrait: Acute to Chronic Pain Signatures

FY 2018 Level: $5.600 million
FY 2019 Level: $6.314 million
Change: +$0.714 million

In many individuals, acute pain from injury, surgery, or disease persists beyond the initial insult and may last for months, years, or throughout life. The mechanisms driving the transition from acute pain to a chronic state are poorly understood. Developing tools to predict who is at risk and who is resilient to transition to a chronic pain state is a crucial step toward appropriate treatment of acute pain to prevent chronic pain, as well as potentially reversing chronic pain that is already established. Launching as a pilot in FY 2018, this program will focus on identifying mechanistic "signatures" predictive of the transition from acute to chronic pain and for an established chronic pain state. Understanding and identifying at-risk patients could result in preventive treatment plans that may greatly reduce the prevalence of chronic pain and reduce reliance on opioids. The major goal of the program would be to put forward a discovery-focused clinical trial to identify objective signatures (composed of genetic, imaging, molecular, biochemical, and psychosocial data) that associate with the transition from acute to chronic pain. However, feasibility of the study will be demonstrated initially through pilot activities in FY 2018. If the pilot is successful, funds requested in FY 2019 will be used to initiate a full-scale clinical trial.

[110] https://commonfund.nih.gov/workforce

Big Data to Knowledge (BD2K)

As biomedical tools and technologies rapidly improve, researchers are producing and analyzing an ever-expanding amount of complex biological data called "big data." As one component of an NIH-wide strategy, CF, in concert with NIH ICs, is supporting the Big Data to Knowledge (BD2K) program.[111] With the first awards made in 2014, the expectation is that BD2K will result in cultural changes in the way the biomedical research community shares, accesses, queries, cites, and analyzes data. The first stage of BD2K focused on facilitating broad use of biomedical big data, developing and disseminating analysis methods and software, enhancing training relevant for large-scale data analysis, and establishing centers of excellence for big data. The second stage of BD2K, launched in FY 2017, builds from the innovative tools, methods, and data management strategies that were developed in the first phase to establish and test an NIH Data Commons. This project is established as a pilot to test ways to store, access, and share biomedical big data and associated tools in a shared cloud environment. This effort will enable interoperability of data sets, and if the pilot phase is successful, it will enhance access to and use of all NIH data sets. In FY 2019, several Stage 1 initiatives will ramp down, including efforts in software and analysis methods, training, data coordination, sustainability, and the centers of excellence. It is anticipated that completed activities within these initiatives will have achieved their goals, and the tools and resources developed will have been disseminated for use by the broader biomedical research community. The remaining activities within these initiatives will focus on making the products of research usable, discoverable, and disseminated to intended end-users. Other ongoing efforts in BD2K will continue support of the Data Commons Pilot.

Budget Policy: The FY 2019 President's Budget Request is $16.916 million for the BD2K program, a decrease of $5.282 million or 23.8 percent compared to the FY 2018 Annualized Continuing Resolution level. This funding will support the Data Commons, as well as enhancing the usability and impact of products developed during the first stage of BD2K.

Enhancing the Diversity of the NIH Funded Workforce

Enhancing the Diversity of the NIH-Funded Workforce, also known as the Diversity Program Consortium (DPC), is a trans-NIH program funded by the CF and managed by the National Institute of General Medical Sciences (NIGMS).[112] Through this national collaborative, NIH works together with institutions and professional societies to advance the DPC's overarching goal of developing, implementing, assessing and disseminating innovative, effective approaches to research training and mentoring. Unique aspects of this program include: focusing on three levels of impact - student, faculty and institutional; integrating social science research and psychosocial interventions with the process of training and mentoring students and faculty; and rigorously assessing and evaluating the training and mentoring interventions implemented across the program. The DPC consists of three integrated initiatives: Building Infrastructure Leading to Diversity (BUILD), the National Research Mentoring Network (NRMN), and the Coordination and Evaluation Center (CEC). The BUILD initiative supports a set of 10 awards granted to undergraduate institutions, each of which developed quantitative approaches intended to determine the most effective ways to engage and retain students from diverse backgrounds in biomedical research, and to prepare students to become future contributors to the NIH-funded research enterprise. The NRMN is developing a national network of mentors and mentees from

[111] https://commonfund.nih.gov/bd2k
[112] https://www.nigms.nih.gov/training/dpc/Pages/default.aspx

all biomedical disciplines relevant to the NIH mission to provide mentorship, professional development, mentor/mentee training, networking and resources to individuals from the undergraduate to early career faculty levels. The CEC is responsible for coordinating and evaluating the outcomes of DPC activities. In FY 2019, the DPC will complete the first stage of the program and launch a second stage to determine efficacy of the new training and mentoring approaches that the program has developed.

Budget Policy: The FY 2019 President's Budget Request is $47.513 million for the DPC, a decrease of $3.304 million or 6.5 percent compared to the FY 2018 Annualized Continuing Resolution level. The level of support will be used to determine efficacy of the novel training and mentoring approaches developed in the first stage of the program.

Extracellular RNA (ExRNA) Communication

Ribonucleic acid (RNA) was once thought to exist in a stable form only inside cells, where it regulates gene expression by serving as an intermediate product in the process by which cells translate the information coded in genes into proteins that carry out all cellular functions. However, research indicates that RNAs can play a role in a variety of complex functions, including mechanisms of cell-to-cell communication via RNAs that are exported from the cell. The impact of these extracellular RNAs, or exRNAs, is currently unknown. The Extracellular RNA Communication program capitalized on the opportunity to understand entirely new paradigms of information exchange based on the release, transport, uptake, and regulatory role of exRNAs.[113] In the first stage, this program supported awards with the following aims: 1) to determine the biological principles that guide exRNA generation, secretion, uptake, and function; 2) to develop a catalogue of exRNAs found in healthy human body fluids; 3) to identify exRNA biomarkers that can be used to diagnose and monitor disease progression and response to therapy; 4) to develop and demonstrate the potential for clinical utility of exRNAs as therapeutic agents; and 5) to develop a community-wide resource for exRNA standards, protocols, and data. The success of these initiatives allowed several exRNA program investigators to garner additional non-CF IC support. As of September 2017, the exRNA Atlas contained 2,067 exRNA profiles and 21 billion RNA sequence reads across multiple body fluids from both healthy and various disease states. Since the launch of the exRNA Atlas, there have been over 29,400 downloads of datasets by 1,355 users across six continents, demonstrating the broad utility of data generated from the program. In addition to the exRNA Atlas, several bioinformatic tools have been made widely available so that researchers everywhere are able to analyze exRNA data. Translational success is evidenced by the fact that seven program awardees have met with FDA representatives to discuss preliminary biomarker qualification or pre-Investigational New Drug submissions. A review of the first stage of this program demonstrated enthusiasm for a second stage of support, including potential initiatives for validation of datasets to understand inter- and intra-individual exRNA variability over time; development of enabling resources, tools, and technologies; and improved data coordination, analysis, and outreach. Funds requested in FY 2019 will support these activities in the second stage.

Budget Policy: The FY 2019 President's Budget Request is $5.241 million for the Extracellular RNA Communication program, a decrease of $1.671 million or 24.2 percent compared to the FY 2018 Annualized Continuing Resolution level. A review of the first stage of this program

[113] https://commonfund.nih.gov/exrna

indicated additional scientific opportunities ripe for investment, and FY 2019 funds will be used to launch a second stage of support.

Gabriella Miller Kids First Pediatric Research

The Gabriella Miller Kids First Pediatric Research program (Kids First) aims to catalyze pediatric research by making large amounts of high-quality genetic and clinical data from pediatric patient cohorts widely available and easy to use for the entire biomedical research community.[114] The Kids First program supports a data resource that will integrate data from patients with childhood cancer or structural birth defects, conditions which have profound, lifelong effects on patients and their families. By sequencing the genomes of patients along with their parents, we will have a full picture of the genetic contributions to these conditions. This genetic information, in combination with other clinical data, will help researchers understand how genetic mutations lead to birth defects or to cancer, as well as understanding whether there are shared contributions to both conditions. There is considerable scientific evidence that examining childhood cancer and structural birth defects data together will uncover new connections between them that would not have been discovered if they were examined independently. Having these data sets together in a single, widely accessible resource is anticipated to facilitate new discoveries and novel ways of thinking about these conditions. Importantly, the Kids First Data Resource will aggregate Kids First-generated data together with many additional existing data sets, thus increasing researchers' ability to detect rare genetic changes that contribute to these conditions. To date, the Kids First program is supporting sequencing of 23 cohorts, for a total of 18,024 genomes to be sequenced. These cohorts include a wide variety of childhood cancers and structural birth defects, including lymphoma, neuroblastoma, Ewing sarcoma, hearing loss, cleft lip/palate, and diaphragmatic hernia. In FY 2019, the Kids First program will continue to support the Data Resource, and will also launch new demonstration projects to mine Kids First data for novel scientific insights about genetic contributions to childhood cancer and structural birth defects.

Budget Policy: The FY 2019 President's Budget Request is $12.952 million for the Kids First program, an increase of $11.959 million or 1,204.9 percent compared to the FY 2018 Annualized Continuing Resolution level. Programmatic funding remains at the $12.600 million statutory level in FY 2019, with additional requested funds to support research management activities. The decrease in FY 2018 funding levels was due to a lack of funds available in the Pediatric Research Initiative Fund in FY 2018. With a new transfer of funds into this account in FY 2019, funding for Kids First has been restored to the statutory level. FY 2019 funding for this program will support the developing Data Resource and launch new demonstration projects.

High-Risk, High-Reward Research

Research that aims to transform science is inherently difficult and risky but necessary to accelerate the pace of scientific discovery and advance human health. While all CF programs encourage risk-taking to overcome significant challenges in biomedical research, most programs designate funds for particular high-risk objectives or methods. The High-Risk, High-Reward Research (HRHR) program takes a different approach by supporting exceptionally creative scientists proposing innovative and transformative research in any scientific area within the NIH mission through four complementary initiatives: the Pioneer Award, New Innovator Award,

[114] https://commonfund.nih.gov/KidsFirst

Transformative Research Award, and Early Independence Award.[115] The Pioneer Award supports extraordinarily creative scientists who propose bold approaches to addressing major challenges in biomedical and behavioral research. The New Innovator Award supports exceptionally creative, early career investigators who propose innovative, high-impact projects. The Transformative Research Award supports unconventional, paradigm-shifting research projects that are inherently risky and untested, and allows teams of principal investigators when appropriate. The Early Independence Award bypasses the traditional post-doctoral training period by helping establish independent scientific careers for newly graduated scientists with the intellect, creativity, drive, and maturity to flourish independently. Independent evaluations found Pioneer and New Innovator awardees produce more innovative, risky, and impactful research than is funded by typical R01 awards. Examples of innovative research from HRHR awardees include: tracking the Ebola outbreak using genetics and identification of the single animal to human transmission event, discovery of an off-switch for CRISPR-Cas9 gene editing that helps prevent unintended genome changes, creation of a 20-cent replacement for thousand-dollar lab centrifuges designed after a children's toy, and discovery of a promising new antibiotic with no identifiable drug-resistance from pathogens.

Budget Policy: The FY 2019 President's Budget Request is $172.192 million for the HRHR program, an increase of $6.102 million or 3.7 percent compared to the FY 2018 Annualized Continuing Resolution level. This increase in support will allow NIH to continue to support high-risk research with the potential for extraordinary impact.

Human BioMolecular Atlas Program (HuBMAP)

In living organisms consisting of multiple cell types, diverse cells with different functions and structures develop as we grow and age. The Human BioMolecular Atlas Program (HuBMAP) aims to catalyze development of an open, global framework for comprehensively mapping the human body at the level of individual cells.[116] HuBMAP will show proof of principle via preliminary mapping activities of a few organs and distributed systems with existing and emerging technologies, it will establish and validate innovative technologies, and it will demonstrate the utility of these data. HuBMAP will work with the broader community to establish the tools, infrastructure and standards with the expectation that the research community will continue to build upon these maps in the future. Ultimately, these maps will form part of a resource - conceptually like Google Maps for the human body - and as this data resource grows over time, will result in a complete human body map at the cellular level. These maps will enable and encourage future studies and new insights into inter-individual variation and tissue changes across the lifespan and health/disease continuum. This program is expected to establish and leverage close partnerships with other funding agencies so that multiple funding sources are coordinated for this global challenge. Launched in FY 2018, HuBMAP will begin set-up and then move to a scale-up phase in FY 2019. Support for HuBMAP will increase as initiatives for technology development, tissue mapping, and data and coordination ramp up.

Budget Policy: The FY 2019 President's Budget Request is $13.536 million for the HuBMAP program, an increase of $6.057 million or 81.0 percent compared to the FY 2018 Annualized

[115] https://commonfund.nih.gov/highrisk
[116] https://commonfund.nih.gov/HuBMAP

Continuing Resolution level. This increase in funding will support ramping up of the HuBMAP program in FY 2019.

Molecular Transducers of Physical Activity

Physical activity has been demonstrated to contribute to health via a wide variety of measures, and lack of physical activity is at the root of many common chronic health problems. Despite this, we have a poor understanding of the molecular mechanisms by which the benefits of physical activity are realized. A better understanding of the molecules that underlie the benefits of physical activity could lead to the development of improved, personalized exercise recommendations as well as therapies for individuals who are unable to exercise due to illness or disability. The development of a molecular map of physical activity is a daunting task but is now made possible because of recent advances in several powerful high-throughput analytic approaches, including metabolomics, proteomics, genomics, transcriptomics, and epigenomics. The Molecular Transducers of Physical Activity in Humans Consortium (MoTrPAC) will leverage these advances to improve our understanding of the molecular mechanisms by which physical activity improves health.[117] This program will extensively catalogue the biological molecules affected by physical activity in people, identify some of the key molecules that underlie the systemic effects of physical activity, and characterize the function of these key molecules.

Budget Policy: The FY 2019 President's Budget Request is $33.166 million for the Molecular Transducers of Physical Activity program, an increase of $8.176 million or 32.7 percent compared to the FY 2018 Annualized Continuing Resolution level. This increase in funding will support the large, complex clinical study required to discover the molecular mechanisms that underlie the wide range of benefits from physical activity.

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

Neuromodulation of peripheral nerve signals to control organ function has been recognized as a potentially powerful way to treat many diseases and conditions, such as hypertension, heart failure, gastrointestinal disorders, type II diabetes, inflammatory disorders, and more. However, neural control of end-organ function is poorly understood. Consequently, efficacy of neuromodulation therapies has been inconsistent and side effects are difficult to predict. The Stimulating Peripheral Activity to Relieve Conditions (SPARC) program is a high-risk, goal-driven basic research endeavor to develop foundational knowledge and technologies for an entirely new class of therapeutic devices that have the potential to precisely treat a wide variety of diseases and conditions.[118] SPARC supports interdisciplinary teams of investigators to deliver neural circuit maps that illustrate how peripheral nerves control organ function, along with technologies to isolate, measure, and manipulate nerve-organ interactions and their functions. Because these activities are driven by an end goal to catalyze development of next-generation neuromodulation therapies, all SPARC comprehensive mapping projects involve validation in human tissues. The program is designed to be iterative and dynamic, with the novel technologies informing mapping efforts, and mapping results defining new technology requirements. This program uses Other Transaction Authority for selected initiatives, which allows high levels of flexibility, responsiveness to adjust program components, and ability to engage with non-

[117] https://commonfund.nih.gov/MolecularTransducers/
[118] https://commonfund.nih.gov/sparc

traditional partners as needed to address specific, high-risk goals within this complex, interdisciplinary, and rapidly evolving area of science. While distinct from the NIH BRAIN initiative and DARPA's ElectRx program, SPARC shares approaches with BRAIN and ElectRx so that all three programs will likely benefit from innovations made in the others. These initiatives are therefore being closely coordinated with NIH and DARPA staff.

Budget Policy: The FY 2019 President's Budget Request is $41.734 million for the SPARC program, a decrease of $5.334 million or 11.3 percent compared to the FY 2018 Annualized Continuing Resolution level. This level of support will allow SPARC to continue supporting efforts towards developing functional and anatomical neural circuit maps of peripheral organs, tool development, leveraging existing technologies for novel applications, and data coordination.

Program Portrait: Somatic Cell Genome Editing

FY 2018 Level: $19.370 million
FY 2019 Level: $35.315 million
Change: +$15.945 million

Recent developments in genome editing techniques to precisely change specific sequences in the human genome raise the possibility of a fundamentally new approach to treat genetic diseases, as well as opportunities to impact common diseases. Editing the genomes of somatic cells can be done outside the body (ex vivo) with subsequent transplantation of the edited cells into the patient. Alternatively, cells can be modified within the body (in vivo). However, efficacy, specificity, and delivery remain challenges, especially for approaches that target cells in vivo, which lag behind ex vivo approaches in development even though they are applicable to many more diseases. The Somatic Cell Genome Editing program aims to improve the efficacy and specificity of in vivo genome editing approaches.[119] This program could transform the practice of medicine and reduce the burden of both rare and common diseases. The program will be a coordinated effort towards the development of effective delivery methods and more precise technologies for accurate ("on-target") genome editing, while limiting "off-target" genetic changes and unintended consequences such as altered cells becoming cancerous, provoking an immune response, or causing long term physiological abnormalities. The major goal of the program is to develop enabling tools and technologies to facilitate the filing of successful Investigational New Drug applications, especially applications perceived to have little financial reward by industry.

Transformative High Resolution Cryo-Electron Microscopy

Knowing the structure of a molecule reveals important information about how it functions and can provide insight into potential drug targets for fighting disease. Cryo-electron microscopy (cryo-EM) is a method used to image frozen biological molecules in their natural state and offers considerable advantages in sample requirements over other techniques. Until recently, cryo-EM has been substantially limited in the level of structural detail that can be obtained, but technological advances in the past few years have dramatically extended cryo-EM resolution, making it possible to image proteins and "cellular machinery" in great detail. However, the high cost of cryo-EM instrumentation limits the method's availability to researchers. The Transformative High Resolution Cryo-Electron Microscopy program aims to provide nationwide access for researchers to cryo-EM through the creation of national service centers, improvement of technology, and the development of an expert workforce.[120] In FY 2019, the Transformative

[119] https://commonfund.nih.gov/editing
[120] https://commonfund.nih.gov/CryoEM

High Resolution Cryo-Electron Microscopy program will support national service centers to provide biomedical researchers access to state-of-the-art equipment, technical support, and instruction for the production and analysis of high-resolution cryo-EM data, as well as training for cryo-EM microscopists.

Budget Policy: The FY 2019 President's Budget Request is $13.440 million for the Transformative High Resolution Cryo-Electron Microscopy program, a decrease of $12.815 million or 48.8 percent compared to the FY 2018 Annualized Continuing Resolution level. The FY 2018 budget reflected substantial start-up equipment purchases. The FY 2019 level of support will continue the operations of national cryo-EM service centers while expanding support for training.

Strategic Planning and Evaluation

The CF's 10-year restriction on support for any given program is designed to create a churn of funds so that new challenges and opportunities may be addressed each year. Strategic planning is therefore a critical activity for the CF. Conducted annually, the strategic planning process allows CF to be nimble and adaptive to the changing scientific landscape. This process is a collaborative activity between the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)/Office of Strategic Coordination (OSC) and the ICs. CF strategic planning encompasses both the identification of broadly relevant scientific challenges and opportunities for strategic investments using the CF (Phase 1 planning), and the articulation of specific goals, milestones, and implementation plans for each broadly defined potential program topic identified in Phase 1 (Phase 2 planning). Phase 1 strategic planning often involves gathering broad input from external stakeholders with diverse expertise as well as internal discussions about shared challenges and emerging opportunities. Phase 2 strategic planning often involves more specific consultations with external experts, analysis of NIH and worldwide portfolios of research on the given topic, and literature reviews to articulate specific gaps and areas of research where opportunities for transformative progress are possible.

Since CF programs are goal driven, evaluation is critical and increasingly important as more programs near the end of their support period. Evaluation is conducted as a partnership between DPCPSI/OSC and the ICs, and it includes both formal and informal evaluative activities. Informal evaluation involves convening grantees and NIH-wide teams to review progress, discuss new challenges, and develop strategies to adapt as part of routine program management.

It also involves gathering input from external consultants and using their input, together with internal analysis, to help guide the implementation of the program. Formal evaluations involve the development of baseline data for new programs and the development of multiple metrics of outcomes. The utility of data, resources, technologies, and other program outputs is assessed through surveys, expert opinion, and the analysis of bibliometric data such as citation analyses.

Funds Available for New Programs

As mature initiatives end or transition out of the CF, or as information gathered through evaluations indicates a need for decreased support of existing programs, funds are available to address new challenges. The CF plans to launch a new program in FY 2019:

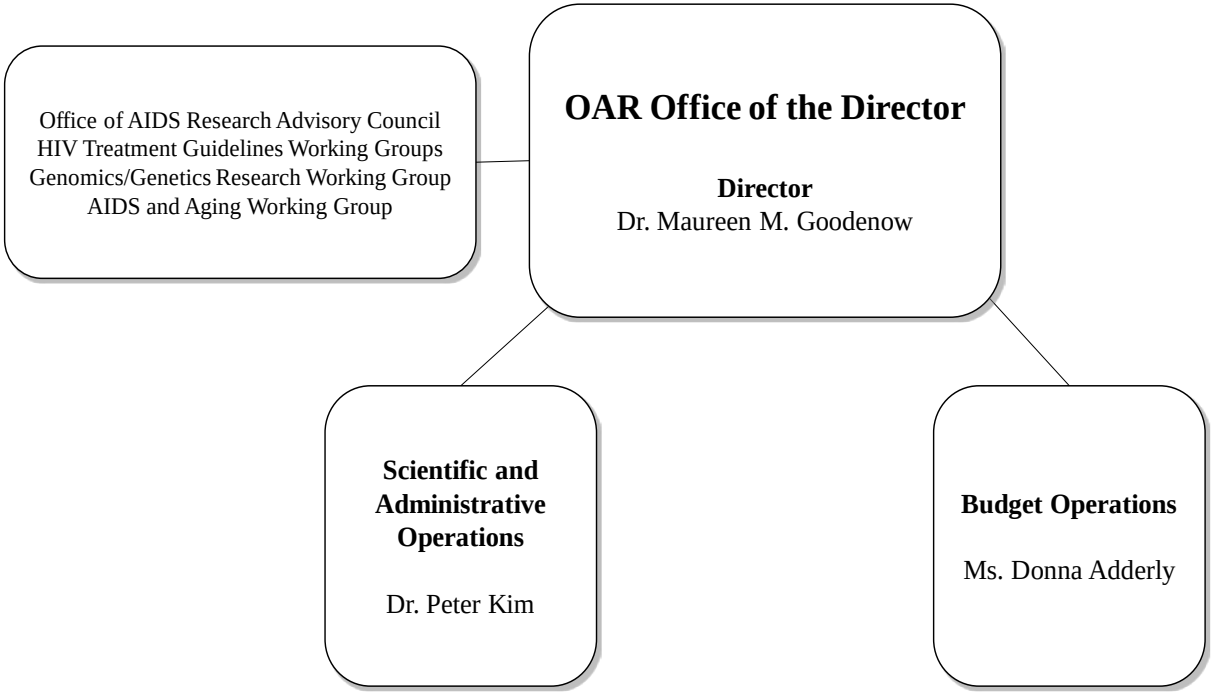
- **Common Fund Innovation Prize Program** – Beginning in FY 2019, the CF will administer an Innovation Prize Program, using up to $50 million to accelerate research in defined areas of need across the NIH. Use of an Innovation Prize Program has several advantages: the ability to establish a goal without predetermination of the most likely way to achieve the goal; paying only for results; increasing the number and diversity of individuals or organizations that address a specific problem or challenge; stimulating private sector investment so the winning result could be greater than the value of the prize; and attracting more interest and attention to a defined program, activity, or issue of concern. This program will be administered by the Common Fund, but all ICs as well as Common Fund programs can propose ideas for potential Innovation Prize competitions.

OFFICE OF AIDS RESEARCH

Trans-NIH HIV/AIDS Research Budget

ORGANIZATION CHART

National Institutes of Health
Office of AIDS Research



NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Institute and Center
(Dollars in Thousands)

Institute / Center	FY 2017 Actual	FY 2018 CR	FY 2019 President's Budget	FY 2019 +/- FY 2018 CR
NCI	$249,019	$247,328	$241,676	-$5,652
NHLBI	77,512	76,986	75,227	-1,759
NIDCR	18,015	17,893	17,483	-410
NIDDK	32,904	32,681	31,934	-747
NINDS	45,464	45,155	44,123	-1,032
NIAID	1,673,531	1,662,166	1,624,190	-37,976
NIGMS	52,484	52,128	50,936	-1,192
NICHD	144,125	143,146	139,875	-3,271
NEI	1,162	1,154	1,127	-27
NIEHS	5,342	5,306	5,185	-121
NIA	9,514	9,449	9,234	-215
NIAMS	4,587	4,556	4,452	-104
NIDCD	1,878	1,865	1,822	-43
NIMH	167,570	166,432	162,629	-3,803
NIDA	276,711	274,832	268,551	-6,281
NIAAA	28,566	28,372	27,724	-648
NINR	12,180	12,097	11,821	-276
NHGRI	2,502	2,485	2,428	-57
NIBIB	1,092	1,085	1,059	-26
NIMHD	20,917	20,775	20,301	-474
NCCIH	777	772	754	-18
FIC	23,884	23,722	23,180	-542
NLM	8,822	8,762	8,562	-200
OD				
OAR	62,256	61,833	60,420	-1,413
ORIP	79,247	78,709	76,910	-1,799
Subtotal, OD	141,503	140,542	137,330	-3,212
TOTAL, NIH	**$3,000,061**	**$2,979,689**	**$2,911,603**	**-$68,086**

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Activity
(Dollars in Thousands)

Overarching Priorities	FY 2015 Actual	FY 2016 Actual	FY 2017 Actual	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018 CR
Reducing Incidence of HIV/AIDS	$700,771	$732,003	$687,495	$684,200	$669,966	-$14,234
Next Generation HIV Therapies	449,716	360,085	362,820	358,939	345,848	-$13,091
Research Toward a Cure [1/]	65,206	108,337	170,375	168,875	164,458	-$4,417
HIV-associated Comorbidities, Coinfections, and Complications	588,444	614,090	556,608	551,112	539,216	-$11,896
Crosscutting	1,195,924	1,185,546	1,222,763	1,216,563	1,192,115	-$24,448
Total	$3,000,061	$3,000,061	$3,000,061	$2,979,689	$2,911,603	-$68,086

[1/] Beginning in FY 2017, Research Toward a Cure for HIV/AIDS became a separate activity. Dollars for Research Toward a Cure for HIV/AIDS were previously included within other science areas, such as Next Generation Therapies, Crosscutting--Basic Research, and Reducing Incidence of HIV/AIDS. The FY 2015 and FY 2016 amounts are comparable budget figures.

Justification of Budget Request

Office of AIDS Research
Trans-NIH AIDS Research Budget Justification
(see also: OAR section in Office of the Director/DPCPSI)

Budget Authority (BA):

FY 2017 Actual	FY 2018 Annualized Continuing Resolution	FY 2019 President's Budget	FY 2019+/- FY 2018
$3,000,061,000	$2,979,689,000	$2,911,603,000	-$68,086,000

Director's Overview

Groundbreaking Accomplishments with Unprecedented Scientific Opportunities
Since the first cases of AIDS were reported, NIH has been the global leader in sponsoring research to prevent, diagnose, and treat HIV and its associated comorbidities, coinfections, and complications. Currently, there are 1.1 million people living with HIV (PLWH) in the United States (U.S.) and 37 million PLWH globally.[121] In 2016, 1.8 million people globally became newly infected with HIV.[121] To date, 35 million people have died because of HIV/AIDS.[121]

NIH has established a comprehensive and coordinated HIV research program that has demonstrated unprecedented progress against the global HIV pandemic. NIH-sponsored research has led to groundbreaking advances in understanding the HIV life cycle, development of safe and effective antiretroviral drugs and drug regimens for the treatment of HIV-infected individuals, and strategies to prevent HIV transmission and acquisition. While significant progress has been made, the HIV pandemic continues to spread, representing a serious global public health threat. NIH will continue to build on the scientific discoveries and knowledge that have been gained to advance research to end the epidemic and improve the health outcomes of PLWH.

Coordinated NIH-wide HIV Research Program
The Office of AIDS Research (OAR) manages the NIH-wide HIV/AIDS research program. As HIV/AIDS affects virtually every organ system in the body, leading to a myriad of HIV-associated coinfections, comorbidities, and clinical complications, almost every NIH Institute and Center (IC) is involved in HIV-related research. OAR coordinates the scientific, budgetary, and policy elements of this NIH-wide research program. OAR has established comprehensive HIV/AIDS planning, budgeting, and portfolio analysis processes to identify the highest-priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that

[121] UNAIDS Fact Sheet July 2017.
http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

precious research dollars are invested effectively. OAR also identifies specific funding for emerging scientific opportunities and public health challenges that require focused attention; facilitates cross-Institute activities and collaborations; fosters research by designating funds and supplements for pilot programs; facilitates HIV research training; and sponsors scientific workshops to identify cutting-edge initiatives and catalyze change in the field.

Priority Setting Review
The Congressional Budget Justification reflects resources needed to meet the highest priorities identified through OAR's NIH-wide strategic planning, priority-setting, portfolio analysis, and budget processes; and to address the evolving clinical profile of the epidemic.

This budget request also establishes the biomedical and behavioral research foundation necessary to end the HIV/AIDS epidemic as well as mirrors the key themes established by the NIH Director, which align with OAR's priorities as indicated below.

- **Tackling Complex Challenges by Leveraging Partnerships**: NIH currently supports a significant number of partnerships across scientific disciplines and across the public and private sectors to advance HIV/AIDS research. NIH will continue to establish and leverage collaborations with academia, industry and other private partnerships to address public health needs and support opportunities to implement new approaches to accomplish these goals. For example, the OAR in collaboration with several ICs is leading an effort to re-envision the Multi-Center AIDS Cohort Study and the Women's Interagency HIV Study Combined Cohort Study (MACS/WIHS-CCS) to address the changing research needs of the pandemic. Because HIV/AIDS is such a complex disease, this effort will allow the NIH ICs to study and characterize HIV-related co-morbidities and co-infections among U.S. adults.

- **Supporting Basic Research to Drive New Understanding of Health and Disease in Living Systems:** The HIV/AIDS research field has been driven by innovative research. NIH will continue to advance all the HIV/AIDS research priorities by investing in basic research to elucidate the fundamental mechanisms that drive HIV infection and its associated diseases.

- **Investing in Translational and Clinical Research to Improve Health:** NIH supports a broad portfolio of translational and clinical research in HIV/AIDS to rapidly advance the most important findings in basic research into clinically relevant tools and strategies for treatment and prevention. NIH will continue to fund translational and clinical research to develop promising vaccine candidates, new diagnostic tools, and new drugs and formulation technologies, to address the critical needs of clinicians and public health professionals engaged in the fight against HIV/AIDS.

- **Fostering a Diverse and Talented Biomedical Research Workforce for Today and Tomorrow**: Training the biomedical, behavioral, and social science workforce required to conduct high-priority HIV/AIDS research has long been a goal of the OAR. OAR will continue to fund NIH ICs to ensure that a diverse and talented workforce is supported for

driving innovation, fostering creativity, and encouraging the development of new ideas and perspectives in combating the HIV pandemic.

The key overarching scientific priorities identified within this NIH-wide budget include:

- **Reducing Incidence of HIV/AIDS**: developing and testing promising vaccines; developing and testing microbicides and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.

- **Next Generation HIV Therapies with Better Safety and Ease of Use**: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens; implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.

- **Research Toward a Cure**: developing novel approaches and strategies to identify and eliminate viral reservoirs and sanctuaries, including studies of viral persistence, latency, and reactivation, that could lead toward a cure or lifelong remission of HIV infection.

- **HIV-associated Comorbidities, Coinfections, and Complications**: addressing the impact of HIV-associated comorbidities across the lifespan, including tuberculosis (TB), malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.

- **Cross Cutting Areas**:

  - **Research to Reduce Health Disparities** in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
  - **Behavioral and Social Sciences Research (BSSR)**: understanding behavioral and social determinants of transmission, prevention, and treatment outcomes, and elucidate potential interventions to end the epidemic.
  - **Epidemiological Research:** conducting epidemiologic and modeling research to improve understanding of the epidemic at the population level and help prioritize strategies that will have the greatest impact on the pandemic and the health of PLWH.
  - **Research Training** of the workforce required to conduct high-priority HIV/AIDS or HIV/AIDS-related research.
  - **Basic Research**: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.

Overall Budget Policy: The FY 2019 President's Budget estimate for the trans-NIH AIDS research program is $2,911.603 million, a decrease of $68.086 million compared to the FY 2018

Annualized Continuing Resolution (CR) level. The OAR is authorized to allocate all dollars associated with this area of research across the entire NIH. The NIH HIV/AIDS research budget is tightly focused on high priority HIV/AIDS research, including: 1) discovery, translation, and development of new prevention and treatment modalities for HIV/AIDS including vaccines, monoclonal antibodies, and new drugs, 2) clinical trials to test and enhance these new products, 3) research for achieving a cure or sustained HIV remission, 4) exploration of new opportunities for basic scientific research on HIV interactions with cells and the immune responses to the virus and its components, and 5) comorbidities, coinfections, and complications associated with HIV/AIDS. This request reflects the reallocation of funds across the ICs to address new and exciting scientific opportunities in HIV/AIDS research identified through OAR's unique trans-NIH strategic planning, priority setting, portfolio analysis, and budget processes and to address the evolving clinical profile of the epidemic. In addition, these resource alignment practices have opened opportunities to incorporate improved risk-assessment tools and to enhance study designs to deliver effective interventions for prevention and treatment of HIV/AIDS.

Program Descriptions and Accomplishments

Reducing the Incidence of HIV/AIDS: NIH-sponsored studies have proven the effectiveness of viral suppression via combined anti-retroviral therapy to reduce transmission to sexual partners and have delineated modern strategies to prevent the transmission of infection from mothers to newborns. However, the pandemic continues, and further research is needed. The best long-term strategy for controlling the HIV/AIDS pandemic is the development of safe, effective, and affordable HIV prevention strategies that are easily implementable with wide uptake across all populations affected by HIV. The development of an effective HIV vaccine would be a groundbreaking advancement for the field. NIH continues to support a broad research portfolio encompassing basic, preclinical, and clinical studies to advance research on HIV vaccines and other preventive measures.

Basic and translational research to assess the human immune response to vaccines remains a high priority. While a vaccine has been elusive to date, two major HIV vaccine efficacy trials testing two different vaccine candidates will continue in 2019 with results anticipated in 2020. These candidate vaccines are built on the scientific advances of the past 10 years and showed promise in small, early phase clinical trials. NIH-funded investigators are developing next generation vaccine candidates that will be ready for testing in humans by applying novel vaccine approaches including immunization with unique, sequential proteins, designed over time to induce potent antibodies. Advances in imaging technologies have led to the development of structures that more closely mimic HIV, and in turn, could serve as improved vaccines to induce protective immunity. In preparation for these clinical trials, NIH has strategically invested in expanding manufacturing capabilities to meet current and future research demand.

NIH has made dramatic advances in research and development related to non-vaccine HIV prevention in both adults and infants. One prevention trial conducted in Sub-Saharan Africa and the Americas called AMP (antibody-mediated protection) gives participants an infusion of monoclonal antibodies–known to be highly protective in blocking infection. If successful, the trial will demonstrate that antibodies given to humans can prevent HIV infection. If the

antibodies can be produced economically on a large scale and are well-accepted by at-risk populations, antibodies could become a viable prevention option.

A new long acting formulation of the drug Cabotegravir opens the possibility for future prevention modalities that would be effective with monthly, rather than daily dosing. Studies are also underway to evaluate the long-term impact of these prevention modalities on the overall health of PLWH.

The development of microbicides, intra-vaginal rings and other modalities to protect women and men from sexual acquisition of HIV, a long-standing goal of NIH, remains a promising component of the HIV prevention toolkit that offers advantages for women who may not have other options for protection. A recently completed trial of an antiretroviral (ARV)-based intravaginal ring was up to 62 percent effective in preventing sexually-transmitted HIV infection in women who used the ring monthly.[122] Research to improve upon early successes and to better understand factors contributing to adherence will be critical to advance the development of a vaginal ring.

Budget Policy: The FY 2019 President's Budget request for Reducing the Incidence of HIV/AIDS is $669.966 million, a decrease of $14.234 million compared to the FY 2018 CR level.

Next Generation of HIV Therapies: Antiretroviral therapy (ART) has improved the health of many PLWH. Combination ART (cART) significantly suppresses virus replication to reduce damage to the host immune system, prolongs the development of viral resistance, and lessens the spread of HIV/AIDS. In addition, cART has delayed the progression of HIV infection to AIDS and reduced HIV-associated comorbidity and mortality from opportunistic infections (e.g., cryptococcal meningitis and pneumocystis pneumonia), AIDS defining cancers, and HIV-associated metabolic and neurologic syndromes.

However, even with the current cART regimens, daily, life-long treatment is required and only 17-18 million of the approximately 37 million PLWH currently receive treatment.[1] Obstacles for PLWH to receive and adhere to cART include: 1) costs associated with daily regimens, 2) toxicity and other side effects, 3) drug-drug interactions with other critical medications such as treatment for TB, 4) HIV drug resistance, and 5) disparities in access to HIV treatment which impact treatment outcomes across race, sex and gender, age, and socioeconomic status.

NIH has led efforts to advance the discovery and development of a wide range of technologies and treatment modalities that will benefit PLWH and help bring the pandemic to an end. NIH-funded research efforts are underway to develop and test longer acting, less toxic regimens with fewer side effects and complications. In the near future, PLWH may be able to receive monthly (or even longer acting) injections of sustained release cART, anti-HIV antibody infusions, or a six month long therapeutic implant. Simpler treatment schedules compared to the current daily cART regimens are expected to improve adherence. Immune-based treatment regimens, while still early in development, hold promise for a treatment that suppresses viral replication and also

[122] Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. NEJM, December 1, 2016; 375: 2121 – 2132.

addresses the immune dysfunction that continues, even with viral suppression. Immune based modalities would also provide treatment for PLWH where the virus has become resistant to all known anti-retroviral drugs. Ten percent of people on ARV are resistant to at least one drug.[123]

NIH in partnership with industry, academia, and other research organizations is supporting a broad array of basic and clinical research to develop cutting edge diagnostic technologies that quickly identify infection, measure treatment efficacy, and determine drug resistance. NIH is also investing in research focused on the epidemiology of HIV drug resistance to inform treatment strategies and disease outcomes; and, behavioral social science, and implementation research to foster innovative strategies that will increase uptake of treatment upon HIV diagnosis, and engage PLWH in care to achieve viral suppression, prevent transmission, and improve health.

Budget Policy: The FY 2019 President's Budget request for Next Generation HIV Therapies is $345.848 million, a decrease of $13.091 million compared to the FY 2018 CR level.

Research Toward a Cure for HIV/AIDS: The most significant hurdles that prevent developing a cure for HIV infection are latent viral reservoirs resulting from the integration of the viral genome into the human DNA of infected cells and sanctuary sites that protect the virus from the natural immune response and current therapies. To cure HIV, new therapies that target and eliminate or silence cells harboring integrated HIV must be developed.

NIH invests in research to advance the understanding of the mechanisms that govern the establishment, persistence, and reactivation of the HIV reservoir in different cell types. Continued investment will support innovative approaches to identify and characterize the persistent HIV reservoir, including single cell and imaging technologies. A comprehensive understanding of the dynamics of the HIV reservoir will inform the development of new targeted therapeutic cure strategies. In parallel, NIH is leading efforts to advance the research and development of a wide array of technologies and strategies aimed at eradicating the reservoir or inhibiting viral reactivation.

NIH invests in a complex portfolio of research toward an HIV cure that includes phased innovation awards with research milestones and small business awards to support biotech startups to foster a diverse and talented research workforce. The research to find a cure supported by the NIH involves several public-private partnerships that conduct basic, translational, and clinical research to drive new targeted therapeutics for improved health outcomes. The investment by NIH in a multifaceted HIV/AIDS research portfolio is crucial to advance the scientific discoveries that will lead to a cure for HIV that is as safe as cART, simple to implement, and readily scalable for all PLWH.

Budget Policy: The FY 2019 President's Budget request for Research Toward a Cure for HIV/AIDS is $164.458 million, a decrease of $4.417 million compared to the FY 2018 CR level.

[123] World Health Organization: HIV Drug Resistance Report 2017; http://apps.who.int/iris/bitstream/10665/255896/1/9789241512831-eng.pdf?ua=1

HIV-Associated Comorbidities, Coinfections, and Complications (CCC): HIV directly and indirectly causes a complex array of health issues that are not improved by cART and may be exacerbated by treatment. At the same time, infections such as TB and hepatitis have a negatively synergistic reaction with HIV leading to increased disease severity and worse treatment outcomes for both diseases. Research is currently aimed at understanding how the mechanisms underlying HIV infection, such as immune dysfunction and inflammation, may result in increased risk for cardiovascular disease, accelerated aging, neurologic and cognitive dysfunction, and increased mortality. NIH funds a portfolio of basic, translational, and clinical research to elucidate these mechanisms and their impact on HIV-related end-organ disease. This area of research is important not only for PLWH, but also promises to inform research strategies for other key public health challenges impacting the general population, such as cancer, heart disease, and neurologic disorders.

Through partnerships across various research sectors, these findings are actively being translated into clinical trials of new drugs and diagnostics to accelerate improvement in the health outcomes for PLWH. NIH is funding clinical trials of new diagnostic tools and drugs to facilitate early identification as well as prevention and treatment of heart disease, TB, hepatitis and other opportunistic infections, underlying inflammation, and neurologic complications in PLWH.

Budget Policy: The FY 2019 President's Budget request for HIV-associated Comorbidities, Coinfections, and Complications is $539.216 million, a decrease of $11.896 million compared to the FY 2018 CR level.

Cross Cutting Areas: A significant proportion of HIV/AIDS research has relevance to not one, but all the overarching NIH HIV/AIDS priority research areas, including research in health disparities, behavior and social sciences, and epidemiology as well as training and capacity building, information dissemination, and basic research.

- **Research to Reduce Health Disparities:** NIH continues to invest in research to address disparities in the rate of infections in African Americans, Hispanics, Native Americans and other minority groups. More research is needed to understand the factors contributing to disparities, both in prevention and treatment outcomes. Data estimates from the Centers for Disease Control and Prevention (CDC) indicate that more than 70 percent of all new HIV diagnoses in the U.S. occurred in racial and ethnic populations, with less than 50 percent of PLWH being virally suppressed.[124]

  Globally, young people aged 15-24 are often unaware of their HIV status and are less likely to be linked to treatment and care, consequently continuing the cycle of new infections. Defining the gaps and the biologic, genetic, epidemiologic, and behavioral factors involved in health disparities, will improve understanding of the course of HIV infection in these populations, especially in young women and men of color who are most at risk.

[124] Centers for Disease Control and Prevention: HIV Surveillance Report, 2015; vol. 27, published November 2016. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.

- **Behavioral and Social Sciences Research:** HIV/AIDS-related behavioral and social sciences research is integrated within all of the high-level priorities for HIV/AIDS research including prevention and treatment of HIV infection, developing a cure, and research on comorbidities and co-infections. Behavioral and social sciences research findings continue to reveal a wide range of individual, interpersonal, social, structural, and other factors that contribute to and drive the HIV/AIDS pandemic. NIH-supported studies have led to developments in reducing HIV-related stigma, improvements in medication adherence, and the use of innovative HIV prevention technologies such as mobile health (mHealth). Other studies are improving the application of social network analysis, the creation of socioculturally specific interventions, and testing other key elements and integrative approaches needed to prevent HIV infection.

    - **Epidemiological Research:** The lifetime risk of being diagnosed with HIV in the U.S. is greater for people living in the South, including the District of Columbia, than in other regions of the country.[125] Understanding causes, patterns, and social phenomena that have led to higher rates of HIV infection in the Southern and Midwestern U.S. is key to rapidly identifying and preventing HIV outbreaks. The recent outbreak in Indiana was fueled by injection drug use. With a surging opioid epidemic, particularly among U.S. youth, methodology to detect infection clusters early and prevent future outbreaks is a cross cutting and cross-disciplinary priority.

- **Training, Infrastructure, and Capacity Building:** NIH continues a strong commitment to training the biomedical, behavioral, and social science workforce required to conduct high-priority HIV/AIDS research. NIH provides research infrastructure and capacity building support through funding equipment, shared instrumentation, and tissue and specimen repositories. NIH also provides support for infrastructure and capacity building as integral components of its commitment to carry out highly productive HIV-related research that is scientifically and ethically sound.

- **Information Dissemination:** NIH supports initiatives to enhance the dissemination of research findings to the diverse communities that rely on this information including patients, clinicians, researchers, and other stakeholders in HIV research. For example, NIH sponsors the development and dissemination of the U.S. HIV/AIDS Treatment and Prevention guidelines used by clinicians in the U.S. and globally. The Guidelines facilitate rapid translation of HIV/AIDS research into clinical practice and keep the medical and patient communities abreast of the latest advances.

- **Basic Research**: Major gaps remain in our understanding of the basic biology of HIV transmission and pathogenesis including the development of immune dysfunction, chronic inflammation, and virus/host cell interactions; the impact of the host microbiome on therapeutic efficacy, prevention and disease outcomes; genetic determinants of HIV susceptibility and disease progression; innate immune factors that may either prevent or accelerate disease; and

[125] Centers for Disease Control and Prevention: HIV in the United States, At a Glance; published September 2017. https://www.cdc.gov/hiv/statistics/overview/ataglance.html.

other fundamental issues that underpin the development of high-priority strategies for the prevention, treatment, and cure of HIV and related co-morbidities and coinfections.

Budget Policy: The FY 2019 President's Budget request for Crosscutting Areas: Research to Reduce Health Disparities; Behavioral and Social Sciences Research; Epidemiological Research; Training, Infrastructure, and Capacity Building; Information Dissemination; and Basic Research is $1,192.115 million, a decrease of $24.448 million compared to the FY 2018 CR level.

Benefits of AIDS Research to Other Areas: NIH investment in HIV/AIDS research has resulted in critical scientific accomplishments that have contributed knowledge to the prevention, diagnosis, and treatment of many other diseases and conditions. HIV/AIDS research has informed a better understanding of immunology, virology, microbiology, molecular biology, cell biology, and the impact of genetics on human health. HIV/AIDS research continues to make discoveries that can be applied to other infections and conditions such as cancer, neurologic, autoimmune, and metabolic diseases, as well as to the complex issues of aging and dementia.

Conclusion: NIH investment in HIV/AIDS research continues to produce significant groundbreaking scientific advances, unprecedented opportunities, and new challenges. NIH's leadership and commitment to build upon these advances and strategically allocate funds to the highest priorities are essential to successfully bringing an end to the HIV pandemic and improving the life of PLWH.

DRUG CONTROL PROGRAMS

	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Drug Resources by Budget Decision Unit and Function:			
Decision Unit 1: National Institute on Drug Abuse			
Research and Development: Prevention	$380.513	$385.002	$404.176
Research and Development: Treatment	$690.300	$698.443	$733.227
Total, Decision Unit 1	$1,070.813	$1,083.445	$1,137.403
Decision Unit 2: National Institute on Alcohol Abuse and Alcoholism			
Research and Development: Prevention	$45.504	$45.281	$44.240
Research and Development: Treatment	$5.134	$4.883	$4.441
Total, Decision Unit 2	$50.638	$50.164	$49.011
Total Funding	$1,121.451	$1,133.609	$1,186.414
Drug Resources Personnel Summary			
Total FTEs (direct only)	380	382	382
Drug Resources as a Percent of Budget			
Total Agency Budget (in Billions)	$34.2	$34.1	$34.8
Drug Resources percentage	3.28%	3.33%	3.41%

Program Summary

MISSION

The National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), two of NIH's Institutes and Centers, support *the National Drug Control Strategy*: [126] NIDA, by funding research on the prevention and treatment of drug use, addiction, and its harmful consequences; and NIAAA, by funding research on the prevention and treatment of underage drinking and its harmful consequences.

The societal impact of the misuse of illicit drugs in 2007 was estimated at $193 billion in health care, crime-related, and productivity losses.[127] Knowledge is the foundation of the transformative agenda needed to strike at the heart of this stubborn and costly challenge. To provide a comprehensive public health response, NIDA will continue to build on science advances from the Institute's investments in genetics, neuroscience, pharmacotherapy, and behavioral and health services research that have led to innovative strategies for preventing and treating substance use disorders (SUDs) in this country and worldwide.

[126] https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs
[127] U.S. DOJ National Drug Intelligence Center. The Economic Impact of Drug Use in American Society. April 2011

Studying drug use, SUDs, and their causes is a complex challenge compounded by societal stigma and misunderstanding that most other illnesses do not face. The landscape of drug addiction in America evolves from year to year; we are currently seeing the terrible results of a decades-long epidemic of prescription drug misuse that is leading to a rise in heroin use as well as new HIV and Hepatitis C outbreaks. A growing number of states are legalizing marijuana for medical or recreational use, producing natural experiments whose outcomes cannot yet be predicted. New synthetic drugs as well as new delivery systems such as electronic cigarettes (e-cigarettes) are changing how people use drugs. NIDA is supporting research to address today's drug use-related challenges in several key areas, including supporting the Secretary of HHS to respond to opioid abuse and overdose; spearheading a landmark longitudinal study of adolescent substance use and brain development[128]; studying the impact of the changing marijuana landscape[129]; studying the impact of new synthetic drugs[130]; and contributing to scientific and public understanding of the brain mechanisms underlying addiction.

Alcohol misuse has profound effects on the health and well-being of individuals, families, and communities, and costs the United States $249 billion per year.[131] Since its creation, NIAAA has led the national effort to define alcohol problems as medical in nature and address them using evidence-based findings. The research supported by the Institute has transformed the understanding and treatment of alcohol misuse and its consequences, including alcohol use disorder (AUD). NIAAA is working to reduce the considerable burden of alcohol misuse for individuals at all stages of life by supporting research on: the neurobiological mechanisms underlying alcohol misuse, AUD, and co-occurring disorders; fetal alcohol spectrum disorders; the effects of alcohol misuse on the developing adolescent brain and on other tissues and organs; the development of strategies to prevent and treat alcohol misuse and its consequences. NIAAA also supports efforts to translate and implement research findings into improved health care for individuals with AUD and with co-occurring conditions, as well as to disseminate research-based information to health care providers, researchers, policy makers, and the public.

METHODOLOGY

NIDA's entire budget is drug-related and scored as a part of the National Drug Control Budget.

The prevention and treatment components of NIAAA's underage drinking research program are scored as a part of the national drug control budget. Underage drinking research is defined as research that focuses on alcohol use by youth (individuals under the legal drinking age of 21), as well as the negative consequences of underage alcohol use (e.g., alcohol-related injuries, impact on adolescent development, including on the developing brain, and risk for AUD).[132] It includes

[128] NIDA ABCD Study description: https://www.drugabuse.gov/related-topics/adolescent-brain/longitudinal-study-adolescent-brain-cognitive-development-abcd-study
[129] NIDA's marijuana research is described here: https://www.drugabuse.gov/drugs-abuse/marijuana/nida-research-marijuana-cannabinoids
[130] NIDA NDEWS System: https://www.drugabuse.gov/related-topics/trends-statistics/national-drug-early-warning-system-ndews
[131] Sacks, J. J., Gonzales, K. R., Bouchery, E. E., Tomedi, L. E., & Brewer, R. D. (2015). 2010 national and state costs of excessive alcohol consumption. *American Journal of Preventive Medicine, 49*(5), e73-e79.
[132] U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking. U.S. Department of Health and Human Services, Office of the Surgeon General, 2007.

basic research, epidemiological studies, behavioral research, screening and intervention studies, and the development and testing of preventive interventions. NIAAA's methodology for developing budget estimates for the *Budget and Performance Summary* is a two-step process. First, NIAAA identifies its underage drinking projects using NIH's automated, electronic text mining system for research, condition, and disease categorization. Once all underage drinking projects are identified through this process, NIAAA conducts a manual review of the project listing and identifies only those projects and amounts that are relevant to prevention and treatment. This is used to generate the NIAAA drug control budget estimate.

BUDGET SUMMARY

The FY 2019 President's Budget request for drug-related activities at NIH is $1,186.4 million ($1,137.4 million for NIDA and $49.0 million for NIAAA), an increase of $52.8 million compared with the FY 2018 Annualized CR level.

NIH-supported research has and will continue to provide the scientific basis for budget policy. For example, NIH continues to explore the many biological, behavioral, and environmental influences on drug addiction vulnerability, which will allow the development of more targeted and effective prevention approaches. Research reveals that universal prevention programs not only reduce drug use, underage drinking, and other risky behaviors that can lead to HIV and other adverse outcomes, but can also promote other positive outcomes, such as strengthening young people's sense of community or "connection" to school—key to reducing substance misuse, violence, and mental health problems.

Another top priority continues to be the development of therapeutic interventions to treat SUDs, including medications, biologics, and non-pharmacological interventions such as transcranial magnetic stimulation or neurofeedback. NIH is now poised to capitalize on a greater understanding of the neurobiology underlying addiction, and of newly identified candidate molecules and brain circuits that show promise as potential targets for the treatment of SUDs. NIH is also exploring ways of improving the dissemination and implementation of evidence-based practices (implementation science) in real world settings to improve the prevention and treatment of SUDs and co-occurring conditions such as HIV, thereby enhancing the public health impact of NIH-supported research.

National Institute on Drug Abuse

FY 2019 Request: $1,137.4 million
($53.9 million above the FY 2018 Annualized CR level)

NIDA's efforts consist of Neuroscience and Behavioral Research; Epidemiology, Services and Prevention Research; Pharmacotherapies and Medical Consequences; Clinical Trials Network; Intramural Research Program (IRP); and Research Management and Support (RMS).

Neuroscience and Behavior Research

The Division of Neuroscience and Behavior (DNB) seeks to expand our understanding of the fundamental neurological, genetic/epigenetic, and behavioral processes that underlie SUDs. Central to this goal are efforts to delineate the multiple neurobiological factors that contribute to

drug use and addiction risk, with particular emphasis on individual differences in vulnerability and drug sensitivity. NIDA is supporting research to develop advanced technologies that improve our ability to study the organization of the living brain from cells to networks. This is helping to elucidate the interactions of complex neural circuits and how they encode reward, craving, compulsive behavior, and related decision making that drive substance use. Ongoing pharmacological research is developing and testing new compounds that target the neurobiological factors that underlie addiction, as is research on the development of novel non-pharmacological strategies such as transcranial magnetic stimulation (TMS), transcranial direct current stimulation (tDCS), deep brain stimulation (DBS), and neurofeedback. NIDA also supports research on the interactions between HIV infection and addiction to understand how this comorbidity influences outcomes for both illnesses. Finally, NIDA is working to support big data science to promote efficient analysis of large, diverse data sets on a scale not previously possible. Collectively, this research will provide new perspectives on the effects of drugs on multiple biological systems and improve our understanding of the basic neural and genetic mechanisms that underlie drug use and addiction, thus guiding the development of novel therapies for treating addiction.

In addition, under the Collaborative Research on Addiction at the NIH (CRAN) initiative, NIDA and NIAAA, along with other components of NIH and the Centers for Disease Control and Prevention, are supporting a longitudinal study to examine the neurodevelopmental consequences of substance use. The Adolescent Brain Cognitive Development (ABCD) study will follow the biological and behavioral development of more than 10,000 children beginning at ages 9-10 through adolescence into early adulthood. Over the course of the next decade, scientists will use advanced brain imaging, interviews, and behavioral testing to determine how childhood experiences interact with each other and with a child's changing biology to affect brain development and—ultimately—social, behavioral, academic, health and other outcomes. Understanding these relationships may help reveal the biological and environmental building blocks that contribute to successful and resilient young adults. This enhanced knowledge also may lead to ways to predict potential developmental problems including mental illness and SUD so that they can be prevented or reversed. Families that volunteer will be part of groundbreaking research that promises to inform future substance use prevention strategies, educational priorities, child development innovations, research priorities, and public health interventions.

Epidemiology, Services, and Prevention Research

NIDA's Division of Epidemiology, Services, and Prevention Research (DESPR) supports integrated approaches to understanding and developing strategies to address the interactions between individuals and environments that contribute to drug use, addiction, and related health problems. The Division supports the annual Monitoring the Future survey, which tracks drug use and related attitudes among adolescent students nationwide, and the National Drug Early Warning System (NDEWS), a surveillance network that monitors emerging trends related to illicit drug use around the country so that rapid, informed, and effective public health responses can be developed and implemented when and where they are needed. DESPR also supports research on integrating prevention and treatment services into healthcare and community systems to reduce the burden of drug problems across the lifespan. For example, ongoing research is exploring SUD treatment in the criminal justice system, including studies on implementation of

medication-assisted treatment (MAT) and seek, test, treat, and retain (STTR) strategies for people with SUDs who are also at risk for HIV. NIDA also funds research into the efficacy of screening brief intervention and referral to treatment (SBIRT) in primary care settings for reducing drug use and SUD.

Program efforts also focus on research to optimize implementation of evidence-based prevention interventions and treatment services in real-world settings. For instance, NIDA is funding researchers to partner with states as they use the State Targeted Response funding from the 21st Century Cures Act to test approaches for expanding access to MAT for opioid use disorder and naloxone for the reversal of overdose.[133] NIDA is also partnering with Appalachian Regional Commission (ARC), the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA), to address the opioid crisis in rural U.S. regions. Nine grants issued over the past year aim to help communities develop comprehensive approaches to prevent and treat substance use disorder, overdose, and HIV.[134] These projects will work with state and local communities to develop best practices that can be implemented by public health systems in the nation's rural regions.

Therapeutic and Medical Consequences

NIDA's Division of Therapeutics and Medical Consequences is focused on developing therapeutics for the treatment of SUDs. Since the pharmaceutical industry has traditionally made limited investment in the development of medications to treat SUDs, the responsibility for supporting their development has rested largely with NIDA. To most effectively leverage NIDA resources, this program encourages the formation of alliances between strategic partners (pharmaceutical and biotechnology companies, as well as academic institutions) with the common goal of advancing medications through the development pipeline toward FDA approval in a timely manner. NIDA conducts research to decrease the risks associated with medications development to make it more feasible for pharmaceutical companies to complete costly phase IIb and III clinical studies. Preclinical studies with this class of molecule indicate they could be effective for treating cannabis use disorders and possibly sleep and anxiety disorders, which are highly common in individuals with substance use disorders. NIDA also invests in research supporting the development of vaccines and monoclonal antibodies for the treatment of SUDs. For example, an ongoing collaboration with Selecta Biosciences is working to develop a novel nicotine vaccine[135] and another with InterveXion Therapeutics is working to develop a monoclonal antibody to treat methamphetamine addiction, both of which are now being evaluated in clinical trials.[136]

[133] More information about the SAMHSA grants is available here: https://www.samhsa.gov/grants/grant-announcements/ti-17-014

[134] More information about this funding is available here: https://www.drugabuse.gov/news-events/news-releases/2017/08/grants-awarded-to-address-opioid-crisis-in-rural-regions

[135] https://projectreporter.nih.gov/project_info_description.cfm?aid=9110936&icde=37966795&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=

[136] https://projectreporter.nih.gov/project_info_description.cfm?aid=9067432&icde=37966812

Clinical Trials Network

The CTN comprises 13 research nodes with 25 principal investigators affiliated with academic medical centers and large health care networks, two research coordinating centers, and more than 240 community anchored treatment programs and/or medical settings in over 40 States plus the District of Columbia and Puerto Rico. The overarching mission of the CTN is to improve the effectiveness of, and accelerate the adoption of, evidence-based SUD prevention and treatment interventions. The network evaluates interventions, implementation strategies, and health system approaches to addressing SUDs and related disorders, such as co-occurring mental health disorders and HIV, in randomized controlled trials (RCTs) and other clinical studies that are conducted in diverse treatment settings and patient populations. Another pilot study is developing and testing a clinical decision support (CDS) tool to treat opioid use disorder for use in electronic health record (EHR) systems. Additional studies are investigating the effectiveness and safety of a combination pharmacotherapy for treatment of methamphetamine use disorder. The CTN has also undertaken a multi-pronged initiative to develop effective methods for using the big healthcare data generated via EHRs to speed the pace and reduce the costs of SUD RCTs and to improve clinical care for SUDs. These efforts include developing a pilot patient registry to follow outcomes for opioid use disorder patients longitudinally; investigating patient- and system-level factors associated with quality measurement across health systems; and exploring methods for capturing health and behavioral data from mobile technology and linking those data to EHRs to facilitate monitoring and longitudinal follow-up of hard-to-reach patient populations.

Intramural Research Program

In addition to funding extramural scientists, NIDA conducts research in high priority areas through our IRP. Intramural research at NIDA focuses on conducting multidisciplinary cutting-edge research to: 1) elucidate the underlying causes of addiction; 2) evaluate the potential of emerging new therapies for SUDs, including pharmacological and non-pharmacological (e.g. psychosocial, biofeedback, brain stimulation technologies); and 3) evaluate the long-term consequences of drug use on health, with particular emphasis on the brain and its development. For example, the IRP is collaborating with pharmaceutical industry partners to study a potential medication that can decrease methamphetamine craving and collaborating with researchers in Italy to study the efficacy of TMS for treatment of cocaine use disorders. In addition, the IRP is working to understand and develop interventions to reverse the impact of deficits in the prefrontal cortex caused by cocaine and heroin use. The IRP is also working to develop clinically useful indicators (biomarkers) of addiction severity or treatment efficacy that will support the development of more effective treatments. IRP scientists are also working to better understand factors that contribute to cravings and relapse. Researchers are developing interventions that might be used in humans to selectively impair harmful addiction memories. The IRP is also planning a large translational study of a novel medication, with promising results in animal studies, to treat opioid use disorder and compare the efficacy with buprenorphine. In addition, IRP scientists are developing a mobile health toolbox to collect data on the daily-life reality of addiction with the goal of developing tools that can predict relapse and deliver help just when a person needs it.

Research Management and Support

RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. Additionally, the functions of RMS encompass strategic planning, coordination, and evaluation of NIDA's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. NIDA currently oversees more than 1,662 research grants and more than 82 research and development contracts. NIDA also provides evidence-based resources and educational materials about SUDs and to raise awareness of the science relating to cutting-edge issues such as opioid overdose prevention, marijuana research, synthetic drug trends and MAT. The RMS portfolio also incorporates education and outreach activities to inform public health policy and practice by ensuring the institute is the primary trusted source for scientific information on drug use and addiction. NIDA is also committed to being at the forefront of training the next generation of innovative researchers by supporting both pre-doctoral and postdoctoral-level scientists interested in drug use and addiction research. NIDA leads the NIH Pain Consortium Centers of Excellence in Pain Education (CoEPEs); these twelve centers work to enhance patient outcomes by improving the education of healthcare professionals about pain and its treatment. The CoEPEs act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing and pharmacy schools to improve how health care professionals are taught about pain and its treatment.

Program Portrait: NIH Public-Private Partnerships to End the Opioid Crisis

Opioid misuse and addiction is an ongoing and rapidly evolving public health crisis. Millions of Americans suffer from opioid use disorder, and millions more suffer from chronic pain. The urgency and scale of this crisis calls for innovative scientific solutions. As part of a government-wide effort to address this crisis, the NIH is planning to supplement existing research efforts with a public-private collaborative research initiative to develop new, safe, and effective strategies to prevent and treat pain, opioid use disorder, and overdose in half the time it currently takes.

In collaboration with the Food and Drug Administration (FDA), NIH is moving forward with establishing public-private partnerships to address the opioid crisis facing the Nation. Three major areas for advancement have been targeted: (1) *safe, more effective, and non-addictive strategies* for chronic pain management to improve pain care and reduce reliance on opioids; (2) *new and innovative opioid addiction treatments* and *overdose reversal interventions* to promote access to treatment and reduce mortality.

To identify the scientific strategies with the greatest potential for solutions to the opioid crisis, NIH brought together innovative experts from government, industry, and academia for a series of three cutting-edge science meetings in 2017. The meetings explored how to accelerate our understanding of the neurological mechanisms of pain; the development of safe, effective, non-addictive pain treatments; and medications development to treat opioid use disorders and for overdose prevention and reversal.

The initiative will focus on a few key areas related to treatment of OUD and overdose prevention and reversal including:

- Developing new treatments for opioid use disorder – such as extended release formulations of existing medications used to treat OUD (methadone, buprenorphine, and naltrexone) and alternative therapeutics including vaccines and antibodies.
- Overdose prevention and reversal – such as stronger formulation of naloxone to reverse overdose from powerful synthetic opioids like fentanyl and carfentanil, and devices to detect and reverse overdose (i.e. naloxone autoinjectors).

National Institute on Alcohol Abuse and Alcoholism

FY 2019 Request: $49.0 million
($1.2 million below the FY 2018 Annualized CR level)

Alcohol screening and brief intervention in primary care has been recognized as a leading preventive service for reducing harmful alcohol use in adults, and a growing body of evidence demonstrates its effectiveness in preventing and reducing alcohol misuse in youth. Yet research indicates that adolescents are not routinely asked about drinking when they interface with the health care system. NIAAA supports research on the implementation of alcohol screening and brief intervention among youth and young adult populations, including those disproportionally affected by alcohol misuse. NIAAA also supports efforts to encourage the adoption of alcohol screening and brief intervention in healthcare and other appropriate settings.

Reducing alcohol misuse among college students, many of whom are underage, continues to be a high priority for NIAAA. Binge drinking (drinking 4 or more drinks for women and 5 or more drinks for men, in approximately two hours) and extreme binge drinking (drinking at levels two or more times the binge drinking threshold) are especially pervasive among college students; these practices are particularly troubling as they increase risks for alcohol-related blackouts, alcohol overdoses, sexual assault, sexually transmitted diseases, AUD, and other detrimental consequences. To assist college and university officials in addressing alcohol misuse on their campuses, NIAAA developed the College Alcohol Intervention Matrix (*CollegeAIM*), a user-

friendly guide and website that rates nearly 60 evidence-based alcohol interventions in terms of effectiveness, costs, and other factors. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address harmful and underage student drinking.

NIAAA's investment in underage drinking research also includes studies to understand how alcohol affects the developing brain. For example, NIAAA supports the National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA), an accelerated longitudinal study of more than 800 youth ages 12-21 to assess the vulnerability of the adolescent brain to alcohol exposure. NCANDA has laid the methodological foundation for the NIH Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of brain development and child health in the United States. Over 10,000 9- to 10-year olds are being invited to participate in the ABCD study, which will use brain imaging and neuropsychological and behavioral assessments to track the biological and behavioral development of youth before and after they start to use alcohol and/or other addictive substances. These two studies are expected to illuminate the neurobiological, cognitive, and behavioral precursors of alcohol and other drug misuse and ultimately inform preventive and treatment strategies. Complementing NCANDA and ABCD, NIAAA's Neurobiology of Adolescent Drinking in Adulthood Initiative is enabling investigators to examine, in animal models, the molecular, cellular, and circuit-level mechanisms by which adolescent drinking affects brain structure and function in the short- and long-term and how the changes observed during this critical period persist into adulthood.

PERFORMANCE

Information regarding the performance of the drug control efforts of NIH is based on agency GPRMA documents and other information that measures the agency's contribution to the *National Drug Control Strategy*.[137] NIH's performance measures are representative of Institute contributions to NIH's priorities regarding specific scientific opportunities, identified public health needs, and Presidential priorities. Such measures, reflecting NIH's broad and balanced research portfolio, are not Institute-specific. Many measures are trans-NIH, encompassing lead and contributing institutes and centers. This approach reflects NIH's commitment to supporting the best possible research and coordination of research efforts across its institutes and centers. All performance results reported were achieved in FY 2017.

NIDA and NIAAA lead and support a number of trans-NIH measures in the Scientific Research Outcome (SRO) functional area. While NIDA and NIAAA engage in many research and related activities, three measures best reflect the breadth of their efforts in the prevention and treatment of substance use, misuse, addiction, and its consequences.

One of these measures, led by NIAAA and supported by NIDA, is SRO-5.15: "By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations." This measure, which began in FY 2014, is indicative of NIDA's and NIAAA's efforts to support research to foster the development and implementation of prevention-based strategies for reducing substance misuse and addiction. NIH's prevention portfolio encompasses

[137] https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs

a broad range of research on the efficacy and cost effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to misuse or addiction—and how these programs can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of substance use or SUDs.

NIDA created and leads SRO-7.3: "By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery and adherence for substance use disorders and related health consequences." This measure began in FY 2014 and has been updated to reflect NIDA's current focus in exploring and leveraging technological advances to improve the efficiency and quality of health care delivery for SUDs.

In addition to developing and leading SRO-5.15, NIAAA contributes to SRO-8.7: "By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems." This measure, which began in FY 2008 and has been updated over time, reflects NIH's ongoing commitment to supporting research on the implementation of preventive and treatment interventions and improving the translation of research into practice.

National Institute on Drug Abuse		
Selected Measures of Performance	**FY 2017 Target**	**FY 2017 Achieved**
» Scientific Research Outcome-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.	Assess the efficacy or effectiveness of at least two indicated/selective interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations.	The efficacy or effectiveness of three interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations was tested.
» Scientific Research Outcome-7.3: By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery and adherence for substance use disorders and related health consequences.	Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings	Research testing the feasibility and efficacy of 3 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including research in 2 different care delivery settings.

Prevention – Scientific Research Outcome-5.15

The 2017 target for SRO-5.15 was met. The efficacy or effectiveness of three interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations was tested. Prevention of the initiation of drug use and escalation to addiction continues to be one of NIDA's primary strategic goals (see NIDA's Strategic Plan). NIDA continues to fund a robust prevention portfolio that builds upon solid epidemiological findings and insights from genetics and neuroscience research, applying this knowledge to develop effective strategies to prevent initiation of drug use and escalation of use to addiction among youth.

Substance use problems are highly prevalent among youth in foster care. Such problems in adolescence have long-lasting implications for subsequent adjustment throughout adulthood and even across generations. Although several programs have demonstrated positive results in reducing substance use in at-risk youth, few studies have systemically examined how such programs work for foster youth and whether they are effective for both genders. A NIDA-funded study examined the efficacy of KEEP SAFE, a family-based and skill-focused program designed to prevent substance use and other related health risking behaviors among youth in foster care. The authors hypothesized that improving the caregiver-youth relationship would lead to later reductions in youths' involvement with deviant peers, which subsequently would lead to less substance use, and that this mechanism would work comparably for both genders. 259 youth (105 boys and 154 girls, age range = 11-17) in foster care and their caregivers participated in a randomized controlled trial and were followed for 18 months post-baseline. Results indicated that the intervention significantly reduced substance use in foster youth at 18 months post-baseline and that the intervention influenced substance use through two processes: youths' improved quality of relationships with caregivers at 6 months post-baseline and fewer associations with deviant peers at 12 months post-baseline. This suggests that these two processes may be fruitful immediate targets in substance use prevention programs for foster youth. The authors also found little gender differences in the effects of the intervention, suggesting KEEP SAFE may be effective for both genders in foster care.[138]

Another study examined an intervention for disruptive behavior. Prior research suggests that under some conditions, interventions that aggregate high-risk youth may be ineffective, or at worst, may even exacerbate risk. However, group formats have considerable practical utility for delivery of preventive interventions, and thus it is crucial to understand child and therapist factors that predict which children who demonstrate increased aggressive behaviors benefit from group intervention and which do not. To address these questions, researchers video-recorded group Coping Power intervention sessions (938 sessions) and analyzed both therapists' and children's behaviors in the sessions that predicted changes in teacher and parent reports of problem behavior at one-year follow up. The sample included 180 high-risk children (69% male) who received intervention in 30 separate Coping Power intervention groups (six children assigned per group). The evidence-based Coping Power prevention program consists of 32 sessions delivered during the 4th and 5th grade years. The behavioral coding system used in the analyses included two clusters of behaviors for children (positive; negative) and two for the primary therapists (group management; clinical skills). The analyses suggest that high levels of children's negative behaviors usually predicted increases in teacher and parent rated aggressive and conduct problem behaviors during the follow-up period. Therapist use of clinical skills (e.g.,

[138] https://www.ncbi.nlm.nih.gov/pubmed/28523585?dopt=Summary

warmth, nonreactive) predicted less increase in children's teacher-rated conduct problems. These findings suggest the importance of clinical training in the effective delivery of evidence-based practices, particularly when working with high-risk youth in groups.[139]

Treatment—Scientific Research Outcome-7.3

The FY 2017 target for SRO-7.3 was met. NIDA funds a broad portfolio of research on the potential of HIT tools to improve health care delivery and health outcomes related to SUDs. In FY 2017, research testing the feasibility and efficacy of three technology-based strategies to improve substance use disorder treatments and adherence was conducted, including research in two different care delivery settings. Research findings leveraging HIT to address NIDA research priority areas include:

Approval of the ReSET mobile application for SUD Treatment – A major development in mHealth in 2017 was the FDA approval of the reSET mobile app. ReSET – previously known as the Therapeutic Education System (TES) – is a mobile app that is approved for use in outpatient treatment for substance use disorders related to cocaine, other stimulants, cannabis, and alcohol. The mobile app delivers cognitive behavioral therapy, which aims to change behavior by changing an individual's cognitive processes. The app rewards users for continuing with therapy with various incentives, which can improve adherence. When adopted widely, evidence-based advances in digital therapeutics will broaden the spectrum of substance use disorder treatment options, particularly in rural and underserved communities.

This treatment tool was created through NIDA's behavior-therapy development program and validated through a major nationwide multi-site trial conducted in the NIDA Clinical Trials Network (CTN) program. In the clinical trial, the 12-week abstinence rate from drugs and alcohol for users of the app, 40 percent, was more than twice the abstinence rate for individuals who received standard care (18 percent). Pear Therapeutics, Inc. acquired the right to rebrand TES as reSET and used the CTN trial results as pivotal evidence to gain approval from the Food and Drug Administration as the first prescription digital therapeutic to improve clinical outcomes in a disease. The reSET app is not approved for treating opioid use disorder, but with a Small Business Innovation Research grant from NIDA, a new version of the app called reSET-O is currently being developed.

Implementation of Evidence-Based HIT Tools – A recent study by NIDA explored strategies to support the implementation of a combination of evidence-based technologies in the primary care setting – including both reSET and a mobile application that provides SUD recovery support (ACHESS). When these combined technologies, branded Seva, were pilot tested using proven implementation strategies (informed by quality improvement), researchers found that they supported patients' sustained, positive use of Seva.[140]

---

[139] Lochman, John E; Dishion, Thomas J; Boxmeyer, Caroline L; Powell, Nicole P; Qu, Lixin. J Abnorm Child Psychol. 2017; Jan. 5. https://www.ncbi.nlm.nih.gov/pubmed/28058517

[140] Mares, M.L., et al., *Implementing an mHealth system for substance use disorders in primary care: a mixed methods study of clinicians' initial expectations and first year experiences.* BMC Med Inform DECIS Mac, 2016. 16:126.

My Mobile Advice Program (MyMAP) – Other NIDA-funded research is exploring a mobile optimized website accessed via smartphone to improve medication adherence and provide tailored advice to manage symptoms to help users quit smoking. An initial pilot study in a large health system determined that MyMAP is a feasible, acceptable, and potentially effective means to support varenicline use to quit smoking.[141] Future studies are planned to determine the efficacy of this intervention for smoking cessation.

National Institute on Alcohol Abuse and Alcoholism		
Selected Measures of Performance	**FY 2017 Target**	**FY 2017 Achieved**
» Scientific Research Outcome-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.	Continue to promote the *College Alcohol Intervention Matrix* (*CollegeAIM*).	NIAAA promoted and disseminated *CollegeAIM* and initiated efforts to update *CollegeAIM* to reflect the latest evidence-based alcohol interventions.
» Scientific Research Outcome-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems.	Continue to support studies evaluating screening and brief alcohol interventions in underage or young adult populations.	NIAAA supported a multi-site, school-based study to evaluate NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*, and another study to evaluate a brief alcohol intervention for adolescents hospitalized for a suicide plan or attempt who report co-occurring alcohol use.

Prevention – Scientific Research Outcome-5.15

The FY 2017 target for SRO-5.15 was met.

In September 2015, NIAAA released the *College Alcohol Intervention Matrix* (*CollegeAIM*) guide and website, important new resources to address harmful and underage student drinking.

[141] McClure, J.B., et al., *Evaluating an Adaptive and Interactive mHealth Smoking Cessation and Medication Adherence Program: A Randomized Pilot Feasibility Study.* JMIR Mhealth Uhealth, 2016. 4(3): p. e94.

Developed with input from researchers and college staff, *CollegeAIM* is an easy-to-use and comprehensive tool to help colleges and universities identify evidence-based alcohol interventions. *CollegeAIM* rates nearly 60 alcohol interventions in terms of effectiveness, costs, and other factors, and presents the information in a user-friendly and accessible way. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address student drinking.

With the release of *CollegeAIM*, NIAAA embarked on a multifaceted promotion and dissemination effort to introduce college and university officials to this new resource. NIAAA senior staff and selected researchers from the *CollegeAIM* development team made numerous presentations, including at national higher education conferences and regional workshops, to demonstrate how to use the guide and website. For example, in FY 2017, NIH staff presented *CollegeAIM* at a special workshop of the New Jersey Higher Education Consortium on Alcohol and Other Drug Prevention at Rutgers University and at the Substance Abuse and Mental Health Services Administration Prevention Day, which was held at the Community Anti-Drug Coalitions of America (CADCA) National Leadership Forum. NIAAA also continued to promote *CollegeAIM* through its communication outlets, including Twitter and the NIAAA website. Since its launch in 2015, the *CollegeAIM* website has received over 47,000 visitors (16,146 in FY 2017), the digital *CollegeAIM* booklet was downloaded more than 8,000 times (2,275 in FY 2017), and NIAAA distributed more than 14,000 print copies of the booklet (2,824 in FY 2017). NIAAA is also in the process of updating *CollegeAIM* to ensure that it reflects the latest research on evidence-based alcohol interventions for college-age individuals. The Institute reconvened the original group of developers to begin working on the updated *CollegeAIM*, which is scheduled to be completed in 2018.

Treatment – Scientific Research Outcome-8.7

The FY 2017 target for SRO-8.7 was met. NIAAA continued to support studies evaluating screening and brief alcohol interventions in underage populations. In one ongoing study, researchers are performing a multisite, school-based evaluation of *NIAAA's Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*. The evaluation is designed to assess the extent to which the questions in NIAAA's youth screening guide predict current and subsequent alcohol use, alcohol-related problems, and AUD, as well as illicit drug use, sexual risk behavior, and problem behaviors (e.g., aggression, rule breaking), in a diverse sample of 6th, 8th, and 10th graders attending public schools in Miami-Dade County, Florida and the Maryland suburbs of Washington, D.C. The study will also examine the extent to which the validity of the screening tool varies based on contextual factors, such as the density of alcohol outlets near participants' homes and schools, neighborhood socioeconomic factors, family characteristics, as well as the gender and ethnicity of participants.

NIAAA is also supporting the development of a brief alcohol intervention, iASIST (integrated Alcohol and Suicide Intervention for Suicidal Teens), for adolescents hospitalized for a suicide plan or attempt who report co-occurring alcohol use. Alcohol can play a significant role in suicidal ideation and attempts as disinhibition caused by alcohol can increase the likelihood of acting on suicidal thoughts. The iASIST emphasizes the assessment and initial treatment of alcohol use in adolescent inpatient psychiatric settings and involves three components: 1) an

individual intervention with the adolescent using motivational enhancement techniques to explore alcohol use as a risk factor for continued suicide-related thoughts and behaviors, build his or her motivation to reduce or stop drinking, and create a complementary change plan; 2) a family intervention to facilitate a discussion between the adolescent and parent about the change plan and strengthen the adolescent's commitment to the plan and the parent's ability to support the adolescent in their plan; and 3) a post-discharge mobile health "booster" intervention to strengthen the child's commitment to the plan and the parent's ability to support him or her. The investigators are planning to conduct a randomized trial with 50 adolescents and their parents to test the feasibility and acceptability of iASIST, as well as alcohol- and suicide-related outcomes among adolescents three months after discharge from the hospital.