On behalf of the National Institutes of Health (NIH), I am transmitting the Congressional Justification of the NIH request for the fiscal year (FY) 2020 budget. This request for a $34.4 billion total program level seeks to recognize the need for fiscal austerity, while advancing NIH's mission to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. Importantly, this budget provides the support to transform inspiration into innovation by providing new insights into how biological systems function and how that understanding can be brought forward to catalyze medical advances.

The NIH FY 2020 budget will ensure that NIH continues to prioritize transformational tools and technologies, clinical breakthroughs, and pushing the next frontier of biomedical research. NIH-funded researchers are at the leading edge of creating faster, more accurate diagnostics and hope for treatments for currently intractable diseases and conditions. Gene-editing, 3D tissue printing, single cell biology, and neurotechnologies are just a few areas of science in which innovative discoveries are underscoring the promise of biomedical research.

In order to advance the NIH mission, the FY 2020 budget prioritizes the continued support of basic research and its translation into clinical practice. By unlocking the secrets of how living systems function, NIH can then apply that knowledge to the development of novel treatments and cures. This type of research provides vital clues for important topics, such as how genetic risk factors contribute to Alzheimer's disease and how the microbiome interacts with the immune system in the development of cancer. Basic research also plays a substantial role in the continued development of a lifesaving universal influenza vaccine. Lastly, fundamental research serves as the foundation for the NIH Helping to End Addiction Long-term (HEAL) Initiative, which aims to curb the opioid epidemic and provide non-addictive alternatives for individuals who suffer from chronic pain.

Finally, the FY 2020 budget allows NIH to continue to catalyze the next generation of biomedical research advances. NIH has the ability, more than ever before, to advance scientific discovery by harnessing the incredible power that large biomedical datasets hold. An example of this is the historic NIH *All of Us* Research Program, which aims to capitalize on recent advances in genomics, environmental science, and big data analytics to develop precision medicine treatment options for one million or more patients across all population groups in this country. The Next Generation Research Initiative also provides NIH with an opportunity to address the challenges of tomorrow's scientific workforce. As such, NIH plans to prioritize meritorious applications from early stage investigators and develop evidenced-based strategies to support mission-specific workforce issues.

The FY 2020 budget provides resources for NIH, and the researchers around the country it supports, to continue to develop, maintain, and renew scientific resources that will enhance our ability to prevent and ultimately cure disease. I look forward to discussing the FY 2020 budget request.

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

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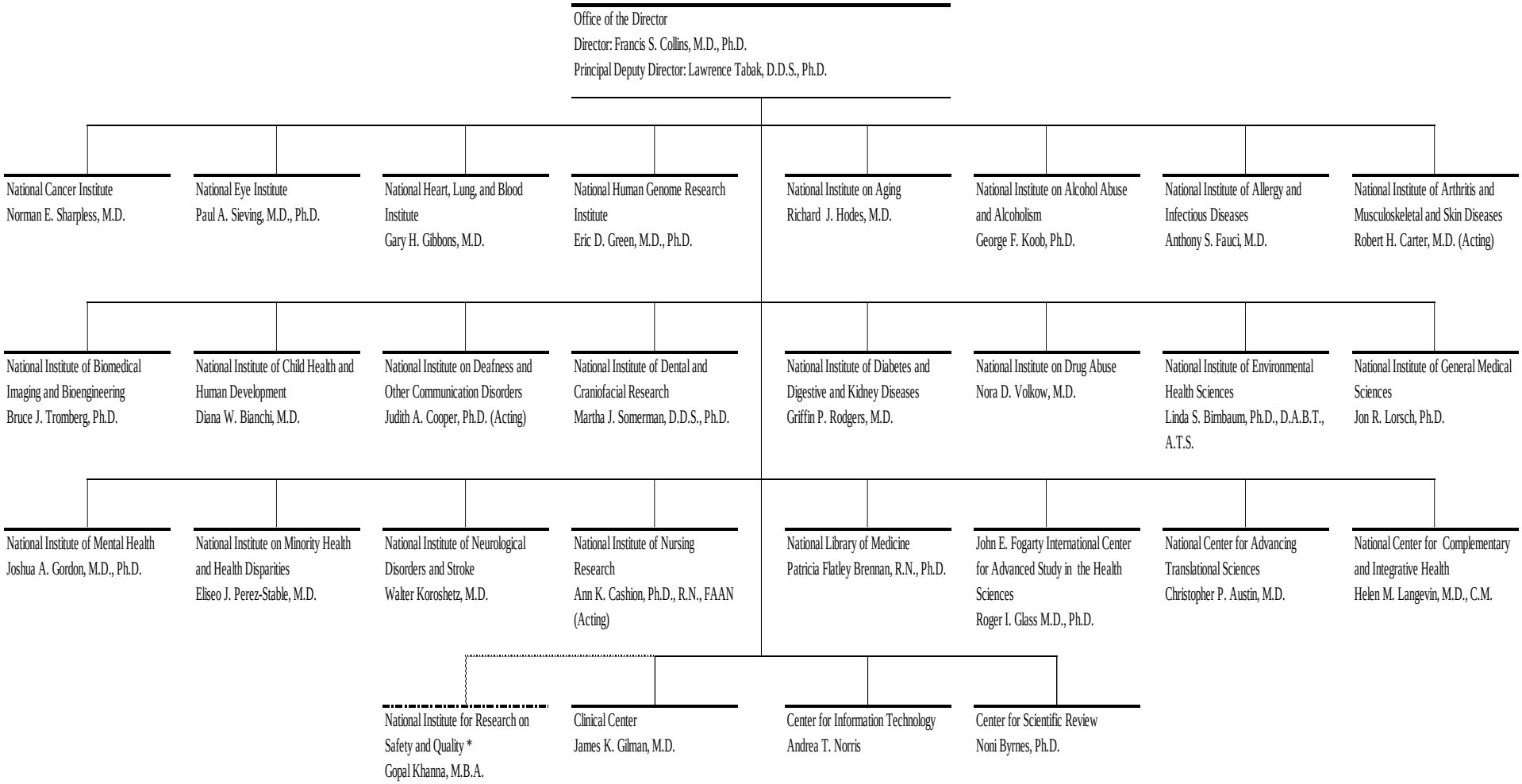

* The FY 2020 Budget proposes to consolidate the Agency for Healthcare Research and Quality into NIH as the National Institute for Research on Safety and Quality

Introduction and Mission

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

As the Nation's premier biomedical research agency, NIH plays a critical role in advancing basic and clinical biomedical research to improve human health and pave the foundation for ensuring the Nation's economic well-being. NIH also works to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease and disability. The biomedical research enterprise depends upon not only NIH's support of cutting-edge science and technology but also its wise investment of tax dollars. Through careful stewardship of public resources in pursuit of its mission, NIH strives to enhance the lives of all Americans.

Overview of Budget Request

Introduction

For FY 2020, the National Institutes of Health (NIH) requests a total program level of $34.4 billion, which is $4.9 billion less than the FY 2019 Enacted level. This budget reflects the need for fiscal austerity, but will still fuel NIH's mission to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. As a leader of the biomedical research enterprise, NIH will leverage 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. Investing in new technology will push the boundaries of what is possible in imaging, device design, health monitoring, bioinformatics, and countless other areas. Today, 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 possibilities for groundbreaking approaches to better human health never have been greater.

The request of $34.4 billion incorporates investments to address the opioid epidemic, support development of a universal flu vaccine, implement the Strategic Plan for Data Science, and support cutting-edge intramural research by addressing the significant backlog of repair and improvements across NIH facilities. NIH's FY 2020 research investments will be guided by the NIH-Wide Strategic Plan for FY 2016-2020.[1]

The request proposes to move the highest priority activities of the Agency for Healthcare Research and Quality (AHRQ) into NIH as a new National Institute for Research on Safety and Quality (NIRSQ). The creation of NIRSQ, which was included in the Administration's June 2018 Government Reform Plan, would improve the coordination of research within the Department of Health and Human Services (HHS), with a continued emphasis on NIRSQ's integral role in support of the Secretary's priority to transfer the Nation's health care system to one that pays for value.

The request maintains funding for the Buildings & Facilities (B&F) account at $200 million, consistent with the FY 2019 Enacted level, and part of NIH's long-term effort to stem the deterioration of its facilities. NIH's Backlog of Maintenance & Repair is over $1.8 billion and is growing at an accelerating rate. An independent review of the facility needs of NIH's main campus will be completed this winter by the National Academies of Science, Engineering and Medicine.

From Inspiration to Innovation

NIH funds innovative research, supporting the best ideas submitted by talented researchers across the nation. Through these investments, NIH expands the frontiers of biomedical

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

knowledge, and brings hope of delivering new measures for prevention, treatments, and cures for our most challenging diseases and conditions. In FY 2020, NIH will focus on:

1. Developing Transformative Tools and Technology
   Advanced tools and techniques enable the development of faster and more accurate diagnostics, screening instruments, and treatment methods.

2. From Basic Science to Clinical Breakthroughs
   Fundamental science discoveries yield enormous long-term returns, providing the foundation for scientific advancement that leads to the clinical applications that ultimately help patients.

3. Exploring the Next Frontier in Biomedical Research
   Through ambitious research endeavors, harnessing the power of big data and revolutionary applications, and cultivation of the best and brightest biomedical research workforce, NIH will invest resources to ensure that the U.S. remains on the cutting edge of biomedical science.

Strategic investments in these areas will enable NIH and the U.S. to remain the world leader in biomedical research and to improve the health of all Americans.

Developing Transformative Tools and Technology

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

Research That Can Revolutionize the Practice of Medicine

Rapid, early, and accurate identification of disease improves the chances of treatment success and ultimately is key to saving lives. Recognizing that technology is key to delivering improved medical outcomes, NIH supports a diverse portfolio of research focused on developing cutting-edge diagnostic technologies. Examples include a miniature device that simultaneously detects and distinguishes between various tick-borne diseases, and another that captures mutated genetic material and proteins shed by brain tumors into the bloodstream for developing personalized treatments – both devices using just a single drop of blood. Technologies for non-invasively imaging the human body are also advancing rapidly, including a light-based, 15-second scan that could replace painful mammograms, and using screen-printing technology (like that used to print a logo on a T-shirt) to produce flexible MRI coils, custom-fit to patients, for faster imaging and better resolution. Other advances in the area of cancer research include the development of

fluorescent nanoparticles that can be used to identify and track breast cancer as it spreads through the body.

NIH-funded technological advances are pushing the boundaries of disease treatment and prevention. For example, an injectable hydrogel bandage is currently being developed that can stop potentially fatal internal bleeding and save lives in emergencies such as penetrating shrapnel wounds on the battlefield. Another team of engineers is developing a smart bandage designed to actively monitor the condition of chronic wounds and deliver appropriate drug treatments to improve the chances of healing. In addition, our ability to create complex artificial tissues, through technologies like 3D tissue printing, continues to progress, leading us closer to their use in transplants and other surgeries. NIH also invests in mobile health (mHealth) technology by arming smart devices with built-in sensors, making lifesaving healthcare more accessible. One application of mHealth that was designed by NIH researchers includes a reusable glucose meter system built into a smartphone case, providing people with diabetes with a mobile option for monitoring their glucose levels.

Other feats of biomedical engineering that have yielded advances include the use of painless microneedles for drug or vaccine delivery, which is now moving from concept to the clinic. NIH funded the development of a skin patch containing dissolving microneedles, and initial studies indicate that it will work as effectively as a regular shot in delivering the influenza vaccine. This influenza patch has the potential to eliminate the discomfort of an injection in addition to the benefits of being more convenient and less expensive than visiting a health care facility. Additional applications for microneedles are being piloted, including a pain-free skin patch that both measures and responds to sugar levels that could help manage type 2 diabetes.

Developing Gene Editing Technologies

Gene editing technologies equip researchers with tools for a broad range of research applications, including investigating gene function, developing better animal models to study specific human diseases, and diagnosing and fighting infectious diseases. Furthermore, through the ability to introduce, disrupt, or correct genes, these technologies show great promise for advancing therapies to treat genetic or acquired diseases including HIV, cancer, and genetic disorders such as sickle cell disease, muscular dystrophy, and hemophilia. One specific gene editing technique, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), is being studied to correct or compensate for the mutations that cause sickle cell disease, by editing the genome of stem cells derived from the bone marrow of an affected person. (It is important to point out that these gene editing therapeutic strategies will be applied to the appropriate cells of an affected child or adult – NOT to human embryos.) While these technologies hold tremendous potential, additional research is needed to improve the efficacy, specificity, and safety of gene editing systems. The ultimate goal is to develop approaches that could successfully treat any of the thousands of genetic disorders where the DNA misspelling is already known. In 2018, the NIH Common Fund launched a program called Somatic Cell Genome Editing[2] with these challenges

[2] https://commonfund.nih.gov/editing

in mind, and the research tools, assays, and delivery systems developed through this program will be made widely available to the research community. Ultimately, investment in this program will dramatically accelerate the development of these gene editing technologies and potentially reduce the time and cost required to develop new therapies for millions of patients with rare genetic disorders.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

Launched in 2013, the NIH Brain Research through Advancing Innovative Neurotechnologies[3] (BRAIN) Initiative seeks to develop and apply technologies that will revolutionize our understanding of the human brain in health and disease. For example, BRAIN-funded investigators have developed a breakthrough method for identifying the gene expression patterns of different subtypes of brain cells that can identify what makes different types of cells unique. This approach identified new brain cell subtypes in the frontal cortex of the brain, thus expanding our understanding of the different neurons that contribute to brain cell diversity. The BRAIN Initiative also supports research on neurotechnologies with clinical applications, including deep brain stimulation (DBS). A team of BRAIN researchers successfully demonstrated the use of adaptive DBS in patients with Parkinson's disease using a fully implanted device that both senses brain activity and delivers electrical stimulation, allowing for fine-tuned stimulation in real-time with neuronal feedback, maintaining therapeutic efficacy and minimizing side effects. Finally, based on the successes of technologies emerging from the BRAIN Initiative, researchers are mapping functional circuits across the brain, paving the way for an unprecedented level of understanding of the human brain and improving human health. As the NIH BRAIN Initiative approaches the halfway point of its 10-year vision, NIH has launched an outreach and planning process for BRAIN 2.0, in order to ensure that the original strategic plan – *BRAIN 2025*[4] – keeps pace with the scientific and technological advances spurred by the Initiative.

From Basic Science to Clinical Breakthroughs

In pursuit of its mission, NIH invests more than half of its research budget in basic biomedical research, which provides the key for unlocking the secrets of how living systems function. With this substantial level of support, NIH lays the groundwork for discoveries that will ultimately lead to novel interventions, treatments, and cures. In fact, a recent study found that NIH funding contributed to published research associated with every single one of the 210 new drugs approved by the Food and Drug Administration (FDA) from 2010 through 2016. More than 90 percent of this NIH funding was for basic research.[5] Basic research results are driving improved diagnostic and treatment approaches for key diseases and conditions such as cancer, opioid addiction, and influenza, and NIH is working to ensure that clinical trials to test new approaches for a variety of diseases are available to everyone, including medically underserved and rural populations.

[3] https://www.braininitiative.nih.gov/
[4] https://www.braininitiative.nih.gov/2025/index.htm
[5] Galkina Cleary E. Contribution of NIH funding to new drug approvals 2010-2016. Proc Natl Acad Sci USA. 2018 115(10):2329-2334. PMID: 29440428.

Changing the Course of Childhood Cancer

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

In FY 2020, NIH will invest an additional $50 million above the FY 2019 level to accelerate research on pediatric cancer. This investment reflects the first year of a new 10-year, $500 million initiative launched by the President in the 2019 State of the Union address. The initiative will expand upon current progress to enhance drug discovery and clinical trials, seek to understand the biology of all pediatric cancers, and create a national data resource. This initiative will support research to develop new, more effective, and safer treatments for childhood cancers, and will complement ongoing research within the National Cancer Institute (NCI) and the Cancer Moonshot. Through this initiative, NCI will also aggregate data from pediatric cancer cases and coordinate with others that maintain data sets to create a comprehensive, shared resource to support childhood cancer in all its forms. This knowledge, spanning from basic biology to clinical outcomes, can provide a path for changing the course of cancer in all children.

Understanding and Harnessing the Immune System

Basic research continues to deliver valuable insights into the relationship between the immune system and a plethora of complex conditions, which in turn help inform the development of new treatments. For example, recent research indicates that the microbiome, comprising bacteria and other microbes that live in or on the body, likely interacts with the immune system to influence health and susceptibility to diseases like obesity, diabetes, and autoimmune disorders. Researchers also are investigating how the microbiome may interact with the immune system to influence the development of cancer or Alzheimer's disease. Findings from these and similar studies could lead to new therapies that interrupt or reverse disease progression.

The rapidly advancing field of cancer immunotherapy builds on NIH's long-term investment in basic research on the immune system. Immunotherapies reflect a new tool in our fight against cancer, as they focus on harnessing the body's own immune system to fight off the disease. Investment in cancer immunotherapy, including resources from the Beau Biden Cancer Moonshot,[6] will help accelerate these efforts. Current research involving one type of immunotherapy, called adoptive cell transfer (ACT)—in which tumor-killing immune cells are harvested and grown to large numbers in the laboratory, then infused back into the patient—shows the potential to target diverse tumors based on their DNA mutations rather than the specific type of cancer. The use of ACT in an ongoing Phase 2 clinical trial has yielded positive results for potential treatment of a variety of previously incurable metastatic solid tumors, including breast, liver, and colorectal cancer. Other immunotherapy treatments are in earlier

[6] https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

preclinical stages of development. For example, one exciting approach involves tumor vaccination, in which treatments are injected directly into a tumor and then not only lead to destruction of that tumor, but also other tumors of the same type throughout the body. Because a tumor vaccine does not depend on knowing the unique characteristics of a tumor, the technique may potentially be applied to many forms of cancer.

NIH is also working to identify which patients are most likely to respond to immunotherapy treatments. Researchers recently found a biomarker that may identify patients who will benefit from a type of ACT immunotherapy called CAR T-cell therapy. If confirmed in larger studies, the biomarker could be used to guide treatment options. Recognizing the importance of identifying and validating biomarkers to advance new immunotherapy treatments, NIH launched the Partnership for Accelerating Cancer Therapies (PACT) in October 2017 as part of the Cancer Moonshot. PACT is a five-year public-private research collaboration between NIH and 12 biopharmaceutical companies, with the aim of developing biomarkers that can predict responses and advance cancer immunotherapy.

Helping to End Addiction Long-term (HEAL) Initiative

More than 2 million Americans have an opioid use disorder (OUD), and millions more misuse opioids by taking opioid medications longer or in higher doses than prescribed. To help bring scientific solutions to this crisis, and to provide safe and effective options for the more than 25 million Americans who suffer from daily chronic pain, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative.[7] Introduced in April 2018, and funded in the FY 2018 Congressional appropriation, this initiative will direct an additional $500 million annually towards research across NIH aimed at improving treatments for opioid misuse and addiction, and enhancing pain management strategies. Through HEAL, NIH is building on basic science discoveries to accelerate the development of novel medications and devices to treat all aspects of the opioid addiction cycle, including chronic use, withdrawal symptoms, craving, relapse, and overdose. In addition, studies on integrating prevention and treatment approaches into practice, including the HEALing Communities study,[8] will inform understanding of how the implementation of promising and evidence-based strategies and treatments can decrease OUD and overdose deaths. The FY 2020 request supports a total of $1.3 billion for opioids and pain research across NIH, including $500 million for the HEAL Initiative.

Long-lasting solutions to the opioid crisis will require additional pharmacological and non-pharmacological options for pain management -- to protect patients from the risk of opioids. NIH is working with experts from the biopharmaceutical industry and federal partners to develop a data sharing collaborative, new biomarkers for pain, and a clinical trials network for testing new pain therapies, as well as to enhance clinical practice for pain management. Launched in FY 2019, the Acute to Chronic Pain Signatures program from the NIH Common Fund will collect neuroimaging, -omics (high-throughput biomedical experiments), sensory testing, and

[7] https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative
[8] https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative/heal-initiative-research-plan

psychosocial data from patients with acute pain associated with a surgical procedure or acute musculoskeletal trauma. Through this study, NIH will seek to predict which patients will develop long-lasting chronic pain, and guide precision acute pain management approaches to seek to block that transition.

To improve both short- and long-term developmental outcomes for infants with Neonatal Abstinence Syndrome (NAS)/Neonatal Opioid Withdrawal syndrome (NOWs), HEAL will determine the best approaches to identify and treat newborns exposed to opioids by expanding the Advancing Clinical Trials in Neonatal Opioid Withdrawal syndrome (ACT NOW) pilot studies. ACT NOW will assess NOWs prevalence and the variation in current approaches to clinical management, as well as develop common protocols for conducting large-scale studies across the country, particularly in areas hardest hit by the opioid epidemic. Results from the study will be used to conduct clinical trials to determine best clinical practices, including assessment of drug-free treatment approaches and currently used medications.

In the current fiscal year, NIH will rapidly expand on these efforts with a variety of new projects in the HEAL Initiative, such as research on prevention approaches for adolescents and young adults at risk for addiction, and long-term evaluation of infants born dependent on opioids. Other projects will focus on treatment of OUD, including optimal duration of medications and the study of behavioral interventions in addition to medication. Non-pharmacological strategies for pain management and novel non-addictive pain medications also will be explored through clinical studies of different pain conditions and the collection of real-world data. HEAL Initiative research projects will be conducted in partnership with colleagues across government, the private sector, and in communities nationwide, ensuring that all hands are on deck to respond to the crisis of pain and addiction.

Working Towards a Universal Influenza Vaccine

NIH-supported research is helping advance understanding of how flu (influenza) strains emerge, evolve, infect, and cause disease. These research results are informing design of new and improved therapies, diagnostics, and vaccines, including a "universal" influenza vaccine. Circulating and emerging influenza viruses pose an ever-present public health threat and place substantial health and economic burdens on the U.S. and the world. Annual influenza vaccination remains the most effective way to reduce influenza morbidity and mortality. However, traditional vaccine development strategy relies heavily on predicting which strains will be in circulation each year, which is a suboptimal approach when dealing with constantly evolving and newly emerging virus strains. NIH is investing in ways to make seasonal flu vaccines longer lasting and more effective in order to better protect the population. At the same time, to move toward durable protection against multiple influenza strains—including those that may pose a pandemic threat—NIH is making parallel efforts in rational design of a universal influenza vaccine.

In FY 2018, NIH unveiled a strategic plan to guide future basic, translational, and clinical research investments in areas essential to creating a safe and effective universal influenza

vaccine.[9] Along this path, NIH is funding basic research to understand the transmission, natural history, and disease process of influenza, in addition to characterizing how immunity occurs and how to tailor vaccination responses to both achieve immunity and extend the duration of protection. By applying cutting-edge vaccine technology, NIH is modernizing vaccine development approaches in pursuit of its goal to design a broadly protective flu vaccine for all ages. Several universal flu vaccine strategies are already being tested in NIH-supported clinical trials.

Spurring New Models for Drug Discovery

Significant resources are invested in developing new drugs, yet 90 percent of candidate drugs are later found to be either unsafe or ineffective in humans. Discovering which drugs are ineffective or toxic earlier in the drug development process would save time and money. Propelled by basic and preclinical translational research, and in collaboration with the Defense Advanced Research Projects Agency (DARPA) and the FDA, the Tissue Chip for Drug Screening Program[10] is among the NIH-supported initiatives focused on developing new tools and resources to facilitate this process. Tissue chips are engineered 3D platforms that are lined with living human cells and designed to replicate the complex biological functions of a specific human organ, such as the lung, liver, kidney, or heart. The ultimate goal of the program is to accelerate the translation of basic discoveries into the clinic by allowing researchers to test candidate drugs across model organs before doing any testing in humans. In FY 2017, NIH funded 13 two-year awards totaling about $15 million per year to develop 3D microphysiological system platforms that model human disease. For example, NIH-funded scientists used stem cells to create an adult-like cardiac model that mimics human heart functionality. This model can be used to improve predictions of the effects that drugs or environmental factors have on the actual heart tissue of a patient. NIH-supported scientists also have used stem cells and tissue chips to mimic conditions in early spinal cord development that enabled the discovery that blood vessels in the brain can trigger the growth and maturation of spinal cord neurons during development. These insights are important in understanding neurodegenerative diseases like amyotrophic lateral sclerosis (ALS) and hold the hope of finding custom, effective treatments for patients. Future phases of this group of awards will include plans to use the models for efficacy and safety testing of compounds to treat or prevent diseases.

IDeA States Pediatric Clinical Trials Network

Children living in rural and medically underserved states are less likely to be enrolled in clinical trials than children living in other states across the nation. To address this gap, in FY 2016 NIH created the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN), a component of the National Pediatric Research Network, under the Environmental Influences on Child Health Outcomes (ECHO) Program. The goal of the IDeA program is to broaden geographic distribution of NIH funding, and the goals of the ISPCTN include providing medically underserved and rural populations with access to cutting-edge clinical trials and

[9] Erbelding EJ et al. A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases. J Infect Dis. 2018 Jul 2;218(3):347-354. PMID: 29506129

[10] https://ncats.nih.gov/tissuechip

applying findings from other relevant pediatric cohort studies to children in IDeA state locations.[11] The ISPCTN will also build national pediatric research capacity by providing professional development opportunities for faculty and their support teams as well as supporting investment in infrastructure. In FY 2020, NIH will increase ECHO funding by $15 million to continue the ISPCTN and support studies such as the multi-site clinical trial on the Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care (POPS) Study, which evaluates the dosing, safety, and efficacy of drugs that are commonly prescribed to children. The ISPCTN is also partnering on ACT NOW pilot studies to develop best practices for treatment of Neonatal Opioid Withdrawal syndrome, as well as advancing clinical trial protocols for a study that aims to decrease pediatric obesity rates in rural areas through use of mobile health technology.

Exploring the Next Frontier in Biomedical Research

Biomedical research aims to push the frontier of knowledge, and success relies on constantly pursuing the next scientific question. NIH will continue to invest in people, programs, and technology with this goal in mind, consistently striving for breakthroughs that culminate in improvements in human health and wellbeing. From harnessing new technologies such as big data analytics and artificial intelligence to supporting the next generation of researchers, NIH will invest its resources to ensure that the U.S. remains on the cutting edge of biomedical research.

Making Sense of Big Data

NIH has initiated a variety of programs to advance scientific discovery and cures by leveraging the incredible growth in the volume, speed of delivery, and complexity of large biomedical datasets. In June 2018, NIH released the Strategic Plan for Data Science[12] (Plan). The Plan articulates NIH's vision for making big data sustainable, interoperable, accessible and usable for the broader community by 1) optimizing data infrastructure, 2) modernizing data resources, 3) advancing data management, analytics, and tools, 4) promoting workforce development, and 5) enhancing policy stewardship and sustainability. NIH is now mapping out implementation activities, which will intensify over the next year. NIH is also creating a new position–the NIH Chief Data Strategist–to collaborate closely with key stakeholders and lead implementation of the Plan.

Additionally, NIH is focused on the promise of artificial intelligence (AI) and machine learning (ML) for catalyzing advances in basic (e.g., image interpretation, neuroscience, genomic variants and disease risk, gene structure, and epigenomics) and clinical research (e.g., robotic surgery, natural language processing of electronic health record data, inferring treatment options for cancer, reading radiology results). NIH recognizes that there are many areas of biomedical research where novel computing, machine intelligence, and deep learning techniques have the potential to advance human health. NIH is committed to pushing those frontiers. For example, in July 2018, NIH hosted a high-level workshop, "Harnessing Artificial Intelligence and

[11] https://www.nigms.nih.gov/research/crcb/IDeA/Pages/default.aspx
[12] https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf

Machine Learning to Advance Biomedical Research" which brought together experts from across the community to examine new directions and challenges in AI and ML and identify ways NIH can contribute to solving these obstacles. NIH has convened a new working group of the Advisory Committee to the Director to further these goals.

All of Us: Creating a National Research Resource to Advance Precision Medicine

Precision medicine represents a key frontier of human health and disease, taking into account individual differences in lifestyle, environment, and biology to enable prevention and treatment strategies tailored to individuals. Initiated in FY 2016, the NIH *All of Us* Research Program,[13] a key element of the Precision Medicine Initiative (PMI), is a historic effort to gather data from one million or more people living in the U.S. to accelerate research and improve health. Unlike research studies that are focused on a specific disease or population, *All of Us* will serve as a national research resource to support thousands of studies, covering a wide variety of health conditions. *All of Us* also represents a new frontier in the way in which research is conducted, through engaged participants and open, responsible data sharing. *All of Us* is working to capitalize on recent advances in genomics, big data analytics, environmental science, and other technologies to revolutionize biomedical research and increase precision medicine prevention and treatment options for individuals and their communities.

National enrollment for *All of Us* launched in May 2018, after extensive design and testing of the many systems involved. By late January 2019, more than 175,000 people have registered with the program as the first step in the participant journey. More than 100,000 participants have completed all the steps in the initial protocol (i.e., consented, agreed to share data from their electronic health records, completed the first three surveys, and provided physical measurements and biospecimens). Greater than 75 percent of these participants are from communities that have been historically underrepresented in biomedical research, and nearly 50 percent are from racial and ethnic minority groups. To encourage enrollment of diverse populations, NIH has created a network of community engagement partners to help with outreach and building trust in these communities. NIH also issued three Genome Center awards in September 2018 to generate genotype and whole genome sequence data from participants' biospecimens—a critical component in the program's research platform. Additionally, *All of Us* is planning a pilot on the responsible return of genetic information to participants, which will include education and genetic counseling, as part of the program's commitment to make participant data available to participants themselves.

Supporting the Next Generation of Researchers

NIH leadership, scientists in the research community, Congress, and the public have grown increasingly concerned about the long-term stability of the biomedical research enterprise. Over time, the number of applications seeking NIH support has increased faster than available funding, which may contribute to early-stage career scientists turning away from careers in research. But they are our future, and we cannot afford to lose them.

[13] https://allofus.nih.gov/

In August 2017, NIH launched the Next Generation Researchers Initiative (NGRI). This initiative – which also responds to provisions in the 21st Century Cures Act – addresses challenges faced by early-stage investigators trying to embark upon and sustain independent research careers.[14] As a key part of the initiative, NIH is prioritizing meritorious applications from early stage investigators seeking their first award, and also for investigators currently supported by NIH who are at risk of losing all research support. Moreover, in their award decisions, NIH Institutes and Centers will consider factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce, including enhanced workforce diversity.

Using a systems-oriented, data-driven approach, an NGRI working group, operating under the Advisory Committee to the NIH Director, made recommendations for change, and will continue to monitor the success of the new initiative. Further, NIH is currently assessing recommendations in a related report from the National Academy of Sciences,[15] released in April 2018, which suggested that funders and institutions should consider addressing barriers that may extend periods of training, time to independence, or impede sustained success in research. NIH will incorporate guidance from both groups in the future design, testing, implementation, and evaluation of policies to ensure the success of the next generation of talented biomedical researchers. The FY 2020 Budget includes a dedicated $100 million in the Office of the Director for NGRI to supplement efforts undertaken by the Institutes and Centers with their own appropriations.

The request will reduce the direct cost of research by capping the percentage of an investigator's salary that can be paid with NIH grant funds at 90 percent. This administrative policy will complement the statutory provision that limits salaries paid through a grant or other extramural mechanism to a rate not in excess of Executive Level II, which the Budget reduces to Executive Level V, and will help target available funding to support the highest priority research on diseases that affect human health.

Conclusion

NIH is at the vanguard of biomedical research, leading the world in support of groundbreaking science in the 21st Century. By strategically investing in scientific opportunities such as those described above, NIH will help ensure the U.S. remains at the forefront of innovation and discovery. In striving to achieve its mission, NIH also operates as a powerful economic engine that drives industry and stimulates investment and growth in pharmaceutical, biotechnology, and medical device companies. The fruits of NIH research–a healthier, longer-living population–also have substantial economic benefits.[16] Continued, targeted support of NIH is therefore an

[14] https://grants.nih.gov/grants/guide/notice-files/not-od-17-101.html
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-214.html
[15] https://www.nap.edu/catalog/25008/the-next-generation-of-biomedical-and-behavioral-sciences-researchers-breaking
[16] https://ucema.edu.ar/u/je49/capital_humano/Murphy_Topel_JPE.pdf

investment not only in the health and well-being of all Americans, but also in the economic health of our country.

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 2020 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 Institutes and Centers (ICs) and the Office of the Director (OD). OD is the central office responsible for setting policy for NIH, and for planning, managing, and coordinating the programs and activities of all NIH components. The NIH Director provides leadership to the ICs and helps identify needs and opportunities, especially for efforts that involve multiple ICs. ICs and OD offices carry out priority setting, performance monitoring, and progress reviews, and also make adjustments based on progress achieved in their respective areas of science. In addition to the performance management processes that occur for the NIH research program, there are equivalent processes for administrative management functions.

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

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

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, in which scientific excellence is assessed, consists of chartered scientific review groups composed of outside experts in particular scientific disciplines. The second level, in which public health relevance is assessed, is conducted by National Advisory Councils of the ICs. For the Intramural Research Program, the progress of individual scientists and their laboratories is evaluated once

every four years by Boards of Scientific Counselors composed of external experts. These reviews enable ongoing assessments of all intramural labs and the accomplishments of the scientists who contribute to them. It is through this well-honed system of peer review that NIH maintains its focus on supporting research of the highest possible quality with the greatest potential of furthering NIH's mission.

The NIH approach to performance management is undergirded by the NIH Governance Structure. That structure includes the NIH Steering Committee and seven standing Working Groups.[17, 18] 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.

[17] 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.
[18] 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)[1,2,3,4]	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total, NIH Program Level	**$37,224,080**	**$39,306,349**	**$34,367,629**	**-$4,938,720**
Less mandatory and funds allocated from different sources:				
PHS Program Evaluation	922,871	1,146,821	741,000	-405,821
Type 1 Diabetes Research	150,000	150,000	150,000	0
Total, NIH Discretionary Budget Authority	**$36,151,209**	**$38,009,528**	**$33,476,629**	**-$4,532,899**
Interior Budget Authority[5]	77,349	77,349	66,581	-10,768
Total, NIH Labor/HHS Budget Authority	**$36,073,860**	**$37,932,179**	**$33,410,048**	**-$4,522,131**
Number of Competing RPGs[6]	*11,461*	*11,675*	*7,894*	*-3,781*
Total Number of RPGs[6]	*39,354*	*41,389*	*38,565*	*-2,824*
FTE[7]	*17,532*	*18,101*	*18,339*	*238*
NEF[8]	*NA*	*96,000*	*NA*	*NA*

1 Excludes Ebola-related and hurricane-related supplemental financing.

2 Includes 21st Century Cures Act funding.

3 Numbers may not add due to rounding.

4 Figures for FY 2020 reflect the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

5 This activity was operating under an FY 2019 Continuing Resolution at the time the budget estimates were prepared.

6 Figure for FY 2020 include the consolidation of NIRSQ into NIH. Figures for FY 2018 and FY 2019 do not include amounts for AHRQ.

7 FTE levels exclude 4 NIH FTEs funded by PHS trust funds in FY 2018 through FY 2020 and 7 FTEs funded by the Patient-Centered Outcomes Research Trust Fund in FY 2020. Figures for FY 2018 and FY 2019 do not include AHRQ.

8 Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018; HHS has not yet notified for FY 2020.

Impact of Budget Level on Performance

Programs and Measures (Dollars in Millions, except where noted)	**FY 2019 Enacted**	**FY 2020 President's Budget**[3]	**FY 2020 +/- FY 2019**
Research Project Grants	$22,579.392	$19,544.723	-13.4%
Competing Average Cost (in thousands)	$540.593	$471.985	-12.7%
Number of Competing Awards (whole number)	11,675	7,894	-32.4%
Estimated Competing RPG Success Rate	20.3%	13.5%	-33.5%
Research Centers	$2,688.141	$2,217.953	-17.5%
Other Research	$2,489.688	$2,209.720	-11.2%
Training	$888.955	$801.873	-9.8%
Research & Development Contracts	$3,132.619	$2,795.430	-10.8%
Intramural Research	$4,129.550	$3,633.805	-12.0%
Research Management and Support	$1,898.356	$1,739.376	-8.4%
Common Fund (non-add)	*$619.166*	*$532.967*	*-13.9%*
Buildings & Facilities Appropriation	$200.000	$200.000	0.0%
Other Mechanisms[1]	$1,299.648	$1,224.749	-5.8%
Total, Program Level[2]	**$39,306.349**	**$34,367.629**	**-12.6%**

[1] Includes Office of the Director-Other, Buildings and Facilities funding in the National Cancer Institute, 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 Type 1 Diabetes account and Program Evaluation Financing.

[3] Mechanism distribution includes funding for NIRSQ in FY 2020.

Appropriations Language

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$5,743,892,000]*$5,051,737,000*, of which up to $30,000,000 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, [$3,488,335,000]*$3,002,696,000*.

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, [$461,781,000]*$397,493,000*.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, [$2,029,823,000]*$1,746,493,000*.

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, [$2,216,913,000]*$1,956,031,000*.

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, [$5,523,324,000]*$4,754,379,000*.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [$2,872,780,000]*$2,472,838,000*, of which [$1,146,821,000]*$741,000,000* shall be from funds available under section 241 of the PHS Act: Provided, That not less than [$361,573,000]*$311,236,000* is provided for the Institutional Development Awards program.

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, [$1,506,458,000]*$1,296,732,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [$796,536,000]*$685,644,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [$774,707,000]*$666,854,000. (Department of Health and Human Services Appropriations Act, 2019.)*

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, $66,581,000.

Note.—A full-year 2019 appropriation for this account was not enacted at the time the budget was prepared; therefore, the budget assumes this account is operating under the Continuing Appropriations Act, 2019 (Division C of P.L. 115–245, as amended). The amounts included for 2019 reflect the annualized level provided by the continuing resolution.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, [$3,083,410,000]*$2,654,144,000*.

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, [$605,065,000]*$520,829,000*.

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, [$474,404,000]*$408,358,000.*

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [$162,992,000]*$140,301,000.*

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, [$525,591,000]*$452,419,000.*

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [$1,419,844,000]*$1,296,379,000*

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [$1,812,796,000]*$1,560,422,000.*

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [$575,579,000]*$495,448,000.*

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, [$389,464,000]*$335,986,000*.

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, [$146,473,000]*$126,081,000.*

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, [$314,679,000]*$270,870,000.*

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), [$78,109,000]*$67,235,000.*

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [$441,997,000]*$380,463,000: Provided,* That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2020]*2021: Provided further,* That in fiscal year [2019]*2020*, 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, [$806,373,000]*$694,112,000: Provided,* That up to [$80,000,000]*10 percent of the amounts made available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network[: *Provided further,* That at least $559,736,000 is provided to the Clinical and Translational Sciences Awards program].

OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, [$1,909,075,000]*$1,756,544,000: 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 [$165,000,000]*$157,065,000* shall be for the Environmental Influences on Child Health Outcomes study: *Provided further,* That [$606,566,000]*$520,367,000* 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[: *Provided further,* That $50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities][: *Provided further,* That $5,000,000 shall be transferred to and

merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further,* That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further,* That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2019 and 2020 no later than 30 days after the date of enactment of this 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 of, 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, [2023]*2024.*

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 2020: 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.

NIH INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

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 NIH in this Act, [$711,000,000]*$492,000,000,* to remain available until expended: *Provided,* That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further,* That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: *Provided further,* That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. (Department of Health and Human Services Appropriations Act, 2019.)

Language Analysis

Language Provision to be Changed	Explanation/Justification
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES *Provided*, That up to [$80,000,000]*10 percent of the amounts made available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network	NIH requests that the provision regarding funding within NCATS for the Cures Acceleration Network (CAN) be structured as a percentage of the NCATS budget level. The unique authorities associated with CAN – use of Other Transactions Authority (OTA) and matching funding – give NCATS flexibility to quickly create or terminate parts of an initiative based on programmatic need and scientific opportunity. Specifying the CAN ceiling as a percentage of the overall NCATS budget ensures that the CAN funding adjusts relative to overall funding levels and enables NCATS to plan CAN activities more strategically.
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES [: *Provided further*, That at least $559,736,000 is provided to the Clinical and Translational Sciences Awards program]	NIH requests that this provision be removed to provide flexibility in the amounts allocated to the Clinical and Translational Sciences Awards program in order to preserve flexibility for NCATS in managing its budget within the President's Budget request level.
OFFICE OF THE DIRECTOR [: *Provided further*, That $50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities]	NIH requests that this provision be removed as the President's Budget does not request continued funding for construction and renovation of extramural research facilities.

Language Provision to be Changed	Explanation/Justification
OFFICE OF THE DIRECTOR [: *Provided further*, That $5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further*, That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2019 and 2020 no later than 30 days after the date of enactment of this Act]	NIH requests these provisions be removed because the President's Budget requests funding for the HHS Office of Inspector General via direct appropriation rather than via transfer from NIH.

Budget Mechanism Table

(Dollars in Thousands)[1,2,3]	FY 2018 Final[4]		FY 2019 Enacted[5]		FY 2020 President's Budget[6]		FY 2020 +/- FY 2019	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	25,858	$13,776,726	27,492	$14,677,360	28,760	$14,536,572	1,268	-$140,788
Administrative Supplements[3]	*(2,743)*	483,035	*(2,695)*	506,430	*(1,858)*	361,166	*(-837)*	-145,264
Competing	11,461	$5,943,802	11,675	$6,311,423	7,894	$3,725,852	-3,781	-$2,585,571
Subtotal, RPGs	37,319	$20,203,562	39,167	$21,495,213	36,654	$18,623,590	-2,513	-$2,871,623
SBIR/STTR	2,035	1,001,946	2,222	1,084,179	1,911	921,133	-311	-163,046
Research Project Grants	39,354	$21,205,508	41,389	$22,579,392	38,565	$19,544,723	-2,824	-$3,034,669
Research Centers:								
Specialized/Comprehensive	1,003	$1,813,976	1,079	$1,908,419	924	$1,547,608	-155	-$360,811
Clinical Research	68	417,709	66	421,640	64	362,000	-2	-59,640
Biotechnology	91	159,963	91	160,916	80	138,518	-11	-22,398
Comparative Medicine	67	129,881	79	133,759	67	115,233	-12	-18,526
Research Centers in Minority Institutions	21	61,478	20	63,407	20	54,594	0	-8,814
Research Centers	1,250	$2,583,007	1,335	$2,688,141	1,155	$2,217,953	-180	-$470,188
Other Research:								
Research Careers	4,040	$747,017	4,161	$780,492	3,792	$708,160	-369	-$72,332
Cancer Education	76	21,182	85	24,857	81	23,614	-4	-1,243
Cooperative Clinical Research	229	409,660	278	497,025	243	411,324	-35	-85,701
Biomedical Research Support	118	85,524	112	73,696	95	62,825	-17	-10,872
Minority Biomedical Research Support	283	101,245	294	104,359	228	81,111	-66	-23,248
Other	2,064	1,081,442	2,066	1,009,259	1,805	922,686	-261	-86,572
Other Research	6,810	$2,446,070	6,996	$2,489,688	6,244	$2,209,720	-752	-$279,968
Total Research Grants	47,414	$26,234,584	49,720	$27,757,221	45,964	$23,972,395	-3,756	-$3,784,825
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,500	$161,753	3,697	$173,134	3,335	$157,779	-362	-$15,355
Institutional Awards	12,697	694,093	12,969	715,821	11,657	644,094	-1,312	-71,727
Total Research Training	16,197	$855,845	16,666	$888,955	14,992	$801,873	-1,674	-$87,082
Research & Develop. Contracts	2,212	$3,072,532	2,177	$3,132,619	1,862	$2,795,430	-315	-$337,189
(SBIR/STTR) (non-add)[3]	*(85)*	*(60,608)*	*(98)*	*(74,336)*	*(79)*	*(64,122)*	*(-19)*	*(-10,214)*
Intramural Research		$3,996,276		$4,129,550		$3,633,805		-$495,745
Res. Management & Support		1,816,210		1,898,356		1,739,376		-158,979
Res. Management & Support (SBIR Admin) (non-add)[3]		*(0)*		*(5,172)*		*(3,559)*		*(-1,613)*
Office of the Director - Appropriation[3,7]		*(1,914,345)*		*(2,112,675)*		*(1,926,144)*		*(-186,531)*
Office of the Director - Other		1,024,420		1,204,300		1,144,168		-60,132
ORIP (non-add)[3,7]		*(289,209)*		*(289,209)*		*(249,009)*		*(-40,200)*
Common Fund (non-add)[3,7]		*(600,716)*		*(619,166)*		*(532,967)*		*(-86,199)*
Buildings and Facilities[8]		146,863		218,000		214,000		-4,000
Appropriation[3]		*(128,863)*		*(200,000)*		*(200,000)*		*(0)*
Type 1 Diabetes[9]		-150,000		-150,000		-150,000		0
Program Evaluation Financing[9]		-922,871		-1,146,821		-741,000		405,821
Subtotal, Labor/HHS Budget Authority		**$36,073,860**		**$37,932,179**		**$33,410,048**		**-$4,522,131**
Interior Appropriation for Superfund Research[10]		77,349		77,349		66,581		-10,768
Total, NIH Discretionary Budget Authority		**$36,151,209**		**$38,009,528**		**$33,476,629**		**-$4,532,899**
Type 1 Diabetes		150,000		150,000		150,000		0
Total, NIH Budget Authority		**$36,301,209**		**$38,159,528**		**$33,626,629**		**-$4,532,899**
Program Evaluation Financing		922,871		1,146,821		741,000		-405,821
Total, Program Level		**$37,224,080**		**$39,306,349**		**$34,367,629**		**-$4,938,720**

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

2 Includes 21st Century Cures Act funding and excludes Ebola-related and supplemental financing.

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

4 Includes $63.3 million of 21st Century Cures, $428.9 million of Opioids, and $123.7 million of Type 1 Diabetes funding not obligated in FY 2018, and carried over into FY 2019. Numbers of grants and dollars for carryover are distributed by mechanism.

5 Reflects transfer of $5.0 million to the HHS OIG.

6 Includes the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ), distributed by mechanism.

7 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as non-adds. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

8 Includes B&F appropriation and monies allocated ($18.0 million in FY 2018, $18.0 million in FY 2019, and $14.0 million in FY 2020) pursuant to appropriations acts provisions that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

9 Number of grants and dollars for mandatory Type 1 Diabetes (T1D) and NIGMS Program Evaluation financing are distributed by mechanism above; therefore, T1D and Program Evaluation financing amounts are deducted to provide subtotals for Labor/HHS Budget Authority.

10 This activity was under a Continuing Resolution at the time the budget estimates were prepared.

Authorizing Legislation

(Dollars in Thousands)	FY 2019 Amount Authorized	FY 2019 Amount Appropriated[1]	FY 2020 Amount Authorized	FY 2020 President's Budget
National Institutes of Health Activity:				
1. Biomedical Research under Section 301 and title IV of the PHS Act:				
General Authorization: Section 402A(a)(1) of the PHS Act	35,585,871	38,360,400	36,472,443	33,390,488
Pediatric Research Initiative: Section 402A(a)(2) of the PHS Act	12,600	12,600	12,600	12,600
2. Superfund Research Program: 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	Indefinite	77,349	Indefinite	66,581
3. 21st Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	186,000	186,000	149,000	149,000
BRAIN Initiative: Section 1001(b)(4)(B)	115,000	115,000	140,000	140,000
Cancer Moonshot: Section 1001(b)(4)(C)	400,000	400,000	195,000	195,000
Regenerative Medicine: Section 1001(b)(4)(D)	10,000	10,000	8,000	8,000
4. Special Diabetes Programs: Section 330B(b) of the PHS Act	150,000	150,000	150,000	150,000
5. Research on Healthcare and Quality: Titles III and Title IX and Section 947(c) of the PHS Act, as amended	SSAN	338,000	SSAN	255,960

[1]The amount appropriated in FY 2019 for the Superfund Research Program reflects the annualized CR level.

SSAN = Such sums as necessary

Appropriations History

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2011	$32,136,209,000		$31,989,000,000	$30,935,000,000 [2]
FY 2012	$31,979,000,000		$30,630,423,000	$30,852,187,000 [3]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [4]
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 [5]
FY 2016	$31,311,349,000 [6]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [7]
FY 2017	$33,136,349,000 [8]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [9]
FY 2018	$26,919,710,000 [10]	$35,184,000,000	$36,084,000,000	$37,311,349,000 [11]
FY 2019	$34,766,707,000 [12,13]	$38,564,000,000	$39,312,349,000	$39,311,349,000 [14]
FY 2020 PB	$34,367,629,000 [15,16]			

[1] Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special type 1 Diabetes Research mandatory funding included. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019 and $492,000,000 in FY 2020.

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

[3] 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.

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

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

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

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

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

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

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

[11] Includes Program Evaluation Financing of $922,871,000. Excludes supplemental hurricane funding of $50,000,000 to the Office of the Director for extramural construction.

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

[13] Includes funding for National Institute for Research on Safety and Quality (NIRSQ), National Institute for Occupational and Safety Health (NIOSH), and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) associated with the proposed FY 2019 consolidation as well as Patient-Centered Outcomes Research Trust Fund (PCORTF) and Energy Employee Occupational Illness Compensation Program (EEOICPA) mandatory accounts.

[14] Includes Program Evaluation Financing of $1,146,821,000,000. Reflects Continuing Resolution level for Superfund. Does not reflect $5,000,000 transfer from NIH to the HHS Office of Inspector General.

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

[16] Includes funding for NIRSQ associated with the proposed FY 2020 consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH. Figures prior to FY 2020 do not include amounts for AHRQ. For information on AHRQ Funding History, see the NIRSQ chapter of the NIH Congressional Justification.

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2018 Final [1]	FY 2019 Enacted[2]	FY 2020 President's Budget	FY 2020 +/- FY 2019
Program Level[3,4]	$37,224,080	$39,306,349	$34,367,629	-4,938,720
FTE[3,5]	17,536	18,105	18,350	245

[1] Excludes Ebola-related and supplemental financing.

[2] Amount for Superfund program for FY 2019 reflects the Annualized CR level at the time the budget estimates were prepared.

[3] Figures for FY 2020 reflect the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

[4] Includes 21st Century Cures Act funding, Mandatory Type 1 Diabetes, and Superfund in all years; includes NIGMS Program Evaluation funding of $923 million in FY 2018, $1,147 million in FY 2019, and $741 million in FY 2020.

[5] Represents NIH target FTE level, including direct funded and reimbursable funded FTE.

Authorizing Legislation: For existing NIH program, Section 301 and Title IV of the Public Health Act, as amended. For NIRSQ, Title 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.

Allocation Methods: Competitive Grants; Contract; Intramural; Other

Program Description and Accomplishments

NIH Contributions to Improvements in Human Health

Since its establishment more than 100 years ago, NIH has served as the Nation's premier biomedical research agency, supporting and conducting research that has contributed significantly to the extension of healthy lifespans and the reduction of illness and disability. Between 1970 and 2016, the life expectancy of the average American increased by eight years.[19] Further, the yearly death rate for Americans from all causes dropped by 43 percent from 1969 to 2015.[20] At age 65, Americans today can expect to live 19.4 more years, nearly 40 percent longer than in 1950.[21] We can attribute these remarkable improvements in longevity in part to NIH research advances leading to a fundamental understanding of health that has resulted in a host of new ways to prevent, treat, and cure a multitude of diseases and conditions.

Improving Health Across the Lifespan

NIH research has improved health across the lifespan, from the youngest Americans to the oldest. In 1960, 26 of every 1,000 babies born in the U.S. died before their first birthday. By 2016, that rate had fallen to under 6 per 1,000 babies[22] thanks in large part to NIH research to reduce preterm births, neonatal mortality, and other complications. NIH research on preventing and treating HIV/AIDS has resulted in a more than 90 percent decrease since the mid-1990s in the number of children perinatally infected with HIV in the U.S.[23] Because of all these improvements to treatment in the first year of life, infants that survive today will likely live longer, healthier lives than previous generations. In older children and young adults, the leading cause of death is unintentional injuries,[24] yet from 1999 to 2016, deaths from unintentional injuries for those aged 10-19 declined by 24 percent, reaching its lowest point in 2013.[25] Much of this change can be attributed to improvements in clinical care, such as treatment for burns and other traumatic injuries, derived in large part from biomedical research. NIH research advances have also turned the dial for many of the diseases and conditions that can strike throughout the lifespan, including those that cause the greatest disease burden (heart disease and cancer) so that Americans are not only living longer, but are staying healthier. As just one important example in oral health, in the 1960s, almost 50 percent of people had lost all their teeth by age 75. By 2012, that rate was down to 13 percent.[26]

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[19] Kochanek KD, Murphy SL, Xu J, Arias, E. Mortality in the United States, 2016. NCHS Data Brief, no. 293. National Vital Statistics Report. 2017 Dec;(66):1-73.
[20] 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
[21] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[22] Kochanek KD, Murphy SL, Xu J, Tejada-Vera B. Deaths: Final Data for 2014.*National Vital Statistics Reports*. 2016;65(4)
[23] Taylor AW, Nesheim SR, Zhang X et al., Estimated perinatal HIV infection among infants born in the United States, 2002-2013. JAMA Pediatrics. 2017;171(5):435-442.
[24] https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_05.pdf
[25] https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_04.pdf
[26] Dye B, Thornton-Evans G, Li X, Iafolla T.Dental caries and tooth loss in adults in the United States, 2011-2012(link is external). NCHS data brief. 2015(197):197.

Combatting Heart Disease

Though heart disease remains the leading cause of death among Americans, deaths from heart disease decreased by approximately 67 percent between 1969 and 2015, due in large part to NIH research.[27] Begun in 1948, the long-running NIH-funded Framingham Heart Study was the first to identify major cardiovascular disease risk factors, including smoking, high cholesterol, and high blood pressure.[28] By targeting these risk factors, significant progress has been made in preventing heart disease. For example, the first statins (e.g., lovastatin and simvastatin), a class of drugs that help control cholesterol levels, were approved in the late 1990s. These were followed by several second-generation statins, including Crestor in 2003, which was developed and patented by NIH-funded scientists.[29] NIH-supported clinical trials spurred the development of effective pharmacological and behavioral interventions to treat heart disease, including safe and effective surgical and catheter-based procedures to open clogged coronary arteries.[30] These successes have led to increases in U.S. life expectancy from 1970-2000 that have been estimated to add approximately $1.6 trillion per year to national wealth.[31]

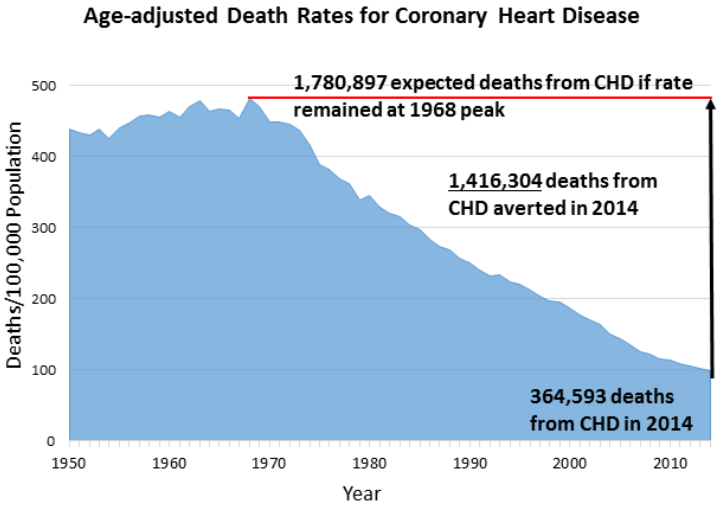


Figure 1. The age-adjusted death rates for coronary heart disease (CHD) have been dropping steadily since 1968. If they had remained at the 1968 peak levels, over one million more heart disease deaths would have occurred. Source: National Vital Statistics Reports, CDC National Center for Health Statistics.

[27] 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

[28] Mahmood SS, Levy D, Vasan RS, Wang TJ. The Framingham Heart Study and the epidemiology of cardiovascular disease: a historical perspective. *Lancet (London, England)*. 2014;383(9921):999-1008. doi:10.1016/S0140-6736(13)61752-3.

[29] Several patents related to Crestor have been granted (6858618; 6316460; 7030152; 7964614; RE37314). Those patents cite NIH support from the following grants: R01CA034944; R01CA040360; R01CA042182; R01HL026490; R01HL034595; R01HL046696.

[30] Ford ES, Ajani U a, Croft JB, et al. Explaining the decrease in U.S. deaths from coronary disease, 1980-2000. *N Engl J Med*. 2007;356(23):2388-2398. doi:10.1097/sa.0b013e31815c1098.

[31] Murphy KM, Topel RH. The Value of Health and Longevity. *J Polit Econ*. 2006;114(5):871-904. doi:10.1086/508033.

Working to Cure Cancer

Thanks to remarkable scientific progress, we can now envision a future in which cancer is curable, or at least a chronic, manageable condition. The death rate for all cancers combined has been declining since the early 1990s for adults, and since the 1970s for children.[32] Overall cancer death rates have dropped by nearly 26 percent in total from 1991-2015 thanks to improvements in cancer treatment, detection, and prevention.[33] Today we can apply a deep understanding of the basic mechanisms by which cancer works towards developing new and highly innovative treatments. Vaccines for human papilloma virus (HPV), made possible by understanding mechanisms of both cancer and immunity, provide nearly 100 percent protection against HPV types 16 and 18, which account for about 70 percent of cervical cancers and an even higher percentage of some other types of HPV-caused cancers.[34] In another example, because scientists were able to isolate the underlying genetic cause of a rare cancer known as chronic myelogenous leukemia (CML), NIH researchers and others developed Gleevec®, approved in 2001. With the availability of this treatment, the 10-year survival rate of CML patients has gone from 30 percent to 83 percent.[35] Gleevec's® effectiveness has paved the way for a new industry of cancer drugs that precisely target similar mechanisms in other cancers, such that by mid-2018, at least 43 new cancer drugs similar to Gleevec® have been approved by the FDA.[36] Cancer immunotherapy, in which a patient's own immune system is harnessed to attack cancer cells, promises to revolutionize cancer treatment. The immunotherapy drug Keytruda was first approved for the treatment of melanoma in 2014 and has now been approved to treat Hodgkin's Lymphoma, non-small cell lung cancer, and squamous cell carcinoma of the head and neck.[37]

Eliminating the Pandemic Threat of HIV/AIDS

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 and there were dire predictions of a potential pandemic that would significantly reduce the world's population. Now, thanks to an unprecedented effort made by NIH and others, there are powerful treatments that can suppress the virus to undetectable levels. Death rates dropped more than 80 percent between 1990 and 2015,[38] and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s.[39] The most significant gains have been made with the development of antiretroviral therapy, which can

[32] Jemal A, Ward EM, Johnson CJ, et al. Annual report to the nation on the status of cancer, 1975-2014, featuring survival. JNCI. September 2017. https://doi.org/10.1093/jnci/djx030
[33] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA Cancer J Clin*. January 2018;68(1):7-30.
[34] Gillison ML, Chaturvedi AK, Lowy DR. HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women. Cancer. 2008 Nov 15;113(10 Suppl):3036-46. PMID: 18980286
[35] Hochhaus A, Larson RA, Guilhot F, et al. Long-term outcomes of imatinib treatment for chronic myeloid leukemia. N Engl J Med 2017; 376:917-27.
[36] http://www.brimr.org/PKI/PKIs.htm
[37] https://directorsblog.nih.gov/2017/08/30/fda-approves-first-car-t-cell-therapy-for-pediatric-acute-lymphoblastic-leukemia/
[38] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[39] Samji H, et al. *PLoS One* 2013; Dec 18;8(12):e81355 PMID: 24367482
http://www.ncbi.nlm.nih.gov/pubmed/24367482

now effectively suppress the virus to undetectable levels.[40] With further research, it is possible to imagine a world in which the threat of AIDS has been eliminated altogether. Not only has NIH's investment in AIDS resulted in the real potential of an AIDS-free world, but the intensity of the research led to an in-depth understanding of viral biology and the workings of the human immune system that has been applied more broadly. For example, new understanding of how viruses may disrupt immune function has revealed mechanisms underlying certain cancers, autoimmune conditions, and other infectious diseases such as Ebola, Zika, and influenza. Research on HIV pathogenesis also uncovered information about the role of immune activation and inflammation in human disease; for example, increased incidence of heart disease among HIV patients has led to increased understanding of heart disease absent HIV infection as well.[41] Studying the basic immunology of HIV, a lentivirus, led to development of FDA-approved lentiviral gene therapy technology to treat certain cancers such as acute lymphoblastic leukemia. Furthermore, the effort to create a vaccine against HIV has contributed to the creation of other effective vaccines such as one against respiratory syncytial virus, and the knowledge gained in drug development for antivirals has been applied to the development of other medications, including a highly effective treatment for hepatitis C.[42] These are just a few of the advances in diverse fields that resulted from supporting HIV/AIDS research, and ongoing and future investment in HIV research promises to yield similar wide-ranging benefits.

Focusing on Rare Diseases

Not only has NIH research made great strides in alleviating those diseases and conditions that cause the greatest burden, but it has also made significant contributions to understanding and treating rare diseases, offering hope to those patients for whom little or no treatment options are available. Prior to 1995, there were no FDA approved treatments for Gaucher's Disease, a rare genetic disease in which harmful quantities of a fatty substance accumulate throughout the body and brain. The first treatment, approved in 1995 and pioneered by NIH intramural investigators,[43] has now been followed by a newer, orally administered treatment approved in 2014 and based on research performed and patented by NIH-funded researchers.[44] Another rare disorder, lipodystrophy, benefitted from NIH intramural research investment as well. In 2014, the FDA approved a treatment for this disorder in which the body is unable to produce and maintain healthy fat tissues.[45] NIH research also led to breakthrough development of a new class of drugs to treat a family of rare autoinflammatory diseases, each with its own devastating consequences, leading to life-saving and health-preserving treatments.[46] In other research on rare diseases, NIH-supported scientists identified specific disease-related genes which can be

[40] Schwetz TA, Fauci AS. The Extended Impact of Human Immunodeficiency Virus/AIDS Research. J Infect Dis. jiy441, 28 Aug 2018. https://doi.org/10.1093/infdis/jiy441
[41] Schwetz TA, Fauci AS. The Extended Impact of Human Immunodeficiency Virus/AIDS Research. J Infect Dis. jiy441, 28 Aug 2018. https://doi.org/10.1093/infdis/jiy441
[42] Wyles DL. Antiviral resistance and the future landscape of hepatitis C virus infection therapy. J Infect Dis 2013; 207(Suppl 1):S33–9.
[43] https://irp.nih.gov/accomplishments/therapy-for-inherited-enzyme-deficiencies
[44] The FDA approval indicates 3 patents, 1 of which has NIH Funding: 6916802, funded by NIH grants P30CA046592, P50DK039255, and R01DK041487
[45] https://irp.nih.gov/accomplishments/from-hormone-to-pharmaceutical-lipodystrophy
[46] http://directorsblog.nih.gov/2013/04/09/meet-alex-before-and-after-nih-clinical-trial/

targeted with cutting-edge genetic therapies for a rare form of inherited vision loss,[47] other retinal diseases[48] and in 2018, a rare, inherited form of rickets.[49]

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.

Differences in Opioid Drug Receptor Activation

Opioid pain relievers, such as morphine and oxycodone, are generally safe when used for a brief time and as prescribed by a doctor. But some people misuse opioid drugs for their euphoric effects. When misused, these drugs can lead to addiction, overdose, and death. Scientists have previously assumed that all opioids – whether produced by the body (endogenously) or taken as a drug – interact in the same way with opioid receptors. In order to test this assumption, NIH-supported researchers designed a tiny sensor, called a nanobody, which would generate a fluorescent signal when an opioid receptor was activated. Their research found that opioid drugs and the brain's natural opioids differ in how they activate receptors in nerve cells. The different and more rapid ways that opioid drugs, as opposed to endogenous opioids, interact with these receptors may help in explaining their undesired side effects. These findings could have the potential of helping guide the design of pain relievers that would be effective without the negative side effects.

Mouse Immune System Destroys Tumors

All malignant tumors harbor genetic alterations. Some of these alterations lead to the production of modified proteins, known as antigens, which can trigger an immune response. Since tumors are often infiltrated by immune cells that can recognize these antigens, there has been tremendous interest in the burgeoning field of cancer immunotherapy. NIH-supported researchers have taken an approach to stimulating immune cells in the tumor to mount a vigorous response to the cancer cell antigens around them – essentially a cancer vaccination. In studies using mouse models, researchers found a combination of agents that, when injected into a tumor, directs the immune system to destroy not only the injected tumor, but tumors of the same type throughout the body. The results of this experiment also show that the tumor vaccination approach is not dependent on knowing the unique characteristics of the tumor, making it potentially applicable to many different forms of cancer. A clinical trial is now being launched using this vaccination approach in combination with low dose local radiation for individuals with lymphoma.

[47] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm
[48] https://www.nih.gov/news-events/news-releases/nih-funded-study-points-way-forward-retinal-disease-gene-therapy
[49] https://www.niams.nih.gov/newsletters/niams-update/2018/niams-update-june-7-2018

Ultrasound Bacterial Monitoring

Improved understanding of the beneficial roles played by bacteria in the human body has motivated research into the use of microbes for therapeutic applications; for example, probiotics to treat irritable bowel syndrome and bacteria as tumor-targeting drug carriers. Until recently, image-based methods for tracking therapeutically administered bacteria were limited, since light-based detection methods are not effective at penetrating through human tissue. NIH-supported researchers recently developed an ultrasound-based method of imaging bacteria through tissue. The researchers genetically engineered bacterial production of gas-filled internal structures that scatter ultrasound waves in a way that can be detected. This new technique gives researchers the ability to detect bacteria using non-invasive ultrasound, providing a promising potential means of tracking microbes used in therapeutic applications.

New 'Liquid Biopsy' Shows Early Promise in Detecting Cancer

Early detection of cancer increases the chances for more effective treatment. However, many tumors are not caught until they have grown relatively large and spread to other parts of the body. Researchers are developing new and more effective early screening methods. One innovative approach is a "liquid biopsy." A liquid biopsy detects cancer by screening for specific molecules that tumors release into the bloodstream. CancerSEEK, a universal liquid biopsy test funded by NIH, is an advanced biopsy test that analyzes blood samples to detect a significant proportion of eight common cancers. The test detected cancer with 70 percent accuracy and gave very few false positive results. Another advantage of this test compared to other biopsy tests is the machine learning approach that researchers employed to determine the location of a cancer. Researchers were able to trace the tissue of origin to one of two organs in 83 percent of the patients with a positive test result. The next step is to enroll 10,000 participants in a trial to test how well CancerSEEK works in detecting cancer among people with no history of the disease. More data will also be needed to answer questions about whether people with inflammatory or other health conditions that cause detectable tissue damage might also test positive.

Flexible Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is a non-invasive technology that produces three dimensional detailed anatomical images. Soft tissues, such as the brain, spinal cord, muscles, ligaments, and tendons, can be seen much more clearly with MRI than with x-rays. A limitation with modern MRI sensors is that the current model uses low impedance coils that allow current to flow more easily. However, these coils must be precisely arranged to avoid interfering with each other thus corrupting the image. This has resulted in detector designs with limited flexibility that must either sacrifice image sensitivity or restrict a person's movements during the MRI scan. An NIH-supported research project investigated whether high impedance coils could be used to design an MRI that is more versatile, reasoning that the high impedance coils could lower interference and allow imaging while people are moving. As part of the study, high impedance coils were stitched into each finger of a flexible glove so that the fingers could move freely during scans of volunteers playing a piano or grabbing a piece of fruit. The scans with the high impedance coils improved the image sensitivity by more than 80 percent in fingers

compared with the rigid, low impedance coils. The results show promise in using MRI scans to look at moving joints and may help lead to the diagnosis of complex tissue injuries.

Wearable mHealth Device Detects Abnormal Heart Rhythms Earlier

As many as 6 million Americans experience an irregular heartbeat, called atrial fibrillation (AFib), which increases their risk of heart failure and stroke if not detected and treated at an early stage. To detect AFib and start treatment early, NIH supported the mHealth screening to Prevent Strokes (mSToPS) Trial. Notably, the entire study was conducted remotely – the participants and researchers never met face to face. The trial tested a wearable health technology: an FDA-approved wireless electrocardiogram (EKG) patch, called Zio patch, which can monitor a person's heart rate at home. In the mSToPS trial, researchers recruited participants from around the United States who were at increased risk of AFib. More than 2,600 people signed up and were randomly assigned to one of two groups. The first group received a Zio patch by mail within two weeks of enrollment with instructions about how to apply and wear it at home. The second group received a Zio patch in the mail four months later with the same instructions. Researchers diagnosed AFib in 3.9 percent of the participants assigned to the group that received patches within two weeks of enrollment, compared to only 0.9 percent in the group that waited four months before wearing the patch. The researchers also conducted a year-long observational study that followed more than 1,700 participants who underwent EKG monitoring at home in the mSToPS trial and over 3,400 unmonitored matched controls. At the end of the year, about 6 percent who used the Zio patch at home were diagnosed with AFib compared to about 2 percent of controls who didn't use the patch. In most cases, an AFib diagnosis led to early treatment. However, the long-term benefits of the Zio patch in reducing the incidence of strokes, ER visits, and hospitalizations remains unknown. The researchers have recently begun a three-year follow-up study to get those answers.

Advances in Tissue Chips Expand to Recreating Spinal Cord

Tissue chips are designed as accurate models of the structure and function of human organs, and NIH has invested in developing these chips to test therapeutics more quickly and effectively than current methods. Unlike traditional petri dish systems, tissue chips often provide the fluidity and depth necessary to grow both neurons and blood vessels in more life-like environments. An NIH-supported study used organ chips to grow spinal cord sections out of human skin cells. The idea came from a previous study where researchers used stem cells from a participant's skin to recreate interactions between blood vessels and neurons that generally occur when the human fetal spinal cord is forming. For the current study, researchers were able to convert stem cells into a type of cell that lines the walls of brain blood vessels. As the experiment progressed, researchers found that the neurons were firing more often and that the cells were showing similar activity to those found in fetal spinal cord cells. Although more research and analysis is needed, researchers agree that this is a promising start towards developing chips that could potentially mimic the human nervous system.

Molecular Basis for Mental Disorders

NIH-supported researchers are attempting to understand, at the molecular level, the cause of five mental disorders—autism spectrum disorders, schizophrenia, bipolar disorder, depression, and alcoholism—to further explore past evidence showing that these disorders share genetic risk factors. When researchers examined the active genes in the cerebral cortex of deceased patients with the above-mentioned mental health disorders, the researchers found thousands of genes whose activities were either elevated or suppressed. They also found significant overlapping mechanisms between autism spectrum disorder, schizophrenia, and bipolar disorder; and between schizophrenia, bipolar disorder, and depression. Further analysis also supported the idea that there is a substantial genetic component to these mental health disorders. While more research is needed, these findings help provide a framework for understanding the processes that affect the risk for developing mental disorders.

Hope for Infants with Rare Disease Spinal Muscular Atrophy

Spinal muscular atrophy (SMA) is a hereditary neurodegenerative disease that can affect movement, breathing, and swallowing. Individuals with SMA suffer from a specific mutation that is vital for motor function. Although cells have safeguards in place to counteract mutations, these safeguards may not be enough to overcome cell dysfunction. Researchers found that the drug Spinraza is able to overcome the mutation by bypassing certain gene production and increasing essential protein production. Two companies decided to use this innovative approach and launched a clinical study using Spinraza in children with a less severe form of SMA. The trial was successful and led to two subsequent studies in infants suffering from severe SMA. Both studies proved to be successful, with one study dramatically improving the infants' abilities to breathe and eat unassisted, something they could not regularly do on their own. The other study showed that the treatment was safe and effective, with most of the infants gaining control of their heads. Due to these astonishing results, the FDA designated SMA gene therapy as a breakthrough therapy and it has been licensed to a drug company for further development. More infants are being recruited to take part in Phase 3 clinical trials, giving hope to families that new treatments are within reach.

Early Identification of Gestational Diabetes Risk

Gestational diabetes[50] (GD) occurs only in pregnancy and results when the level of blood sugar, or glucose, rises too high. GD increases the mother's chances for high blood pressure disorders of pregnancy and the need for cesarean delivery, as well as the risk for cardiovascular disease and type 2 diabetes later in life. Screening for GD typically occurs between 24 and 28 weeks of pregnancy unless there is a known risk factor, such as obesity. Identifying women at risk for GD earlier in pregnancy could allow for lifestyle changes that may be more effective at reducing their risk. Researchers from NIH evaluated whether the HbA1c test (also called the A1C test[51]), a blood test commonly used to diagnose type 2 diabetes, could identify signs of GD in the first trimester of pregnancy. The HbA1c test indicates the average blood glucose levels over the previous 3 months based on the amount of glucose that has accumulated on the surface of red

[50] https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/gestational/definition-facts
[51] https://www.niddk.nih.gov/health-information/diabetes/overview/tests-diagnosis/a1c-test

blood cells. Using records from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Fetal Growth Study, researchers compared the HbA1c of women who went on to develop GD and those that did not. Women who went on to develop GD had higher HbA1c levels compared to those without GD (an average of 5.3 percent compared to 5.1 percent, respectively). Each 0.1 percent increase in HbA1c above 5.1 percent in early pregnancy was associated with a 22-percent higher risk for GD. The results suggest that the HbA1C test potentially could help identify women at risk for gestational diabetes early in pregnancy.

Role of Stress Gene in Chronic Pain

People respond to pain differently; for most people, acute pain will fade away as an injury heals, but for others, the pain persists beyond the initial healing and becomes chronic. Previous research has shown a connection between chronic pain and blood levels of a particular microRNA. MicroRNAs attach to messenger RNA (mRNA) and block translation of the mRNA into a particular protein. Looking for other clues to explain why some people are more susceptible to chronic pain, researchers recently discovered subtle differences in a gene that controls how the body responds to stress. The stress controlling gene, called *FKBP5*, has at least six different variants. According to recent studies, people who carry one variant of this gene are more likely to develop chronic pain after a trauma. Connecting these results to the earlier finding about microRNA, researchers suggest that the pain-associated *FKBP5* variant does not fold up properly for the microRNA to properly attach, allowing more *FKBP5* proteins to be produced from the *FKBP5* mRNA. Consequently, high levels of *FKBP5* protein leads to release of higher levels of the stress hormone cortisol. Cortisol sensitizes the peripheral nerves, signaling pain. Thus, high levels of cortisol could signal pain even in the absence of nerve damage and lead to chronic pain. More research is needed, but these results could point to a new non-addictive strategy for preventing and controlling chronic pain.

Gene Editing to Treat Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a genetic disease in which the muscles, including skeletal, heart, and diaphragm muscles, weaken to a point where they are not functional. It is ultimately fatal. DMD is caused by errors in the production of dystrophin proteins, which are vital to muscle health. Because it is a genetic disease, gene therapy presents a possible treatment option for DMD. However, a challenge in developing gene therapy for DMD is that the dystrophin gene is especially long and there are thousands of possible mutations that can result in DMD. Researchers funded by NIH endeavored to learn whether the clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (CRISPR/cas9) gene editing system, which uses specific guide RNA to perform precise excision of DNA code in the genome, could excise mutational hot spots in the dystrophin gene, resulting in a shorter but still functional protein. The researchers were able to inject the CRISPR/cas9 cassette using a viral carrier into very young dogs and within 6 weeks the puppies were producing the new dystrophin proteins. The researchers performed a second trial by injecting the cassette intravenously into two young dogs with DMD. In eight weeks, the muscles were producing dystrophins at 3 to 90 percent of normal levels, including production in the heart and diaphragm. Importantly, the dogs did not appear to have an immune response to Cas9, nor was there evidence that the enzyme had cut the DNA in other places, which potentially could cause

other health problems. More studies are needed using larger sample sizes and long-term follow up, but this approach could eventually be tried in children and young adults with DMD.

Funding History

Fiscal Year	Amount[1, 2]
2016	$32,311,349,000
2017 [3]	$34,229,139,000
2018	$37,311,349,000
2019	$39,311,349,000
2020 Budget Request [4]	$34,367,629,000

[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, and NIGMS Program Evaluation financing of $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, and $741,000,000 in the FY 2020 Request. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019, and $492,000,000 in FY 2020.

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

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

[4] Includes the consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ) in the amount of $255,960,000. Figures prior to FY 2020 do not include amounts for AHRQ. For information on AHRQ funding history, see the NIRSQ chapter of the NIH Congressional Justification.

Summary of Request Narrative

The FY 2020 President's Budget request would provide a program level of $34.4 billion to NIH, which is $4.9 billion less than the $39.3 billion received in FY 2019.

The following summary references program level funding, which is the sum of discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriations ($33.4 billion in FY 2020); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research program ($66.6 million in FY 2020); mandatory budget authority provided for Type 1 Diabetes research ($150.0 million in FY 2020); and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act ($741.0 million in FY 2020).

The request includes the consolidation into NIH of Agency for Healthcare Research and Quality (AHRQ) activities as the National Institute for Research on Safety and Quality (NIRSQ). The NIH FY 2020 discretionary budget authority total and the NIH FY 2020 program level include $256.0 million for NIRSQ.

The primary budget mechanisms discussed below include allocations by mechanism of Program Evaluation Financing and Type 1 Diabetes funds. In addition, the mechanism detail for FY 2020 reflects the allocation of discretionary budget authority for NIRSQ.

In FY 2020, NIH will continue providing upfront funding for certain projects, as appropriate, to facilitate efficient management of resources across multiple years. In general, NIH discretionary research project grants are awarded for more than one year and funded incrementally; each year's commitment is obligated from that year's appropriation. Grants are classified as Competing in the first year of award or renewal, and Non-competing in the remaining years of each award. Certain categories of NIH grants are awarded for multiple years with the full funding provided up front. This includes the NIH Director's New Innovator Award (DP2) and the NIH Research Enhancement Award (R15). The latter consists of two programs, the Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions, and the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. In addition, full funding can be provided up front for other NIH grants and cooperative agreements as necessary in special circumstances. This approach requires additional oversight and is used judiciously for select programs and awards. Situations that may require such an approach include appropriations for a new program received late in the fiscal year, rapid increases in funding, or variable outyear funding streams (e.g., under the 21st Century Cures Act). Up-front funding has increased over the last few years (from 2 percent of total research grant dollars to 4 percent in FY 2018), due to the large Congressional increases for Alzheimer's disease research. The use of this approach for Alzheimer's disease research is expected to gradually decrease over time. There is also a one-time increase in up-front funding in FY 2019 due to the HEAL Initiative, because it changed from two-year to one-year money; as a result, more than a year's worth of HEAL appropriations needs to be obligated in FY 2019.

Research Project Grants (RPGs)
The FY 2020 President's Budget would provide $18.6 billion for RPGs, which is $2.9 billion less than the FY 2019 estimate. This amount would fund 7,894 Competing RPGs, or 3,781 less than for the FY 2019 estimate. It would also support 28,760 Noncompeting RPGs, 1,268 more than the FY 2019 estimate. In addition, the projected average cost for Competing RPGs of approximately $472,000 would be 12.7% below the FY 2019 projected average cost of nearly $540,600.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2020 President's Budget would provide $921.1 million for SBIR/STTR program grants, which is $163.0 million below the FY 2019 estimate. The minimum set-aside requirement of 3.65% is achieved in FY 2020.

Research Centers
The FY 2020 President's Budget would provide $2,218.0 million for Research Centers, which is $470.2 million less than the FY 2019 estimate. This amount would fund 1,155 grants, 180 less than the FY 2019 level.

Other Research
The FY 2020 President's Budget would provide $2,209.7 million for this mechanism, which is $280.0 million less than the FY 2019 estimate. This amount would fund 6,244 grants, which is 752 less than the number of awards projected for FY 2019.

Training
The FY 2020 President's Budget would provide $801.9 million for training, which is $87.1 million below the FY 2019 estimate. This amount would fund 14,992 Full-Time Trainee Positions (FTTPs), which is 1,674 fewer than planned for FY 2019.

Research & Development (R&D) Contracts
The FY 2020 President's Budget would provide $2,795.4 million for R&D contracts, which is $337.2 million less than the FY 2019 estimate. The requested amount would fund an estimated 1,862 contracts, or 315 fewer than the FY 2019 level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2020 President's Budget includes a $64.1 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement of 3.65% in FY 2020 is attained through a combination of contracts and grant awards.

Intramural Research (IR)
The FY 2020 President's Budget would provide $3,633.8 million for IR, which is $495.7 million less than the FY 2019 level.

Research Management and Support (RMS)
The FY 2020 President's Budget would provide $1,739.4 million for RMS, which is $159.0 million less the FY 2019 level.

Office of the Director (OD)
The FY 2020 President's Budget would provide $1,926.1 million for OD, which is $191.5 million less than the FY 2019 level.

- **Common Fund (CF)**
  Funding of $533.0 million is allocated for CF-supported programs. This amount is $86.2 million below the FY 2019 level.

- **Office of Research Infrastructure Programs (ORIP)**
  Funding of $249.0 million is allocated for ORIP. This amount is $40.2 million below the FY 2019 level.

- **Other**
  The $1,144.2 million allocated for OD elements other than the Common Fund or the Office of Research Infrastructure Programs is a net decrease of $65.1 million from the FY 2019 level. This is due, in part, to a decrease in the portion of funding authorized by the 21st Century Cures Act that is managed by OD, from $196.0 million to $157.0 million. The 21st Century Cures Act resources for FY 2020 include $149.0 million for the *All of Us* Research Program and $8.0 million for Regenerative Medicine research.

Buildings & Facilities (B&F)
The FY 2020 President's Budget provides $214.0 million for infrastructure sustainment projects associated with the B&F program, which is $4.0 million less than the FY 2019 level. This amount includes $14.0 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Superfund Research Program
The FY 2020 President's Budget would provide $66.6 million, which is $10.8 million less than the FY 2019 Annualized CR level.

Program Evaluation Financing
The FY 2020 President's Budget would provide $741.0 million for Program Evaluation Financing purposes, which is $405.8 million less than the FY 2019 level.

Outputs and Outcomes

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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: As of May 1, 2018, New York, Massachusetts, and Idaho joined the SEER Program as core registries. Target: Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population. (Target Met)	Expand SEER to include links with 1-2 outside sources such as biospecimen acquisition, genomics and molecular profile data.	Provide trends and rates specific to the clinically relevant cancer subtypes represented by molecular characterization of each tumor.	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: Recruitment ended after 20 months, with 5,451 patients enrolled in the STRIDE study. Follow-up is ongoing. Target: Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy. (Target Met)	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.	Complete analyses of secondary outcome data. These outcomes include patient concerns about falling, all falls, all fall-related injuries, physical function, disability, anxiety and depression.	N/A
SRO-2.1 By 2023, develop, optimize, and evaluate the effectiveness of nano-enabled immunotherapy (nano-immunotherapy) for one cancer type. (Output)	FY 2018: Researchers developed and/or optimized, in animal models, 3 unique nanodelivery systems for effective anti-cancer immunotherapeutics. Target: Optimize properties of 3 nanoformulations for effective delivery and antigen-specific response in immune cells. (Target Met)	Further optimize top 2 candidate nanoformulations for co-delivery of multiple antigens to enhance anti-tumor response in one animal model.	Further optimize the top candidate nanoformulation for co-delivery of antigens, adjuvants and immuno-modulators and evaluate its efficacy and long-lasting immunity (over 3 months) in preclinical models with established tumors.	N/A
SRO-2.2 By 2018, assess the efficacy of	FY 2018: Patient recruitment, enrollment, and follow-up are	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	completed. Primary results paper is under review but has not yet been published. Target: Complete study and publish manuscript. (Target Not Met but Improved)			
SRO-2.3 By 2019, evaluate the impact of a community-level combination prevention package (which includes universal HIV testing and intensified provision of HIV antiretroviral therapy and care) on population-level HIV incidence in the developing world. (Outcome)	FY 2018: All follow-up visits were successfully completed, and primary analysis is in progress. Target: Finish conducting follow-up visits and begin data analysis. (Target Met)	Complete data analyses to evaluate the impact of a community-level combination prevention package on population-level HIV incidence.	N/A	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 2018: Scientist has initiated the testing of a new potential treatment option for aphasia (loss of the ability to understand or express speech) caused by damage or injury to the parts of the brain that control language. Patient enrollment has begun. Target: Initiate testing one new potential treatment option for a speech and language disorder. (Target Met)	Initiate testing one new potential treatment option for a hearing disorder.	Initiate testing one new potential treatment option for a taste disorder.	N/A
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	FY 2018: All five teams in the Audacious Goals Imaging Consortium have developed components of their novel imaging tools and shown proof-of-principle in animal models. Four teams have tested their tools in human volunteers. Target: Develop prototypes for four imaging technologies based	Integrate measurements of cell function with anatomical imaging.	Translate two novel imaging technologies from animal studies into human participants.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	on adaptive optics in animal models. (Target Met)			
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 2018: Due to unanticipated technical difficulties, the planned activities are still in progress. Target: 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. (Target Not Met)	Determine and identify, if present, sex differences in three environmentally induced epigenomic signatures in three different mouse tissues.	Determine and identify, if present, sex differences in four additional 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 2018 IND application submission has been delayed to January 2019, but clinical trial recruitment targets are expected to be met on time. Target: Submit IND application with the FDA to launch phase I clinical trial upon approval. (Target Not Met but Improved)	Recruit 3 AMD patients into Phase I clinical trial.	Recruit 9 more AMD patients.	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: 20 new drug discovery projects were initiated, 12 of which are seeking to discover new therapeutic agents against 6 novel therapeutic targets. Target: Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets. (Target Met)	For each of the novel therapeutic targets, select 3-5 candidate therapeutic agents for entry into preclinical optimization studies.	Complete preclinical proof of concept in animal models of AD for 3-5 new candidate therapeutics.	N/A
SRO-2.9 By 2022, evaluate the safety	FY 2018: Analysis of primary results has been conducted and	Strategy 3: Complete final analysis of an	Strategy 1: Complete follow-up of	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	results are in press. Target: Strategy 2: Analyze primary results of a Phase 2a study examining the long-acting injectable, cabotegravir, for the prevention of HIV. (Target Met)	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.	participants in studies testing the safety, tolerability, and effectiveness of VRC01.	
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: Two Resource Centers were funded and are operational. 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. (Target Exceeded)	Submit an Investigational New Drug (IND) application for an FDA-approved tissue regeneration combination product.	Initiate a Phase I clinical trial based on tissue engineering and regenerative medicine for a dental, oral, or craniofacial disease or disorder.	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: Projects funded through the BRAIN Initiative led to novel innovations in four neurotechnologies to enable basic studies of neural activity at the cellular level. Target: Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level. (Target Met)	Test new and/or existing brain stimulation devices for 2 new therapeutic indications in humans through the BRAIN Public Private Partnership.	Provide broad access to new research approaches and techniques for acquiring fundamental insight about how the nervous system functions in health and disease.	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	FY 2018: 12 preclinical projects developing new treatments for neurological disorders are in lead optimization phases. Target: 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.	Initiate animal toxicology studies for 1-2 therapeutic or device candidates.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
toward the point of preparedness for first-in-human studies. (Output)	(Target Exceeded)			
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2018: Research demonstrated that accelerated gray matter volume declines are associated with alcohol use during adolescence. Target: Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development. (Target Met)	Continue to evaluate the impact of adolescent alcohol or other substance use on brain development.	Examine how individual differences in neurobiology contribute to adolescent substance taking behavior and related health outcomes.	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: Four research studies have assessed technologies that image the placenta in real-time during pregnancy, obtaining data on placental blood flow, oxygen levels, and/or metabolism. 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. (Target Exceeded)	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.	Identify 2 biomarkers that are associated with placental development and/or function.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2018: Researchers have enrolled patients with treatment-resistant juvenile dermatomyositis (JDM) and initiated treatment with a Janus Kinase (JAK) inhibitor. Target: 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. (Target Met)	Continue an interventional clinical study of a molecularly targeted therapy for 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

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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 2018: The BrIDGs program acquired GMP-compliant drug material for one project. Target: Acquire GMP-compliant drug material for 1-3 projects. (Target Met)	Initiate formal GLP toxicology studies for 1-3 projects.	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.	N/A
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: The Cancer Systems Biology Consortium has investigated both molecular and cellular complexity of 4 cancer types. Target: Identify the cellular/genetic components of 3 common cancer types. (Target Met)	Identify the role various cellular components play in the phenotype of the 3 cancers.	Based on new understanding of tumor composition, develop 3 computational models to explore new knowledge and treatments.	N/A
SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)	FY 2018: The molecular bases of 29 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	N/A	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 2018: A sharable biorepository, containing biospecimens from ZIKV-infected blood donors who participated in the 2016-2018 US natural history study, was successfully established. Target: 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 biospecimens, 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	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2018: A Phase 3 clinical trial to test a non-opioid medication for managing symptoms of opioid withdrawal was completed. Target: Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment. (Target Met)	Conduct 1 pre-clinical study and 1 clinical trial to develop non-opioid based medications to treat OUD that may avoid the risks of opioid dependence and overdose.	Conduct 1 pre-clinical and 1 clinical study of a longer acting formulation of a medication for the treatment of opioid use disorders or opioid 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: Multiple pre-submission interactions with the FDA were completed. Target: Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials. (Target Met)	Implement regulatory feedback received by the FDA to demonstrate safety and effectiveness.	One patent application of a novel resin will be completed, reflecting the priorities identified by the FDA.	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: 10 receptors have been isolated and identified from human pancreatic islet-infiltrating lymphocytes and tested for their ability to alter islet function in various types of animal model systems. Target: Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D. (Target Met)	Develop a system for rapid and high-fidelity insertion of 2 T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line.	Use in vivo model(s) carrying iPSC-derived human beta cells to test the efficacy of 2 approaches aimed at enhancing beta cell viability and/or expansion.	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic	FY 2018: The extent and durability of improvements in diabetes and its comorbid conditions in response to two	By 2019, evaluate the impact of bariatric surgery for severe obesity during	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
outcomes in response to treatment of adolescents with severe obesity. (Outcome)	treatment modalities (surgical and medical) in adolescents with severe obesity and type 2 diabetes were assessed. 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. (Target Met)	adolescence on weight-related and psychosocial and behavioral outcomes.		
SRO-4.13 By 2018, complete analysis from the oral insulin trial for the prevention of type 1 diabetes in relatives at risk for the disease. (Outcome)	FY 2020: Data analysis from the oral insulin trial was completed in FY 2018. Target: Complete data analysis from the oral insulin trial. (Target Met)	N/A	N/A	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). (Outcome)	FY 2018: Five health risk strategies to reduce modifiable health risks associated with premature mortality in adults with SMI were identified. Target: Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI. (Target Exceeded)	Conduct testing of 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	Conduct testing of an additional 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	N/A
SRO 4.15 By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations. (Output)	(Will begin reporting in December 2019)	Test a screening and brief alcohol intervention in an underage population.	Test a behavioral therapy for intervening with alcohol misuse in an underage population.	N/A
SRO-5.1 By 2020, develop and test the effectiveness of two strategies for	FY 2018: The U54 PACHE Partnerships, through 2 new efforts, developed and/or validated evidence-based	Finalize testing and validating the strategies to translate basic cancer	Finalize testing and validating the strategies to translate basic cancer	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	interventions and tools to help reduce the burden of cancer disparities in underserved communities across the United States. These partnerships continue to work with various community-based organizations (including faith-based organizations and community-based clinical practices and organizations) to disseminate/translate the interventions and tools for use in diverse communities. Target: Develop and support 2 partnerships to test validated basic cancer knowledge, clinical or behavioral interventions to diverse communities in clinical practice. (Target Met)	knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	
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 2018: Investigators identified single nucleotide polymorphisms (SNPs) that correlate with emphysema, but not with specific patterns of emphysema. Eight gene variants have been identified that associate with four emphysema patterns. Target: Identify 1-5 genomic loci that correlate with specific lung patterns of emphysema. (Target Not Met but Improved)	N/A	N/A	N/A
SRO-5.3 By 2023, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-	FY 2018: NIH continued confirmation of genomic regions of interest in the Discovery Phase using samples from the Replication Phase, continued harmonization of Discovery Phase and Replication Phase datasets, and began analysis of	Begin analysis of genomic regions of interest in the ADSP Discovery Follow-Up Phase using whole genome sequence data from ethnically diverse	Continue analysis of ADSP Discovery Follow-Up Phase in ethnically diverse cohorts. Continue confirmation of genomic regions of interest from	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
onset Alzheimer's disease. (Output)	genomes of minority cohorts. Target: Continue confirmation of genomic regions of interest in the Discovery Phase 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. (Target Met)	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.	Discovery Phase and Discovery Follow-Up Phase in ethnically diverse datasets. Compare data on genomic regions of interest by ethnicity.	
SRO-5.5 By 2018, complete pre-commercial development of a point-of-care technology targeted for use in primary care setting. (Output)	FY 2018: Self-collected samples used in a point-of-care device developed for use in a primary care, clinic, or potentially at home, was found to be highly preferably for most patients who participated in the study. The sample collection method was found to be easy and patients were willing to wait 30 minutes to receive the test results. Target: Support research on refinement of one or two devices for use in primary care that includes end-user feedback. (Target Met)	N/A	N/A	N/A
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: HVTN 705, a Phase 2b efficacy study, was initiated and is being conducted in women 18-35 years of age in sub-Saharan Africa. Target: Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population. (Target Met)	Evaluate 1-2 alternative HIV vaccine candidates' suitability for human testing.	Further explore identification of correlates of protection in non-human primate animal models.	N/A
SRO-5.10 By 2020, assess the effectiveness of five to seven	FY 2018: Intervention research projects have completed approximately 80 percent of recruitment, and initiated	Assess intervention progress and collect	Complete analyses of five to seven community-based participatory research	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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)	collection of third year assessment variables to obtain preliminary results and baselines. Target: Assess intervention progress and collect third year assessment variables. (Target Met)	fourth year assessment variables.	interventions to determine effectiveness in impacting health disparity conditions.	
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 2018: Scientists have tested two strategies for managing symptoms such as anxiety, pain, poor sleep quality, and depressive symptoms. Target: Test three strategies for symptom management that improve health outcomes across multiple illness trajectories. (Target Not Met)	N/A	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 2018: Researchers using mouse models identified factors influencing stem-cell lifespan. Characterization of a mouse model in one study revealed that the vitamin D receptor is required for proper skin wound healing. Another study uncovered a role for mitochondrial DNA in skin aging. Target: 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. (Target Met)	Develop and/or characterize a mouse model in which skin stem cell participation in wound repair is impaired.	Describe the role of stem cells in skin cancer development by creating traceable stem cells that allow researchers to study cancer development from its earliest events.	N/A
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly	FY 2018: Researchers developed a minimally invasive method to deliver drugs across the blood brain barrier and a non-invasive way to track therapeutic effects	Initiate research to test and refine one new or improved technology that uses acoustic, optical or	Initiate research of a prototype technology that uses acoustic, optical, or electromagnetic	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	in the brain using engineered bacteria and ultrasound. Target: Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment. (Target Met)	electromagnetic waves to manipulate cells for treatment of illness.	waves as a test case in a specific disease.	
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 2018: Completed enrollment of 364 preterm infants in study of incubator treatment. Study findings have been published. Target: Complete enrollment in study of preterm infants undergoing incubator treatment. (Target Met)	Complete enrollment in transfusion study.	Complete follow-up on subjects enrolled in a comparative-effectiveness study on two surgical procedures to treat intestinal perforation due to necrotizing enterocolitis in infants.	N/A
SRO-5.15 By 2025, 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 2018: Researchers developed and evaluated the effects of combining individual- and community-level interventions to reduce underage drinking by American Indian youth living on rural California reservations. Target: Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native). (Target Met)	Develop an intervention to prevent or reduce alcohol misuse among college age individuals.	Develop a digital technology-based intervention to prevent or reduce alcohol misuse in underage individuals.	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 2018: The Pediatric Trials Network has completed clinical study reports on caffeine, rifampin, and methadone. Target: Complete one Phase I/II clinical trial on a prioritized drug. (Target Exceeded)	Begin one Phase III clinical trial for drug development.	Obtain preliminary pharmacokinetic results to help assess the safety for mothers and infants of at least 3 common, off-patent drugs when used by breastfeeding women.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	FY 2018: Researchers developed and tested the first measure of decisional fatigue in surrogate decision-makers of the critically ill. Target: Initiate development of new strategies for patient- and caregiver-centered decision-making in end-of-life and palliative care. (Target Met)	Test at least one novel strategy for improving care for patients with advanced illness through shared decision-making.	Develop and test one novel strategy for improving end-of-life/palliative care through better support of family members and informal caregivers.	N/A
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2018: The pediatric protocol for the Restoring Insulin Secretion study was completed. Target: Complete at least one Restoring Insulin Secretion protocol. (Target Met)	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.	Complete final visits and analyze the data from the Restoring Insulin Secretion adult medication study.	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: To advance the development of the ghrelin receptor blocker PF-5190457 as a potential treatment for alcohol use disorder, researchers conducted a preclinical study with rodents to evaluate its safety when administered in combination with alcohol. 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. (Target Met)	Conduct at least 1 human laboratory study to evaluate the safety and efficacy of candidate compounds for treating alcohol or other substance use disorders.	Evaluate 1 compound with potential for treating alcohol and other substance use disorders in a clinical trial.	N/A
SRO-7.2 By 2018, develop an evidence-based, online resource to help	FY 2018: Investigators developed an evidence-based, online resource to help people who have low back pain and their	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	health care providers apply clinical evidence when weighing treatment options. Usability testing in collaboration with Consumer Reports showed that the calculator informed patients about their options, was useful for decision making, and was easy to use. Target: 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. (Target Met)			
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 2018: Research testing the feasibility and efficacy of 2 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including (1) reSET-O which is under expedited review by FDA and (2) a web-delivered cognitive behavior therapy for veterans who screen positive for PTSD and SUD. Target: Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities. (Target Met)	Develop and/or evaluate 2 HIT based interventions to prevent or treat substance use disorders or to improve medication adherence.	Develop and test 1-2 FDA-approved digital therapeutic interventions for substance use disorder treatment and/or medication adherence.	N/A
SRO-8.7 By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across	FY 2018: Scientists investigated a range of implementation strategies to determine whether they improved the sustainability and scale-up of evidence-based practices (EBPs) in child welfare, Veterans Affairs and mental health agencies. Findings from four studies suggest that implementation strategies manipulated at the	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
health care systems. (Outcome)	organizational, community and provider levels resulted in improvements in workforce development, staff retention, early adoption, establishment of local expertise in delivering EBPs, increased EBP provider knowledge, expectations and level of confidence in the ongoing utilization, and sustainment and scale-up of EBPs. Target: 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. (Target Exceeded)			
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/ intervention programs in minority communities. (Outcome)	FY 2018: Successful components of the Shake, Rattle, and Roll trial are being disseminated and implemented within community settings. Target: Initiate dissemination and implementation (D&I) data analyses to identify scalable components of successful disparities intervention programs. (Target Met)	N/A	N/A	N/A
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2018: Award rate to comparison group reached 11% Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater	FY 2018: Award rate to comparison group reached 14% and exceeded the target by 4%.	N ≥ 10%	N ≥ 10%	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
retention and long-term success in research careers. (Output)	Target: N ≥ 10% (Target Exceeded)			
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 2018: NBS Cloud Migration is deferred due to priority operational audit findings. 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 Not Met)	(Development [Dev]) Continue development of remediation activities to comply with HHS Accounting Treatment Manual (ATM) and other Treasury Mandates to increase accuracy and functionality of the NIH Business System.	(Deployment [Dep]) Conduct priority deployment activities for the Funds Configuration Initiative to comply with one of the NIH Corrective Action Plan remediation efforts.	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 2018: As of September 2018, over 800 juvenile knockout cell lines have been characterized (phenotyped). Target: Deliver phenotyping on 500 knockout (KO) juvenile lines. (Target Exceeded)	Deliver phenotyping on 600 knockout (KO) juvenile lines.	Deliver phenotyping on 600 knockout (KO) juvenile lines	N/A
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: Three CTSA Trial Innovation Centers and one CTSA Recruitment Centers have been established. Innovative resources to support the Network have been developed, such as a Central IRB, Standard Agreements to streamline the contracting process and facilitate the rapid exchange of contracting information, Trial Innovation Dashboards, and a Proposal Management Database. Target: Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and	Launch at least two multi-site clinical trials within the CTSA trial innovation network.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Recruitment Innovation Centers. (Target Met)			
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: The Biomedical Citizen Science Hub, called CitSciBio, was successfully developed and launched. Target: Complete development & launch the Biomedical Citizen Science Hub. (Target Met)	Establish 200-300 registered users of the site and 5 subgroups for the Biomedical Citizen Science Hub.	N/A	N/A
CBRR-9 By 2020, enroll a total of 2,352 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	FY 2018: A cumulative 1,826 participants were enrolled in GenomeConnect. Target: Enroll 1,652 cumulative participants in GenomeConnect. (Target Exceeded)	Enroll 2,002 cumulative participants in GenomeConnect.	Enroll a total of 2,352 participants in GenomeConnect, ClinGen's Patient Registry.	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: More than 50 children were enrolled in the PHN in 2018. Target: Enroll 50 children with complex congenital heart disease in a clinical research study. (Target Met)	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-14 By 2018, establish and utilize a national clinical network to conduct five stroke clinical trials using shared infrastructure and efficient processes. (Output)	FY 2018: In FY 2018, StrokeNet completed enrollment in four stroke clinical trials that were conducted within the network. Target: Complete enrollment in 1 to 3 trials being conducted within the stroke network. (Target Exceeded)	N/A	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment	FY 2018: A cognitive assessment protocol was applied in the US Health and Retirement Study and in four international comparison	Review results from the assessment protocol as deployed in the US in 2016-	Make data from the Harmonized Cognitive Assessment Protocol	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
for use in large nationally representative samples. (Outcome)	studies. Data have been collected and are being scored. Target: Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample. (Target Met)	2017 and in other countries in 2017 and 2018. Refine protocol as needed to increase sensitivity and specificity.	(HCAP) publicly available to the research community and initiate a follow-up study to the HCAP.	
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: 2,406 T cell and 207 B cell epitopes from infectious disease pathogens and 249 T cell epitopes from allergens were identified and characterized. 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. (Target Exceeded)	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	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: The development of three vaccine or therapeutic candidate products was advanced in FY 2018. Target: Advance the preclinical development of three vaccine and/or therapeutic candidate products. (Target Met)	Advance the preclinical development of three vaccine and/or therapeutic candidate products.	Advance the preclinical development of four 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	FY 2018: Five Partner P&F Projects were supported in FY 2018. Target: 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.	Support 4 P&F projects involving collaboration outside the hematology Centers.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
hematology that are available through the Cooperative Centers of Excellence in Hematology (CCEH). (Output)	(Target Met)			
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: 20 datasets were released that establish the framework for an atlas of the human prostate. Target: Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate. (Target Exceeded)	Identify and map at least 5 specific cell types or subtypes within the kidney, urinary outflow tract, and/or prostate.	Generate and release the human/mouse comparative atlases to the general public.	N/A
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: NIH supported 25 projects (approximately 36,000 sample analyses) at different stages of the project pipeline. 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. (Target Met)	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	N/A
CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)	FY 2018: Since inception of the Maximizing Investigators' Research Award (MIRA) program, there have been 944 MIRA-eligible established investigators, 306 of whom submitted applications, and 231 of whom received awards. Target: 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	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Exceeded)			
CBRR-25 Increase the total number of mentored research career development experiences for trainees from diverse backgrounds, including groups underrepresented in biomedical research, to promote individual development and to prepare them for a range of research-related careers. (Output)	FY 2018: 3,706 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 were supported across all training related stages, exceeding the target. Target: 3505 career experiences across all career stages. (Target Exceeded)	3,522 career experiences across all career stages.	3,539 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 who will pursue health research careers. (Output)	FY 2018: Approximately 1,450 undergraduate students participated in mentored research experiences, consistent with 2017 level. Target: Sustain the number of undergraduate mentored research experiences from 2017 level. (Target Met)	Sustain the number of undergraduate mentored research experiences from 2018 level.	Sustain the number of undergraduate mentored research experiences from 2019 level.	N/A
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	FY 2018: Concurrent validation of the 3-item Patient Safety Screener for adults seen in emergency care was conducted. 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.	Validate risk stratification approaches in emergency care settings for youth who are at risk for suicide.	Validate risk stratification approaches in emergency care settings for youth, and test clinical decision-making approaches based on risk stratification.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
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: Brain tissue from 90 donors was obtained and tissue was distributed to 23 researchers studying mental or neurological disorders. 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. (Target Met)	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.	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: The Data Core successfully planned the infrastructure, provisioned the necessary servers, and had test data from multiple sites in the consortium navigate the system from upload to final storage of the metadata. Target: Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations. (Target Met)	Initiate multi-site validation studies for one candidate biomarker.	Initiate multi-site validation studies for two additional biomarker candidates.	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 2018: Outreach events were conducted with 2 women-targeted organizations and 3 minority-targeted organizations. Target: Complete four outreach events with either a minority-targeted organization or program, or a women-targeted organization or program. (Target Exceeded)	N/A	N/A	N/A
CTR-5 By 2018, increase the number of computer-indexed	FY 2018: The number of computer-indexed MEDLINE journals was increased by 66	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
MEDLINE journals by 469 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	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 60 titles over the previous year. (Target Exceeded)			
CTR-6 By 2018, improve NIH's ability to identify outcomes that result from NIH funded research projects and reports to the public on research outcomes. (Outcome)	FY 2018: NIH deployed the electronic Human Subjects System (HSS), which allows collection of inclusion data at award closeout in a structured format. Target: By 2018, implement system improvements to collect inclusion data (i.e., race, gender, etc.) at award closeout in a structured format. (Target Met)	N/A	N/A	N/A
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 2018: Stakeholders were convened to discuss how to move the National Action Plan towards implementation in rural communities. Target: Conduct annual implementation progress webinars/meetings with stakeholders. (Target Met)	Analyze completed webinars and meeting, and brief stakeholders on Action Plan progress.	Analyze completed webinars and meetings, 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	FY 2018: NIH developed a metric to capture unique individuals who apply for various extramural grants such as the R21 or R01-equivalents over a five-year period. Target: By 2018, develop a metric that captures the unique number of individuals who apply	By 2019, develop a central public report displaying NIH Institute/Center-specific award data on investigator-initiated R01/R37 grants.	By 2020, develop a central standard report to describe NIH research investments to organizations receiving R01-equivalent and Research Project Grant support	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
agency funding decisions, and promote transparency regarding the agency's funding strategies. (Output)	for and receive NIH funding over a five-year time period. (Target Met)		according to Carnegie Classification and Funding Institute/Center.	
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Output)	FY 2018: Assessments of the revised Executive Leadership Program (ExLP) program indicate that the program changes have been successful to date. Target: 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 current content [IM 2017/AS 2018] (Target Met) FY 2018: NIH created a pilot best-practices toolkit for implementation. However, NIH experienced limited hiring and new supervisors all transitioned from existing positions within NIH, so usage of the toolkits has been minimal thus far. Target: 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] (Target Met) FY 2018: Upon examining the results, technical rather than leadership skills were deemed most needed at this time.	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	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Interventions were enacted in the budget (560) series, and a model was built that could be used for longer-term leadership development in any targeted job series. Target: 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] (Target Met)			
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2018: Expansion of the NIH Pathways Program enhanced NIH's scientific workforce by 57 student trainees and was 22% of the Pathways population hired. Target: 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] (Target Met) FY 2018: Results of analysis are still being considered as the effort to include SMEs took a significant amount of time. Target: Implement [IM] key area to enhance recruitment *Implement the creation of a program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019] (Target Not Met) FY 2018: A survey regarding the use of the Human Resources	Examine [EX] key area to enhance recruitment Examine recruitment activities to identify the most opportune times throughout the year for NIH to recruit for varying occupations.	Examine (EX) key area to enhance recruitment. Examine use of the shared recruitment approach, using data gathered in first year of full-time practice, to determine if hiring goals are being met. [IM 2021/AS 2022]	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Classification and Recruitment Documents System (HR CARDS) was disseminated to HR Specialists and administrative staff across NIH who recently were involved in a recruitment. Overall, 78% of the respondents were satisfied with the system and the content. Target: 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] (Target Met)			
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2018: 25% of Principal Investigators were reviewed resulting in approximately 25% of resources recommended to be reallocated. Target: Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and 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). (Ongoing) (Output)	FY 2018: The condition of the facilities portfolio reached a CIwa of 82.42. Target: CIwa=80.86 (Target Exceeded)	CIwa = 79.51	CIwa = 77.78	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	FY 2018: Eleven (11) of the fifteen (15) 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.	23 Active Projects	16 Active Projects	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
cost. (Ongoing) (Output)	Target: 15 Active Projects (Target Not 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. (Ongoing) (Output)	FY 2018: NIH managed the design and construction of eleven (11) of the fifteen (15) funded projects without a plus or minus 10% adjustment to the scope. Target: 15 Active Projects (Target Not Met)	23 Active Projects	16 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2018: Obligated 47% of eligible service contracting dollars to PBC. Target: Obligate the FY 2018 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2019 goal of eligible service contracting dollars to PBC.	Obligate the FY 2020 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 2018: Based on analyses of historical measures and deep institutional knowledge of peer review policies and procedures, NIH has developed a new process to continuously evaluate and maintain the quality and efficiency of peer review at NIH's Center for Scientific Review. The procedures involve both primary and secondary research, evaluations by an external committee of experts from the scientific community and evaluations by an internal committee of NIH leaders. Target: Design and test measures of peer review quality and efficiency.	Refine and test measures of peer review quality and efficiency.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
MPO-11 Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	FY 2018: Of the 106 active awards, 96 instruments (91%) were installed within 18 months of the Notice of Award date. Target: 70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award. (Target Exceeded)	75% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 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: Effective for applications submitted for due dates on or after January 25, 2018, NIH now requires all grant applications with plans to conduct clinical trials to be submitted to a clinical trial FOA. In addition, NIH announced updated review criteria for applications proposing clinical trials and issued updated FOAs in Fall 2017. 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. (Target Met)	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.	Deploy an enterprise-wide system for improved stewardship of NIH-funded clinical trials that will enhance the management and oversight of NIH-funded clinical trials.	N/A

[1] Performance measures do not reflect measures for the Agency for Healthcare Research and Quality (AHRQ), activities of which are proposed to be consolidated into NIH in FY 2020 as the National Institute for Research on Safety and Quality (NIRSQ). For information on AHRQ performance measures, see the NIRSQ chapter of the NIH Congressional Justification.

Grants Awards Table

	FY 2018 Final Allocation[3,4]	FY 2019 Enacted[3]	FY 2020 President's Budget[3,5]
Number of Awards	47,414	49,720	45,964
Average Award (in Whole $s)	$553,309	$558,271	$521,547
Range of Awards (in Whole $s)[1,2]	$1,000 to $38,535,606	$1,000 to $43,696,035	$1,000 to $35,918,115

[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] Figures shown in the FY 2018 column include an estimated 598 awards expected to be made from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[5] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

Nonrecurring Expenses Fund Narrative

Budget Summary
(Dollars in Thousands)

	FY 2018[2]	FY 2019[3,4,5]	FY 2020[6]
Notification[1]	n/a	$96,000	TBD

Authorizing Legislation:

Authorization…….…….Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method……..……..Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

In recent years, the NEF has provided funds for critical infrastructure needs for NIH buildings, structures, and facilities, as a supplement to the regular NIH Building and Facilities appropriations. The four projects, described below, received NEF funds in FY 2015 and FY 2016.

In FY 2016, the NEF granted NIH $162.1 million for the Renovation of the E-Wing in the NIH Clinical Center (Building 10). The mission of NIH is to uncover new knowledge that leads to better health for everyone. It is a “bench to bed side” research and training mission requiring both hospital and biomedical research laboratory functions. The Clinical Center Complex on the Bethesda Campus is a group of facilities that collectively support this mission. Building 10 is a 59-year-old facility built over 2 years beginning in 1950 that provides clinical services, laboratories and supporting office space. The condition of Building 10 has impaired its ability to fully support its role in this mission-critical complex. Without major renovation of its infrastructure, NIH is at risk of:

- Impacting accreditation by "The Joint Commission" and "College of Anatomical Pathologists" relating to the close proximity of the Anatomical Pathology area located in the adjoining F wing;
- Failing to provide the necessary functional adjacency to the existing Institutes and the Center’s outpatient clinics; and
- Causing the NIH to fail in fulfilling its mission.

In FY 2015, the NEF granted $10.0 million for a new warehouse for the National Institute of Environmental Health Services (NIEHS) in Research Triangle Park, North Carolina. The

government-owned warehouse facility is located on the NIEHS main campus and it replaced an off-site leased facility. This eliminated the need to pay for a continuing lease and provided an increased level of security for the warehouse. The location of the warehouse also routes traffic away from the Institute's research and administrative staff facilities therefore improving the continuity of operations.

In FY 2016, the NEF granted NIH $35.3 million for R22 Refrigerant Chillers. This project involves replacing two existing York 5,000 Ton dual steam turbine/electric driven chillers (CH-21 FY 2016, CH-16 FY 2017) in Building 11 with four new 3,000 ton variable speed electric chillers, two in FY 2017 and two in FY 2018. Due to the efficiency achieved in the current chilled water upgrades accomplished between 2013 and 2015 and the additional efficiency and capacity of the four new chillers, the remaining four R22 chillers will not have to be replaced. The refrigerant removed from the demolished chillers will be used as backup for the four remaining chillers if needed.

In FY 2016, the NEF granted NIH $16.5 million for Emergency Generators. The original Building 10 (B10) with the exception of the F wing is currently serviced from a 60+ year old electrical distribution system of wiring and components. In 2009 under the "Hybrid Vault/Riser" project, ORF commissioned four (4) secondary network distribution vaults to replace the aging vaults 1 thru 5 of B10. In addition, transformers in these legacy vaults contain PCB hazardous material. That project provided complete riser level distribution for the E and F wing renovations to proceed as separate projects in meeting the power requirements of those wings. However, the remaining wings A, B, C, D, G, H, and J of the building are still serviced from the old vaults 1 thru 5 of B10. The distributed electrical closets created to install electrical equipment in 1952 throughout the building are inadequate in size and capacity to house the ever-growing power distribution requirement of the current research and clinical programs and do not meet the current National Electrical Code. Additionally, sub distribution systems including wiring and localized panel boards are as old as the building and do not meet the needs of the current research and clinical programs and do not meet the current National Electrical Code.

FY 2019 Budget Allocations

HHS notified the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018 for $600 million in new projects, including modernization of the NIH Clinical Center Complex. The Nonrecurring Expenses Fund Congressional Justification details the current list of approved projects for FY 2019. Additional projects may be funded from the FY 2019 notification letter upon approval from OMB.

[1] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.
[2] There was no Congressional notification for the planned uses of NEF funds in FY 2018.
[3] Notification #6 submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018.
[4] Amounts notified are approximations of intended use. Amounts displayed here are current best estimates.
[5] Does not include NEF FY 2019 allocation of $1.0 million for the Agency for Healthcare Research and Quality, which is proposed to be consolidated into NIH in FY 2020 as the National Institute for Research on Safety and Quality (NIRSQ). For information on the NEF allocation for AHRQ/NIRSQ, see the NIRSQ chapter of the NIH Congressional Justification.
[6] HHS has not yet notified for FY 2020.

Budget Request by IC (Summary Table)

(Dollars in Thousands)	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
NCI	$5,943,706	$6,143,892	$5,246,737
NHLBI	$3,374,283	$3,488,335	$3,002,696
NIDCR	$446,683	$461,781	$397,493
NIDDK[1]	$2,113,453	$2,179,823	$1,897,235
NINDS	$2,145,030	$2,274,413	$2,026,031
NIAID	$5,268,307	$5,523,324	$4,754,379
NIGMS[2]	$2,781,024	$2,872,780	$2,472,838
NICHD	$1,457,226	$1,506,458	$1,296,732
NEI	$770,493	$796,536	$685,644
NIEHS[3]	$826,727	$852,056	$733,435
NIA	$2,571,502	$3,083,410	$2,654,144
NIAMS	$585,283	$605,065	$520,829
NIDCD	$458,893	$474,404	$408,358
NIMH	$1,754,434	$1,870,296	$1,630,422
NIDA	$1,374,374	$1,419,844	$1,296,379
NIAAA	$508,407	$525,591	$452,419
NINR	$157,662	$162,992	$140,301
NHGRI	$556,764	$575,579	$495,448
NIBIB	$376,730	$389,464	$335,244
NIMHD	$304,396	$314,679	$270,870
NCCIH	$141,684	$146,473	$126,081
NCATS	$760,710	$806,373	$694,112
FIC	$75,555	$78,109	$67,235
NLM	$427,546	$441,997	$380,463
B&F	$128,863	$200,000	$200,000
OD	$1,914,345	$2,112,675	$1,926,144
NIRSQ[4]	---	---	$255,960
TOTAL, NIH Program Level	**$37,224,080**	**$39,306,349**	**$34,367,629**
Special Type 1 Diabetes Research	-$150,000	-$150,000	-$150,000
PHS Program Evaluation	-$922,871	-$1,146,821	-$741,000
Interior Approp. (Superfund Research) [5]	-$77,349	-$77,349	-$66,581
Total, NIH Labor/HHS Budget Authority	**$36,073,860**	**$37,932,179**	**$33,410,048**

[1] Includes Type 1 Diabetes Research mandatory funding of $150.0 million in FY 2018, FY 2019, and FY 2020.

[2] Includes Program Evaluation financing of $922.9 million in FY 2018, $1,146.8 million in FY 2019, and $741.0 million in FY 2020.

[3] Includes Interior Appropriation allocation for Superfund Research activities of $77.3 million in FY 2018, $77.3 million in FY 2019, and $66.6 million in FY 2020.

[4] Figures for FY 2020 reflect the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ).

[5] Amount for FY 2019 reflects the Annualized CR level at the time the budget estimates were prepared.

Appropriations Adjustment Tables

(Dollars in Thousands)	FY 2018 Enacted[1]	Permissive Transfer (NIH Innovation Account)[2]	Permissive Transfer (Secretary's 1% Authority)[3]	HIV/AIDS Transfer	FY 2018 Operating Level
NCI	$5,664,800	$300,000	-$13,309	-$7,785	$5,943,706
NHLBI	$3,383,201	---	-$7,949	-$969	$3,374,283
NIDCR	$447,735	---	-$1,052	---	$446,683
NIDDK[4]	$2,120,797	---	-$4,630	-$2,714	$2,113,453
NINDS	$2,145,149	$43,000	-$4,452	-$2,567	$2,181,130
NIAID	$5,260,210	---	-$12,358	$14,455	$5,262,307
NIGMS	$2,785,400	---	-$4,376	---	$2,781,024
NICHD	$1,452,006	---	-$3,411	-$1,369	$1,447,226
NEI	$772,317	---	-$1,815	-$9	$770,493
NIEHS[5]	$828,492	---	-$1,765	---	$826,727
NIA	$2,574,091	---	-$6,048	$3,459	$2,571,502
NIAMS	$586,661	---	-$1,378	---	$585,283
NIDCD	$459,974	---	-$1,081	---	$458,893
NIMH	$1,711,775	$43,000	-$3,223	$2,882	$1,754,434
NIDA	$1,383,603	---	-$2,283	-$6,946	$1,374,374
NIAAA	$509,573	---	-$1,197	$31	$508,407
NINR	$158,033	---	-$371	---	$157,662
NHGRI	$556,881	---	-$1,308	$1,191	$556,764
NIBIB	$377,871	---	-$888	-$253	$376,730
NIMHD	$303,200	---	-$712	$1,908	$304,396
NCCIH	$142,184	---	-$334	-$166	$141,684
NCATS	$742,354	---	-$1,744	---	$740,610
FIC	$75,733	---	-$178	---	$75,555
NLM	$428,553	---	-$1,007	---	$427,546
OD	$2,311,893	-$386,000	-$10,400	-$1,148	$1,914,345
B&F	$128,863	---	---	---	$128,863
Total, NIH Program Level[6]	**$37,311,349**	---	**-$87,269**	---	**$37,224,080**
Less funds allocated from different sources:					
Mandatory Type 1 Diabetes Research	-$150,000	---	---	---	-$150,000
PHS Program Evaluation	-$922,871	---	---	---	-$922,871
Total, NIH Discretionary Budget Authority	**$36,238,478**	---	-$87,269	---	**$36,151,209**
Interior Budget Authority	-$77,349	---	---	---	-$77,349
Total, NIH Labor/HHS Budget Authority	**$36,161,129**	---	**-$87,269**	---	**$36,073,860**

[1] Excludes $50 million in supplemental funding to the Office of the Director for extramural construction.

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

[3] Identifies amounts transferred to other HHS accounts consistent with the Secretary's 1% transfer authority under Section 205 (Division H) of P.L. 115-141.

[4] Includes Type 1 Diabetes ($150 million).

[5] Includes Superfund Research activity.

[6] Program level is not adjusted for the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). For information on the AHRQ FY 2018 appropriation and adjustments, see the NIRSQ chapter of the NIH Congressional Justification.

Budget Mechanism Table

(Dollars in Thousands)[1,2,3]	FY 2018 Final[4]		FY 2019 Enacted[5]		FY 2020 President's Budget[6]		FY 2020 +/- FY 2019	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	25,858	$13,776,726	27,492	$14,677,360	28,760	$14,536,572	1,268	-$140,788
Administrative Supplements[3]	*(2,743)*	483,035	*(2,695)*	506,430	*(1,858)*	361,166	*(-837)*	-145,264
Competing	11,461	$5,943,802	11,675	$6,311,423	7,894	$3,725,852	-3,781	-$2,585,571
Subtotal, RPGs	37,319	$20,203,562	39,167	$21,495,213	36,654	$18,623,590	-2,513	-$2,871,623
SBIR/STTR	2,035	1,001,946	2,222	1,084,179	1,911	921,133	-311	-163,046
Research Project Grants	39,354	$21,205,508	41,389	$22,579,392	38,565	$19,544,723	-2,824	-$3,034,669
Research Centers:								
Specialized/Comprehensive	1,003	$1,813,976	1,079	$1,908,419	924	$1,547,608	-155	-$360,811
Clinical Research	68	417,709	66	421,640	64	362,000	-2	-59,640
Biotechnology	91	159,963	91	160,916	80	138,518	-11	-22,398
Comparative Medicine	67	129,881	79	133,759	67	115,233	-12	-18,526
Research Centers in Minority Institutions	21	61,478	20	63,407	20	54,594	0	-8,814
Research Centers	1,250	$2,583,007	1,335	$2,688,141	1,155	$2,217,953	-180	-$470,188
Other Research:								
Research Careers	4,040	$747,017	4,161	$780,492	3,792	$708,160	-369	-$72,332
Cancer Education	76	21,182	85	24,857	81	23,614	-4	-1,243
Cooperative Clinical Research	229	409,660	278	497,025	243	411,324	-35	-85,701
Biomedical Research Support	118	85,524	112	73,696	95	62,825	-17	-10,872
Minority Biomedical Research Support	283	101,245	294	104,359	228	81,111	-66	-23,248
Other	2,064	1,081,442	2,066	1,009,259	1,805	922,686	-261	-86,572
Other Research	6,810	$2,446,070	6,996	$2,489,688	6,244	$2,209,720	-752	-$279,968
Total Research Grants	47,414	$26,234,584	49,720	$27,757,221	45,964	$23,972,395	-3,756	-$3,784,825
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,500	$161,753	3,697	$173,134	3,335	$157,779	-362	-$15,355
Institutional Awards	12,697	694,093	12,969	715,821	11,657	644,094	-1,312	-71,727
Total Research Training	16,197	$855,845	16,666	$888,955	14,992	$801,873	-1,674	-$87,082
Research & Develop. Contracts	2,212	$3,072,532	2,177	$3,132,619	1,862	$2,795,430	-315	-$337,189
(SBIR/STTR) (non-add)[3]	*(85)*	*(60,608)*	*(98)*	*(74,336)*	*(79)*	*(64,122)*	*(-19)*	*(-10,214)*
Intramural Research		$3,996,276		$4,129,550		$3,633,805		-$495,745
Res. Management & Support		1,816,210		1,898,356		1,739,376		-158,979
Res. Management & Support (SBIR Admin) (non-add)[3]		*(0)*		*(5,172)*		*(3,559)*		*(-1,613)*
Office of the Director - Appropriation[3,7]		*(1,914,345)*		*(2,112,675)*		*(1,926,144)*		*(-186,531)*
Office of the Director - Other		1,024,420		1,204,300		1,144,168		-60,132
ORIP (non-add)[3,7]		*(289,209)*		*(289,209)*		*(249,009)*		*(-40,200)*
Common Fund (non-add)[3,7]		*(600,716)*		*(619,166)*		*(532,967)*		*(-86,199)*
Buildings and Facilities[8]		146,863		218,000		214,000		-4,000
Appropriation[3]		*(128,863)*		*(200,000)*		*(200,000)*		*(0)*
Type 1 Diabetes[9]		-150,000		-150,000		-150,000		0
Program Evaluation Financing[9]		-922,871		-1,146,821		-741,000		405,821
Subtotal, Labor/HHS Budget Authority		**$36,073,860**		**$37,932,179**		**$33,410,048**		**-$4,522,131**
Interior Appropriation for Superfund Research[10]		77,349		77,349		66,581		-10,768
Total, NIH Discretionary Budget Authority		**$36,151,209**		**$38,009,528**		**$33,476,629**		**-$4,532,899**
Type 1 Diabetes		150,000		150,000		150,000		0
Total, NIH Budget Authority		**$36,301,209**		**$38,159,528**		**$33,626,629**		**-$4,532,899**
Program Evaluation Financing		922,871		1,146,821		741,000		-405,821
Total, Program Level		**$37,224,080**		**$39,306,349**		**$34,367,629**		**-$4,938,720**

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

2 Includes 21st Century Cures Act funding and excludes Ebola-related and supplemental financing.

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

4 Includes $63.3 million of 21st Century Cures, $428.9 million of Opioids, and $123.7 million of Type 1 Diabetes funding not obligated in FY 2018, and carried over into FY 2019. Numbers of grants and dollars for carryover are distributed by mechanism.

5 Reflects transfer of $5.0 million to the HHS OIG.

6 Includes the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ), distributed by mechanism.

7 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as non-adds. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

8 Includes B&F appropriation and monies allocated ($18.0 million in FY 2018, $18.0 million in FY 2019, and $14.0 million in FY 2020) pursuant to appropriations acts provisions that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

9 Number of grants and dollars for mandatory Type 1 Diabetes (T1D) and NIGMS Program Evaluation financing are distributed by mechanism above; therefore, T1D and Program Evaluation financing amounts are deducted to provide subtotals for Labor/HHS Budget Authority.

10 This activity was under a Continuing Resolution at the time the budget estimates were prepared.

Budget Authority by Object Class Including Type 1 Diabetes

(Dollars in Thousands)[1,2]

Object Classes	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$1,018,931	$1,050,008	$31,077
Other Than Full-Time Permanent (11.3)	527,731	532,296	4,565
Other Personnel Compensation (11.5)	49,167	50,112	945
Military Personnel (11.7)	19,315	20,500	1,185
Special Personnel Services Payments (11.8)	193,839	185,836	-8,003
Subtotal Personnel Compensation (11.9)	**$1,808,982**	**$1,838,751**	**$29,769**
Civilian Personnel Benefits (12.1)	529,682	548,016	18,334
Military Personnel Benefits (12.2)	11,997	12,625	628
Benefits to Former Personnel (13.0)	0	1,518	1,518
Total Pay Costs	**$2,350,662**	**$2,400,911**	**$50,249**
Travel & Transportation of Persons (21.0)	55,071	42,513	-12,558
Transportation of Things (22.0)	5,513	4,493	-1,020
Rental Payments to GSA (23.1)	20,551	18,231	-2,320
Rental Payments to Others (23.2)	565	462	-103
Communications, Utilities & Misc. Charges (23.3)	36,389	25,342	-11,047
Printing & Reproduction (24.0)	342	283	-59
Consultant Services (25.1)	261,674	188,818	-72,856
Other Services (25.2)	1,364,980	961,436	-403,545
Purchase of goods and services from government accounts (25.3)	3,515,931	3,212,282	-303,649
Operation & Maintenance of Facilities (25.4)	282,236	267,544	-14,691
R&D Contracts (25.5)	1,631,794	1,457,442	-174,353
Medical Care (25.6)	28,317	23,733	-4,584
Operation & Maintenance of Equipment (25.7)	144,141	119,574	-24,567
Subsistence & Support of Persons (25.8)	1,907	1,676	-231
Subtotal Other Contractual Services (25.0)	**$7,230,980**	**$6,232,504**	**-$998,476**
Supplies & Materials (26.0)	231,993	182,763	-49,231
Equipment (31.0)	198,150	158,128	-40,022
Land and Structures (32.0)	0	0	0
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	27,951,899	24,494,365	-3,457,534
Insurance Claims & Indemnities (42.0)	2	2	0
Interest & Dividends (43.0)	62	51	-10
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$35,736,517**	**$31,159,137**	**-$4,577,380**
Total Budget Authority	**$38,082,179**	**$33,560,048**	**-$4,522,131**

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

[2] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2019 do not include AHRQ.

Budget Authority by Object Class Including SSF and MF

(Dollars in Thousands)[1,2]

Object Classes	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$1,400,747	$1,433,275	$32,528
Other Than Full-Time Permanent (11.3)	588,005	592,798	4,794
Other Personnel Compensation (11.5)	79,460	80,520	1,060
Military Personnel (11.7)	28,518	29,977	1,459
Special Personnel Services Payments (11.8)	199,242	191,260	-7,983
Subtotal Personnel Compensation (11.9)	**$2,295,971**	**$2,327,830**	**$31,859**
Civilian Personnel Benefits (12.1)	683,461	704,118	20,656
Military Personnel Benefits (12.2)	18,145	18,956	811
Benefits to Former Personnel (13.0)	1,224	2,742	1,518
Total Pay Costs	**$2,998,801**	**$3,053,646**	**$54,844**
Travel & Transportation of Persons (21.0)	58,765	46,207	-12,558
Transportation of Things (22.0)	7,753	6,699	-1,054
Rental Payments to GSA (23.1)	76,079	71,816	-4,263
Rental Payments to Others (23.2)	88,151	84,108	-4,043
Communications, Utilities & Misc. Charges (23.3)	162,878	139,768	-23,110
Printing & Reproduction (24.0)	367	307	-60
Consultant Services (25.1)	295,579	221,248	-74,331
Other Services (25.2)	2,047,721	1,535,030	-512,690
Purchase of goods and services from government accounts (25.3)	1,349,771	1,206,554	-143,217
Operation & Maintenance of Facilities (25.4)	375,526	352,419	-23,107
R&D Contracts (25.5)	1,631,794	1,457,442	-174,353
Medical Care (25.6)	39,086	34,364	-4,722
Operation & Maintenance of Equipment (25.7)	353,211	309,259	-43,952
Subsistence & Support of Persons (25.8)	7,272	6,909	-362
Subtotal Other Contractual Services (25.0)	**$6,099,959**	**$5,123,224**	**-$976,734**
Supplies & Materials (26.0)	385,629	330,012	-55,618
Equipment (31.0)	251,693	209,706	-41,988
Land and Structures (32.0)	0	0	0
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	27,951,901	24,494,366	-3,457,534
Insurance Claims & Indemnities (42.0)	6	6	0
Interest & Dividends (43.0)	196	183	-13
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$35,088,378**	**$30,506,402**	**-$4,581,975**
Total Budget Authority	**$38,082,179**	**$33,560,048**	**-$4,522,131**

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

[2] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2019 do not include AHRQ.

Salaries and Expenses

(Dollars in Thousands)[1,2]

Object Classes	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$1,018,931	$1,050,008	$31,077
Other Than Full-Time Permanent (11.3)	527,731	532,296	4,565
Other Personnel Compensation (11.5)	49,167	50,112	945
Military Personnel (11.7)	19,315	20,500	1,185
Special Personnel Services Payments (11.8)	193,839	185,836	-8,003
Subtotal Personnel Compensation (11.9)	**$1,808,982**	**$1,838,751**	**$29,769**
Civilian Personnel Benefits (12.1)	529,682	548,016	18,334
Military Personnel Benefits (12.2)	11,997	12,625	628
Benefits to Former Personnel (13.0)	0	1,518	1,518
Total Pay Costs	**$2,350,662**	**$2,400,911**	**$50,249**
Travel & Transportation of Persons (21.0)	55,071	42,513	-12,558
Transportation of Things (22.0)	5,513	4,493	-1,020
Rental Payments to Others (23.2)	565	462	-103
Communications, Utilities & Misc. Charges (23.3)	36,389	25,342	-11,047
Printing & Reproduction (24.0)	342	283	-59
Other Contractual Services:			
Consultant Services (25.1)	203,135	149,956	-53,179
Other Services (25.2)	1,364,980	961,436	-403,545
Purchase of goods and services from government accounts (25.3)[3]	2,691,325	2,413,033	-278,292
Operation & Maintenance of Facilities (25.4)	268,190	258,485	-9,705
Operation & Maintenance of Equipment (25.7)	144,141	119,574	-24,567
Subsistence & Support of Persons (25.8)	1,907	1,676	-231
Subtotal Other Contractual Services	**$4,673,678**	**$3,904,159**	**-$769,519**
Supplies & Materials (26.0)	231,993	182,763	-49,231
Subtotal Non-Pay Costs	**$5,003,551**	**$4,160,014**	**-$843,537**
Total Salaries and Expense / Administrative Costs	**$7,354,213**	**$6,560,925**	**-$793,288**

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

[2] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2019 do not include AHRQ.

[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 2018 Actual	FY 2019 Estimate	FY 2020 Estimate
NCI	2,952	3,035	3,035
NHLBI	901	962	962
NIDCR	228	235	235
NIDDK	630	660	660
NINDS	504	532	532
NIAID	1,935	1,963	1,963
NIGMS	173	184	184
NICHD	539	560	560
NEI	259	273	273
NIEHS	630	662	662
NIA	416	435	435
NIAMS	221	238	238
NIDCD	129	140	140
NIMH	550	563	563
NIDA	355	382	382
NIAAA	227	238	238
NINR	94	96	96
NHGRI	330	349	349
NIBIB	98	102	102
NCATS	172	167	167
NCCIH	68	73	73
NIMHD	72	68	68
FIC	58	61	61
NLM	700	741	741
OD	764	781	781
NIRSQ[4]	---	---	238
Central Services:			
OD - CS	794	841	841
CC	1,857	1,844	1,844
CSR	409	417	417
CIT	233	257	257
ORS	517	539	539
ORF	721	707	707
Subtotal Central Services[1]	**4,531**	**4,605**	**4,605**
PHS Trust Fund (non-add)[2]	*4*	*4*	*4*
CRADA (non-add)[3]	*5*	*5*	*5*
PCOR Trust Fund[4]	---	---	*7*
Total	**17,536**	**18,105**	**18,350**

[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.

[4] Figures for FY 2020 reflect the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ).

Physician's Comparability Allowance Worksheet

		FY 2017 Actual	FY 2018 Actual	FY 2019 Estimate[1]	FY 2020 Estimate [2]
1) Number of Physicians Receiving PCAs		150	134	127	148
2) Number of Physicians with One-Year PCA Agreements		20	25	22	22
3) Number of Physicians with Multi-Year PCA Agreements		130	109	105	126
4) Average Annual Physician Pay (without PCA payment)		$159,133	$165,495	$166,280	$163,034
5) Average Annual PCA Payment		$17,991	$19,003	$18,785	$19,565
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position				
	Category II Research Position	148	132	127	148
	Category III Occupational Health				
	Category IV-A Disability Evaluation				
	Category IV-B Health and Medical Admin.	2	2	0	0

7) If applicable, list and explain the necessity of any additional physician categories designated by your agency (for categories other than I through IV-B). Provide the number of PCA agreements per additional category for the PY, CY and BY.

N/A

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 $5,000 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).

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 to perform the highly-skilled duties related to research and clinical trials at the nation's premier medical research institution.

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.

In FY 2018, there were a total of 134 PCA recipients across NIH. In FY 2019 and beyond, as indicated by the decrease in recipients to-date relative to the prior year, the critical need continues to exist for highly qualified, specialized physicians to support the NIH mission. NIH still requires compensation flexibilities such as PCA to attract and retain qualified physicians.

11) Provide any additional information that may be useful in planning PCA staffing levels and amounts in your agency.

N/A

[1] FY 2019 data will be approved during the FY 2020 Budget cycle.

[2] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for years prior to FY 2020 do not include AHRQ.

History of Obligations by IC

(Dollars in Thousands)	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015[1]	FY 2016[1]	FY 2017[1,7]	FY 2018[1,7,8]	FY 2019 Enacted[7,9]	FY 2020 President's Budget[7,10]
NCI	$5,058,105	$5,062,763	$4,789,014	$4,932,368	$4,944,593	$5,206,169	$5,636,393	$5,948,569	$6,162,094	$5,246,737
NHLBI	$3,069,550	$3,073,302	$2,903,768	$2,988,415	$2,995,546	$3,109,062	$3,209,843	$3,374,154	$3,488,335	$3,002,696
NIDCR	$409,549	$409,947	$387,309	$397,833	$397,672	$412,788	$424,782	$446,656	$461,781	$397,493
NIDDK[2]	$1,942,155	$1,943,706	$1,837,027	$1,884,377	$1,899,088	$1,963,738	$2,009,448	$1,989,700	$2,303,531	$1,897,235
NINDS	$1,622,001	$1,623,344	$1,533,793	$1,588,899	$1,604,581	$1,692,830	$1,778,684	$1,949,067	$2,470,375	$2,026,031
NIAID	$4,478,595	$4,482,369	$4,235,094	$4,401,185	$4,417,529	$4,749,884	$4,905,708	$5,262,398	$5,529,233	$4,754,379
NIGMS[3]	$2,033,663	$2,425,522	$2,293,044	$2,366,429	$2,372,199	$2,508,868	$2,646,059	$2,780,954	$2,872,780	$2,472,838
NICHD	$1,317,682	$1,318,943	$1,246,140	$1,283,314	$1,286,797	$1,338,280	$1,376,541	$1,449,613	$1,513,959	$1,296,732
NEI	$700,781	$701,407	$657,055	$675,551	$676,726	$707,002	$731,203	$770,483	$796,536	$685,644
NIEHS[4]	$762,602	$763,225	$721,331	$743,002	$745,533	$769,730	$789,860	$826,646	$852,056	$733,435
NIA	$1,100,445	$1,120,391	$1,040,565	$1,171,656	$1,197,459	$1,596,005	$2,048,792	$2,571,438	$3,083,410	$2,654,144
NIAMS	$534,260	$534,791	$505,206	$520,314	$521,480	$540,874	$556,568	$585,240	$605,065	$520,829
NIDCD	$415,104	$415,500	$392,540	$404,237	$405,168	$422,311	$435,877	$458,876	$474,404	$408,358
NIMH	$1,477,257	$1,477,516	$1,396,006	$1,419,632	$1,433,603	$1,516,325	$1,604,624	$1,754,423	$1,870,296	$1,630,422
NIDA	$1,050,519	$1,051,410	$993,404	$1,017,957	$1,015,695	$1,048,971	$1,070,813	$1,161,149	$1,632,968	$1,296,379
NIAAA	$458,257	$458,665	$433,247	$446,282	$447,152	$466,713	$482,449	$508,398	$525,591	$452,419
NINR	$144,369	$144,500	$136,516	$140,553	$140,837	$145,701	$149,930	$157,633	$162,992	$140,301
NHGRI	$511,469	$512,258	$483,650	$498,076	$498,648	$512,486	$528,316	$556,741	$575,579	$495,448
NIBIB	$313,787	$337,728	$319,062	$326,989	$327,223	$342,997	$356,971	$376,700	$389,464	$335,244
NIMHD	$209,693	$275,927	$260,671	$268,439	$270,480	$280,264	$287,640	$304,372	$314,679	$270,870
NCRR	$1,257,641	---	---	---	---	---	---	---	---	---
NCCAM	$127,706	$127,820	$120,767	$124,368	$124,046	$129,760	$134,373	$141,667	$146,473	$126,081
NCATS	---	$574,297	$542,598	$633,571	$632,629	$684,366	$704,248	$754,080	$812,976	$694,112
FIC	$69,413	$69,493	$65,627	$67,575	$67,576	$69,996	$71,813	$75,534	$78,109	$67,235
NLM[5]	$344,860	$373,087	$325,088	$334,383	$336,653	$393,074	$406,250	$424,789	$441,997	$380,463
ORIP	---	$303,525	$290,042	$294,486	$294,662	$295,783	$279,130	$289,205	$289,209	$249,009
Common Fund	$543,017	$544,930	$513,461	$531,146	$545,607	$675,628	$695,430	$600,707	$619,166	$532,967
OD - Other	$623,887	$608,713	$608,584	$477,293	$573,328	$599,263	$714,058	$1,016,632	$1,251,699	$1,144,168
B&F	$62,161	$125,308	$106,676	$88,880	$123,464	$79,883	$113,415	$106,434	$200,000	$200,000
NIRSQ[6]	---	---	---	---	---	---	---	---	---	$255,960
Total, NIH Program Level	**$30,638,528**	**$30,860,387**	**$29,137,284**	**$30,027,205**	**$30,295,974**	**$32,258,751**	**$34,149,217**	**$36,642,258**	**$39,924,757**	**$34,367,629**
Less funds allocated from different sources:										
Mandatory - Special type 1 Diabetes Research	-$150,000	-$150,000	-$142,350	-$139,200	-$150,000	-$150,000	-$139,650	-$26,292	-$273,708	-$150,000
PHS Program Evaluation	-$8,200	-$8,200	-$8,200	-$8,200	-$715,000	-$780,000	-$824,443	-$922,871	-$1,146,821	-$741,000
Total, NIH Discretionary Budget Authority	**$30,480,328**	**$30,702,187**	**$28,986,734**	**$29,879,805**	**$29,430,974**	**$31,328,751**	**$33,185,124**	**$35,693,095**	**$38,504,228**	**$33,476,629**
Interior Budget Authority	-$79,045	-$78,928	-$74,864	-$77,345	-$77,349	-$77,252	-$77,337	-$77,342	-$77,349	-$66,581
Total, NIH Labor/HHS Budget Authority	**$30,401,283**	**$30,623,259**	**$28,911,870**	**$29,802,460**	**$29,353,625**	**$31,251,499**	**$33,107,787**	**$33,021,788**	**$38,426,879**	**$33,410,048**

[1] Excludes Ebola, Zika and other supplemental funding or transfers.

[2] Includes Special type 1 Diabetes Research mandatory account funding (through FY 2020). FY 2019 includes carryover of $123,707,707.

[3] Includes PHS Program Evaluation financing of $715,000,000 in FY 2015, $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019 and $741,000,000 in FY 2020.

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

[5] Includes PHS Program Evaluation financing of $8,200,000 for years before FY 2015.

[6] The FY 2020 Budget proposes to consolidate Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for years prior to FY 2020 do not include AHRQ.

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

[8] Includes $60,647,563 of 21st Century Cures carryover from FY 2017.

[9] Includes $428,918,109 of FY 2018 Opioids carryover in various ICs and $65,782,664 of 21st Century Cures carryover from FY 2017 and FY 2018 in various ICs. Amounts assume obligation of all FY 2019 budget authority plus amounts carried over from FY 2018.

[10] Amounts represent estimated or requested budget authority as opposed to obligations displayed in historical years.

History of Obligations by Total Mechanism

(Dollars in Thousands)[1]	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual[4]	FY 2016 Actual[4]	FY 2017 Actual[4]	FY 2018 Actual[4,5]	FY 2019 Enacted[4,6]	FY 2020 President's Budget[4,7]
Research Project Grants	$16,428,047	$16,550,486	$15,445,463	$16,168,246	$16,441,843	$17,839,691	$19,105,304	$20,756,893	$23,028,015	$19,544,723
Research Centers	$3,009,480	$3,040,375	$2,708,744	$2,723,203	$2,663,064	$2,573,774	$2,536,308	$2,581,750	$2,689,641	$2,217,953
Other Research	$1,802,937	$1,808,138	$1,783,481	$1,846,841	$1,802,719	$2,019,736	$2,181,261	$2,371,164	$2,564,594	$2,209,720
Subtotal, Research Grants	$21,240,464	$21,398,999	$19,937,688	$20,738,290	$20,907,625	$22,433,201	$23,822,873	$25,709,807	$28,282,250	$23,972,395
Research Training	$771,766	$761,934	$733,524	$738,429	$758,017	$803,869	$827,397	$855,844	$888,955	$801,873
R & D Contracts	$2,996,640	$2,937,188	$2,927,077	$2,990,037	$2,826,971	$2,913,224	$3,046,759	$3,072,406	$3,155,451	$2,795,430
Intramural Research	$3,330,815	$3,401,506	$3,247,193	$3,373,601	$3,409,362	$3,682,831	$3,780,181	$3,972,054	$4,150,735	$3,633,805
Res. Mgt. & Support	$1,517,630	$1,530,874	$1,485,575	$1,527,131	$1,619,784	$1,653,230	$1,747,406	$1,813,738	$1,900,318	$1,739,376
Office of the Director[2]	$623,887	$609,530	$608,584	$477,293	$573,328	$599,263	$701,864	$1,016,633	$1,251,699	$1,144,168
Subtotal	**$30,481,202**	**$30,640,031**	**$28,939,641**	**$29,844,781**	**$30,095,088**	**$32,085,618**	**$33,928,465**	**$36,440,482**	**$39,629,408**	**$34,087,048**
Buildings & Facilities[3]	$70,081	$133,228	$114,580	$96,880	$123,464	$95,883	$143,415	$124,434	$218,000	$214,000
Interior- Superfund	$79,045	$78,928	$74,864	$77,345	$77,332	$77,252	$77,337	$77,342	$77,349	$66,581
Total	**$30,630,328**	**$30,852,187**	**$29,129,085**	**$30,019,005**	**$30,295,884**	**$32,258,753**	**$34,149,217**	**$36,642,258**	**$39,924,757**	**$34,367,629**

[1] Obligations for actual years exclude lapse. Amounts for all years include Special type 1 Diabetes. All Subtotal and Total numbers may not add due to rounding. FY 2017 through FY 2020 includes 21st Century CURES Act funding. All years exclude Ebola-related and supplemental financing.

[2] Excludes obligations for the Common Fund and the Office of Research Infrastructure Programs, which are distributed by mechanism.

[3] Includes B&F appropriation and monies allocated ($18,000,000 in FY 2018, $18,000,000 in FY 2019, and $14,000,000 in FY 2020) pursuant to appropriations acts provisions that funding may be used for facilities repairs and improvements at the NCI Federally funded Research and Development Center in Frederick, Maryland.

[4] Includes Program Evaluation Financing resources of $715,000,000 in FY 2015, $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, and $741,000,000 in FY 2020.

[5] Includes obligations of $60,647,563 of 21st Century Cures Act funding which was appropriated in FY 2017, but carried over into FY 2018.

[6] Includes obligations of $65,782,664 of 21st Century Cures Act funding which was appropriated in FY 2017 and FY 2018, but carried over into FY 2019. Similarly, includes $428,918,109 of Opioids funding carried over from FY 2018, and 123,707,707 of Type 1 Diabetes funding carried over from FY 2018. Obligations of carryover funding are distributed by mechanism.

[7] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for years prior to FY 2020 do not include AHRQ.

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 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[1]	$17,799,515	$6,838,801	72.2%	27.8%	6.0%	6.1%
FY 2018 Final Allocation[1,2]	$19,595,565	$7,494,864	72.3%	27.7%	10.1%	9.6%
FY 2019 Enacted[1]	$20,704,901	$7,941,275	72.3%	27.7%	5.7%	6.0%
FY 2020 President's Budget[1,3]	$17,958,779	$6,815,490	72.5%	27.5%	-13.3%	-14.2%

Note: Data for fiscal years 2019 and later represent estimates and will change as actual data are received.

[1] Includes 21st Century Cures Act funding.

[2] The amounts shown in the FY 2018 row include an estimated $374 million of Direct Cost and $151 million of Indirect Costs expected to be awarded from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[3] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for years prior to FY 2020 do not include AHRQ.

RPGs – Total Number of Awards and Funding

(Dollars in Thousands)	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017 Final[3]	FY 2018 Final Allocation[3,4]	FY 2019 Enacted[3]	FY 2020 President's Budget[3,5]
No. of Awards:										
Competing	8,706	8,986	8,234	9,168	9,540	10,364	10,123	11,461	11,675	7,894
Noncompeting	26,166	25,631	25,140	23,504	23,261	23,528	24,638	25,858	27,492	28,760
Subtotal	34,872	34,617	33,374	32,672	32,801	33,892	34,761	37,319	39,167	36,654
SBIR/STTR	1,494	1,642	1,466	1,660	1,578	1,689	1,807	2,035	2,222	1,911
Total	**36,366**	**36,259**	**34,840**	**34,332**	**34,379**	**35,581**	**36,568**	**39,354**	**41,389**	**38,565**
Average Annual Cost:										
Competing RPGs	$427	$421	$418	$489	$452	$484	$522	$519	$541	$472
Total RPGs[1]	$453	$459	$444	$474	$479	$502	523	541	549	508
Percent Change in Average Cost from Prior Year[2]										
Competing RPGs	2.5%	-1.5%	-0.8%	17.0%	-7.5%	7.2%	7.8%	-0.6%	4.2%	-12.7%
Total RPGs[1]	0.5%	1.4%	-3.3%	6.7%	1.2%	4.8%	4.0%	3.6%	1.4%	-7.4%
Average Length of Award in Years	**3.7**	**3.5**	**3.5**	**3.5**	**3.5**	**3.6**	**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.

[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] The figures shown in the FY 2018 column include an estimated 390 Competing, 133 Noncompeting and 12 SBIR/STTR grants expected to be awarded from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[5] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for years prior to FY 2020 do not include AHRQ.

RPGs – Success Rates

INSTITUTES & CENTERS[*,1,2]	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017 Final[6]	FY 2018 Final Allocation[6,7]	FY 2019 Enacted[6]	FY 2020 President's Budget[6,8]
NCI	13.8%	13.6%	13.7%	14.1%	13.0%	12.0%	11.7%	11.3%	11.2%	11.7%
NHLBI	17.4%	14.7%	16.9%	18.2%	21.9%	24.2%	23.5%	25.1%	26.9%	29.7%
NIDCR	22.5%	21.2%	19.9%	21.5%	22.0%	19.9%	17.8%	22.2%	23.6%	14.8%
NIDDK	20.7%	19.8%	21.0%	22.9%	20.3%	20.1%	17.8%	22.3%	20.8%	17.3%
NINDS	21.1%	19.5%	19.8%	18.7%	20.5%	19.8%	17.7%	23.0%	19.0%	10.9%
NIAID	20.2%	23.2%	18.8%	22.0%	21.5%	23.8%	19.1%	22.9%	22.7%	17.5%
NIGMS	23.1%	24.4%	19.9%	24.8%	29.6%	29.6%	30.6%	29.2%	30.1%	10.0%
NICHD	12.4%	12.5%	10.8%	12.5%	11.5%	13.2%	16.1%	18.4%	17.8%	10.2%
NEI	28.8%	29.8%	23.7%	26.7%	21.4%	25.7%	24.9%	26.7%	25.6%	16.9%
NIEHS	14.7%	14.3%	15.3%	15.0%	14.7%	14.2%	15.0%	17.1%	15.0%	13.3%
NIA	16.1%	15.5%	13.6%	15.9%	17.7%	22.8%	26.6%	28.9%	35.4%	10.1%
NIAMS	14.9%	15.6%	15.9%	18.1%	16.7%	16.0%	17.0%	16.7%	14.9%	10.6%
NIDCD	27.5%	26.6%	22.5%	25.8%	24.9%	26.7%	24.4%	27.1%	21.7%	10.7%
NIMH	17.1%	21.6%	18.7%	19.4%	20.4%	22.9%	20.9%	22.2%	26.3%	11.0%
NIDA	18.2%	21.2%	19.5%	18.0%	19.6%	15.4%	19.7%	33.3%	19.4%	10.8%
NIAAA	18.6%	18.4%	19.5%	19.2%	16.4%	18.8%	22.0%	26.7%	20.6%	10.2%
NINR	8.5%	13.0%	9.1%	11.6%	8.0%	9.0%	8.9%	10.3%	7.1%	9.1%
NHGRI	27.4%	23.9%	20.5%	17.7%	18.8%	25.6%	23.9%	28.0%	22.2%	10.2%
NIBIB	12.9%	12.1%	13.7%	13.1%	12.0%	14.6%	13.0%	16.8%	17.5%	10.6%
NIMHD	11.9%	9.9%	4.3%	11.9%	13.7%	19.3%	21.5%	10.7%	7.0%	10.0%
NCCIH[3]	9.1%	9.5%	11.6%	8.7%	10.8%	13.9%	16.7%	20.3%	16.4%	11.1%
NCATS[4]	N/A	0.0%	0.0%	16.7%	66.7%	27.7%	21.8%	34.8%	24.1%	5.2%
FIC	11.9%	16.0%	14.6%	9.1%	9.7%	29.5%	10.8%	19.5%	12.9%	10.4%
NLM	16.1%	12.8%	12.3%	19.4%	19.8%	13.0%	14.9%	17.7%	17.4%	8.9%
ORIP & SEPA[5]	21.3%	18.6%	20.0%	19.6%	21.5%	18.8%	16.5%	17.8%	12.3%	9.6%
Common Fund	11.3%	8.0%	9.2%	10.0%	12.1%	12.6%	11.8%	10.9%	12.6%	9.4%
NIH	**17.5%**	**17.5%**	**16.7%**	**18.0%**	**18.3%**	**19.1%**	**18.7%**	**20.9%**	**20.3%**	**13.4%**
NIRSQ										25.0%
NIH	**17.5%**	**17.5%**	**16.7%**	**18.0%**	**18.3%**	**19.1%**	**18.7%**	**20.9%**	**20.3%**	**13.5%**

* Success Rates identified in FY 2019 and FY 2020 are estimates, and will change as applications are received and selected for funding.

[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. Excludes NIEHS Superfund Research and OD Other awards.

[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).

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

[6] Includes 21st Century Cures Act funding.

[7] The FY 2018 column includes an estimated 390 competing RPGs expected to be awarded from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[8] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures prior to FY 2020 do not include AHRQ.

Total R01 Equivalent Data for First Time and Established Investigators

R01 Equivalent Grants[1,2,3,4,7]	FY 2018 Final Allocation[5]	FY 2019 Enacted	FY 2020 President's Budget[6]
Applications			
Received	34,584	36,091	37,663
Funded	7,782	7,834	5,451
Total Investigators			
Received	30,198	31,436	32,675
Funded	9,204	9,303	6,517
Established Investigators			
Received	18,812	19,785	20,547
Funded	6,587	6,697	4,683
First-time Investigators			
Received	11,386	11,651	12,128
Funded	2,617	2,606	1,834

[1] Grant data is based on linear extrapolation of five years of latest actual data.

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

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

[4] Includes 21st Century Cures Act funding.

[5] Figures shown in the FY 2018 column include awards expected to be made from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[6] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

[7] R01 Equivalent Grants form a subset of all RPG awards, comprising roughly 63% of Applications, 69% of Total Investigators, 78% of Established Investigators and 56% of First-time Applicants.

Competing RPGs by Length of Award

(Dollars in Thousands)	FY 2018 Final Allocation[3]		FY 2019 Enacted		FY 2020 President's Budget[4]	
	No.	Amount	No.	Amount	No.	Amount
Competing RPGs:[1,2]						
One-Year Awards	1,024	$1,158,401	1,027	$1,126,694	695	$665,127
Two-Year Awards	2,978	$668,631	2,986	$703,745	2,019	$415,445
Three-Year Awards	548	$297,388	630	$347,341	426	$205,047
Four-Year Awards	2,130	$1,089,080	2,282	$1,225,536	1,543	$723,476
Five or More Year Awards	4,781	$2,730,302	4,750	$2,908,107	3,211	$1,716,757
Total Competing RPGs	11,461	$5,943,802	11,675	$6,311,423	7,894	$3,725,852

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

[2] Includes 21st Century Cures Act funding.

[3] Figures in the FY 2018 columns include about $331 million and 390 Total Competing RPGs expected to be awarded from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[4] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

Non-Competing Commitments

(Dollars in Thousands)	FY 2018 Final Allocation[4,5]	FY 2019 Enacted[4]	FY 2020 President's Budget[4,6]
Research Project Grants (RPGs)			
Noncompeting:			
Number	25,858	27,492	28,760
Amount	$13,776,726	$14,677,360	$14,536,572
Administrative Supp	$483,035	$506,430	$361,166
Competing:			
Number	11,461	11,675	7,894
Amount	$5,943,802	$6,311,423	$3,725,852
SBIR/STTR:			
Number	2,035	2,222	1,911
Noncompeting	821	771	797
Amount[1]	$1,001,946	$1,084,179	$921,133
Noncompeting	$404,205	$376,176	$384,340
Subtotal, RPGs:			
Number	39,354	41,389	38,565
Amount	$21,205,508	$22,579,392	$19,544,723
Research Centers:			
Number	1,250	1,335	1,155
Noncompeting	865	945	924
Amount	$2,583,007	$2,688,141	$2,217,953
Noncompeting	$1,786,555	$1,902,218	$1,774,227
Other Research:			
Number	6,810	6,996	6,244
Noncompeting	4,225	4,942	4,995
Amount	$2,446,070	$2,489,688	$2,209,720
Noncompeting	$1,517,449	$1,758,666	$1,767,642
Training:			
FTTPs	16,197	16,666	14,992
Noncompeting	13,581	12,875	11,575
Amount	$855,845	$888,955	$801,873
Noncompeting	$717,601	$686,738	$619,123
Total Extramural Research[2]	**$27,090,429**	**$28,646,176**	**$24,774,269**
Noncompeting Number/FTTPs	45,350	47,025	47,051
Competing Number/FTTPs	18,261	19,361	13,905
Noncompeting Amount	$18,685,571	$19,907,588	$19,443,070
Competing Amount	$8,404,858	$8,738,588	$5,331,199
Total % Change	**10.0%**	**5.7%**	**-13.5%**
Total Discretionary Budget Authority[3]	**$37,074,080**	**$39,156,349**	**$34,217,629**
% Change	**8.8%**	**5.6%**	**-12.6%**

[1] The 3.65% combined SBIR/STTR program threshold is achieved in FY 2018 and sustained in subsequent years.

[2] Includes both grants and FTTPs for Noncompeting and Competing numbers

[3] Includes Labor/HHS appropriations, the Interior Superfund Research account, 21st Century Cures Act funding, as well as Program Evaluation financing resources. Excludes mandatory accounts such as Type 1 Diabetes.

[4] Includes 21st Century Cures Act funding.

[5] The amount shown in the FY 2018 column for Total Extramural Research includes about $525 million expected to be awarded from FY 2018 two-year and no-year appropriations that were carried over into FY 2019. Similarly, the Total Discretionary Budget Authority amount in FY 2018 includes about $392 million expected to be awarded from FY 2018 appropriations carried over into FY 2019.

[6] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

Management Fund (MF) 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; and police, fire, security, and general administrative support services. The MF is financed through offsetting collections from the NIH Institutes and Centers representing charges for services provided. Funds credited to the NIH Management Fund remain available for one fiscal year after the fiscal year in which they are deposited.

MF Budget Authority by Activity

Budget Authority by Activity
(Dollars in Thousands)

	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019	
Detail:	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**
Clinical Center	1,856	$522,575	1,844	$547,659	1,844	$547,659	0	$0
Center for Scientific Review	409	140,818	417	142,484	417	128,235	0	(14,249)
Office of Research Services, Development & Operations and Administrative Services	517	80,757	539	81,541	539	73,387	0	(8,154)
TOTAL	**2,782**	**$744,150**	**2,800**	**$771,684**	**2,800**	**$749,281**	**0**	**($22,403)**

MF Budget Authority by Object Class

(Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	Increase or Decrease
Total compensable workyears:				
	Full-time employment	2,800	2,800	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$188	$188	0
	Average GM/GS grade	11.3	11.2	-0.1
	Average GM/GS salary	$101	$102	1
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$91	$92	1
	Average salary of ungraded positions	113	114	1
	OBJECT CLASSES	**FY 2019 Enacted**	**FY 2020 President's Budget**	**Increase or Decrease**
	Personnel Compensation:			
11.1	Full-time permanent	$186,926	$187,636	$710
11.3	Other than full-time permanent	51,692	51,889	197
11.5	Other personnel compensation	18,602	18,673	71
11.7	Military personnel	6,591	6,788	197
11.8	Special personnel services payments	5,344	5,364	20
	Total, Personnel Compensation	**269,155**	**270,350**	**1,195**
12.0	Personnel benefits	80,125	81,335	1,210
12.2	Military personnel benefits	4,832	4,976	144
13.0	Benefits for former personnel	0	0	0
	Subtotal, Pay Costs	**354,112**	**356,661**	**2,549**
21.0	Travel and transportation of persons	2,576	2,576	0
22.0	Transportation of things	1,269	1,269	0
23.1	Rental payments to GSA	3	3	0
23.2	Rental payments to others	23	23	0
23.3	Communications, utilities and miscellaneous charges	5,852	5,852	0
24.0	Printing and reproduction	14	14	0
25.1	Consulting services	17,693	17,693	0
25.2	Other services	124,828	111,348	(13,480)
25.3	Purchase of goods and services from government accounts	124,265	115,300	(8,965)
25.4	Operation and maintenance of facilities	4,705	4,705	0
25.5	Research and development contracts	0	0	0
25.6	Medical care	8,009	8,009	0
25.7	Operation and maintenance of equipment	21,526	20,521	(1,005)
25.8	Subsistence and support of persons	2,735	2,735	0
25.0	**Subtotal, Other Contractual Services**	**303,761**	**280,311**	**(23,450)**
26.0	Supplies and materials	73,803	73,803	0
31.0	Equipment	30,248	28,748	(1,500)
32.0	Land and structures	0	0	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	1	1	0
42.0	Insurance claims and indemnities	3	3	0
43.0	Interest and dividends	17	17	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	**417,570**	**392,620**	**(24,950)**
	Total Budget Authority by Object	**771,683**	**749,281**	**(22,402)**

MF Detail of Positions

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	3	3	3
Total, ES Salary	$553,277	$563,538	$565,453
GM/GS-15	115	117	119
GM/GS-14	326	329	344
GM/GS-13	394	407	407
GS-12	518	519	522
GS-11	506	508	509
GS-10	34	34	34
GS-9	126	139	136
GS-8	104	115	112
GS-7	239	246	260
GS-6	51	58	56
GS-5	39	41	39
GS-4	13	13	14
GS-3	13	13	13
GS-2	3	4	3
GS-1	0	0	0
Subtotal	2,481	2,543	2,568
Grades established by Act of July 1, 1944 (42 U.S.C. 207) :			
Assistant Surgeon General	0	0	0
Director Grade	14	14	14
Senior Grade	19	19	19
Full Grade	26	26	26
Senior Assistant Grade	20	20	20
Assistant Grade	1	1	1
Subtotal	80	80	80
Ungraded	379	381	382
Total permanent positions	2,364	2,565	2,591
Total positions, end of year	2,943	3,007	3,033
Total full-time equivalent (FTE) employment , end of year	2,782	2,800	2,800
Average ES salary	$184,426	$187,846	$188,484
Average GM/GS grade	11.4	11.3	11.3
Average GM/GS salary	$99,604	$100,807	$101,874

Service and Supply Fund (SSF) 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. The SSF is financed through offsetting collections from the NIH Institutes and Centers representing charges for goods and services provided.

SSF Budget Authority by Activity

Budget Authority by Activity
(Dollars in Thousands)

	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019	
Detail:	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**
Research Support and Administrative, OD, CC	795	$1,014,914	841	$1,053,480	841	$948,132	0	($105,348)
Office of Research Facilities Development & Operations	721	530,965	707	551,142	707	496,028	0	(55,114)
Information Technology	233	400,470	257	415,688	257	374,119	0	(41,569)
TOTAL	**1,749**	**$1,946,349**	**1,805**	**$2,020,310**	**1,805**	**$1,818,279**	**0**	**($202,031)**

SSF Budget Authority by Object Class

(Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	Increase or Decrease
Total compensable workyears:				
	Full-time employment	1,805	1,805	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$186	$187	1
	Average GM/GS grade	12.2	12.2	0.0
	Average GM/GS salary	$110	$110	0
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$104	$105	1
	Average salary of ungraded positions	135	136	1
	OBJECT CLASSES	**FY 2019 Enacted**	**FY 2020 President's Budget**	**Increase or Decrease**
	Personnel Compensation:			
11.1	Full-time permanent	$194,890	$195,630	$740
11.3	Other than full-time permanent	8,581	8,614	33
11.5	Other personnel compensation	11,691	11,735	44
11.7	Military personnel	2,612	2,690	78
11.8	Special personnel services payments	59	60	1
	Total, Personnel Compensation	**217,833**	**218,729**	**896**
12.0	Personnel benefits	73,655	74,767	1,112
12.2	Military personnel benefits	1,315	1,354	39
13.0	Benefits for former personnel	1,224	1,224	0
	Subtotal, Pay Costs	**294,027**	**296,074**	**2,047**
21.0	Travel and transportation of persons	1,118	1,118	0
22.0	Transportation of things	972	938	(34)
23.1	Rental payments to GSA	55,525	53,582	(1,943)
23.2	Rental payments to others	87,563	83,623	(3,940)
23.3	Communications, utilities and miscellaneous charges	120,638	108,574	(12,064)
24.0	Printing and reproduction	10	10	0
25.1	Consulting services	16,212	14,737	(1,475)
25.2	Other services	557,912	462,247	(95,665)
25.3	Purchase of goods and services from government accounts	501,568	446,532	(55,036)
25.4	Operation and maintenance of facilities	88,585	80,170	(8,415)
25.5	Research and development contracts	0	0	0
25.6	Medical care	2,759	2,621	(138)
25.7	Operation and maintenance of equipment	187,543	169,164	(18,379)
25.8	Subsistence and support of persons	2,630	2,498	(132)
25.0	**Subtotal, Other Contractual Services**	**1,357,209**	**1,177,969**	**(179,240)**
26.0	Supplies and materials	79,833	73,446	(6,387)
31.0	Equipment	23,296	22,830	(466)
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	0	0	0
43.0	Interest and dividends	117	115	(2)
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	**1,726,281**	**1,522,205**	**(204,076)**
	Total Budget Authority by Object	**2,020,310**	**1,818,279**	**(202,031)**

SSF Detail of Positions

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	8	8	8
Total, ES Salary	$1,489,292	$1,491,188	$1,498,608
GM/GS-15	84	89	89
GM/GS-14	265	280	280
GM/GS-13	521	544	544
GS-12	262	270	270
GS-11	76	78	78
GS-10	1	1	1
GS-9	67	62	62
GS-8	19	19	19
GS-7	61	57	57
GS-6	6	6	6
GS-5	13	13	13
GS-4	7	7	7
GS-3	13	13	13
GS-2	6	6	6
GS-1	13	13	13
Subtotal	1,414	1,458	1,458
Grades established by Act of July 1, 1944 (42 U.S.C. 207) :			
Assistant Surgeon General	0	0	0
Director Grade	3	3	3
Senior Grade	4	4	4
Full Grade	7	7	7
Senior Assistant Grade	2	2	2
Assistant Grade	0	0	0
Subtotal	16	16	16
Ungraded	330	330	330
Total permanent positions	1,695	1,741	1,741
Total positions, end of year	1,768	1,812	1,812
Total full-time equivalent (FTE) employment , end of year	1,749	1,805	1,805
Average ES salary	$186,162	$186,398	$187,326
Average GM/GS grade	11.9	12.2	12.2
Average GM/GS salary	$101,774	$109,332	$110,340

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

COMMON FUND (CF)

FY 2020 Budget — Page No.

BUDGET MECHANISM

Budget Mechanism - Total[1,2]

(Dollars in Thousands)

MECHANISM	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 CR	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	185	$132,641	240	$176,462	271	$194,184	31	$17,722
Administrative Supplements	*(32)*	6,762	*(19)*	4,375	*(15)*	3,469	*(-4)*	-906
Competing:								
Renewal	7	10,840	0	0	0	0	0	0
New	126	156,039	130	161,765	89	98,633	-41	-63,132
Supplements	2	1,128	0	0	0	0	0	0
Subtotal, Competing	135	$168,007	130	$161,765	89	$98,633	-41	-$63,132
Subtotal, RPGs	320	$307,411	370	$342,602	360	$296,286	-10	-$46,316
SBIR/STTR	0	0	0	0	0	0	0	0
Research Project Grants	320	$307,411	370	$342,602	360	$296,286	-10	-$46,316
Research Centers:								
Specialized/Comprehensive	29	$33,128	29	$33,524	15	$16,896	-14	-$16,628
Clinical Research	10	17,878	8	14,898	6	11,605	-2	-3,293
Biotechnology	1	577	1	565	0	0	-1	-565
Comparative Medicine	2	729	12	4,249	10	3,702	-2	-547
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	42	$52,312	50	$53,236	31	$32,203	-19	-$21,033
Other Research:								
Research Careers	1	$201	0	$0	0	$0	0	$0
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	90	181,461	82	166,251	80	161,813	-2	-4,438
Other Research	91	$181,662	82	$166,251	80	$161,813	-2	-$4,438
Total Research Grants	453	$541,384	502	$562,089	471	$490,302	-31	-$71,787
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	135	17,121	131	17,010	102	13,251	-29	-3,759
Total Research Training	135	$17,121	131	$17,010	102	$13,251	-29	-$3,759
Research & Develop. Contracts	0	$3,394	0	$2,000	0	$1,335	0	-$665
(SBIR/STTR) (non-add)	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Intramural Research	0	13,091	0	15,205	0	11,021	0	-4,184
Res. Management & Support	0	25,725	0	22,862	0	17,058	0	-5,804
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	$600,716	0	$619,166	0	$532,967	0	-$86,199

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

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

MAJOR CHANGES IN THE 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 2020 President's Budget for the Common Fund, which is $86.2 million less than the FY 2019 Enacted level, for a total of $533.0 million. The FY 2020 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 (-$46.3 million; total $296.3 million): The Common Fund expects to support a total of 360 Research Project Grant (RPG) awards in FY 2020. Estimated awards for FY 2020 include 271 Noncompeting RPGs and the award of 89 Competing RPGs.

Research Centers (-$21.0 million; total $32.2 million): The estimated decrease in Common Fund support for Research Centers reflects a planned ramp down of initiatives within the 4D Nucleome and Library of Integrated Network-based Cellular Signatures programs.

Intramural Programs (-$4.2 million; total $11.0 million): The estimated decrease in support for Intramural Programs reflects a planned reduction in the Stem Cell Translation Laboratory within the Regenerative Medicine Program, as well as the intramural site of the Undiagnosed Diseases Network.

Research Management and Support (-$5.8 million; total $17.1 million): The estimated decrease in Research Management and Support reflects decreased need for these activities as the 4D Nucleome and Library Integrated Network-based Cellular Signatures programs wind down.

Budget by Initiative

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

Common Fund Program	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
4D Nucleome	**28,629**	**27,811**	**203**
Technology Development, Biological Validation, Modeling and Pilot Mapping	10,456	9,939	203
Nucleomic, Imaging, and Computational Tool Development	10,588	10,038	0
4D Nucleome Coordination and Integration	7,584	7,834	0
Acute to Chronic Pain Signatures	**0**	**2,402**	**14,365**
Clinical Observation of Pain	0	1,659	8,084
Omics Data Generation Centers	0	200	3,561
Data Integration and Resource	0	543	2,720
All of Us Research Program	**67**	**0**	**0**
Big Data to Knowledge (BD2K)	**2,208**	**109**	**97**
Enhancing the Diversity of the NIH-Funded Workforce	**50,603**	**52,675**	**47,818**
BUILD Initiative	47,581	40,900	31,960
National Research Mentoring Network (NRMN)	1,784	10,100	8,992
Coordination and Evaluation Center (CEC)	1,239	1,675	6,867
Epigenomics	**45**	**0**	**0**
Extracellular RNA Communication	**6,555**	**6,869**	**5,204**
Data Management and Resource/Repository (DMRR)	2,429	1,633	609
Reference Profiles of Human Extracellular RNA	4,007	0	0
Extracellular RNA Biogenesis, Biodistribution, Uptake, and Effector Function	52	0	0
Clinical Utility of Extracellular RNAs as Biomarkers and Therapeutic Agents	66	0	0
Separating exRNA Carrier Subclasses	0	2,620	2,296
Phenotyping Single Vesicle-Associated exRNAs	0	2,617	2,299
Gabriella Miller Kids First Pediatric Research	**14,043**	**13,028**	**12,956**
Genotype-Tissue Expression (GTEx) Resources	**577**	**565**	**0**
Global Health	**16,750**	**15,459**	**10,296**
Medical Education Partnership Initiative (MEPI)	3,000	3,000	0
Human Heredity and Health in Africa (H3Africa)	11,405	10,126	8,653
Cookstove Initiative	2,346	2,333	1,643
Glycoscience	**20,327**	**19,480**	**11,896**
Health Care Systems Research Collaboratory	**6,397**	**1,750**	**1,558**
NIH-HMORN Coordinating Center	2,396	1,750	1,558
Expansion Activities	4,001	0	0
Health Economics	**60**	**0**	**0**
Changing Incentives for Consumers, Insurers, and Providers	44	0	0
Data Infrastructure to Enable Research on Health Reform	17	0	0
High-Risk Research	**188,232**	**183,250**	**171,908**
NIH Director's Pioneer Award	35,698	44,297	48,260
NIH Director's New Innovator Award Program	103,328	88,466	70,938
Transformative Research Award	27,884	29,642	33,075
NIH Director's Early Independence Award Program	21,322	20,845	19,635
Human BioMolecular Atlas Project (HuBMAP)	**7,442**	**15,006**	**24,065**
Technology Development	1,663	4,205	8,141
Human Tissue Mapping	2,756	7,162	11,820
Data Coordination and Integration	3,023	3,639	4,104
Illuminating the Druggable Genome	**9,395**	**12,400**	**11,920**
Knowledge Management Network	1,571	3,598	3,212
Data and Resource Generation Centers	7,284	8,236	8,222
Dissemination and Outreach Hub	541	566	485
Knockout Mouse Phenotyping Program	**11,542**	**11,000**	**9,793**
Data Coordination	1,256	1,262	1,123
Production, Characterization, Cryopreservation, Phenotyping, and Data Release	10,286	9,738	8,669

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

Common Fund Program	FY 2018 Final	FY 2019 Enacted	FY2020 President's Budget
Library of Integrated Network-Based Cellular Signatures (LINCS)	**10,175**	**10,000**	**0**
Metabolomics	**12,387**	**12,403**	**11,040**
Metabolomics Data Sharing and Program Coordination Core	4,580	4,896	4,401
Metabolomics Data Analysis	7,807	7,507	6,639
Molecular Transducers of Physical Activity	**28,720**	**36,336**	**41,064**
Study Coordination and Data Management	7,637	4,448	4,374
Molecular Transducers of Physical Activity in Humans – Clinical Study	9,390	12,149	14,736
Chemical Analysis of Biological Samples	10,262	18,311	19,344
Characterization of Human Molecular Transducers of Physical Activity in Model Systems	1,431	1,428	2,610
New Models of Data Stewardship	**39,152**	**27,153**	**15,031**
NIH Data Commons Pilot Phase	18,147	17,153	15,031
Science Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES)	21,005	10,000	0
NIH Center for Regenerative Medicine (NCRM)	**5,600**	**7,600**	**5,074**
Cell Therapy Projects	600	600	534
Stem Cell Translation Laboratory (SCTL)	5,000	7,000	4,540
Protein Capture	**1,332**	**0**	**0**
Production of anti-TF antibodies	1,327	0	0
New Reagent Technology Development and Piloting	5	0	0
Science of Behavior Change	**12,215**	**12,617**	**198**
Somatic Cell Genome Editing	**14,153**	**35,785**	**34,663**
S.P.A.R.C. - Stimulating Peripheral Activity to Relieve Conditions	**48,842**	**51,268**	**42,080**
Functional and Anatomical Mapping of Five Organ Systems	25,483	25,405	18,611
Next Generation Tools	13,588	10,079	5,412
Off-Label Use of Existing Market-Approved Technology for Small Markets	2,054	9,205	8,195
Data Coordination	7,717	6,579	5,857
Leveraging SPARC in support of HEAL	0	0	4,006
Strengthening the Biomedical Research Workforce	**2,567**	**0**	**0**
Transformative High Resolution Cryo-Electron Microscopy (CryoEM)	**26,263**	**14,900**	**33,652**
National Centers for Cryo-Electron Microscopy	25,745	14,366	33,182
Training Cryo-electron Microscopists	518	534	470
Undiagnosed Diseases Network	**28,948**	**28,900**	**21,099**
Strategic Planning Funds	7,490	9,829	6,988
Subtotal Common Fund	600,716	608,593	532,967
New Initiatives in Common Fund	0	10,573	0
Total Common Fund	600,716	619,166	532,967

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 2018 Final	FY 2019 Enacted Level	FY 2020 President's Budget	FY 2020 +/- FY 2019
BA	$600,716,000	$619,166,000	$532,967,000	-$86,199,000
FTE	0	0	0	0

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

Common Fund Narrative

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.[52] 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.

CF programs capitalize on some of the most exciting and promising scientific opportunities in biomedical research today, all of which require creative and innovative approaches to overcome challenges and foster new discoveries. Therefore, the CF is an excellent example of how NIH supports and promotes science that addresses the NIH Director's theme for FY 2020, *From Inspiration to Innovation*. Within this theme, many CF programs address the priority areas for NIH. Each of these programs is described in more detail within the Selected Program Descriptions and Accomplishments section.

- *Transformational Tools and Technologies*: Transformational tools and technologies are an integral part of many CF programs. Some of the cutting-edge tools and technologies currently being developed with CF support will allow researchers to perform safe and effective precision genome editing to treat human diseases, or precisely stimulate

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

peripheral nerves to control organ function and relieve symptoms of many different conditions. Another program is pioneering new models and approaches for storing, accessing, and analyzing vast amounts of biomedical data to benefit all researchers and catalyze discovery. CF is also enabling wide-spread access to potentially transformative but prohibitively expensive tools and technologies, such as cryo-electron microscopy for determining protein structure.

- *Building on Basic Science*: Many CF programs build foundational resources and establish fundamental biological principles, which can then catalyze research broadly. As one example, CF is creating a data resource to catalogue all known information about under-studied proteins within several important protein families and is beginning to elucidate their functions. This investment in basic science is anticipated to spur additional research and accelerate drug discovery.
- *Exploring the Next Frontier*: CF programs are exploring newly emerging, cutting-edge areas of science that may lead to entirely new ways to promote health and treat or cure diseases. One CF program is leading the way in understanding how DNA is arranged in the nucleus of a cell over time and how that organization affects development and disease. The Common Fund's High Risk, High Reward awards support exceptionally creative scientists proposing innovative and transformative research; many of these awards are investigating questions that push the boundaries of science in a variety of biomedical research disciplines.

To date, many CF programs have had notable achievements. The Human Microbiome Program, completed in FY 2017, is an excellent example of a CF program that aimed to transform research capabilities and develop new biological paradigms. Largely as a result of this program and collaborative international efforts, our understanding of the human body has been transformed. We now understand that each of us is an ecosystem in which our microbial cells far outnumber our human cells and that our microbes have a profound impact on our health. The Epigenomic Roadmap Program, also completed in FY 2017, provided foundational information about the ways in which genes are turned on or turned off in many different human cell types. The Epigenomics program has changed the way that we understand gene regulation and its impact on health, with many epigenetic changes occurring early in life but contributing to disease years or decades later.

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. Funds will be available in FY 2020 for new challenges and opportunities as programs end, move to other sources of support, or require decreased support as indicated by evaluative data.

Over the next five years, priorities for the CF collectively address three overarching goals:

- Invest in broadly useful, high impact data, methods, and tools that are expected to yield new scientific paradigms, solve cross-cutting challenges, and catalyze further research across the NIH
- Develop and test new models for effective data stewardship that can be adopted NIH-wide to increase the impact and extend the value of data

- Establish and evaluate new funding mechanisms that foster innovation and discovery across the workforce, particularly for early stage investigators

Overall Budget Policy: The FY 2020 President's Budget Request for the CF is $533.0 million, a decrease of $86.2 million or 13.9 percent compared to the FY 2019 Enacted level. This decrease reflects the planned ramping down of several programs and initiatives, and allows for the expansion of several high-priority activities within existing programs, including the Transformative Cryo-Electron Microscopy Program, Human BioMolecular Atlas Project (HuBMAP), and Molecular Transducers of Physical Activity Consortium (MoTrPAC).

Selected Program Descriptions and Accomplishments

The 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. Highlighted below are programs that exemplify the science to be supported in FY 2020, and/or which involve significant budget shifts compared to FY 2019. Also included are CF programs that have achieved the goals set when program plans were originally developed and are now identifying additional scientific challenges and opportunities that may be addressed in a second stage of support. Two CF programs -- Library of Integrated Network-Based Cellular Signatures (LINCS) and Genotype-Tissue Expression Resources (GTEx) -- will receive their final year of support in FY 2019; funds are therefore not requested in FY 2020. Information on these programs and their accomplishments can be found on the program websites.[53]

4D Nucleome (4DN)

It is estimated that each human cell contains approximately 2 meters (6.5 feet) of linear DNA, squeezed inside the cell's microscopic nucleus. We now know that DNA is not randomly arranged within the nucleus; instead, the organization of the nucleus is tightly controlled, and early observations suggests that this organization plays an important role in cell function. However, specific consequences of this organization are not well understood. The Common Fund's 4D (four dimensional) Nucleome program aims to understand principles underlying nuclear organization in space (three dimensions) and time (the fourth dimension), the role nuclear organization plays in gene expression and cellular function, and how changes in nuclear organization affect normal development as well as various diseases.[54] This program is developing technologies, resources, and data that enable the study of the 4D Nucleome, including novel tools to explore the dynamics of nuclear architecture and its role in gene expression programs, and computer models to examine the relationship between nuclear organization and function in both normal development and disease. It will also develop reference maps of nuclear architecture in a variety of cells and tissues. Comparing these maps between healthy and diseased cells is expected to lead to new clues about genomic changes that

[53] https://commonfund.nih.gov/LINCS, https://commonfund.nih.gov/GTEx
[54] https://commonfund.nih.gov/4Dnucleome

occur in various pathologies. Funding for the 4DN program began in FY 2015 and funding for the first stage will end in FY 2019.

Budget Policy: The FY 2020 President's Budget Request is $0.2 million for the 4DN program, a decrease of $27.6 million or 99.3 percent compared to the FY 2019 Enacted level. This decrease reflects a planned ramping down as stage 1 is closed out, with stage 2 anticipated to launch in FY 2021.

Acute to Chronic Pain Signatures (A2CPS)

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. The Acute to Chronic Pain Signatures (A2CPS) program focuses on identifying "signatures" predictive of the transition from acute to chronic pain.[55] 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. Although supported via the Common Fund, the program is part of the trans-NIH HEAL (Helping to End Addiction Long-term) Initiative, an aggressive effort to speed scientific solutions to stem the national opioid public health crisis.[56] The program therefore represents an additional investment on the part of NIH to address pain and opioid addiction. A2CPS will support two clinical studies that follow patients after an acute pain event related to a surgical procedure or musculoskeletal trauma. The studies will use advances in imaging, high-throughput biomedical measurements, sensory testing, and psychosocial assessments to identify potential signatures of the transition from acute to chronic pain or resilience to chronic pain. After a planning year in FY 2019, A2CPS will scale up in FY 2020 as it implements the two clinical studies and begins recruiting study participants.

Budget Policy: The FY 2020 President's Budget Request is $14.4 million for the A2CPS program, an increase of $12.0 million or 498.1 percent compared to the FY 2019 Enacted level. This increase will support the launch of two clinical trials to follow patients after an acute pain event.

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, the CF, in concert with NIH ICs, is supporting the Big Data to Knowledge (BD2K) program.[57] BD2K has 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 remaining activities within these initiatives will focus on making the products of research usable, discoverable, and disseminated to intended end-users. In FY 2020, the BD2K budget will decrease due to the planned ramping down of several initiatives. In addition, funding for the

[55] https://commonfund.nih.gov/pain
[56] https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative
[57] https://commonfund.nih.gov/bd2k

NIH Data Commons Pilot Phase is requested under a new programmatic title, "New Models of Data Stewardship." As described below, this reflects the substantial shift from BD2K goals that the Data Commons Pilot encompasses as well as new goals that have been established via the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) initiative.

Budget Policy: The FY 2020 President's Budget Request is $0.1 million for the BD2K program, a decrease of $12,000 or 10.8 percent compared to the FY 2019 Enacted level. This decrease reflects the planned ramping down of BD2K activities as funds for data science are shifted to the New Models of Data Stewardship program.

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.[58] The Kids First program supports a data resource that integrates data from patients with childhood cancer or structural birth defects; these conditions have profound, lifelong effects on patients and their families. The information in the Kids First Data Resource consists of genetic and clinical information from patients, and genetic information from their parents. Researchers analyze these data to understand how genetic mutations lead to birth defects or to cancer, and to discover 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 is poised to accept many additional existing data sets, increasing researchers' ability to detect genetic changes that contribute to many different conditions. To date, funds for the Kids First program have been used to support research centers to perform genetic sequencing of samples from over 30 patient cohorts representing a wide range of diseases and conditions, as well as support to build the Kids First Data Resource. In accordance with Gabriella Miller Kids First Research Act, all appropriated Kids First funds have been used to support pediatric research. In FY 2020, support for the Kids First Data Resource will be used to enable collaboration with the NIH Data Commons Pilot to establish a Pediatric Data Commons, providing a pathway to efficiently share and analyze trans-NIH pediatric data.

Budget Policy: The FY 2020 President's Budget Request is $13.0 million for the Kids First program, a decrease of $0.1 million or 0.6 percent compared to the FY 2019 Enacted level. Programmatic funding from the Pediatric Research Initiative Fund remains constant at the $12.6 million statutory level in both FY 2019 and FY 2020, with the overall $0.1 million decrease resulting from a reduction in funds requested in the regular Common Fund appropriation to support research management activities.

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

High-Risk, High-Reward Research (HRHR)

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, Transformative Research Award, and Early Independence Award.[59] 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.

Budget Policy: The FY 2020 President's Budget Request is $171.9 million for the HRHR program, a decrease of $11.3 million or 6.2 percent compared to the FY 2019 Enacted level. This level of support will allow NIH to continue to invest in high risk research with the potential for extraordinary impact.

Human BioMolecular Atlas Project (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 Project (HuBMAP) aims to catalyze development of an open, global framework for comprehensively mapping the human body at the level of individual cells.[60] 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 only map a small percentage of the human body (tens of millions of cells out of the trillions in the human body), but it 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. If successful, 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 leverage close partnership with companies and international funding agencies so that multiple funding sources are applied to this global challenge. HuBMAP started in FY 2018 and entered a scale-up phase in FY 2019 that will continue through FY 2020.

[59] https://commonfund.nih.gov/highrisk
[60] https://commonfund.nih.gov/HuBMAP

Support for technology development, tissue mapping, and data coordination will continue to ramp up as improvements are made to generate high quality tissue maps.

Budget Policy: The FY 2020 President's Budget Request is $24.1 million for the HuBMAP program, an increase of $9.1 million or 60.4 percent compared to the FY 2019 Enacted level. This increase will support the planned ramp up of technology development, tissue mapping, and data coordination efforts.

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.[61] 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. Support for MoTrPAC will increase in FY 2020 as clinical studies of exercise in humans will continue to ramp up.

Budget Policy: The FY 2020 President's Budget Request is $41.1 million for MoTrPAC, an increase of $4.7 million or 13.0 percent compared to the FY 2019 Enacted level. This increase in support will allow continued growth of clinical studies to identify key molecules that contribute to health benefits of physical activity.

Program Portrait: New Models of Data Stewardship (NMDS)

FY 2019 Level: $27.2 million
FY 2020 Level: $15.0 million
Change: -$12.2 million

The New Models of Data Stewardship (NMDS) program encompasses goals that began as part of the BD2K program but which have expanded as a result of extensive strategic planning at NIH and as a result of the early work of the NIH Data Commons Pilot. The NMDS program is designed to enhance biomedical discovery and improve efficiency through new digital data management strategies.[62] These strategies contribute to NIH efforts to develop and sustain a modern biomedical data ecosystem as described in the NIH Strategic Plan for Data Science[63] by making data for research findable, accessible, interoperable, and reusable (FAIR) in the cloud environment. NMDS includes two integrated initiatives, the NIH Data Commons Pilot Phase and Science and Technology Research

[61] https://commonfund.nih.gov/MolecularTransducers/
[62] https://commonfund.nih.gov/data
[63] https://datascience.nih.gov/strategicplan

Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES). The overarching goal of the NIH Data Commons Pilot Phase is to accelerate new biomedical discoveries by developing and testing a cloud-based platform where investigators can store, share, access, connect, and interact with digital objects (data, software, etc.) generated from biomedical and behavioral research. The STRIDES initiative was launched in FY 2018 and established partnerships with commercial cloud service providers (CSPs) to reduce economic and technological barriers to accessing and computing on large biomedical data sets to accelerate biomedical advances. STRIDES supports NIH Data Commons Pilot Phase investigators and staff to provide cloud storage and services for data sets used as test cases to develop the Data Commons; data sets that are made available via STRIDES will conform to community-endorsed technical standards that will make them FAIR. Partnerships with CSPs through the STRIDES initiative will be leveraged by non-Common Fund programs across NIH to reduce economic and technological barriers to access, store, and compute on large biomedical data sets in the digital cloud ecosystem. Plans for these activities continue in FY 2020, with funds used to support migration of additional data sets to a cloud environment. No funding is requested for STRIDES in FY 2020 pending an assessment of community uptake of cloud computing.

Program Portrait: Stimulating Peripheral Activity to Relieve Conditions (SPARC)

FY 2019 Level: $51.3 million
FY 2020 Level: $42.1 million
Change: -$9.2 million

Electrical manipulation of nerve signals (called neuromodulation) that 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.[64] Launched in FY 2015, the SPARC program supports interdisciplinary teams of investigators to deliver neural circuit maps and models that illustrate how peripheral nerves control organ function, along with technologies to isolate, measure, and manipulate nerve-organ interactions. Through partnerships with industry and physicians, the program supports human clinical studies that will serve to validate or refine neural circuit maps built from animal data. The mapping data, models, technologies, and protocols generated will be publicly available through an online resource to share tools and advancements. 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-traditional partners as needed to address specific, high-risk goals within this complex, interdisciplinary, and rapidly evolving area of science. In FY 2020, SPARC will develop and refine neural circuit maps and models of the innervation of five organs. This will include efforts launched in FY 2019 in support of the HEAL Initiative to study pain pathways.

Program Portrait: Transformative High Resolution Cryo-Electron Microscopy

FY 2019 Level: $14.9 million
FY 2020 Level: $33.7 million
Change: $18.8 million

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 without the use of chemicals that can alter protein structure, providing a more accurate picture of the molecules and greater understanding of biological function. Additionally, recent technological advances have extended cryo-EM resolution to the atomic level, making it possible to image small molecules in great detail. However, the high cost of cryo-EM 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

[64] https://commonfund.nih.gov/sparc

through the creation of national service centers, improvement of technology, and the development of an expert workforce.[65] In FY 2020, the Transformative High Resolution Cryo-Electron Microscopy program will increase support for 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.

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 the 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.

Planning for new activities in FY 2020 involved discussions with NIH Leadership, NIH Institute and Center Directors, and DPCPSI Leadership about high-priority ideas that may be suitable for CF support. These discussions revealed enthusiasm for developing high-priority initiatives in FY 2020 that extend from existing CF programs and leverage previous investments. Collectively, these new activities capitalize on emerging scientific opportunities, leverage novel technologies, and address urgent public health needs.

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.

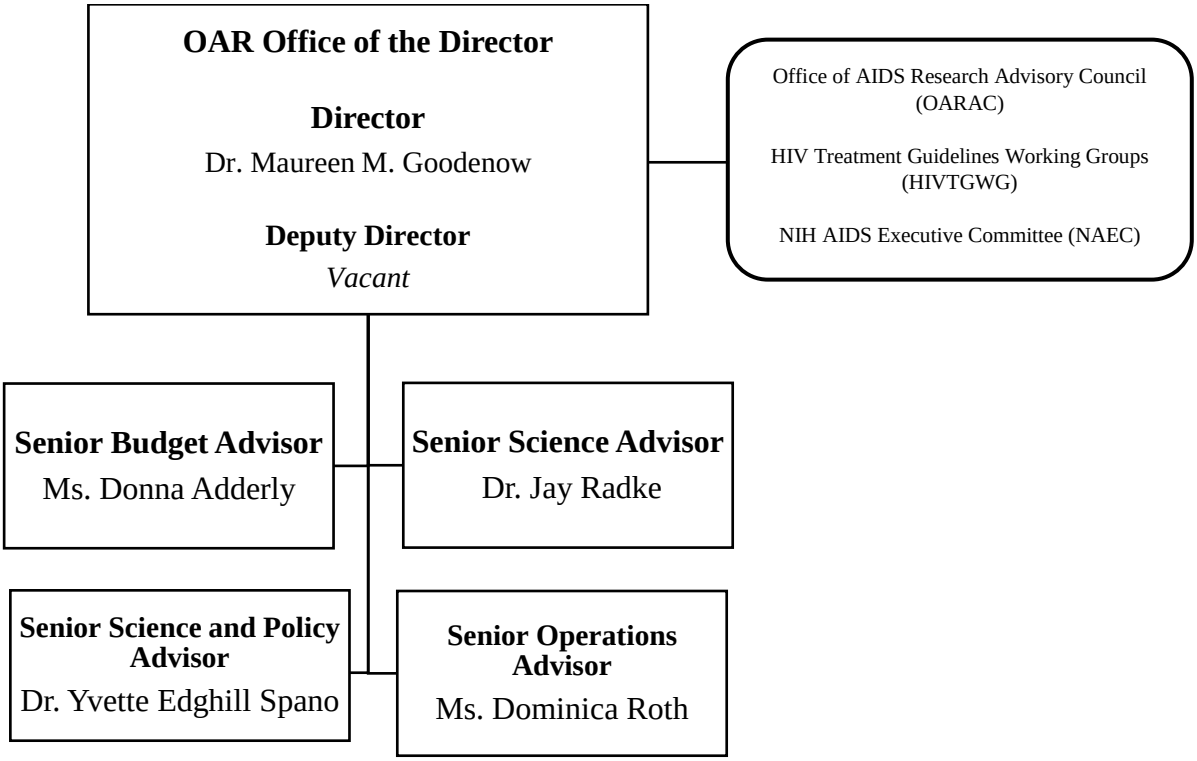
[65] https://commonfund.nih.gov/CryoEM

NIH HIV/AIDS RESEARCH BUDGET

NOTE: Program discussion and amounts do not include HIV/AIDS activities of the Agency for Healthcare Research and Quality, which is proposed for consolidation into NIH in FY 2020 as the National Institute for Research on Safety and Quality (NIRSQ).

Organization Chart

NATIONAL INSTITUTES OF HEALTH
OFFICE OF AIDS RESEARCH



Budget Authority by Institute and Center

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

Institute / Center	FY 2018 Actual [1]	FY 2019 Enacted Level	FY 2020 President's Budget	FY 2020 +/- FY 2019
NCI	$241,234	$244,853	$210,769	-$34,084
NHLBI	76,543	77,691	66,876	-10,815
NIDCR	18,015	18,285	15,740	-2,545
NIDDK	30,119	30,643	26,378	-4,265
NINDS	42,888	43,541	37,480	-6,061
NIAID	1,684,054	1,713,305	1,474,813	-238,492
NIGMS	52,484	53,271	45,856	-7,415
NICHD	142,421	144,897	124,727	-20,170
NEI	1,153	1,170	1,007	-163
NIEHS	5,342	5,422	4,667	-755
NIA	12,973	13,168	11,335	-1,833
NIAMS	4,576	4,656	4,008	-648
NIDCD	1,878	1,906	1,641	-265
NIMH	170,132	173,009	148,926	-24,083
NIDA	269,765	273,811	235,697	-38,114
NIAAA	28,597	29,026	24,986	-4,040
NINR	12,180	12,363	10,642	-1,721
NHGRI	3,693	3,748	3,226	-522
NIBIB	837	852	733	-119
NIMHD	22,825	23,167	19,942	-3,225
NCCIH	611	620	534	-86
FIC	23,884	24,242	20,868	-3,374
NLM	8,822	8,954	7,708	-1,246
OD				
OAR	62,256	63,190	54,394	-8,796
ORIP	78,099	79,271	68,236	-11,035
Subtotal, OD	140,355	142,461	122,630	-19,831
TOTAL, NIH	**$2,995,381**	**$3,045,061**	**$2,621,189**	**-$423,872**

[1] Reflects effects of Secretary's transfer.

Budget Authority by Mechanism

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Mechanism - AIDS [1]
(Dollars in Thousands)

MECHANISM	FY 2018 Actual [2]		FY 2019 Enacted Level		FY 2020 President's Budget		FY 2020 +/- FY 2019	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,487	$1,466,571	1,546	$1,424,857	1,514	$1,262,979	-32	-$161,878
Administrative Supplements	*(94)*	45,765	*(48)*	5,768	*(40)*	4,092	*-8*	-1,676
Competing	472	240,604	435	317,830	361	221,729	-74	-96,101
Subtotal, RPGs	1,959	$1,752,940	1,981	$1,748,455	1,875	$1,488,800	-106	-$259,655
SBIR/STTR	37	20,165	29	20,800	29	17,890	0	-2,910
Research Project Grants	1,996	$1,773,105	2,010	$1,769,255	1,904	$1,506,690	-106	-$262,565
Research Centers:								
Specialized/Comprehensive	57	$114,936	69	$112,647	55	$102,525	-14	-$10,122
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	21	69,860	21	70,940	19	62,725	-2	-8,215
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	78	$184,796	90	$183,587	74	$165,250	-16	-$18,337
Other Research:								
Research Careers	265	$44,881	271	$46,158	221	$38,955	-50	-$7,203
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	6	10,722	0	5,275	0	3,000	0	-2,275
Biomedical Research Support	11	615	11	627	10	600	-1	-27
Minority Biomedical Research Support	1	375	0	0	0	0	0	0
Other	133	53,678	135	56,097	121	49,527	-14	-6,570
Other Research	416	$110,271	417	$108,157	352	$92,082	-65	-$16,075
Total Research Grants	2,490	$2,068,172	2,517	$2,060,999	2,330	$1,764,022	-187	-$296,977
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs			
Individual Awards	85	$3,781	74	$3,390	66	$2,950	-8	-$440
Institutional Awards	277	15,736	246	14,685	217	12,836	-29	-1,849
Total Research Training	362	$19,517	320	$18,075	283	$15,786	-37	-$2,289
Research & Develop. Contracts	71	$334,807	91	$379,506	89	$327,802	-2	-$51,704
(SBIR/STTR) (non-add)	*(7)*	*(5,773)*	*(9)*	*(9,767)*	*(8)*	*(8,607)*	*-1*	*-1,160*
Intramural Research		$357,024		$364,115		$315,290		-$48,825
Res. Management and Support		153,605		159,176		143,895		-15,281
Res. Management & Support (SBIR Admin) (non-add)								
Office of the Director - Appropriation [3]		*140,355*		*141,289*		*122,630*		*-18,659*
Office of the Director - Other		62,256		63,190		54,394		-8,796
ORIP (non-add) [3]		*78,099*		*78,099*		*68,236*		*-9,863*
Total, NIH Discretionary B.A.		**$2,995,381**		**$3,045,061**		**$2,621,189**		**-423,872**

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

[2] Reflects effects of Secretary's transfer.

[3] Number of grants and dollars for the ORIP component of OD are distributed by mechanism and are noted here as a non-add. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

Budget Authority by Activity

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

Overarching Priorities	FY 2016 Actual	FY 2017 Actual	FY 2018 Actual [1]	FY 2019 Enacted Level	FY 2020 President's Budget	FY 2020 +/- FY 2019
Reducing Incidence of HIV/AIDS	$732,003	$687,495	$714,553	$741,203	$634,517	-$106,686
Next Generation HIV Therapies	360,085	362,820	364,484	369,680	322,611	-$47,069
Research Toward a Cure [2]	108,337	170,375	175,757	190,735	159,384	-$31,351
HIV-associated Comorbidities, Coinfections, and Complications	614,090	556,608	517,884	537,435	469,998	-$67,437
Crosscutting	1,185,546	1,222,763	1,222,703	1,206,008	1,034,679	-$171,329
Total	**$3,000,061**	**$3,000,061**	**$2,995,381**	**$3,045,061**	**$2,621,189**	**-$423,872**

[1] Reflects effects of Secretary's transfer.

[2] 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 2016 amount is a comparable budget figure.

Justification of Budget Request

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

Budget Authority (BA):

FY 2018 Actual	FY 2019 Enacted Level	FY 2020 President's Budget	FY 2020+/- FY 2019
$2,995,381,000	$3,045,061,000	$2,621,189,000	-$423,872,000

DIRECTOR'S OVERVIEW

HIV crosses nearly every area of medicine, public health, and scientific investigation; thus, the National Institutes of Health's (NIH) response to the HIV pandemic requires a comprehensive, multidisciplinary, and integrative global research program that traverses the boundaries of nearly every Institute, Center, and Office (ICO). To provide leadership in setting the national and global HIV research agenda, the NIH Office of AIDS Research (OAR) was established in 1988 through Section 2353 of the Public Health Service Act. Located within the NIH Office of the Director, Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), OAR is authorized to—

- **Oversee, coordinate, and manage all NIH HIV-related research.** OAR coordinates the scientific, budgetary, legislative, and policy components of NIH HIV/AIDS research.
- **Establish research priorities.** OAR works across the NIH and with the scientific and HIV communities to establish the scientific research priorities for the global fight against HIV.
- **Develop the strategic plan for HIV research.** OAR produces the *NIH Strategic Plan for HIV and HIV-Related Research*, which identifies research priorities for NIH-funded intramural and extramural research.
- **Ensure that funds are invested in the areas of highest scientific priority.** Based on the strategic plan, OAR plans and evaluates the NIH-wide research portfolio. OAR identifies opportunities and addresses gaps to guide the HIV research agenda.
- **Address emerging needs.** OAR convenes stakeholders, encourages collaboration, and catalyzes innovation to address emerging scientific and public health challenges.

Groundbreaking Accomplishments with Unprecedented Scientific Opportunities

The NIH-wide HIV research program has achieved unprecedented progress against the global HIV pandemic. Since HIV/AIDS was discovered more than three decades ago, HIV has been transformed from a fatal condition to a manageable chronic illness. Such a remarkable achievement is due in large part to NIH's significant investments in scientific research, which continue to produce groundbreaking discoveries and advances in our understanding of basic virology, human immunology, HIV pathogenesis, and socio-behavioral dynamics. The advances

have led to the development of safe and effective antiretroviral therapies (ART), improved systems of wellness and care, and novel intervention strategies to prevent HIV acquisition and transmission.

Coordinated NIH-wide HIV Research Program and Priority Setting Review

Although significant progress has been made, the HIV pandemic continues to spread, representing a serious global public health threat across the lifespan. To date, 35 million people have died because of HIV. Currently, there are 1.1 million people with HIV (PWH) in the United States and 37 million PWH globally.[66, 67] In 2017, 1.8 million people worldwide became newly infected with HIV.[2] Continued investment in the NIH-wide HIV research program is essential to sustain the accomplishments already made and secure future advances to prevent the spread of HIV; improve health outcomes for persons with, at risk for, or affected by HIV; and ultimately to find a cure for HIV.

The Budget is proposing a once-in-a-generation opportunity to eliminate new HIV infections in our nation. *Ending the HIV Epidemic: A Plan for America* will work to reduce new infections by 75 percent in the next five years and by 90 percent in the next ten years, averting more than 250,000 HIV infections in that span. The multi-year program will infuse 48 counties, Washington, D.C., San Juan, Puerto Rico, as well as 7 states that have a substantial rural HIV burden with the additional expertise, technology, and resources needed to end the HIV epidemic in the United States. HHS's four strategies – diagnose, treat, protect, and respond – will be implemented across the entire U.S. within 10 years. Without this new intervention, new infections will continue and could increase, costing more lives and the U.S. government more than $200 billion in direct lifetime medical costs for HIV prevention and medication.

NIH-funded research has supported development of the science and tools that make the ambitious goals of this initiative possible. NIH will inform HHS partners in this initiative on best practices, based on state-of-the-art biomedical research findings, and by collecting data on the effectiveness of approaches used in this initiative.

To ensure that essential research dollars are invested strategically and effectively, OAR has established comprehensive planning, budgeting, and portfolio analysis processes to identify the highest priority areas of scientific research necessary to end the HIV pandemic and to facilitate maximum return on NIH's investment.

The strategic planning and budget process coordinated by OAR allocates NIH research funds for:

- NIH-wide HIV research agenda aligned with the highest HIV research priorities;
- Initiatives that address HIV research gaps and emerging scientific opportunities that require focused attention;
- Cross-Institute activities and collaborations to catalyze integrative scientific research, enhance discovery, leverage resources, and minimize duplication; and

[66] "Basic Statistics," Centers for Disease Control and Prevention, accessed October 17, 2018, www.cdc.gov/hiv/basics/statistics.html.
[67] "Global HIV & AIDS statistics — 2018 fact sheet," UNAIDS, accessed October 17, 2018, www.unaids.org/en/resources/fact-sheet.

- Basic science to accelerate scientific discoveries into the next frontier of clinical and public health applications.

Overall Budget Policy: The FY 2020 President's Budget request for the NIH-wide HIV/AIDS research program is $2,621.2 million, a decrease of $423.9 million or 13.9 percent compared to the FY 2019 Enacted level. The FY 2020 budget includes $6 million for NIH to support the President's Ending the HIV Epidemic Initiative to end HIV transmission in the United States by 2030. This will be accomplished by geographic concentration of efforts and utilizing significant recent research developments focused at reducing new infections, including pre-exposure prophylaxis (PrEP) and treatment as prevention. NIH-sponsored Centers for AIDS Research (CFARs) will inform HHS partners on evidence-based best practices to expand existing prevention and treatment resources and evaluate the effectiveness of approaches used in this initiative. In the long term, development of a safe, effective, practical, and affordable HIV/AIDS vaccine is our best hope to end the HIV pandemic. NIH continues to support a broad HIV/AIDS vaccine research portfolio encompassing basic, pre-clinical, and clinical research, including studies to identify and better understand potentially protective immune responses in HIV-infected individuals and studies of improved animal models for the pre-clinical evaluation of vaccine candidates. The NIH will also continue to support research related to HIV across the lifespan. Although there has been progress in the reduction of the number of HIV-infected infants through expansion of programs for perinatal prevention of mother-to-child transmission (PMTCT), pediatric infection by breast-feeding continues as a challenge. Because the number of HIV-exposed but uninfected (HEU) infants is increasing worldwide, studies to compare rates of pre-term delivery, mortality, growth, and other outcomes are critical to better understand how HIV exposure impacts the health and well-being of a child, long after exposure to both HIV and antiretroviral therapy (ART) has ended. At the other end of the spectrum, as the number of older people living with HIV increases, chronic HIV infection, extended exposure to ART, and aging may all interact to increase risk of neurological impairment, other comorbid conditions, and mortality. Therefore, basic science, epidemiological, clinical, and translational research studies, focused on HIV in aging populations and utilizing multi-disciplinary research teams, are critically necessary.

Program Descriptions

OAR manages the NIH-wide HIV program and allocates funds to the ICOs to advance the HIV research agenda, ensuring that funds are aligned with the highest priorities of HIV research to:

- Reduce the incidence of HIV.
- Develop next-generation HIV therapies.
- Promote research toward an HIV cure.
- Address HIV-associated comorbidities, coinfections, and complications.
- Advance the critical framework of crosscutting research areas to combat the HIV pandemic.

The overarching research priorities identified within the NIH-wide budget, as well as selected programs that reflect the NIH Director's key themes, are described below.

Reduce the incidence of HIV. Preventing new infections is crucial to ending the HIV pandemic. An effective HIV vaccine would be a groundbreaking advancement essential to preventing new infections and controlling the pandemic. Several major HIV vaccine efficacy studies are testing different vaccine candidates, with results anticipated by 2022. Candidate vaccines are built on the scientific advances of the past 10 years and showed promise in small, early phase clinical trials. Currently, there is a robust pipeline of products in assessment for immunogenicity in humans, with more than 30 clinical studies in various phases of testing.

In parallel with vaccine-based prevention strategies, antibody-mediated protection (AMP) studies are testing a new alternative for prevention in HIV-negative individuals with studies to determine whether periodic infusions or injections of certain broadly neutralizing antibodies (bNAbs) can prevent HIV acquisition in approximately 5,000 PWH in multiple countries. Although the studies represent advances toward treatment and prevention of HIV, further research is needed to expand upon these results by extending the half-life of the antibodies, developing more potent antibodies and vector-based bNAbs for HIV prevention, and identifying bNAb combinations that can suppress HIV long-term in people whose HIV sensitivity to bNAbs is unknown.

Basic, clinical, and translational research to evaluate the human immune response to vaccines remains a high priority. Advances in imaging technologies have led to the development of vaccine candidates that more closely mimic HIV structural components and could be the foundation of improved vaccines to induce protective immunity. In preparation for clinical trials, NIH has strategically invested in expanding manufacturing capabilities, such as enhancing automation processes, to meet current and future research demands.

While developing vaccine strategies, the HIV prevention field has had considerable success in developing novel, global nonvaccine prevention strategies. NIH-sponsored studies led to the development of treatments and strategies to prevent the acquisition and transmission of HIV, including pre-exposure prophylaxis (PrEP), which can reduce the risk of sexual transmission of HIV by as much as 92 percent, and post-exposure prophylaxis (PEP), which can protect individuals who have had a one-time exposure to HIV. Research discoveries found that treatment as prevention (TasP) with ART significantly reduces transmission of HIV during pregnancy and breast-feeding and enables PWH to achieve undetectable viral loads, thereby improving their health and effectively reducing the risk of HIV transmission to zero.

One long-standing NIH goal is to develop multipurpose prevention technologies (MPTs), including microbicides and intravaginal rings, to protect women and men from acquiring HIV through sex. Such methods will offer particular advantages for women who may not have other options for protection. Several clinical trials are currently underway to test the effectiveness of a variety of MPTs.

Budget Policy: The FY 2020 President's Budget request to reduce the incidence of HIV is $634.5 million, a decrease of $106.7 million or 14.4 percent compared to the FY 2019 Enacted level.

Develop next-generation HIV therapies. NIH-sponsored research has led to the development of combination antiretroviral therapy (cART), which has significantly improved the health outcomes of PWH. Consistent use of cART reduces damage to the immune system of PWH by

suppressing viral replication, delaying the development of viral resistance, and leading to undetectable viral loads, thus preventing sexual transmission of HIV to an uninfected partner. However, even with simplified daily one-pill treatment regimens capable of suppressing HIV only 22 million of the approximately 37 million PWH worldwide currently receive treatment.[68] Barriers to receiving and adhering to cART include treatment availability, the high cost, the need for daily treatment, the possibility of interactions with other drugs, and the potential for drug resistance and/or adverse events. In addition, stigma and disparities in access to cART adversely impact health outcomes in PWH across race, ethnicity, sex and gender, age, and socioeconomic status.

NIH has allocated funding for the development of new long-acting medications with fewer side effects and complications, including monthly injections of continuously released cART, anti-HIV antibody infusions, and a 6-month cART implant. Simpler treatment schedules compared to current daily medication regimens are expected to improve adherence. Parallel research is focusing on development of novel delivery and testing technologies, including sensitive, rapid point-of-care or self-administered viral load testing, to provide increased ease of monitoring for enhanced prevention of HIV transmission and improved treatment adherence leading to viral suppression. An estimated 10 percent of people receiving cART worldwide are resistant to at least one drug.[69] Immune-based treatments may reverse the weakening of the immune system that occurs even when the virus is suppressed.

Budget Policy: The FY 2020 President's Budget request to develop next-generation HIV therapies is $322.6 million, a decrease of $47.1 million or 12.7 percent compared to the FY 2019 Enacted level.

Promote research toward a HIV cure. Latent HIV reservoirs, DNA coding for HIV that persists in PWH despite the use of cART, present a significant challenge to finding a cure for HIV. Reservoirs of HIV can be found in certain "sanctuary" sites in the body, including the brain, allowing the virus to hide and be protected from both the immune system and cART, preventing either sustained, ART-free viral remission, also known as a functional cure, or viral eradication, and leading to a permanent HIV cure. Because the mechanisms that underlie reservoir dynamics are not well understood, NIH invests in basic research to identify, characterize, and eradicate HIV or to inhibit viral reactivation through novel approaches and treatments that target HIV reservoirs. A range of techniques, including single-cell and imaging technologies, are being used to identify and describe the HIV reservoir and discover mechanisms of viral reactivation from latently infected cells. Experimental treatments in development include therapeutic vaccines, genetically engineered immune cells that are resistant to HIV infection, drugs that reactivate latent HIV to make the virus visible to the immune system so that the virus can be cleared, cure-inducing immunotherapies, and interventions to prolong the time between antiretroviral treatments from one day to a few months or longer for an ART-free viral remission. The ultimate goal is to permanently eradicate HIV with cure interventions and

[68] "Global HIV & AIDS statistics — 2018 fact sheet," UNAIDS, accessed October 17, 2018, www.unaids.org/en/resources/fact-sheet.
[69] World Health Organization. 2017. *HIV Drug Resistance Report 2017.* Available at apps.who.int/iris/bitstream/handle/10665/255896/9789241512831-eng.pdf;jsessionid=3A32877D555CB649B1A56DF89DD72C99?sequence=1.

treatments that are at least as safe, effective, and available for widespread use as current cART regimens.

Budget Policy: The FY 2020 President's Budget request to promote research toward a HIV cure is $159.4 million, a decrease of $31.4 million or 16.4 percent compared to the FY 2019 Enacted level.

Address HIV-associated comorbidities, coinfections, and complications (CCCs). HIV is associated with complex health issues and although the use of cART results in significant improvement in PWH, HIV-associated CCCs continue to challenge the clinical management of disease conditions across the lifespan. NIH invests in basic, translational, and clinical research to understand how the mechanisms underlying HIV infection, such as immune dysfunction and inflammation, may increase the risk for cardiovascular disease, certain cancers, neurologic and cognitive disorders, mental illness, substance use disorders, metabolic and bone abnormalities, accelerated aging, and increased mortality. Adherence to cART regimens not only slows the progression to AIDS, but also reduces HIV-related concomitant conditions or comorbidities, such as cardiovascular disease, kidney disease, and cancer, as well as infections and other complications, in PWH.

Research is needed to differentiate between complications related to aging, immune dysfunction, long-term antiretroviral use, and HIV-associated disease and/or co-occurring chronic illnesses, such as diabetes or hypertension. To that end, it is necessary to understand interactions between antiretroviral treatment and medications that are used to treat comorbidities and to develop novel therapies for HIV and CCCs that minimize side effects and toxicities. For example, neuroimaging is being developed to detect and measure changes in the brain more accurately. Advances in brain imaging promise powerful ways to noninvasively assess the status of the brain over time in PWH and may enable the use of observed changes in the brain as endpoints for clinical trials.[70] The development and testing of low-cost, rapid techniques that require minimal infrastructure to prevent, diagnose, and monitor HIV-associated CCCs is a particular need in resource-limited settings.

Due to the integrative nature of such diseases, research to address CCCs is not only important for PWH but promises to inform research strategies for other key public health challenges that affect the general population, such as cancer, heart disease, and neurologic disorders.

Budget Policy: The FY 2020 President's Budget request to address HIV-associated comorbidities, coinfections, and complications (CCCs) is $470.0 million, a decrease of $67.4 million or 12.5 percent compared to the FY 2019 Enacted level.

Advance the critical framework of crosscutting areas of research to end the HIV pandemic. A significant proportion of HIV research has relevance to not just one, but all five overarching NIH HIV priority research areas. The crosscutting research areas contribute to fundamental knowledge that advances HIV research.

[70] Clifford, D.B. "HIV Associated Neurocognitive Disorder," *Current Opinion in Infectious Diseases* 30, no. 1 (February 2017): 117–122. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC5382956.

- **Basic science research** provides the underlying foundation for all HIV research areas and includes studies on HIV virology, transmission, susceptibility, and investigations of HIV-related immunology and host-viral interactions. Research on the viral, cellular, molecular, genetic, and immune mechanisms of pathogenesis is essential to better understand HIV acquisition, prevention, and disease progression; the mechanisms leading to the pathogenesis of HIV-associated CCCs; and a potential cure. Efforts must be made to ensure linkages to NIH-supported HIV cohorts, biorepositories, and databases and to integrate animal studies, particularly studies using nonhuman primates, into the discovery pipeline. For example, characterizing similarities and differences in the immune response by using animal models to develop cross-reactive antibodies between species may provide promising new treatment options.

  NIH partners with industry, academia, and other research organizations to support a broad array of basic and clinical research to develop cutting-edge diagnostic technologies that will quickly identify infection, measure treatment efficacy, and determine drug resistance. NIH focuses on behavioral social science and implementation research to develop innovative strategies to increase treatment uptake and engage PWH in their own care to prevent transmission, achieve viral suppression, and improve health.

- **Epidemiology research** and epidemiologic methods provide accurate, real-time information to understand the changing demographics of the HIV pandemic. NIH invests in research on the epidemiology of HIV drug resistance to inform treatment strategies and disease outcomes. Understanding the causes, patterns, and social phenomena that have led to higher rates of HIV infection in the southern and midwestern United States is key to rapidly identifying and preventing HIV outbreaks, and with a surging opioid epidemic, methodologies to detect infection clusters early and prevent future outbreaks is a priority. The use of big-data science, machine learning, modeling, registries, phylodynamics, and other epidemiologic approaches will determine where research should be conducted, inform prevention and treatment approaches, and contribute to early detection and improved outcomes across the HIV prevention and care continuum.

- **Behavioral and Social Sciences Research (BSSR)** ranges from basic to applied research, with an emphasis on behavioral interventions. Research systematically examines the behavioral, social, cultural, environmental, and organizational factors, as well as individual and interpersonal dynamics and community beliefs, to provide essential insights to factors that influence the transmission, prevention, treatment, and management of HIV. Results are essential to understand the most effective strategies to engage individuals in treatments or products to prevent transmission or maximize treatment effectiveness. NIH-supported studies have helped to reduce HIV-related stigma, improve medication adherence, increase retention in the HIV prevention and care continuums, and develop innovative HIV prevention/treatment technologies. For example, a recent study designed to facilitate treatment for HIV and substance abuse was associated with a 50 percent reduction in mortality when PWH who also inject illicit drugs adhered to an intervention consisting of psychosocial counseling and guidance in navigating the health care system. Other studies are improving the application of social network analyses, leading to the creation of socioculturally-specific interventions, and testing other key elements and integrative approaches to prevent and treat HIV infection.

- **Implementation science research** is needed to develop approaches to support the uptake of interventions developed within the five overarching priorities and to identify factors that are barriers to or can help facilitate effective treatment, as well as health care programming and policy development. NIH has an increasing focus on studying and integrating evidence-based health interventions and strategies into clinical and community settings to improve patient outcomes and public health. Further research is needed to define approaches and models for scaling up comprehensive, integrated interventions for expanding testing, prevention, and treatments that optimize adherence, retention, and health outcomes in real-world settings.

- **Health disparities research** is essential to better understand and address how complex biological, behavioral, structural, and sociocultural factors that may be linked to race/ethnicity, sex and gender, age, and geography lead to disparities in HIV prevention, incidence, treatment, and health outcomes. NIH seeks to define and address the factors that contribute to health disparities and worsen health outcomes among key populations disproportionately affected by the pandemic and to develop effective interventions to eliminate disparities.

- **Training, infrastructure, and capacity building (TICB)** are crucial to the development of the next generation of HIV researchers, both in the United States and globally. TICB includes building laboratories, developing education systems, and designing novel multidisciplinary approaches to mentoring and training a broad and diverse scientific workforce. Fundamental HIV-related research training will provide support to the field in general and to achieving the specific research priorities to end the HIV pandemic and improve the health of PWH. NIH supports opportunities for early exposure to and increased awareness of careers in the biomedical, behavioral, and social sciences, including HIV research, particularly for students from underrepresented communities and disadvantaged backgrounds.

- **Information dissemination** of research findings to diverse communities and stakeholders, including patients, clinicians, researchers, and the public, remains a critical component of NIH-supported HIV research and is essential to the prevention and treatment of HIV. The creation and incorporation of new communication strategies and state-of-the-art technologies to improve access to hard-to-reach, underserved, and underrepresented populations within diverse settings and to strengthen the broad dissemination of HIV research findings is a priority. Because social media use has become deeply entrenched in most industrialized societies and among all populations, the development of HIV-preventive interventions on social media platforms to reach such populations as adolescents and young adults, men who have sex with men, and transgender populations would be a valuable tool in curbing the rates of new infections.

Budget Policy: The FY 2020 President's Budget request to advance the critical framework of crosscutting areas of research to end the HIV pandemic is $1,034.7 million, a decrease of $171.3 million or 14.2 percent compared to the FY 2019 Enacted level.

Programs and Activities to Support NIH's Highest Scientific Priorities

In addition to the five overarching HIV research priorities, OAR allocates funds to support select forward-thinking initiatives and innovations that advance the NIH-wide HIV research agenda. The following activities reinforce the key themes established by the NIH Director to speed the pace of research and improve the translation of scientific discovery into new treatment approaches:

- **Invest in transformational tools and technologies.** OAR invests in innovative information technology tools to perform analyses of the NIH-wide HIV research portfolio to identify research gaps and emerging opportunities, as well as facilitate budget projection. OAR has integrated new innovative data systems and tools, such as the AIDS Budget System and AIDS Portfolio Review System, to enhance the effectiveness of the budget development and review process.

- **Leverage existing resources to support interdisciplinary collaborations to accelerate research innovations and discoveries.** OAR is pursuing innovative approaches to leverage resources for funding new and existing HIV research. Cost-sharing initiatives between ICOs and OAR maximize the use of NIH's research dollars and promote interdisciplinary and integrative collaborations to accelerate research innovations and discoveries that impact the health outcomes of PWH. Collaborations include the Centers for AIDS Research (CFAR) to support multidisciplinary HIV research at NIH-funded research centers of academic institutions across the United States. The CFAR partnership with the Claude D. Pepper Older American Independence Centers of the National Institute on Aging (NIA) is generating interdisciplinary research on aging with HIV. OAR's commitment to collaboration includes bringing together research on HIV-related and non-HIV-related comorbidities/coinfections through the recent renewal and expansion of two long-standing longitudinal research studies—the Multicenter AIDS Cohort Study (MACS) and the Women's Interagency HIV Study (WIHS)—into one combined study. The combined study, supported through 15 ICOs, places greater emphasis on HIV-associated comorbidities, especially conditions linked to aging, and is an unparalleled opportunity for investigators to study the effects of HIV infection and aging. OAR is partnering with the NIA to further explore HIV-associated neurocognitive disorders, HIV persistence in the central nervous system, and the added impact of aging. Research awards for the OAR/NIA Funding Opportunity Announcement (FOA) on the Pathogenesis of Age-Related HIV Neurodegeneration (RFA-AG-18-023) were announced in September 2018 and will contribute to the development of a cadre of interdisciplinary research.

- **Build on basic science to foster translational and clinical research to improve health.** NIH will continue to invest in basic research to understand the fundamental mechanisms that drive HIV infection and the development of related diseases and conditions. Advances in basic and clinical research have led to a better understanding of the relationship between HIV and associated comorbidities, including AIDS-defining and non-AIDS-defining cancers, and of the potential impact of HIV treatment on such conditions. Clarifying the biological role of HIV and its associated immune dysfunction in the mechanisms that lead to the development of cancers will require continued research efforts. It is critical to investigate the complications of treating cancers in PWH to improve treatment outcomes across the lifespan,

minimize adverse events, and decrease morbidity and mortality in PWH with cancer. Developing improved therapies, including immunotherapy for HIV-associated cancers, continues to be a top scientific priority. NIH will continue funding basic, 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.

- **Support urgent and emerging scientific needs.** OAR supports urgent and/or emerging scientific needs, such as providing supplemental funding to evaluate the short- and long-term effects of dolutegravir (an ART medication) and other integrase inhibitors after recent data suggested a potential relationship between *in utero* exposure and neural tube defects in infants born to mothers on treatment. In addition, OAR supports new high-priority projects with funds recovered from the annual review of the NIH-wide HIV research portfolio.

- **Explore the next frontier.** OAR sets the direction of HIV research through NIH-wide collaborations and strategic partnerships among stakeholders. The Office works in partnership with the ICOs through the NIH AIDS Executive Committee to identify NIH-wide HIV research priorities, scientific gaps and opportunities in emerging areas of research, all of which guide the development of the *NIH Strategic Plan for HIV and HIV-related Research* and the annual NIH HIV budget.

  NIH is undertaking new, complex challenges by enhancing strategic partnerships among stakeholders from the community, academia, and government to advance future HIV research. For example, OAR is collaborating with the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institute of Allergy and Infectious Diseases (NIAID) to plan for an immuno-bioengineering funding opportunity targeting and integrating cross-disciplinary research involving immunologists, bioengineers, and other investigators to advance HIV vaccine research and development.

NIH will continue to support innovative preclinical, translational, and clinical studies of HIV treatment and cure interventions across the lifespan. Key scientific opportunities include transforming the vaccine field of research with a novel strategy to direct B cells to make antibodies that protect vaccinated individuals from acquiring HIV. Other opportunities include gene modification/gene silencing approaches, immuno-therapeutic agents (including monoclonal antibodies) and their derivatives, and cell modification–based interventions to boost or to direct the immune system against HIV. Novel technologies with the potential to enable accurate self-administered testing for viral replication will be sought as another key enabler of cure clinical trials. The ultimate goal is a cure intervention that is simple, safe, sustainable, and scalable.

Drug Control Programs

Resource Summary

	Budget Authority (in millions)		
	FY 2018 Final[1]	FY 2019 Enacted	FY 2020 Request
Drug Resources by Budget Decision Unit and Function:			
Decision Unit 1: National Institute on Drug Abuse			
Research and Development: Prevention	$533.346	$550.992	$503.079
Research and Development: Treatment	$841.028	$868.852	$793.300
Total, Decision Unit 1	$1,374.374	$1,419.844	$1,296.379
Decision Unit 2: National Institute on Alcohol Abuse and Alcoholism			
Research and Development: Prevention	$49.034	$50.691	$43.635
Research and Development: Treatment	$6.857	$7.089	$6.102
Total, Decision Unit 2	$55.891	$57.780	$49.737
Total Funding	$1,430.265	$1,477.624	$1,346.116
Drug Resources Personnel Summary			
Total FTEs (direct only)	355	382	382
Drug Resources as a Percent of Budget			
Total Agency Discretionary Budget (in billions)[2]	$36.2	$38.0	$33.5
Drug Resources percentage	3.96%	3.89%	4.02%

[1] Total for NIDA includes $213.124 million of Opioid funding not obligated in FY 2018, and carried over into FY 2019.

[2.] Total includes amounts requested in FY 2020 for consolidation of the Agency for Healthcare Research and Quality into NIH as the National Institute for Research on Safety and Quality (NIRSQ). NIRSQ does not have any programs classified as part of the National Drug Control Budget.

Program Summary

MISSION

The NIDA and the NIAAA, two of the 27 Institutes and Centers of the National Institutes of Health (NIH), support research in pursuit of the *National Drug Control Strategy*. NIDA funds research on the prevention and treatment of drug use, addiction, and its harmful consequences. NIAAA supports 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.[71] 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, NIH-supported research will continue to build on scientific advances from previous and ongoing investments in basic, translational, and clinical research that have led to innovative strategies for preventing and treating substance misuse and substance use disorders (SUDs) in this country and worldwide.

Studying substance misuse, 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; a decades-long prescription drug misuse epidemic has led to a rise in heroin use, and now the use of synthetic opioids such as fentanyl and carfentanil is becoming more widespread. The rising use of synthetic drugs as well as new drug delivery systems such as electronic cigarettes (e-cigarettes) are changing how people use drugs. New HIV and Hepatitis C outbreaks arise as a byproduct of intravenous drug use. In addition, the growing number of states that are legalizing marijuana for recreational and medical use present an opportunity to study the outcomes of these policy changes as natural experiments.

NIDA is supporting research to address today's drug use-related challenges in several key areas, including supporting the Secretary of HHS in responding to opioid misuse, addiction, and overdose; spearheading a landmark longitudinal study of adolescent substance use and brain development in collaboration with NIAAA and other Federal partners; studying the impact of new synthetic drugs; studying the impact of the changing marijuana landscape; and contributing to scientific and public understanding of the brain mechanisms underlying addiction.

Opioid misuse, addiction, and overdose is an ongoing and rapidly evolving public health crisis. Millions of Americans suffer from opioid use disorder (OUD), 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 launched the Helping to End Addiction Long-term (HEAL) Initiative in April 2018. HEAL is an aggressive effort to speed scientific solutions to stem the national opioid public health crisis, bolstering research to develop and improve treatments for opioid misuse and addiction and to enhance pain management.

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.[72] Since its creation, NIAAA has supported a diverse portfolio of research to elucidate the effects of alcohol on health and reduce the burden of alcohol misuse for individuals at all stages of life. This research encompasses studies on: the biological and behavioral mechanisms underlying alcohol misuse and alcohol use

[71] U.S. DOJ National Drug Intelligence Center. The Economic Impact of Drug Use in American Society. April 2011.
[72] Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; et al. 2010 national and state costs of excessive alcohol consumption. American Journal of Preventive Medicine 49(5):e73–e79, 2015.

disorder (AUD), epidemiological research to track patterns of alcohol use, and the development of interventions to diagnose, prevent, and treat alcohol misuse and its consequences, including among youth. NIAAA also supports efforts to translate and implement research findings into improved health care for individuals with AUD and co-occurring conditions, as well as to disseminate evidence-based information to health care providers, researchers, policy makers, and the public. This work has significantly broadened our understanding of AUD, helping to reduce the stigma associated with it and providing support for integrating alcohol prevention and treatment services into mainstream health care.

METHODOLOGY

NIDA's entire budget is drug-related and classified as a part of the National Drug Control Budget. The prevention and treatment components of NIAAA's underage drinking research program are classified 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). It includes basic biological and behavioral research, epidemiological research, screening studies, the development and testing of preventive and treatment interventions, and efforts to disseminate evidence-based information. 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 these projects are verified as underage drinking projects, NIAAA conducts a manual review of the project listing and codes each project as relevant to prevention or treatment. This is used to generate the NIAAA drug control budget estimate.

Budget Summary

The FY 2020 request for drug-related activities at NIH is $1,346.1 million ($1,296.4 million for NIDA and $49.7 million for NIAAA), an 8.9% decrease compared with the FY 2019 Enacted level.

NIH-supported research has provided 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 substance misuse and 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 and deployment of therapeutic interventions to treat SUDs, including medications, biologics, behavioral interventions, 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. However, discovering new therapies is not sufficient to combat SUD if these therapies do not reach the people who need them. In many cases, such as medication-assisted treatment (MAT) for OUD, studies suggest that effective treatments are under-utilized despite strong evidence of their effectiveness. To address this issue, 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 and psychiatric disorders, thereby enhancing the public health impact of NIH-supported research.

In April 2018, NIH launched the NIH Helping to End Addiction Long-term (HEAL) Initiative^{SM}, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. This Initiative will build on extensive, well-established NIH research, including basic science of the complex neurological pathways involved in pain and addiction, implementation science to develop and test treatment models, and research to integrate behavioral interventions with medications for opioid use disorder (OUD).

As part of the NIH HEAL Initiative, NIDA (and to a lesser extent, NIAAA) support a variety of projects aimed at advancing our understanding of how to prevent and treat opioid misuse and addiction and reverse opioid overdose. This includes research studies to (1) develop new and reformulated medications to treat OUD; (2) determine strategies to reduce opioid overdose in communities hardest hit by the opioid crisis; (3) conduct clinical trials to enhance widespread implementation of evidence-based interventions; and (4) determine ways to improve the effectiveness and adoption of interventions within justice systems.

National Institute on Drug Abuse
FY 2020 Request: $1,296.4 million
($123.5 million below the FY 2019 Enacted level)

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

Neuroscience and Behavior Research
FY 2020 Request: $423.4 million
($50.4 million below the FY 2019 Enacted level)

The Neuroscience and Behavior research portfolio seeks to advance knowledge of the fundamental molecular, cellular, genetic/epigenetic, neurological, and behavioral processes that underlie SUDs. Additionally, a goal of this research is to elucidate the effects of drugs of abuse on brain structure and function. Central to these goals are efforts to delineate the multiple neurobiological factors that contribute to drug abuse, physical dependence and addiction risk, with particular emphasis on determining the bases for individual differences in vulnerability and drug sensitivity. NIDA supports research to develop advanced technologies that improve our ability to study the organization of the living brain from cells to networks and 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 discovering, developing, and testing new compounds for the treatment of substance abuse, physical dependence, and addiction. NIDA pharmacological research is also involved in the discovery of molecules and mechanisms that can relieve pain without producing adverse effects, including tolerance, dependence, and addiction. NIDA also supports 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. Notable projects are investigating the effects of drugs on gene expression and brain development and function; how an individual's genes interact with environmental conditions, such as stress and early exposure to drugs to influence risk for addiction; basic processes underlying resilience against SUDs in childhood and adolescence; and gender-related differences in these effects. 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 nine other components of the NIH and the Centers for Disease Control and Prevention (CDC), are supporting a longitudinal study that will not only examine how substance use affects neural development, but also identify risk factors and biomarkers that make adolescents vulnerable to substance use disorder. 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, including both substance use and broader health 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. The ABCD study has enrolled more than 11,000 participants and released curated data on the first approximately 4,500 participants to the scientific community in February 2018. Curated baseline data on the full ABCD cohort will be released in early 2019.

Epidemiology, Services, and Prevention Research
FY 2020 Request: $289.5 million
($34.5 million below the FY 2019 Enacted level)

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 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.

NIDA recently partnered with the Appalachian Regional Commission (ARC), the CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) and have issued nine grants to help communities develop comprehensive approaches to prevent and treat consequences of opioid injection, including substance use disorder, overdose, HIV, hepatitis B and C virus infections, as well as sexually transmitted diseases. Once developed, these projects will work with state and local communities to develop best practice responses that can be implemented by public health systems in the nation's rural regions.

Therapeutics and Medical Consequences
FY 2020 Request: $146.6 million
($17.5 million below the FY 2019 Enacted level)

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 supports and conducts pre-clinical and clinical research with new or repurposed compounds with the goal of advancing their development towards FDA approval. This research also supports efforts to reduce the medical risks of compounds and to make them more feasible for pharmaceutical companies to complete costly phase IIb and III clinical studies for SUD indications. NIDA also invests in research supporting the development of vaccines and monoclonal antibodies for the treatment of SUDs.

Clinical Trials Network
FY 2020 Request: $37.2 million
($4.4 million below the FY 2019 Enacted level)

The Clinical Trials Network (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 allow medical and specialty treatment providers, treatment researchers, participating patients, and NIDA to cooperatively develop, validate, refine, and deliver new treatment options to patients. This unique partnership enables the CTN to conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions in rigorous, multisite clinical trials to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations. It also allows the CTN to ensure the transfer of research results to physicians, clinicians, providers, and patients. 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.

The CTN is conducting studies to evaluate strategies for integrating OUD screening and treatment into emergency departments, pharmacies, primary care clinics, and American Indian communities. The CTN has also supported studies to integrate OUD care into electronic health record (EHR) systems, to capture important data for research on SUD in EHR systems for primary care and emergency departments, and is currently developing and testing a clinical decision support (CDS) tool for OUD care for use in EHR systems. Additional studies are

investigating the effectiveness and safety of a combination pharmacotherapy for treatment of methamphetamine use disorder, assessing the effectiveness of OUD treatments for HIV-positive individuals with OUD, and improving the ability of healthcare providers to detect and address cocaine use using smartwatch technology. The CTN is currently developing a variety of studies, including examining the effects of medications for OUD in pregnant women and studying the effects of medical cannabis use via electronic health records.

Responding to the Opioid Crisis
FY 2020 Request: $250.0 million
(Unchanged from the FY 2019 Enacted Level)

As part of the NIH HEAL Initiative, NIDA will continue to expand its support for new research efforts to combat opioid addiction, with several major projects beginning or ramping up in FY 2019 with continued support into FY 2020. Initiatives under consideration include studies to determine the optimal length of medication treatment for OUD; management of subsyndromal and low-severity OUD; preventing OUD in older adolescents and young adults; and understanding consequences of prenatal opioid exposure on brain and behavioral development.

NIDA supports research to accelerate the development of novel medications and devices to treat all aspects of the opioid addiction cycle, including progression to chronic use, withdrawal symptoms, craving, relapse, and overdose. This includes developing longer-acting formulations of existing addiction medications to promote adherence to treatment while preventing medication misuse, as well as developing stronger, longer-acting formulations of opioid antagonists (including longer-lasting naloxone formulations and novel compounds) to reverse opioid overdose. HEAL also includes focused development efforts for OUD treatment, such as:

- Repurposing already-approved medications to treat OUD
- Evaluating medications already in use internationally but not in the U.S.
- Discovering and validating novel biological targets
- Developing novel immunotherapies for OUD and overdose
- Reducing drug craving and harm in people with OUD
- Developing devices to prevent and treat OUD and overdose

NIDA also plans to expand the size and scope of research conducted by the CTN to address emergent needs presented by the opioid crisis. The CTN has already generated important findings on the effectiveness and safety of medications to treat OUD and the utility of behavioral interventions for OUD management. By incorporating new research sites and investigators into existing research nodes and centers, the CTN will incorporate OUD-related research questions into studies currently underway, expedite new studies of OUD treatment in general medical and other settings, and enhance clinical and research training opportunities. While MAT is known to be effective to OUD, there is significantly less evidence about how long individuals should remain in treatment, or what the minimum length of MAT should be, given that most patients do not want to take medication for longer than necessary. Starting with buprenorphine, the NIDA CTN will be studying the optimal length of treatment in order to better understand how best to

deploy this highly effective, evidence-based intervention. NIDA is also in the planning stages of using the CTN to build the evidence base for early detection and intervention in individuals with opioid misuse who do not meet diagnostic criteria for severe OUD.

While misuse of prescription opioids like Vicodin™ and OxyContin™ and use of heroin are at record low levels among middle and high school students, the prevalence of opioid misuse has risen dramatically among older adolescents and young adults. As part of its efforts to address the opioid crisis, NIDA will focus on preventing OUD during this vulnerable time of transition. The goal of this prevention initiative is to develop and disseminate evidence-based prevention interventions targeting adolescents and young adults ages 16-30 residing in areas that are affected by the opioid crisis. Studies will be conducted to improve our understanding of risk factors to opioid misuse, transition to OUD, and opioid overdose as well as other adverse health consequences. Research grants in this initiative will also support studies to test interventions in a variety of settings in the healthcare, community, and justice systems. Settings selected will encompass those most likely to reach the targeted audience including primary care centers, emergency departments, urgent care centers, HIV/sexually transmitted infection clinics, school-based and community college health centers, the workplace, and the justice system.

It is well established that the first few years of life are a period of exponential brain growth and development. However, there is much to be learned about typical brain development beginning prenatally through early childhood, its variability, and how it contributes to cognitive, behavioral social, and emotional function. Knowledge of normative brain trajectories is critical to understanding how brain development may be affected by exposure to opioids and other substances (e.g., alcohol, tobacco, cannabis), stressors, trauma and other significant environmental influences. This knowledge is critical to help predict and prevent some of the known impacts of pre-/postnatal exposure to certain drugs or adverse environments, including risk for substance use, mental disorders, and other behavioral and developmental problems. Currently, no large prospective cohort study has been conducted to comprehensively assess brain development or the long-term consequences of early adverse experiences or exposure to opioids, other drugs (including prescribed medication), or other substances (e.g., tobacco, alcohol, cannabis). Furthermore, establishing a causal link between substance exposures and specific outcomes is very difficult due to confounding factors such as socioeconomic, environmental, cultural, and genetic influences. To disentangle these factors, the HEALthy Brain and Cognitive Development study will establish a large cohort of pregnant women from regions of the country significantly affected by the opioid crisis and follow them and their offspring into early childhood, collecting data in the following domains: pregnancy/fetal development measures; infant and early childhood structural and functional brain imaging; medical history; family history; biospecimens; and social, emotional, and cognitive development. This prospective approach will allow for the investigation of pre-symptomatic changes in brain and behavioral development resulting from early exposure to opioids and other substances, as well as associated adverse conditions that might predict emergence of SUD and other mental illness. It will also identify protective and resiliency factors that may ameliorate the effects of these exposures and inform the development of early interventions

Opioid misuse and addiction is an ongoing and rapidly evolving public health crisis that affects millions of Americans and requires innovative scientific solutions. A great tragedy of the opioid crisis is that so many effective tools already exist but are not being deployed effectively in communities that need them. Only a fraction of people with opioid use disorder (OUD) receive any treatment, and of those, less than half receive the medications that are universally acknowledged to be the standard of care, or they receive treatment for too short a duration. In partnership with the SAMHSA, and as part of the broader NIH HEAL Initiative, NIDA is leading a multisite research effort called the HEALing Communities Study.

This study will develop and test strategies to help communities respond rapidly and effectively to their opioid crisis with a focus on significantly reducing opioid-related overdose fatalities by 40 percent in 3 years and improving other outcomes. More specifically, the funding opportunities released in September 2018, (RFA-DA-19-0164 and its companion RFA-DA-19-0175), call for cooperative agreement applications for a data coordinating center and up to three research sites to measure the impact of integrating evidence-based prevention, treatment, and recovery interventions for opioid misuse, OUD, opioid-related overdose events and fatalities across multiple settings including healthcare, behavioral health, and justice. Each research site will be made up of several counties, towns, or cities within a single state, and will involve community resources such as police departments, faith-based organizations, and schools, with a focus on strong partnerships with state and local governments. The study also aims to decrease the incidence of OUD; increase the number of individuals receiving medications for OUD, staying in treatment beyond six months, and receiving recovery support services; and expand the distribution of naloxone. The lessons learned from this study will allow us to parlay the power of science to tackle one of the worst drug crises our country has ever seen.

Intramural Research Program
FY 2020 Request: $86.6 million
($9.6 million below the FY 2019 Enacted level)

In addition to funding extramural scientists, NIDA also conducts research in high priority areas through its Intramural Research Program (IRP). Intramural research at NIDA focuses on conducting multidisciplinary cutting-edge research to: 1) elucidate the mechanisms underlying the development of addiction; 2) evaluate the potential of emerging new therapies for SUDs, including pharmacological and non-pharmacological interventions (e.g. psychosocial, biofeedback, brain stimulation technologies); and 3) identify and pharmacologically characterize emerging designer drugs such as synthetic opioids, stimulants, and cannabinoids providing data-based evidence to the public on the dangers of these street drugs. Two specific examples of current and translational IRP research are described below.

First, a group of IRP investigators has begun a large translational study of a novel biased mu opioid receptor agonist to treat OUD. They have designed cross-species translational studies to test the efficacy of chronic delivery of a proprietary lead compound on oxycodone self-administration and relapse to drug seeking induced by acute exposure to the self-administered

drug and drug-associated cues, in rat and monkey models, developed at the IRP. A human lab study is also planned with prescription opioid addicts on the effect of chronic delivery of the compound on opioid craving induced by acute exposure to the prescription opioid or cues associated with the drug. In both the animal studies and the human study, the efficacy of this novel drug relative to buprenorphine will be compared. The long-term goal is to provide preclinical and clinical evidence to support the use of a biased mu opioid agonist as a novel opioid agonist maintenance treatment for treatment of OUD.

Second, the IRP is furthering OUD research, in partnership with a pharmaceutical company that has recently licensed NIH patents. The lead compounds are dopamine D3 receptor antagonist/partial agonists that show promise in reducing opioid self-administration, reinstatement to drug seeking, and acquisition to drug taking, while having no effect on opioid antinociception, in rodents and nonhuman primates. These novel drugs may prevent the development of dependence in patients who require long-term prescription opioids for the treatment of pain, but also have therapeutic potential for the treatment of OUD.

Research Management and Support
FY 2020 Request: $63.0 million
($7.0 million below the FY 2019 Enacted level)

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. RMS staff at NIDA are also helping to coordinate NIDA's involvement in the HEAL Initiative, spearheading NIH's response to the opioid overdose epidemic. NIDA currently oversees more than 1,700 research grants and more than 80 research and development contracts. In addition to the infrastructure required to support research and training, NIDA also strives to provide 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 medication-assisted treatment for opioid use and addiction.

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.

National Institute on Alcohol Abuse and Alcoholism
FY 2020 Request: $49.7 million
($8.0 million below the FY 2019 Enacted level)

NIH's underage drinking portfolio encompasses a broad range of research on the effectiveness and implementation of interventions designed to prevent and treat alcohol use, misuse, and addiction. These include both individual-, family-, school-, community-, and policy-level interventions for underage individuals at large, as well as those designed or adapted for specific populations and settings. 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[73] and high-intensity drinking (i.e., two or more times the gender-specific binge thresholds) among young people remain a significant concern; 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, including individual- and environmental-level strategies (e.g., policies related to alcohol sales, taxes, and advertising), 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. 11,874 youth, ages 9-10, have been enrolled in the ABCD study which will use brain imaging and neuropsychological and behavioral assessments to track the 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

[73] NIAAA defines binge drinking as a pattern of drinking that increases an individual's blood alcohol concentration to 0.08 percent or higher. This typically occurs after 4 drinks for women and 5 drinks for men – in about 2 hours.

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 documents related to the Government Performance and Results Modernization Act (GPRMA) and other information that measures the agency's contribution to the *Strategy*. 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.

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, four 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 2025, 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 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 contributed 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 was 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. NIAAA's contribution to SRO-8.7 ended in FY 2018, and a replacement measure – SRO: 4.15: "By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations" – has been developed for future reporting.

National Institute on Drug Abuse		
Selected Measures of Performance	**FY 2018 Target**	**FY 2018 Achieved**
» Scientific Research Outcome-5.15: By 2025, 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 strategies or interventions to prevent prescription drug abuse in youth and young adult populations.	The effect of an intervention to prevent prescription drug abuse in youth and young adult populations was tested, and several ongoing studies are assessing the efficacy or effectiveness of strategies to prevent prescription drug abuse in this target population.
» 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.	Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities.	Research testing the feasibility and efficacy of 2 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including (1) reSET-O which is under expedited review by FDA and (2) a web-delivered cognitive behavior therapy for veterans who screen positive for PTSD and SUD.

Prevention – Scientific Research Outcome-5.15

The FY 2018 target was partially achieved. NIDA tested the effect of one intervention to prevent prescription drug abuse in youth and young adult populations as part of its ongoing portfolio of research. NIDA funds research to assess the Partnership Model for Diffusion of Proven Prevention (PROSPER), which is a partnership-based delivery system to support the implementation of effective universal family and youth preventive interventions (e.g., Strengthening Families Program, Life Skills Training, Project ALERT, All Stars) in communities targeting known risk and protective factors. Substance misuse, antisocial behavior and health-risk taking sexual behavior are increasingly prevalent in young adulthood. The environments in

which adolescents socialize (e.g., school, family, peers) can exert substantial influence on both risk and protective factors for substance use and progression to misuse. As such, universal prevention interventions have been developed and tested to influence the family-, school-, and peer related risk and protective factors.

With a family-based prevention intervention delivered in 6th grade and school-based prevention intervention in 7th grade, NIDA-funded studies of PROSPER have demonstrated the model's sustained impact on substance use outcomes, including prescription drug use. A paper published in FY 2018[74] reported the long-term impact of PROSPER on a 'Prescription Drug Misuse Index' which measured overall prescription drug misuse and included three items addressing lifetime non-prescribed use of narcotics (e.g., Vicodin, Oxycontin, Percocet) and barbiturates. When study participants were re-assessed at age 19, they were 20 percent less likely to report having misused prescription narcotics. These and other related findings provide support for the potential public health impact of the PROSPER delivery system on reducing the initiation of substance use into emerging adulthood.

NIDA's portfolio of prescription drug abuse prevention is in the early stages of expansion, in response to the Nation's opioid crisis. As part of this expansion, several ongoing studies testing strategies and interventions are underway, but have yet to publish findings on effectiveness, though there have been qualitative reports of the possible impact of novel approaches to prevent prescription drug abuse. One such report, Young et al.,[75] demonstrated both the acceptability and potential benefit of an online social media intervention, Harnessing Online Peer Education (HOPE), to prevent addiction and overdose among individuals receiving opioid therapy for chronic non-cancer pain. Now that acceptability and potential benefit have been demonstrated, the researchers are moving forward with additional testing.

NIDA believes that as its prevention portfolio continues to make progress, the FY 2018 target will be fully met in FY 2019 as studies are completed and their findings published.

Treatment – Scientific Research Outcome-7.3

The FY 2018 target was met. Research testing the feasibility and efficacy of two technology-based strategies to improve SUD treatments and adherence was conducted in FY 2018. An additional byproduct of ongoing efforts in this area is a funding opportunity announcement designed to test technology-based treatments to increase adherence to FDA-approved

[74] Spoth R, Redmond C, Shin C, Greenberg MT, Feinberg ME, Trudeau L. PROSPER delivery of universal preventive interventions with young adolescents: long-term effects on emerging adult substance misuse and associated risk behaviors. Psychol Med. 2017;47(13):2246-2259. doi: 10.1017/S0033291717000691.
[75] Young SD, Heinzerling K. The Harnessing Online Peer Education (HOPE) Intervention for Reducing Prescription Drug Abuse: A Qualitative Study. J Subst Use. 2017;22(6):592-596. doi: 10.1080/14659891.2016.1271039. Epub 2017 Jan 31.

pharmacotherapies for SUD (https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-19-015.html). Funding has been allocated to support 3-4 technology-based treatments.

The research findings leveraging technology-based treatments to address NIDA's research priority areas and the FY 2018 target are summarized below.

- *Approval of the ReSET and ReSET-O mobile application for SUD Treatment* – A major development in mHealth (mobile health) was the 2017 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 SUD related to cocaine, other stimulants, cannabis, and alcohol. 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 was 40 percent, more than twice the abstinence rate for individuals who received standard care such as medication-assisted treatment with buprenorphine (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 FDA as the first prescription digital therapeutic to improve clinical outcomes in a disease.

  The reSET app was not approved for treating OUD, but with a Small Business Innovation Research grant from NIDA in FY 2018, a new version of the app called reSET-O was developed and tested for use as an adjunct to buprenorphine and standard treatment for patients with OUD. reset-O, along with the evidence from the earlier CTN studies, was reviewed by FDA under a process known as Breakthrough Therapy Designation, which is designed to expedite the development and review of products that are intended to treat a serious condition and preliminary clinical evidence indicates that the products may demonstrate substantial improvement over available therapy. reSET-O was approved by the FDA on December 10, 2018.

  reSET-O delivers cognitive behavioral therapy, which aims to change behavior by changing an individual's cognitive processes. The app is composed of digital multimedia modules delivering validated cognitive behavioral therapy and contingency management to promote recovery from OUD. 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 SUD treatment options, particularly in rural and underserved communities.

- *Web-Delivered CBT in Veterans with SUD and PTSD* – The primary aim of this study was to test a web-based self-management intervention based on cognitive behavioral therapy (CBT), targeting post-traumatic stress disorder (PTSD) symptoms and hazardous substance use in a group of symptomatic combat veterans enrolled in VA primary care. Veterans with PTSD/subthreshold PTSD and hazardous substance use were randomized to primary care treatment as usual (TAU; $n = 81$) or to TAU plus a web-based CBT intervention called Thinking Forward ($n = 81$). Thinking Forward consisted of 24 sections (approximately 20

minutes each), accessible over 12 weeks. Participants completed baseline and 4-, 8-, 12-, 16- and 24-week follow-up assessments. Three primary outcomes of PTSD, alcohol and other drug use, and quality of life were examined. Significant treatment effects were found for heavy drinking, but not for PTSD symptoms or quality of life. The effect of the intervention on heavy drinking was mediated by intervening increases in coping, social support, self-efficacy, and hope for the future. These results demonstrate the promise of a web-based, self-management intervention for difficult-to-engage OEF (Operation Enduring Freedom) and OIF (Operation Iraqi Freedom) veterans with behavioral health and substance use concerns.[76]

National Institute on Alcohol Abuse and Alcoholism		
Selected Measures of Performance	**FY 2018 Target**	**FY 2018 Achieved**
» Scientific Research Outcome-5.15: By 2025, 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.	Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native).	Researchers developed and evaluated the effects of combined individual- and community-level interventions to reduce underage drinking by Native American youth on rural California Indian reservations.
» 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.	Disseminate findings from studies evaluating the effectiveness of alcohol screening and brief intervention.	Investigators published research findings from an evaluation of NIAAA's Youth Guide, and NIAAA staff disseminated information about studies evaluating the effectiveness of alcohol screening and brief intervention.

[76] Acosta et al. (2017). Web-Delivered CBT Reduces Heavy Drinking in OEF-OIF Veterans in Primary Care with Symptomatic Substance Use and PTSD. *Behavior Therapy, 42(2), 262-276.*

Prevention – Scientific Research Outcome-5.15

The FY 2018 target was met. Researchers supported by NIAAA developed and evaluated the effects of combining individual- and community-level interventions to reduce underage drinking by American Indian youth living on rural California reservations.

In the individual-level intervention, eligible youth aged 13-20 years were assigned to receive either a culturally-tailored brief motivational interviewing intervention (a type of therapist-delivered counseling strategy for changing behavior) or an educational intervention that provided information about the consequences of drinking. Participation in either the motivational interviewing or educational intervention was associated with significant reductions in drinking and problem behaviors when assessed at a six-month follow up appointment.

The community-level intervention included a "recognition and reminder" program wherein shoppers aged 21 or older who posed as minors attempted to purchase alcoholic beverages from convenience stores on or near the reservations assigned to the intervention. Clerks who asked for identification were rewarded with gift cards and congratulatory letters; those who did not were reminded of the law regarding sales to minors. The community intervention also included outreach activities to raise awareness about the risks of underage drinking and to mobilize community support for the interventions.

To evaluate the impact of the overall intervention program, the researchers analyzed data from the California Healthy Kids Survey, specifically data that was collected from ninth- and eleventh-grade American Indian and non-American-Indian students who attended schools in the intervention area. This data was compared to survey data collected from American Indian students living outside the intervention area. Among current drinkers, researchers found significant reductions in the frequency of past-month alcohol use and heavy alcohol use (defined as drinking five or more drinks on an occasion within the past 30 days) in American Indian youth exposed to the combined interventions relative to the comparison groups.[77]

Treatment – Scientific Research Outcome-8.7

The FY 2018 target was met. NIAAA-supported investigators published the results of a study to evaluate NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*. The study, one of six NIAAA-funded studies to evaluate the *Guide* independently, validated the *Guide's* utility in appropriately identifying youth at risk for AUD in primary care clinics serving racially and ethnically diverse patients. In the study, the researchers performed alcohol screening of youth aged 12-18 years and used statistical analyses to determine the optimal drinking threshold (number of reported days of drinking in the past year) for identifying those with AUD. The thresholds found varied by age and grade in school and were consistent with the

[77] Moore RS, Gilder DA, Grube JW, Lee JP, Geisler JA, Friese B, Calac DJ, Finan LJ, Ehlers CL. Prevention of Underage Drinking on California Indian Reservations Using Individual- and Community-Level Approaches. Am J Public Health. 2018 Aug;108(8):1035-1041. Epub 2018 Jun 21.

risk thresholds presented in the *Guide*, with the exception of 18-year-olds for whom a lower drinking threshold was recommended.[78]

In FY 2018, NIAAA staff disseminated information about studies evaluating the effectiveness of alcohol screening and brief intervention to the public. For example, findings from youth alcohol screening and brief intervention studies were disseminated in presentations to the Community Anti-Drug Coalitions of America's National Leadership Forum and its Mid-Year Training Institute and to the Institute for Public Strategies.

[78] Parast L, Meredith LS, Stein BD, Shadel WG, D'Amico EJ. Identifying adolescents with alcohol use disorder: Optimal screening using the National Institute on Alcohol Abuse and Alcoholism screening guide. Psychol Addict Behav. 2018 Aug;32(5):508-516.