DEPARTMENT of HEALTH and HUMAN SERVICES

FISCAL YEAR 2018

NATIONAL INSTITUTES OF HEALTH - Volume I

Overview

Justification of Estimates for Appropriations Committees

As the Director of the National Institutes of Health (NIH), it is my responsibility to present the Congressional Justification of the NIH fiscal year (FY) 2018 budget. This request for a $26.920 billion total program level provides additional detail on the proposals in the President's Budget Blueprint, including dissolving the Fogarty International Center and consolidating the Agency for Healthcare Research and Quality within NIH as the National Institute for Research on Safety and Quality. It also reflects the recent passage of the first major authorization act for NIH in a decade, the 21st Century Cures Act, which contains numerous provisions intended to expedite research and development of new treatments and cures.

The Cures Act authorized $4.8 billion over a 10-year period for four priority Innovation Projects: the Precision Medicine Initiative's *All of Us*℠ Research Program ($1.5 billion), a national resource of clinical, environmental, lifestyle, and genetic data from one million or more participants who will contribute health information over many years; the *Beau Biden Cancer Moonshot*℠ ($1.8 billion), which aims to accelerate progress in cancer research and break down barriers by enhancing data access and facilitating collaborations, particularly with respect to cancer immunotherapy; the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative ($1.5 billion), which seeks to understand how individual cells and the neural circuits they form interact in time and space; and a new Regenerative Medicine project ($30 million) to support clinical research using adult stem cells, in coordination with the Food and Drug Administration. The FY 2018 budget request includes $496 million for these four projects from the NIH Innovation Account created in the Cures Act, an increase of $144 million over the initial funding in FY 2017.

The budget request also discusses some of the most exciting scientific research areas that NIH plans to support in FY 2018. NIH continues its strong commitment to fundamental science, including development of new methods and technologies, to lay the foundation for discoveries that eventually lead to new treatments or preventive measures. Research to help battle public health crises will be a priority, including efforts to fight the opioid epidemic and to develop effective vaccines against Zika virus infection using the $152 million emergency supplemental appropriation for Zika provided by Congress at the end of FY 2016. In addition, NIH continues to seek ways to strengthen the biomedical research workforce, especially new and early-stage investigators who represent the future but need support to achieve research independence.

Investments will be guided by our NIH-Wide Strategic Plan (Fiscal Years 2016-2020), which articulates the goals of the agency and its commitment to responsible stewardship of public funds. By capitalizing on groundbreaking advances in science and technology, and judiciously leveraging new research investments, biomedical science is poised to make substantial gains in diagnosing, treating, and preventing disease. I look forward to discussing the FY 2018 budget request and NIH's plans for the future.

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

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

OVERALL APPROPRIATIONS

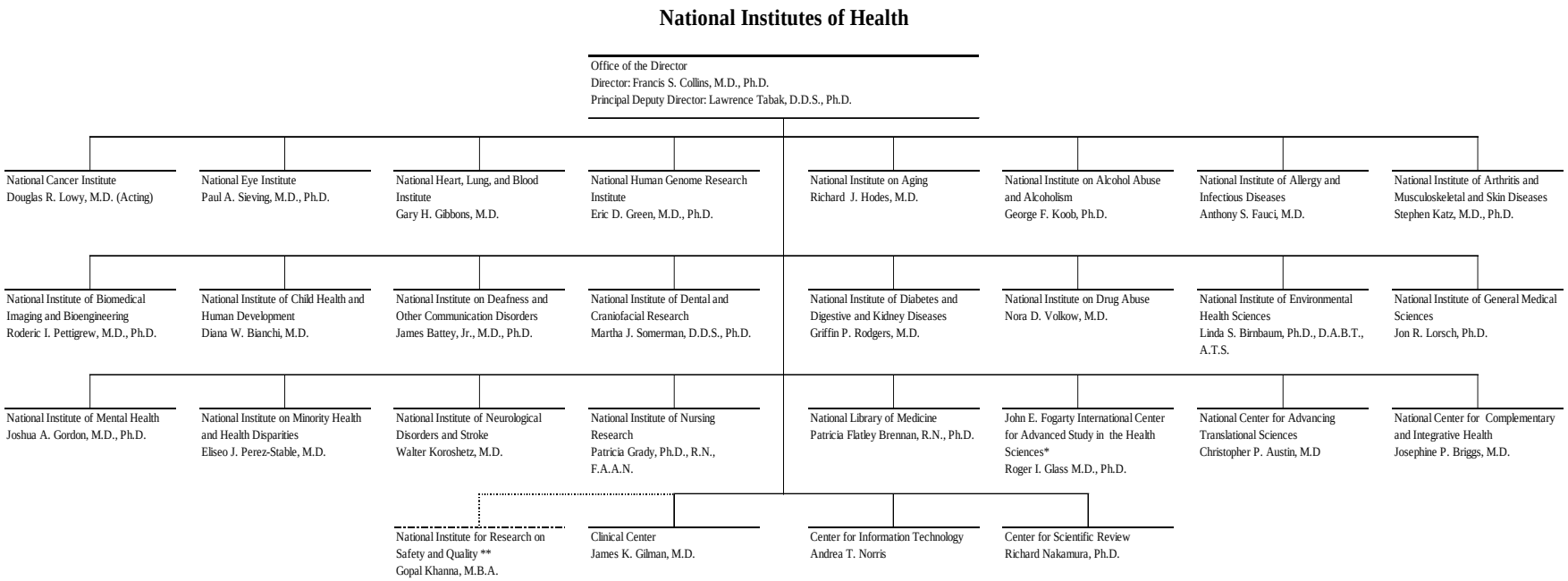
SUPPLEMENTARY TABLES

COMMON FUND

OFFICE OF AIDS RESEARCH

DRUG CONTROL PROGRAMS

ORGANIZATION CHART



* The FY 2018 Budget proposes to dissolve the Fogarty International Center.
** The FY 2018 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 or supports research designed to understand the basic biology of human health and disease; apply this understanding towards designing new approaches for preventing, diagnosing, and treating disease and disability; and ensure that these new approaches are available to all.

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

OVERVIEW OF BUDGET REQUEST

Introduction

For FY 2018, NIH requests a total program level of $26.9 billion, which is -$5.7 billion below the FY 2017 Continuing Resolution level. As announced in the President's Budget Blueprint, a major reorganization of NIH's Institutes and Centers is proposed. The FY 2018 Budget eliminates the Fogarty International Center, while retaining certain mission-critical international research and research-related activities. Approximately $25 million within the Office of the Director will be dedicated to coordinating global health research across the NIH, including issues regarding workforce development and engagement with NIH's international biomedical research partners. The FY 2018 Budget also consolidates the activities of the Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality (NIRSQ). The Budget includes $272 million in budget authority for NIRSQ, to preserve key activities to improve the quality and safety of American health care while reducing or eliminating lower priority programs that may potentially overlap with activities administered by other components of HHS. These continued activities include critical survey activities, evidence-based practice centers, research to enhance patient safety and health services, and researcher training grants. In addition, NIRSQ is projected to receive $107 million in mandatory resources from the Patient-Centered Outcomes Research Trust Fund to continue the targeted dissemination of study results and workforce development efforts in research designed to help patients and providers make better informed health care decisions. Other reorganization activities proposed for FY 2018 include moving the *All of Us* Research Program out of the Common Fund (but remaining in the Office of the Director), and moving the Science Education Partnership Award program from the Office of the Director to the National Institute of General Medical Sciences.

In FY 2017, Congress enacted the 21st Century Cures Act, authorizing $4.8 billion over ten years in support of high priority NIH initiatives and research areas: the Precision Medicine Initiative's *All of Us* Research Program, the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, the Beau Biden Cancer Moonshot, and Regenerative Medicine. Initial funding of $352 million was appropriated in the Further Continuing and Security Assistance Appropriations Act, 2017. The FY 2018 Budget includes the full $496 million authorized for these initiatives, requested in the new NIH Innovation Account managed by the Office of the Director. The funding for the Cancer Moonshot ($300 million) is to be transferred to the National Cancer Institute; the funding for the BRAIN Initiative is to be transferred to the National Institute of Neurological Disorders and Stroke ($43 million) and the National Institute of Mental Health ($43 million). The remaining funding is $100 million for the *All of Us* Research Program and $10 million for Regenerative Medicine.

Increasing efficiencies within the NIH remains a priority of the Administration. The FY 2018 Budget includes an indirect cost rate for NIH grants that will be capped at 10% of total cost (currently NIH expends approximately 28% of its extramural budget on indirect costs). This approach would be applied to all types of grants with a rate higher than 10 percent. Other entities, including private foundations and payers, spend a much higher portion of their grants on direct science. The current indirect rate setting process requires each grantee to provide hundreds of pages of documentation to negotiate their indirect rate with the government. The

reform approach will release grantees from the costly and time-consuming indirect rate setting process and reporting requirements. The approach will also seek to develop a uniform indirect cost rate to all grants that mitigates the risk for fraud and abuse by simplifying and uniformly applying the rate for grantees.

To continue in the pursuit of cutting-edge advances at the frontier of biomedical research, in FY 2018, NIH will focus on the following priority themes:

1. Fundamental Science Enhanced by Technological Advances
2. Treatments and Cures
3. Health Promotion and Disease Prevention
4. Enhancing Stewardship

By using these themes to guide strategic investments, NIH will continue to drive biomedical discovery and innovation in the United States, maintain the country's competitive edge as a global leader in research, bolster the U.S. economy, and ultimately make significant inroads in improving the health of the Nation.

Theme 1: Fundamental Science Enhanced by Technological Advances

Key to the achievement of its mission is NIH's investment in the essential building blocks of science, which can be applied across NIH's disease portfolio. This includes basic science (knowledge of the mechanisms of biology and behavior), data science, and the development of new technologies. NIH-funded basic science provides the foundation for translational and clinical studies that can lead to major medical advances, such as cancer-fighting drugs, vaccines, and medical devices, as illustrated by case studies of research impact.[1]

In March 2016, the NIH Director, along with several senior agency leaders, penned a letter in the leading biomedical journal *Science* to reaffirm NIH's deep commitment to basic science, stating "that many of the most important medical advances trace back to basic research that had no explicit disease link."[2] Because the private sector funds a limited amount of basic research, NIH's support of fundamental science is vital to the whole U.S. biomedical research enterprise. Basic research continues to represent more than half of NIH's research budget,[3] and provides a substantial return on investment. This investment drives progress along the entire research continuum, ultimately resulting in improved health.

The BRAIN Initiative

The Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative – which includes ten NIH Institutes and Centers (ICs), multiple Federal agencies, and several private partners – continues to support basic neuroscience research aimed at accelerating the development of innovative technologies for understanding the brain. New, cutting edge tools

[1] https://www.nih.gov/about-nih/what-we-do/impact-nih-research/our-stories.
[2] http://science.sciencemag.org/content/351/6280/1405.1.full.
[3] https://officeofbudget.od.nih.gov/pdfs/FY15/Basic%20and%20Applied%20FY%202002%20-%20FY%202015%20%28Transmit%29.pdf.

help scientists better understand not only how intricate networks of brain cells enable us to think, act, and perceive, but also how changes in these networks lead to neurological disease and impairment. A variety of high-impact research is supported by the BRAIN Initiative, including developing tools that can visualize and alter neural activity, creating a molecular census of the myriad cell types in the brain, understanding how and why brain cells connect to one another, and designing better electrodes that can therapeutically stimulate the human brain. FY 2018 funds will continue to support basic neuroscience research, human neuroscience research, scientific training, collaborative activities with other Federal agencies, and partnerships with industry to develop and test novel neurotechnologies, all with the aim of increasing our understanding of the brain and uncovering new ways to treat, cure, or prevent brain disorders.

Single Cell Analysis: Understanding Individual Cells Within a Group

Individual cells within a cluster of the same "type," such as neurons or nephrons, are not identical. In fact, they can differ dramatically and may change rapidly in response to stimuli in their environment. This has important consequences for the health and function of the entire organism. Understanding more about how single cells function could help researchers identify rare cells in a group (e.g., ones that could become cancerous), cells infected latently with a virus, or cells that develop drug resistance. NIH supports the development of game-changing technologies to analyze the dynamic states of single cells. Researchers supported by the NIH Common Fund's Single Cell Analysis Program (SCAP) used single cell analysis to reveal a huge diversity of neuronal subtypes within the human brain.[4] The SCAP Single Cell Analysis Challenge reached out to a diverse array of researchers to develop new tools and methods to measure single cell changes within a complex tissue environment in order to elucidate any functional changes that might affect the health status of the cell. Finalists from Phase 1 took their theoretical ideas into practical applications in the lab for Phase 2. The winners of Phase 2 will be announced in July 2017. Supporting single cell analysis has the potential to uncover fundamental biological principles and ultimately improve the detection and treatment of diseases.

Advances in Microscopy for Enhanced Drug Development

Advances in imaging techniques are providing a window to observe molecular interactions in extraordinary detail. For example, researchers at NIH's National Cancer Institute (NCI) are using cryo-electron microscopy (cryo-EM)—the 2015 scientific method of the year by *Nature Methods*—to view a key protein in cancer cells at a nearly atomic level.[5] Cryo-EM enables researchers to see molecules in a relatively natural state by flash-freezing a sample and bombarding it with electrons to produce images that can be captured with a special type of camera. Although there has been tremendous progress in this technology, it is still far from reaching its full potential, and NIH is supporting efforts to try to achieve that goal. For instance, one recent recipient of an NIH Director's Early Independence Award, a high-risk, high-reward funding mechanism, is developing new cryo-EM techniques to model the atomic structures of proteins much smaller than currently can be imaged. Cryo-EM advances should aid the

[4] Lake BB, et al. *Science* 2016;352(6293):1586-90. PMID:27339989. http://www.ncbi.nlm.nih.gov/pubmed/27339989

[5] Banerjee S, et al. *Science* 2016;351(6275):871-5. PMID: 26822609. http://www.ncbi.nlm.nih.gov/pubmed/26822609

development of more effective treatments, as determining accurate protein structures is key to designing more targeted and effective drugs.

Theme 2: Treatments and Cures

Thanks to fundamental research, we are in the midst of a paradigm shift in medicine – one that seeks to understand the roots of disease and impairment at their most elemental, molecular levels. NIH is investing in technologies that allow researchers and practitioners to screen rapidly for small but meaningful markers in a patient's molecular profile. One thing that is increasingly clear is that many seemingly disparate diseases have commonalities at the molecular level. Not only does this insight allow for new understanding of mechanisms that cause disease, but it also provides opportunities to repurpose existing drugs for use in other conditions. For example, as a result of a public-private partnership, an experimental drug originally developed to fight cancer is now being tested for Alzheimer's disease in human clinical trials. Scientists realized that the way the drug worked in cancer cells might also target a protein that plays a role in how brain cells are damaged in Alzheimer's disease.

Designing effective treatments and cures depends upon innovative, creative researchers translating fundamental knowledge about cells, systems, and organisms, into models for therapeutic development. Cell or tissue samples, animal models, and computer simulations often are used to design and test candidate approaches for diagnostics, devices, treatments, and cures. The most promising are then moved into human clinical trials, where they are tested for safety and efficacy. It is through this innovation pipeline that NIH aims to continue pushing the boundaries of what is possible in modern medicine.

Promising Advances for Sickle Cell Disease

Several NIH-supported researchers are applying a novel method, derived from basic science research, to develop possible treatment options for myriad diseases. The method, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), can alter DNA precisely to correct disease-causing mutations. One group of researchers is applying this method to "fix" the mutations that cause sickle cell disease (SCD). SCD affects as many as 100,000 people in the U.S., and about 1 of every 13 African Americans carries the sickle cell trait. In *in vitro* experiments, these scientists corrected the disease-causing mutation in cells that then went on to produce new red blood cells with healthy hemoglobin. Although the mutation was not fixed in all cells, the frequency was high enough that this result, in addition to studies in mice by the same researchers, indicates that this method could yield an effective treatment for this debilitating disease. While much more research is needed before this approach is ready for human clinical trials, NIH support for developing cutting-edge techniques that can be applied to find new treatments and cures in studies such as this could be a revolutionary approach for drastically improving human health.

Intervening in the Opioid Epidemic

The Nation is in the grips of a public health crisis due to an opioid epidemic. In 2015, a record number of Americans – more than 33,000 – died from overdosing on opioid drugs. These drugs

include prescription pain relievers as well as heroin and illicitly manufactured synthetic opioids such as fentanyl – an opioid that is 80 times more potent than morphine.[6] Addressing this crisis continues to be a high priority across the Department of Health and Human Services (HHS), and NIH is working closely with our partner federal agencies to address the complex problems of prescription opioid misuse and illicit opioid use. NIH supports research efforts focused on: preventing opioid misuse and addiction; developing new and improved treatments for opioid addiction; improving the deployment of evidence based strategies for combatting overdose and preventing and treating addiction; and developing more effective treatments for pain with reduced potential for addiction and misuse, as underscored by the HHS National Pain Strategy, released in March 2016.[7]

With FY 2018 funds, NIH intends to leverage recent scientific advances to combat opioid addiction and overdoses. For example, National Institute on Drug Abuse (NIDA)-supported research contributed to the development of Probuphine©, an implantable formulation of buprenorphine (an opioid used to treat opioid addiction) that delivers a constant dose for six months, which can improve treatment compliance and outcomes. NIDA and several other ICs also will continue their multi-pronged research and dissemination strategy, which may include development and deployment of new formulations of naloxone designed to combat fentanyl overdoses; large-scale epidemiological studies to understand evolving patterns of opioid misuse in hard-hit communities; testing of strategies to improve implementation of preventive interventions; clinical trials on new pharmacological and non-pharmacological interventions (e.g., vaccines and transcranial magnetic stimulation) for opioid addiction; development of alternative pain treatment strategies; and educational and outreach initiatives geared towards multiple audiences, including prescribing physicians and the public.

Combating Antimicrobial Resistance

Though antimicrobial drugs have been used successfully to treat infectious diseases for decades, at least 2 million people in the United States become infected with resistant bacteria annually, leading to 23,000 deaths each year. To address this growing problem, NIH supports the Antibacterial Resistance Leadership Group, which has established a robust program to: perform clinical studies to optimize currently licensed drugs; test diagnostics; and examine best practices in infection control programs and stewardship. NIH also participates in a national, multi-agency effort focused on advancing antimicrobial resistance research, as outlined in the National Action Plan for Combating Antibiotic-Resistant Bacteria.[8] In one effort, NIH is co-sponsoring a monetary prize competition with the HHS Biodefense Advanced Research and Development Authority (BARDA).[9] This prize competition is geared towards developing rapid, point-of-care diagnostics that may be used by healthcare providers to identify bacterial infections, improve treatment of drug-resistant infections, and facilitate antibiotic prescribing and monitoring.[10] NIH

[6] http://www.cdc.gov/media/releases/2015/p1218-drug-overdose.html
[7] https://iprcc.nih.gov/docs/HHSNational_Pain_Strategy.pdf
[8] https://obamawhitehouse.archives.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf
[9] https://www.challenge.gov/challenge/antimicrobial-resistance-rapid-point-of-care-diagnostic-letter-of-intent/
[10] https://www.nih.gov/news-events/news-releases/antimicrobial-resistance-diagnostic-challenge-selects-10-semifinalists-first-phase-competition

sought public input to help identify the desired characteristics for the diagnostics.[11,12] To support other innovative research, including new classes of antibiotics and non-traditional therapeutic options, NIH's National Institute of Allergy and Infectious Diseases (NIAID) is collaborating with BARDA and others on the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a new global public-private partnership to advance high-quality antibacterial products into human testing. NIAID will provide in-kind preclinical research support and technical expertise to CARB-X awardees.

Cancer Immunotherapy

The immune system's natural capacity to detect and destroy abnormal cells may be able to prevent the development of many cancers, but this ability often is compromised by cancer cells that avoid detection and destruction by the immune system. However, researchers have developed a powerful new technique to harness a patient's own immune system to attack the cancer cells. This technique, commonly referred to as immunotherapy, is showing great promise. Patients with a variety of cancers, including melanoma, non-small cell lung, chronic lymphocytic leukemia, acute lympoblastic leukemia, colorectal, and breast cancers, already have benefitted from immunotherapy. This rapidly advancing field, based on basic research on the immune system, has produced several new methods of treating cancer. For example, NIH researchers recently created a way to target the cancer-causing protein produced by a mutant form of the gene that causes most pancreatic and many colorectal cancers. This targeted immunotherapy led to cancer regression in the single patient tested in a proof-of-principle study.[13] Additional research is needed to validate this promising method and evaluate its effectiveness in other patients. Another NIH-funded study identified a cell surface receptor that is present on breast, colon, and lung cancer cells. Treatment with an antibody directed to this receptor prevented metastasis in a mouse model of lung cancer, suggesting that this may be a promising treatment for human cancer.[14]

Collectively, the early successes of cancer immunotherapy led the Blue Ribbon Panel (BRP) that is providing scientific direction for the Cancer Moonshot[SM] to recommend creating a translational science network devoted exclusively to immunotherapy. The goal of this network is to develop and implement a national strategy to discover new immune targets and to evaluate new immune-based approaches.[15] In addition to considering the BRP recommendation, ongoing and future NIH-supported research aims to understand what enables immunotherapy to work in some patients, but not in others, as well as to expand the use of immunotherapy to other types of cancer. Studies also will test cancer immunotherapies earlier in disease progression as well as in combination with other standard cancer treatments.

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[11] https://www.federalregister.gov/articles/2015/09/09/2015-22690/announcement-of-public-consultation-on-antimicrobial-resistance-rapid-point-of-care-diagnostic-test
[12] https://dpcpsi.nih.gov/news/AMRpublicforum
[13] Tran E, et al. *N Engl J Med.* 2016; 375(23):2255-2262. https://www.ncbi.nlm.nih.gov/pubmed/27959684
[14] Metelli A, et al. *Cancer Research*. 2016; 76(24):7106-7117. https://www.ncbi.nlm.nih.gov/pubmed/27913437
[15] https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/blue-ribbon-panel-report-summary.pdf

Theme 3: Health Promotion and Disease Prevention

NIH supports research to promote health, prevent disease, and develop strategies to address the progression of disease before symptoms appear. Advances in these research areas require a deep understanding of the many factors that affect health, and include identification and assessment of genetic and environmental risk factors, screening of at-risk individuals for diseases, development of risk reduction strategies, as well as translation, dissemination, and implementation of strategies to prevent conditions. NIH regularly collaborates with other Departmental agencies to support health promotion and disease prevention activities. A notable example is the coordination between NIH and the Centers for Disease Control and Prevention (CDC) on Ebola virus disease surveillance and clinical trials of candidate Ebola vaccines in West Africa.[16]

All of Us Research Program

Precision medicine aims to develop tools that accurately will tailor medical treatment to an individual patient, a revolutionary approach to disease treatment and understanding of human health. Toward this goal, NIH is establishing a group of one million or more volunteer participants that reflect the diversity of the United States to contribute health information over many years, known collectively as the *All of Us*[SM] Research Program. This cohort will leverage advances in lab technologies, including genomics, computing and data analytics, and adoption of electronic health records, as well as capitalize on mobile health technology that uses smart phones to track health and fitness. In FY 2016, NIH announced awards totaling $55 million to build important partnerships and infrastructure for the *All of Us* program, including a Data and Research Support Center, a Participant Technologies Center, and a network of participating healthcare provider organizations, which includes Federally Qualified Health Centers. The valuable data from this study will help uncover new information about the relationships between a person's environment, genes, and lifestyle. This information can be used to find new strategies for preventing illness as well as effective treatments that account for individual variability, with the eventual goal to improve health and reduce health disparities.

Preventing Public Health Threats Through Vaccine Research

Vaccines represent the safest, most cost-effective, and efficient way to reduce the burden of infectious diseases by preventing them altogether. Creating a safe and effective vaccine often requires understanding how a particular virus or bacteria infects the human body, as well as the various molecules that the immune system might use to target it, requiring a multi-pronged research approach. NIH engages in vaccine research to prevent many diseases, including both emerging threats and recurring maladies.

NIH is at the forefront of efforts to design and test a vaccine to protect against Zika virus infection. The public health threat related to this virus heightened in 2015 and continues to grow. Although the Zika virus is transmitted to humans primarily through mosquitoes, it also can be passed from one person to another through sexual contact, blood transfusion, or from mother to child. The illness caused by this virus is generally mild in adults, but Zika virus

[16] http://www.niaid.nih.gov/topics/ebolamarburg/research/pages/default.aspx

infection can sometimes cause serious birth defects if a mother is infected during pregnancy. NIH's research priorities to combat Zika virus infection include efforts to understand the virus and disease as well as to develop diagnostics, treatments, and vaccines. Several vaccine candidates currently are being developed using different approaches,[17] and NIH's National Institute of Allergy and Infectious Diseases (NIAID) launched the first clinical trial to test the safety and efficacy of one vaccine candidate in August 2016. Early results indicate that the vaccine is safe and that it induces an antibody response against Zika virus. With these promising indicators, a Phase 2/2b clinical trial of the vaccine began in March 2017 to obtain additional safety and immune response data in humans as well as to gauge whether the vaccine protects against disease caused by natural Zika infection.[18]

NIH also is engaged in efforts to develop a "universal" influenza vaccine to protect against the seasonal infection that can sometimes lead to serious health complications. While a new influenza vaccine is released every year, this vaccine currently is created by selecting the most likely strains of virus for a given year months in advance of the flu season, which can result in a less effective vaccine if the predominant strain is not included. In addition, many molecular components of the flu virus mutate rapidly, and so the molecules used to create a vaccine one year may not be effective in future years. Thus, NIH-supported research seeks to develop a "universal" influenza vaccine that induces a potent, durable immune response to conserved elements of the influenza virus that undergo few changes from season to season and strain to strain. Several NIH-funded researchers have made progress towards this goal by targeting a particular protein on the surface of the virus, several versions of which are being evaluated for further clinical study. In addition, Phase 1/2 clinical trials already are underway for an alternative approach involving a DNA-based vaccine and a seasonal booster.

Theme 4: Enhancing Stewardship

As stewards of Federal investments in biomedical research, it is essential that NIH earns and maintains the public's trust. The role of the United States as a leader in biomedical research depends not only on innovation in the laboratory and the clinic, but also innovation in how science is funded, performed, managed, and regulated. NIH is committed to being an efficient and effective steward of taxpayer funds and to encouraging good stewardship practices across all levels of the biomedical research enterprise. NIH strives to allocate its resources with sufficient transparency to allow taxpayers to see how their money is invested. For example, starting in 2017, NIH IC will make information about each IC's funding decisions for each fiscal year more publically available. In coordination with other scientific agencies, NIH continually looks to streamline administrative processes that can take investigators' time away from their research, and is engaged in efforts to make sure that the research conducted with NIH funds is of the highest quality. Most importantly, NIH invests in the long-term health of the Nation by strengthening and sustaining a diverse, world-class research workforce. These efforts ensure that NIH not only funds the best science, but also effectively manages both the present and future of the nation's biomedical research enterprise.

Increasing the Rigor and Reproducibility of NIH Research

[17] https://www.niaid.nih.gov/diseases-conditions/zika-vaccines
[18] https://www.nih.gov/news-events/news-releases/phase-2-zika-vaccine-trial-begins-us-central-south-america

One of the key ways in which NIH is enhancing stewardship is through the promotion of rigorous, unbiased biomedical research. To continue to support this goal, NIH recently released and implemented a policy to enhance reproducibility through increased scientific rigor and transparency in reporting.[19] In addition to the new policy, NIH released principles and guidelines for reporting preclinical research and created training materials for graduate students and fellows. Planned future activities include extending the previously established Rigor and Reproducibility Policy to institutional training grants and fellowships, collaborating with scientific journal editors to improve rigor and reproducibility in publications, and working to improve data sharing and accessibility. NIH also has engaged the Advisory Committee to the Director of NIH to make recommendations, informed by existing activities, to enhance rigor and reproducibility of scientific research funded by NIH. These approaches are designed to strengthen a culture that encourages best practices for rigorous scientific research and reporting.

Supporting New Investigators

Excellence in biomedical research depends upon cultivating a world-class biomedical research workforce – one that is diverse, creative, innovative, and productive. NIH works to make sure that the next generation of scientists thrives, including those from underrepresented groups. To ensure fairness in the funding process, NIH has created procedures to normalize success rates between early and more experienced investigators. In addition, a number of funding opportunities directly target new and early stage investigators, including programs that allow exceptional individuals to skip the traditional postdoctoral training period or that provide support to bridge the gap from early to mid-career stages. Another of these high risk, high reward programs is the NIH Director's New Innovator Award, which supports remarkably creative new investigators with groundbreaking, novel research ideas at an early stage of their career. With an emphasis on innovation and originality, preliminary data are not needed for this award. Following these models, several ICs also have specialized award programs to support investigators during early career stages. In addition to supporting specific grant policies and awards, programs like the Early Career Review Program provide young investigators with an invaluable opportunity to participate in NIH's peer review process and to understand better how to generate a successful grant application. In FY 2018, NIH will use the Next Generation Researchers Initiative, established by the 21st Century Cures Act, to further address how best to support new investigators. This initiative aims to coordinate policies and programs at NIH that provide opportunities for new researchers and could lead to earlier research independence.

Conclusion

NIH funds rigorous science that expands our understanding of living systems and drives improvements in health. The programs, activities, and investments described here illustrate NIH's strategic vision for biomedical research, one that capitalizes on new opportunities for scientific exploration and addresses major challenges for human health. This process was exemplified in FY 2016 when NIH released a centralized NIH-Wide Strategic Plan. While each of NIH's component Institutes, Centers, and Offices routinely publishes strategic plans that align with their congressionally mandated missions, the NIH-Wide Strategic Plan coalesces the goals

[19] https://grants.nih.gov/reproducibility/index.htm

of the agency and harmonizes decision-making across the agency. The Plan emphasizes NIH's commitment to advancing opportunities in the full range of biomedical research, while ensuring that it makes smart, well-managed investments as stewards of taxpayer funds. From setting careful priorities, to cultivating the research workforce of the future, to developing and applying the tools NIH needs to understand the content and results of its research portfolio, NIH strives to capitalize on the most promising opportunities and combat the most pressing challenges facing society today.

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 2018 budget request reflects the Agency's longstanding commitment to invest strategically using performance-based analysis, as emphasized in 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. The measures also support the Administration's goal of protecting and improving the health and well-being of the American people.

Performance Management

Performance management at NIH is an integrated and collaborative process to ensure that the Agency is achieving its mission to conduct and support research to improve public health. At the Agency level, the NIH Director sets priorities, monitors performance, and reviews results across the 27 ICs and OD. OD is the central office responsible for setting policy for NIH, and for planning, managing, and coordinating the programs and activities of all NIH components. The NIH Director provides leadership to the ICs and helps identify needs and opportunities, especially for efforts that involve multiple ICs. Each IC and OD office carries out priority setting, performance monitoring, progress reviews, and makes adjustments based on progress achieved in their respective areas of science. In addition to the performance management processes that occur for the NIH research program, there are equivalent processes for administrative management functions.

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

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

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

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

The NIH approach to performance management is undergirded by the NIH Governance Structure. That structure includes the NIH Steering Committee and seven standing Working Groups.[20, 21] 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.

[20] 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.
[21] The seven standing working groups are: Extramural Activities, Diversity, Facilities, Management and Budget, Scientific Data Council, Administrative Data Council, and Clinical Center Governing Board.

ALL PURPOSE TABLE

All Purpose Table[1]
(Dollars in Thousands)

(Dollars in Thousands)[1]	FY 2016 Final	FY 2017 Annualized CR[2]	FY 2018 President's Budget[2,3]	FY 2018 President's Budget +/- FY 2017 Annualized CR
Total, NIH Program Level	**$32,311,349**	**$32,593,341**	**$26,919,710**	**-$5,673,631**
Less mandatory and funds allocated from different sources:				
Mandatory Type 1 Diabetes Research	150,000	139,650	150,000	10,350
PHS Program Evaluation	780,000	780,000	780,000	0
Patient-Centered Outcomes Research Trust Fund	NA	NA	106,546	NA
Total, NIH Discretionary Budget Authority	**$31,381,349**	**$31,673,691**	**$25,883,164**	**-$5,790,527**
Interior Budget Authority	77,349	77,202	59,607	-17,595
Total, NIH Labor/HHS Budget Authority	**$31,304,000**	**$31,596,489**	**$25,823,557**	**-$5,772,932**
Number of Competing RPGs	*10,364*	*8,974*	*7,326*	*-1,648*
Total Number of RPGs	*35,580*	*35,349*	*33,403*	*-1,946*
FTEs	*17,723*	*18,105*	*18,365*	*260*

[1] Excludes Ebola-related and Zika-related supplemental appropriations.

[2] Includes 21st Century Cures Act funding.

[3] Includes funding and FTE for the National Institute for Research on Safety and Quality; does not include funding for the Fogarty International Center

IMPACT OF BUDGET LEVEL ON PERFORMANCE

Programs and Measures (Dollars in Millions, except where noted)	**FY 2017 Annualized CR**	**FY 2018 President's Budget**	**FY 2018 +/- FY 2017**
Research Project Grants	$17,927.331	$14,188.712	-20.9%
Competing Average Cost (in thousands)	$484.800	$389.436	-19.7%
Number of Competing Awards (whole number)	8,974	7,326	-18.4%
Estimated Competing RPG Success Rate (absolute rate)	17.1%	13.7%	-19.9%
Research Centers	$2,496.279	$2,079.715	-16.7%
Other Research	$2,151.400	$1,731.883	-19.5%
Training	$843.291	$737.508	-12.5%
Research & Development Contracts	$2,911.704	$2,489.201	-14.5%
Intramural Research	$3,672.888	$3,064.128	-16.6%
Research Management and Support	$1,718.144	$1,576.596	-8.2%
Common Fund (non-add)	$674.355	$454.423	*-32.6%*
Buildings & Facilities Appropriation	$128.618	$98.615	-23.3%
Other Mechanisms[1]	$743.687	$953.352	28.2%
Total, Program Level[2]	**$32,593.342**	**$26,919.710**	**-17.4%**

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

[2] Includes discretionary budget authority received from Labor/HHS appropriations (ICs) and the Interior appropriation (Superfund). Also includes mandatory budget authority derived from the Special Type 1 Diabetes account and Patient-Centered Outcomes Research Trust Fund (PCORTF), and Program Evaluation Financing.

BUDGET BY HHS STRATEGIC OBJECTIVE

National Institutes of Health
FY 2018 Budget by HHS Strategic Objective
(Dollars in Millions)

(Dollars in Millions)	FY 2017 Annualized CR
1.Strengthen Health Care	
1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured	
1.B Improve health care quality and patient safety	
1.C Emphasize primary and preventive care, linked with community prevention services	
1.D Reduce the growth of health care costs while promoting high-value, effective care	
1.E Ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations	
1.F Improve health care and population health through meaningful use of health information technology	
2. Advance Scientific Knowledge and Innovation	**32,448**
2.A Accelerate the process of scientific discovery to improve health	32,448
2.B Foster and apply innovative solutions to health, public health, and human services challenges	
2.C Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation	
2.D Increase our understanding of what works in public health and human services practice	
2.E Improve laboratory, surveillance, and epidemiology capacity	
3. Advance the Health, Safety and Well-Being of the American	
3.A Promote the safety, well-being, resilience, and healthy development of children and youth	
3.B Promote economic and social well-being for individuals, families, and communities	
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults	
3.D Promote prevention and wellness across the life span	
3.E Reduce the occurrence of infectious diseases	
3.F Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies	
4. Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs	**145**
4.A Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance, and risk management	
4.B Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people	
4.C Invest in the HHS workforce to help meet America's health and human services needs	
4.D Improve HHS environmental, energy, and economic performance to promote sustainability	145
TOTAL	**32,593**

BUDGET MECHANISM TABLE

(Dollars in Thousands)	FY 2016 Final[1,3]		FY 2017 Annualized CR[1,3,4]		FY 2018 President's Budget[1,4,10]	
	No.	Amount	No.	Amount	No.	Amount
Research Projects:						
Noncompeting	23,528	$11,726,633	24,595	$12,535,005	24,499	$10,531,990
Administrative Supplements	*(1,832)*	281,273	*(1,456)*	173,272	*(955)*	100,722
Competing:						
Renewal	1,641	925,443	1,400	755,198	1,108	439,836
New	8,689	4,071,994	7,558	3,589,996	6,204	2,409,846
Supplements	34	21,342	16	5,403	14	3,322
Subtotal, Competing	10,364	$5,018,779	8,974	$4,350,597	7,326	$2,853,005
Subtotal, RPGs	33,892	$17,026,685	33,569	$17,058,875	31,825	$13,485,717
SBIR/STTR	1,689	810,307	1,780	868,456	1,578	702,996
Research Project Grants	35,580	$17,836,992	35,349	$17,927,331	33,403	$14,188,712
Research Centers:						
Specialized/Comprehensive	1,053	$1,812,218	1,044	$1,769,290	1,011	$1,524,921
Clinical Research	67	406,678	67	377,967	67	282,432
Biotechnology	98	179,563	96	173,920	87	132,574
Comparative Medicine	47	120,096	48	118,451	51	100,132
Research Centers in Minority Institutions	23	56,759	27	56,651	18	39,656
Research Centers	1,288	$2,575,314	1,282	$2,496,279	1,234	$2,079,715
Other Research:						
Research Careers	3,618	$642,441	3,626	$666,150	3,554	$591,562
Cancer Education	74	23,261	76	23,261	74	20,901
Cooperative Clinical Research	345	404,684	327	397,967	298	343,564
Biomedical Research Support	107	67,235	109	69,949	112	55,907
Minority Biomedical Research Support	272	105,494	271	104,885	265	93,799
Other	1,855	776,404	2,000	889,189	1,492	626,150
Other Research	6,271	$2,019,519	6,409	$2,151,400	5,795	$1,731,883
Total Research Grants	43,139	$22,431,826	43,040	$22,575,010	40,432	$18,000,310
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs	
Individual Awards	3,282	$148,181	3,445	$160,074	3,076	$136,690
Institutional Awards	12,446	656,284	12,474	683,217	11,203	600,818
Total Research Training	15,728	$804,466	15,919	$843,291	14,279	$737,508
Research & Develop. Contracts	2,716	$2,915,277	2,509	$2,911,704	1,965	$2,489,201
(SBIR/STTR) (non-add)[2]	*(114)*	*(66,841)*	*(118)*	*(71,943)*	*(76)*	*(61,829)*
Intramural Research	6,884	$3,684,875	6,986	$3,672,888	7,009	$3,064,128
Res. Management & Support	5,410	1,653,326	5,762	1,718,144	5,947	1,576,596
Res. Management & Support (SBIR Admin) (non-add)[2]		*(3,427)*		*(6,187)*		*(26,285)*
Office of the Director - Appropriation[2,5]		*(1,570,790)*		*(1,620,212)*		*(1,452,433)*
Office of the Director - Other		599,368		650,485		777,199
ORIP (non-add)[2,5]		*(295,784)*		*(295,373)*		*(220,811)*
Common Fund (non-add)[2,5]		*(675,639)*		*(674,355)*		*(454,423)*
Buildings and Facilities[6]		144,863		144,618		108,615
Appropriation		*(128,863)*		*(128,618)*		*(98,615)*
Type 1 Diabetes[7]		-150,000		-139,650		-150,000
Program Evaluation Financing[8]		-780,000		-780,000		-780,000
Subtotal, Labor/HHS Budget Authority		**$31,304,000**		**$31,596,489**		**$25,823,557**
Interior Appropriation for Superfund Research		77,349		77,202		59,607
Total, NIH Discretionary B.A.		**$31,381,349**		**$31,673,691**		**$25,883,164**
Type 1 Diabetes and PCORTF[9]		150,000		139,650		256,546
Total, NIH Budget Authority		**$31,531,349**		**$31,813,341**		**$26,139,710**
Program Evaluation Financing		780,000		780,000		780,000
Total, Program Level		**$32,311,349**		**$32,593,341**		**$26,919,710**

1 All Subtotal and Total numbers may not add due to rounding.
2 All numbers in italics and brackets are non-add.
3 Excludes Ebola-related and Zika-related supplemental appropriations.
4 Includes 21st Century Cures Act funding.
5 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as a non-add. The Office of the Director - Appropriations also is noted as a non-add because the remaining funds are accounted for under OD - Other.
6 Includes B&F appropriation and funds for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
7 Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/ HHS Budget Authority.
8 Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.
9 Patient-Centered Outcomes Research Trust Fund included in FY 2018.
10 Includes funding for the National Institute for Research on Safety and Quality; does not include funding for the Fogarty International Center.

APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, $4,174,222,000 of which up to $10,000,000 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, $2,534,803,000.

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, $320,749,000.

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, $1,449,534,000.

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, $1,312,998,000.

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, $3,782,670,000.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, $2,185,509,000 of which $780,000,000 shall be from funds available under section 241 of the PHS Act.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, $1,032,029,000 .

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, $549,847,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, $533,537,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For necessary expenses for the National Institute of Environmental Health Sciences in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9660(a)) and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, $59,607,000.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, *$1,303,541,000*.

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, $417,898,000.

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, $325,846,000.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, $113,688,000.

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, $361,356,000.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, $864,998,000.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, $1,201,901,000.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, $399,622,000.

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, $282,614,000.

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, $101,793,000.

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, $214,723,000.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, $373,258,000: Provided, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, 2019: Provided further, That in fiscal year 2018, 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, $557,373,000: Provided, That up to $24,496,593 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network.

BUILDINGS AND FACILITIES

For the study of, construction or demolition of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, $98,615,000, to remain available through September 30, 2022.

OFFICE OF THE DIRECTOR

For carrying out the responsibilities of the Office of the Director, NIH, $1,329,833,000: 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 $441,823,000 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 $4,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act:

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, $12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code, for the

purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act.

NIH INNOVATION ACCOUNT

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the National Institutes of Health in this Act, $496,000,000, to remain available until expended: Provided, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act and are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act: Provided further, That of the amount appropriated under this heading, $300,000,000 shall be transferred to the "National Cancer Institute" for the purposes described in section 1001(b)(4)(C) of such Act, $43,000,000 shall be transferred to the "National Institute of Neurological Disorders and Stroke" for the purposes described in section 1001(b)(4)(B) of such Act, and $43,000,000 shall be transferred to the "National Institute of Mental Health" for the purposes described in section 1001(b)(4)(B) of such Act: Provided further, That remaining amounts may be transferred by the Director of the National Institutes of Health to any accounts of the National Institutes of Health: Provided further, That upon a determination by the Director that funds transferred pursuant to any of the previous provisos are not necessary for the purposes provided, such amounts may be transferred back to this account: Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

NATIONAL INSTITUTE FOR RESEARCH ON SAFETY AND QUALITY

For carrying out titles III and IX of the PHS Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, $272,000,000: Provided, That section 947(c) of the PHS Act shall not apply in fiscal year 2018: 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.

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AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2017 Annualized CR	FY 2018 Amount Authorized	FY 2018[1] President's Budget
National Institutes of Health:			
Section 301 and Title IV of the PHS Act	$32,241,343		
Section 1001 (b)(3)(A) of the 21st Century Cures Act	$352,000	$496,000	$496,000
Section 402A(a)(1)(D) of the PHS Act		$34,851,000	$26,423,710
Public Law 114-10, Medicare Access and CHIP Reauthorization Act of 2015.	$139,650		$150,000
Section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and Section 126(g) of the Superfund Amendments and Reauthorization Act of 1986	$77,202	$59,607	$59,607

[1]See NIRSQ chapter for Authorizing Legislation on NIRSQ.

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APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2009	$29,457,070,000	$30,607,598,000	$30,404,524,000 [2]	$30,545,098,000
FY 2009 ARRA				$10,400,000,000
FY 2010	$30,988,000,000	$31,488,000,000	$30,988,000,000	$30,934,413,000 [3]
FY 2011	$32,136,209,000		$31,989,000,000	$30,935,000,000 [4]
FY 2012	$31,979,000,000		$30,630,423,000	$30,852,187,000 [5]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [6]
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 [7]
FY 2016	$31,311,349,000 [8]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [9]
FY 2017 CR	$33,136,349,000 [10]	$33,463,438,000	$34,311,349,000	$32,593,341,000
FY 2018 PB	$26,919,710,000 [11]			

[1] Does not include comparability adjustments. Superfund and Type 1 Diabetes are included except where indicated.

[2] Excludes funding for Superfund Research activities for which the Appropriations Committee did not mark up a figure.

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

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

[5] 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.

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

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

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

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

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

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

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APPROPRIATIONS NOT AUTHORIZED BY LAW

Program	Last Year of Authorization	Authorization Level in Last Year of Authorization	Appropriations in Last Year of Authorization	Appropriations in FY 2017
Research on Health Costs, Quality, and Outcomes……..	FY 2005	$250,000,000	$260,695,000	$272,000,000

NARRATIVE BY ACTIVITY TABLE/ HEADER TABLE

(Dollars in Thousands)	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 President's Budget +/- FY 2017 Annualized CR
Program Level[1,2]	$32,311,349	$32,593,341	$26,919,710	-$5,673,631
FTE[3]	17,723	18,105	18,365	260

[1] Excludes Ebola-related and Zika-related supplemental appropriations.

[2] Includes Mandatory Type 1 Diabetes and Superfund in FY 2016, FY 2017, and FY 2018 and NIGMS Program Evaluation funding of $780 million in FY 2016, FY 2017, and FY 2018 and the Patient-Centered Outcomes Research Trust Fund in FY 2018 ($107 million).

[3] FTE in FY 2018 include staff consolidated from AHRQ.

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

Allocation Methods: Competitive Grants; Contract; Intramural; Other

PROGRAM DESCRIPTIONS AND ACCOMPLISHMENTS

Long-Range NIH Research Contributions to Improvements in Health Care and Public Health: Selected Examples

NIH has supported biomedical research to enhance health, lengthen life, and reduce illness and disability for more than 100 years. Between 1970 and 2013, the life expectancy of the average American increased by eight years.[22] Older Americans are not just living longer; they are staying healthy and active longer. Rates of reported risk factors for chronic disease (uncontrolled cholesterol or high blood pressure, smoking, etc.) have dropped by more than ten percent since 1999. At age 65, Americans today can expect to live 19.3 more years, nearly 40 percent longer than in 1950,[23] and the vast majority of adults continue to live without any activity limitations, a major improvement in just the past 30 years.[24] The largest growing demographic group in the United States consists of individuals living beyond the age of 85. We can attribute these remarkable improvements, in part, to NIH research. NIH-funded projects have made many contributions that have advanced health care and enhanced public health. The following are some selected examples.

Heart Disease

At the outset of the 20th Century, the three leading causes of death in the United States were pneumonia, tuberculosis, and infectious diarrhea, but by 1950, heart disease had surpassed all other maladies to become the leading cause of death. Through research advances supported in large part by NIH, deaths from heart disease and stroke decreased by approximately 78 percent between 1968 and 2013.[25] The Framingham Heart Study introduced the concept of risk factors, identifying factors that lead to heart disease, such as smoking, high blood pressure, and high cholesterol, and generating research findings that have led to more than 3,200 publications. This research, along with NIH-supported clinical trials, has spurred the development of effective pharmacological and behavioral interventions and prevention strategies, including safe and effective surgical and catheter-based procedures to open clogged coronary arteries. Current NIH research focuses on elucidating new biological pathways, new treatment and prevention models, dissecting genetic vs. environmental contributions, developing and understanding the value of new diagnostic and imaging tests, resolving the contributing role of social networks to disease, and enhancing device technologies for treatment.

Diabetes

In the recent past, adults diagnosed with diabetes during middle age lived on average 10 years less than adults without diabetes. Thanks to the development of early screening methods and treatments that enable better control of diabetes-related complications, adults with diabetes are now living longer and healthier lives. Between 1969 and 2013, the death rate among adults with

[22] http://www.cdc.gov/nchs/data/hus/hus14.pdf
[23] http://www.cdc.gov/nchs/data/hus/hus14.pdf
[24] Calculated from http://www.cdc.gov/nchs/data/hus/hus10.pdf and http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_06.pdf
[25] http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

diabetes declined by 16.5 percent,[26] and from 1990 to 2010 the rates of major diabetes complications dropped dramatically, particularly for heart attacks related to diabetes, which declined by 68 percent, and stroke related to diabetes, which declined by 53 percent.[27] These remarkable improvements are due largely to clinical trials supported by NIH. In addition, basic science research, including a recent international "big data" study that NIH helped support,[28] has unveiled genes that may be involved in the development and progression of diabetes. NIH research also is generating important insights into the prevention and management of diabetes, highlighting the importance of family support. Studies funded through the Diabetes Prevention Program also have shown that lifestyle changes, such as diet and physical activity, can lower the risk of developing type 2 diabetes by 58 percent in adults at high risk for the disease. For individuals with type 1 diabetes, islet cell transplantation trials and progress toward the development of a fully reliable artificial pancreas provide hope for an end to the daily routine of finger sticks and insulin injections.

Stroke

Fewer people are dying of stroke today—the age-adjusted stroke mortality rate has decreased by 78 percent since 1950,[29] due to treatment and prevention strategies based on NIH-funded research. In 1995, an NIH-funded clinical trial established the first and only FDA-approved treatment for acute ischemic stroke. The drug tissue plasminogen activator (tPA) reduces the risk of disability and maximizes the potential for patient recovery. A recent analysis estimated that tPA can provide considerable cost savings—nearly $74 million annually for the first post-stroke year alone—if used in just 20 percent of all ischemic stroke patients in the United States. However, tPA must be administered quickly after the onset of symptoms. Current estimates suggest that fewer than ten percent of stroke patients are treated with the drug. Recent NIH-funded research has led to the revision of tPA administration guidelines to extend the timing from three hours to four and a half hours in some cases.[30,31] NIH researchers are currently working to improve public awareness of stroke and to educate high risk populations on the importance of seeking immediate medical attention in order to increase the number of those receiving this life-saving and disability-reducing treatment.

Lung Cancer

Lung cancer is the second most common cancer and is the primary cause of cancer-related death in both men and women in the United States. However, both incidence rates and mortality rates continue to decline for men and women. NIH-funded research has contributed to the decrease in

[26] Ma J, et al. *JAMA* 2015; 314(16):1731-1739. PMID: 26505597
http://jama.jamanetwork.com/article.aspx?articleid=2466136&linkid=18099832
[27] Gregg EW, et al. *N Engl J Med* 2014; 370(16):1514-23. PMID: 24738668
http://www.ncbi.nlm.nih.gov/pubmed/24738668
[28] Fuchsberger C, et al. *Nature* 2016; epub ahead of print. PMID: 27398621
http://www.nature.com/nature/journal/vaop/ncurrent/full/nature18642.html
[29] http://www.cdc.gov/nchs/fastats/stroke.htm
[30] Jauch EC, et al. *Stroke* 2013; 44(3):870-947 PMID: 23370205
http://www.ncbi.nlm.nih.gov/pubmed/23370205
[31] http://www.medpagetoday.com/Cardiology/Strokes/41156

mortality, lowering the death rate by 20 percent from 1990 to 2010.[32] The recent development of targeted therapies, such as erlotinib and crizotinib, has led to dramatic responses in individuals whose lung cancers harbor particular genetic mutations. Advances in genetic screening techniques have helped NIH-funded researchers identify genes that may influence the risk for lung cancer development and genetic errors that cause lung cancer, and new precision medicine clinical trials are targeting some types of this disease.

HIV/AIDS

HIV, the virus that causes AIDS, was first recognized more than 30 years ago. In that time, NIH has established the world's leading AIDS research program. Each year, 50,000 people in the United States still become infected with HIV. Currently, there are more than one million people in the United States, and over 35 million people globally, who are living with HIV infection. In the early 1980s when the HIV/AIDS epidemic began, those infected with the virus were not likely to live longer than a few years. Now, thanks to research funded in large part by NIH, there are powerful treatments that can suppress the virus to undetectable levels, allowing those infected with HIV to live for many years. As a result, death rates dropped more than 50 percent between 1987 and 2010,[33] and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s.[34] NIH research also has informed the implementation of HIV testing and preventive interventions that have reduced the rate of mother-to-child infection by more than 90 percent in the United States.[35] Ongoing efforts seek to develop new and even more effective treatment approaches, including new research in primates that could prove useful in suppressing HIV in humans.[36] These treatments, combined with encouraging advances toward the development of an HIV vaccine and research to find a cure, mean that a future AIDS-free generation is possible with sustained effort.

Childhood Vaccine Development: Haemophilus influenzae type b

Vaccines represent one of the most powerful tools used today to prevent disease, save lives, and reduce health care expenditures. Between 1994 and 2013, the CDC estimates that childhood vaccination prevented 322 million illnesses, 21 million hospitalizations, and 732 thousand deaths, with savings of $295 billion in direct costs and $1.38 trillion in total societal costs.[37] Included in this analysis was the vaccine against Haemophilus influenzae type b (Hib), which was FDA-approved and CDC-recommended for use in infants in the late 1980s. Prior to the vaccine, the Hib bacterium was the leading cause of meningitis and acquired mental retardation in children less than five years of age in the United States. Even with effective antibiotic treatment, 5 percent of patients died and about 30 percent had residual central nervous system damage. NIH support, including critical research performed in the NICHD intramural program and NIAID-funded clinical trials, played a major contributing role in the development of the Hib vaccine. As a result, the incidence of Hib has dropped by more than 98 percent from

[32] http://www.cdc.gov/cancer/lung/statistics/
[33] http://www.cdc.gov/hiv/pdf/statistics_surveillance_hiv_mortality.pdf
[34] Samji H, et al. *PLoS One* 2013; Dec 18;8(12):e81355 PMID: 24367482 http://www.ncbi.nlm.nih.gov/pubmed/24367482
[35] http://www.niaid.nih.gov/topics/HIVAIDS/Understanding/Prevention/Pages/perinatal.aspx
[36] https://www.nih.gov/news-events/nih-research-matters/dual-antibody-treatment-suppresses-hiv-virus-monkeys
[37] Whitney CG, et al. *MMWR Morb Mortal Wkly Rep* 2014; 63(16):352-5. PMID: 24759657

approximately 20,000 cases annually in the early 1980s to less than 30 per year today.[38] The CDC has estimated that Hib vaccination has prevented 361,000 illnesses, 334,000 hospitalizations, and 13,700 deaths.

Breast Cancer

Primarily because of NIH-supported research, multiple breast cancer susceptibility genes now have been identified, including BRCA1, BRCA2, TP53, and PTEN/MMAC1. Genetic testing now allows for tailored, safer, and more efficient treatments. Recent research studies identified 55 genes linked to a tumor suppressor gene that can predict breast cancer survival as well as a natural compound that can attack human epidermal growth factor receptor 2 (HER2) positive breast cancer cells. Scientists also conducted studies in mice in which they found a protein that reduces the risk that breast cancer will spread. In addition, a new imaging technique to improve diagnosis in women with dense breast tissue has been developed. As a result of these and many other advances, the relative 5-year survival from breast cancer in women has increased from 74.8 percent in 1980 to greater than 91 percent, as of a 2015 CDC report.[39]

Prostate Cancer

Prostate cancer is one of the most common cancers and the second leading cause of cancer-related death for men in the United States. NIH-supported research on the treatment of prostate cancer has improved surgical approaches as well as radio-, chemo-, and hormonal therapies. The success of these advances has contributed to the significant decline in the death rate. Between 2003 and 2013, the prostate cancer death rate dropped by 3.4 percent per year, or nearly 29 percent in total,[40] with a 5-year survival rate approaching 99 percent.[41] Current research focuses on increasing understanding of the epidemiology and genetics of prostate cancer and improving treatment and diagnostic options.

Infant Health

In 1960, 26 of every 1,000 babies born in the United States died before their first birthday. By 2014, the infant mortality rate was below 6 per 1,000 births, considerably less than a generation before.[42] A sustained, long-term effort, informed in large part by NIH research to reduce preterm births, neonatal mortality, and other complications that increase the risk of infant death, contributed to these substantial improvements in the survival rates of infants born preterm and to advances in care for all newborns.

[38] Briere EC, et al. *MMWR Morb Mortal Wkly Rep* 2014; 63(1) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm
[39] https://www.cdc.gov/nchs/data/hus/hus15.pdf , Table 37
[40] Cancer of the Prostate - SEER Stat Fact Sheets. http://seer.cancer.gov/statfacts/html/prost.html
[41] Cancer of the Prostate - SEER Stat Fact Sheets. http://seer.cancer.gov/statfacts/html/prost.html
[42] https://www.cdc.gov/nchs/data/hus/hus15_inbrief.pdf

Burns and Traumatic Injury

NIH-funded research on fluid resuscitation, wound cleaning, skin replacement, infection control, and nutritional support has improved greatly the chances of surviving catastrophic burns and traumatic injuries. In the mid-1970s, burns that covered even 25 percent of the body were almost always fatal. Today, people with burns covering 90 percent of their bodies can survive, although often with some impairments. From 1990 to 2010, the death rate per 100,000 people from motor vehicle traffic injury decreased from 18.5 to 11.3, and firearm fatalities dropped from 14.6 to 10.1. These dramatic increases in survival rates, as well as increased health, functioning, and quality of life of survivors, are due in large part to research findings that have transformed clinical practice.

Science Advances from NIH Research:

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

CRISPR Used in Wide-Ranging Applications

Hailed as the 2015 Breakthrough of the Year by Science magazine, the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) system allows relatively easy and precise genome-editing. It can be used for a range of applications, from studying gene function to treating genetic diseases and developing therapeutics for clinical trials. In one study, researchers funded by NIH demonstrated the use of CRISPR to remove a disease-causing section of the dystrophin gene in a mouse model of Duchenne muscular dystrophy, reducing the severity of the disease in the mice.[43] In another project, NIH-funded scientists isolated cells with two copies of the mutation that causes sickle cell disease and used CRISPR to remove one copy of the mutation. With only one copy of the gene, the cultured cells went on to produce healthy hemoglobin at a frequency that might be able to help patients.[44] In the future, this technology could potentially be applied to treat people affected by these and other devastating diseases.

Designing More Safe and Effective Opioids

Opioids are powerful drugs that can relieve severe pain through the activation of opioid receptors on nerve cells throughout the body. While opioids generally are safe when used as directed, they frequently are misused, resulting in addiction and dangerous side effects that include lethal overdoses. NIH-funded researchers screened more than 3 million compounds in an attempt to identify pain relievers with less potential for addiction and fewer side effects than current

[43] Nelson CE, et al. *Science* 2015; epub ahead of print. PMID: 26721684
http://www.ncbi.nlm.nih.gov/pubmed/26721684
Tabeborbar M, et al. *Science* 2015; epub ahead of print. PMID: 26721686
http://www.ncbi.nlm.nih.gov/pubmed/26721686
Long C, et al. *Science* 2015; epub ahead of print. PMID: 26721683
http://www.ncbi.nlm.nih.gov/pubmed/26721683
[44] DeWitt MA, et al. *Sci Transl Med*. 2016 Oct 12;8(360):360ra134. PMID: 27733558
https://www.ncbi.nlm.nih.gov/pubmed/27733558

opioids. Using an interdisciplinary approach combining basic biology, computer science, and pharmacology, the researchers identified a compound related to opioids, called PZM21, and tested it on mice. They found that mice treated with PZM21 showed a similar level of pain relief as mice treated with morphine. However, the effects lasted longer. Additionally, the mice treated with PZM21 did not display the drug-seeking behaviors of those given morphine. Further study will be needed to determine whether PZM21 could serve as a safe and effective pain reliever in people.

High-Resolution Map of the Human Brain

Despite recent advances in brain imaging technologies, most attempts at making an atlas of the human brain have been low-resolution or incomplete. A prime candidate for mapping is the cerebral cortex. This outermost layer of the human brain, which comprises nearly 80 percent of its mass, is responsible for complex traits like language and abstract thought. A recent study conducted by NIH-funded researchers used data from over 200 healthy young men and women participating in the NIH-funded Human Connectome Project to learn more about individuals' brains, including the structures and connections within those brains, and the areas that were active during particular tasks.[45] Using a sophisticated computer algorithm, the researchers were able to analyze an enormous amount of data for each person and create a high-resolution map of the cerebral cortex. This map included 97 new areas, more than doubling the number of identified regions within the cerebral cortex, and reliably identified these same brain regions in a second group of 200 individuals 96.6 percent of the time. Brain mapping approaches hold promise for identifying and understanding the differences that underlie neurological disorders.

Helping to Reconnect the Eye with the Brain

One of the biggest challenges to treating blinding eye diseases like glaucoma, is that damaged neurons in the optic nerve, which carries signals from the eye to the brain, do not normally regenerate their connections. Using a mouse model of the visual system, NIH-funded scientists recently uncovered a new way to encourage regrowth in the damaged optic nerve.[46] Researchers found that high-contrast visual stimulation, in combination with chemically-induced neural stimulation, allows the connections in a damaged optic nerve to grow further than had been shown previously, and to connect to the right targets in the brain. Mice treated with this strategy partially regained visual function, suggesting that mammals have a greater capacity for central nervous system regeneration than had previously been thought. The authors of the study plan to test this same approach in a model that more closely mimics glaucoma, and to isolate the specific elements of high-contrast stimulation that are most effective in driving regeneration.

[45] Glasser MF, et al. *Nature* 2016; epub ahead of print. PMID: 27437579 http://www.ncbi.nlm.nih.gov/pubmed/27437579
[46] Lim JA, et al. *Nat Neurosci* 2016; 19(8):1073-84. PMID: 27399843. http://www.ncbi.nlm.nih.gov/pubmed/27399843

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

For many scientists studying large cohorts of research participants, one of the biggest challenges is collecting data about what happens outside the lab or clinic. The brief period in which a participant provides samples or answers interview questions is just a small slice of a much larger set of both physiological states and lifestyle behaviors. With the advent of wearable technologies that can track a user's heart rate, blood oxygenation, physical activity, sleep, and more, it is now possible to provide study participants with devices that can generate a stream of data—as many as 250,000 measurements per person per day. A recent NIH-funded study evaluated many of these wearable technologies in a real-world setting, and found that they can provide useful, health-relevant information about an individual's physiology, detecting changes related to fatigue, inflammation, Lyme disease, and insulin resistance.[47] As researchers continue to validate wearable technologies, they will provide promising opportunities for gathering useful, real-world data for clinical research, including integration into larger studies like the All of Us research program.

Discovering a Biological Mechanism for Schizophrenia

Schizophrenia is a chronic, severe mental disorder that affects approximately 1 percent of the population. This disease tends to run in families, and the onset of symptoms typically occurs during late teens or early adulthood. Previous NIH-funded studies have identified a number of genetic factors that may be tied to schizophrenia risk, and researchers are building off of these results to probe how certain genes may have a role in the development of mental illness. This year, an NIH-funded study identified a new genetic risk factor for schizophrenia in a family of related genes. In healthy individuals, this molecule supports "synaptic pruning", helping the brain to eliminate excess or unnecessary connections throughout life. The researchers suggest that patients with schizophrenia may undergo abnormally high levels of synaptic pruning from an early age, with the abnormal process building up over time. This phenomenon may explain why symptoms of schizophrenia typically appear after adolescence.[48] In further support of these findings, other studies have shown that brain tissue of patients with schizophrenia has an altered neuronal structure.[49] NIH-funded studies on schizophrenia and the mechanisms that underlie this condition will help guide better treatments for patients in the future.

Non-invasive Spinal Cord Stimulation to Address Paralysis

An estimated 1.2 million people in the United States live with paralysis due to spinal cord injury. NIH is funding leading research on understanding severe spinal cord injuries (SCI) and improving outcomes for SCI patients. Previous NIH-funded research enabled four patients with complete paralysis to regain some voluntary movement via physiotherapy and spinal cord stimulation through a device implanted on the spinal cord. In a recent study, some of the same researchers successfully restored voluntary leg movement through physiotherapy plus a non-invasive method called trans-cutaneous spinal stimulation, in which electrodes are strategically

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

placed on the skin of the lower back. By the end of the treatment, these patients were able to move their legs without electrical stimulation. Future studies will determine if this type of spinal stimulation will allow patients to bear weight while moving and regain autonomic functions that were lost due to paralysis. Another NIH-funded study showed that electrical stimulation could restore some hand and grip strength in patients with complete paralysis-- improvements that remained even in the absence of further electrical stimulation. NIH-funded studies on spinal cord stimulation offer hope to patients with SCI that they may be able to regain some function lost during injury.

Targeted Use of Antibiotics

Antibiotics are ineffective against viruses, but doctors often have no way of quickly determining whether an illness is viral or bacterial, which can lead to inappropriate use of antibiotics in patients who will not benefit from them. In addition to wasting medical resources, this behavior also can accelerate the development of antibiotic-resistant bacterial strains. To meet the need of rapid diagnostics, NIH-funded researchers have developed quicker, more accurate blood tests that can help distinguish between bacterial and viral infections.[50] Another team is working to create a point-of-care system and smartphone app to not only diagnose bacterial infections, but also to identify the species and test for genetic factors related to virulence and antibiotic resistance.[51] These advances will help clinicians to use the most effective treatments for patients and avoid unnecessary use of antibiotics.

Leveraging Big Data to Find Targets for Future Therapy

Several recent advances are expanding the reach of precision medicine. For example, by using genomic technology to analyze both tumor and blood samples from a large number of children with cancer, an NIH-funded research team uncovered genetic clues with the potential to refine diagnosis, identify inherited cancer susceptibility, and guide treatment for nearly 40 percent of the children.[52] In addition, a large international study, partly funded by NIH, discovered that "Big Data" tools can help to identify a drug's potential side effects much earlier in the drug development process. The study, which analyzed genomic and clinical data collected from more than 50,000 people, indicated that anti-diabetes therapies that lower glucose by targeting the product of a specific gene, called GLP1R, are unlikely to boost the risk of cardiovascular disease.[53] The hope is that this teaming of genomic and clinical Big Data will help to streamline the drug development process, helping to avoid late-stage failures attributable to lack of efficacy or adverse safety profiles.

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[50] Sweeney TE, et al. *Sci Transl Med* 2016; 8(346):346ra91. PMID: 27384347
http://www.ncbi.nlm.nih.gov/pubmed/27384347
Tsalik EL, et al. *Sci Transl Med* 2016; 8(322):322ra11. PMID: 26791949
http://www.ncbi.nlm.nih.gov/pubmed/26791949
[51] Park KS, et al. *Sci Adv* 2016; 2(5):e1600300
http://advances.sciencemag.org/content/2/5/e1600300
[52] Parsons DW, et al. *JAMA Oncol* 2016; 2(5):616-624. PMID: 26822237
http://www.ncbi.nlm.nih.gov/pubmed/26822237
[53] Scott RA, et al. *Sci Transl Med* 2016; 8(341):341ra76. PMID: 27252175.
http://www.ncbi.nlm.nih.gov/pubmed/27252175

Mitigating the Effects of Aging

As we age, our bodies accumulate cells which are no longer able to divide and renew themselves. As these cells enter this state, called senescence, they send out signals to the rest of the body that affect inflammation and promote the cellular processes associated with aging. NIH-supported researchers tested whether eliminating these cells from the body might mitigate the effects of aging by using genetically-engineered mice which could eliminate senescent cells from the body. The researchers found that these mice had less heart and kidney deterioration at middle age than other mice, and outlived their peers by more than 20 percent.[54] In a follow-up study, the researchers removed senescent cells from arteries in a mouse model of atherosclerosis and found that the fatty, plaque-forming buildup that can cause heart attacks was reduced by 60 percent.[55] While this research is still in early stages, if translated to humans, it could lead to an entirely new class of drugs that target senescent cells for diseases related to aging, such as atherosclerosis, pulmonary fibrosis, osteoarthritis, and kidney dysfunction, for which an initial clinical trial already is underway.[56]

Cancer Photoimmunotherapy

Immunotherapies have been an area of intense focus for the oncology community because of their promise in treating not only cancer but other diseases as well. Immunotherapy approaches harness a patient's immune system and either stimulate or suppress immune responses to fight a disease. Two new studies from NIH researchers provided evidence that a novel type of immunotherapy utilizing infrared light may be effective against cancer.[57] The first study showed that near-infrared photoimmunotherapy (NIR-PIT) can destroy certain cells around the tumor that prevent the immune system from adequately attacking tumor cells.[58] The second study tested a photoimmunotherapy approach in cells and in mice; the results of this study showed that NIR-PIT targets a specific protein present on the surface of tumor cells in several very aggressive human cancers.[59] These promising results may help in the development of new cancer treatments that target hard to treat cancers.

Addressing the Rising Threat of Zika Virus

The recent outbreak of Zika virus, beginning in South America last spring, now has infected more than one million Brazilians, as well as documented cases in the continental U.S. and Puerto Rico[60], and is linked to a steep increase in the number of babies born with microcephaly, a very

[54] Baker DJ, et al. *Nature*. 2016 Feb 11;530(7589):184-189. PMID: 26840489 https://www.ncbi.nlm.nih.gov/pubmed/26840489
[55] Childs BG, et al. *Science.* 2016 Oct 28;354(6311):472-477. PMID: 27789842 https://www.ncbi.nlm.nih.gov/pubmed/27789842
[56]Clinical Trial: Senescence in Chronic Kidney Disease https://clinicaltrials.gov/ct2/show/NCT02848131?term=senolytic+drugs&rank=1
[57] http://www.cancer.gov/news-events/cancer-currents-blog/2016/photoimmunotherapy-cancer
[58] Kazuhide S, et al. Cancer treatment by near infrared photoimmunotherapy targeting intratumoral regulatory T cells. AACR Annual Meeting 2016.
[59] Nagaya T, et al. *Oncotarget* 2016:7(17):23361-9. PMID 26981775, http://www.ncbi.nlm.nih.gov/pubmed/26981775
[60] https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika

serious condition characterized by a small head and brain. In response to this emerging threat, NIH has stepped up its efforts to develop innovative approaches against the virus. One group of NIH-funded researchers has used cryo-electron microscopy to reveal the structure of the virus,[61] and another has shown how it can infect and kill the human neural progenitor cells that give rise to key brain areas affected in microcephaly.[62,63] These studies provided a foundation for future research on Zika prevention and treatment, and NIH built on these results to launch the first clinical trial to test the safety and efficacy of one vaccine candidate in August 2016, with early results suggesting a safe vaccine that induces an immune response against Zika. Based on these preliminary results, a Phase 2/2b trial of the vaccine began in March 2017, which will obtain additional evidence on whether the vaccine is safe and effective against natural Zika infection.[64]

Promising New Treatments for Type 1 Diabetes

Type 1 diabetes, usually diagnosed in childhood, is a serious, chronic condition in which the pancreas does not produce sufficient insulin to maintain healthy blood sugar levels. This form of diabetes appears to be an autoimmune disorder, with the immune system attacking the insulin-producing islet cells of the pancreas. Individuals with type 1 diabetes currently manage their disease with multiple daily injections of insulin or a pump that delivers insulin through a catheter placed under the skin. Recent NIH-funded research is providing hope for better treatment options. In one recent trial, islet cell transplantation combined with immunosuppression provided near-normal control of blood sugar levels in 88 percent of participants for the first year, and in 71 percent for the second year.[65] A large-scale, long-term study on an artificial pancreas that uses a glucose monitor implant and an adaptive smartphone application to automate insulin pump use and eliminate the need for manual finger sticks is currently underway. This study, along with three others that are slated to start in 2017 and 2018, is potentially the last step before requesting regulatory approval for permanent use of these fully automated devices and [66, 67] greatly improving the quality of life for people with this debilitating disease.

Cell-Free Liquid Biopsy

After cells die, fragments of their DNA leak into the bloodstream. Researchers have been trying to detect these free-floating pieces of genetic material to inform clinical care. These "liquid biopsy" techniques have been utilized to test maternal blood for DNA from a fetus; test a cancer patient's blood for specific mutations or possible relapse; or test an organ transplant recipient for signs of organ rejection. Liquid biopsies would also be useful in testing healthy individuals for early signs of future health problems. NIH-funded researchers have advanced liquid biopsy

[61] Sirohi D, et al. *Science* 2016; 352(6284):467-70. PMID: 27033547
http://www.ncbi.nlm.nih.gov/pubmed/27033547
[62]Tang H, et al. *Cell Stem Cell* 2016; 18(5):587-90. PMID: 26952870
http://www.ncbi.nlm.nih.gov/pubmed/26952870
[63] Nowakowski TJ, et al. *Cell Stem Cell* 2016; 18(5):591-6. PMID: 27038591
http://www.ncbi.nlm.nih.gov/pubmed/27038591
[64] https://www.nih.gov/news-events/news-releases/phase-2-zika-vaccine-trial-begins-us-central-south-america
[65] Hering BJ, et al. *Diabetes Care* 2016; 39(7):1230-40. PMID: 27208344
http://www.ncbi.nlm.nih.gov/pubmed/27208344
[66] http://news.harvard.edu/gazette/story/2016/01/artificial-pancreas-system-aimed-at-type-1-diabetes-mellitus/
[67] https://www.nih.gov/news-events/news-releases/four-pivotal-nih-funded-artificial-pancreas-research-efforts-begin

techniques by developing a new method that also identifies the origins of free-floating genetic material.[68] Genetic material within cells is wound around protein complexes in ways that are unique to each cell type, so fragments of DNA that are detected in the blood would have patterns that link them to their cell of origin. The results of this study showed that in both healthy individuals and patients with cancer, the new liquid biopsy technique could link floating pieces of genetic material to particular cells.[69] These results will pave the way for advancing liquid biopsies to test for a range of acute and chronic conditions.

[68] https://directorsblog.nih.gov/2016/02/16/a-new-tool-in-the-toolbox-new-method-traces-free-floating-dna-back-to-its-source/

[69] Snyder MW, et al. *Cell* 2016;164(1-2):57-68. PMID 26771485, http://www.ncbi.nlm.nih.gov/pubmed/26771485

FUNDING HISTORY

Fiscal Year	Amount[1]
2014 [2]	$30,061,862,000
2015 [3]	$30,311,349,000
2016 [3]	$32,311,349,000
2017 Annualized CR[4]	$32,593,341,000
2018 Budget Request[5]	$26,919,710,000

[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. Includes mandatory budget authority derived from the Special Type 1 Diabetes account, and from Patient-Centered Outcomes Research Trust Fund in FY 2018; also includes NLM Program Evaluation ($8.20 million) in FY 2014, and NIGMS Program Evaluation financing of $715 mllion in FY 2015, $780 million in FY 2016, FY 2017, and FY 2018.

[2] FY 2014 appropriation includes the effect of Secretary's Transfers, and it also reflects sequestration of the mandatory funding for Type 1 Diabetes.

[3] Excludes Ebola-related and Zika-related supplemental appropriation.

[4] Includes funding authorized by the 21st Century Cures Act, and also reflects sequestration of the mandatory funding for Type 1 Diabetes.

[5] Reflects consolidation of the Agency for Healthcare Research and Quality within NIH as the National Institute for Research on Safety and Quality, and elimination of the Fogarty International Center.

SUMMARY OF REQUEST NARRATIVE

The FY 2018 President's Budget request would provide $26.9 billion to NIH, which is $5.7 billion below the FY 2017 Annualized CR level.

The following summary references program level funding, which includes discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriation and in the Department of the Interior, Environment, and Related Agencies appropriation (dedicated to the Superfund Research program), mandatory budget authority derived from the Special Type 1 Diabetes account and the Patient-Centered Outcomes Research Trust Fund, and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act.

The primary budget mechanisms discussed below include mechanism allocations of Program Evaluation Financing, the Special Type 1 Diabetes account, and discretionary budget authority of the National Institute for Research on Safety and Quality; Superfund Research and the Patient-Centered Outcomes Research Trust Fund are treated separately.

Research Project Grants (RPGs)
The FY 2018 President's Budget would provide $14.2 billion for RPGs, which is $3.7 billion less than the FY 2017 Annualized CR level estimate. This amount would fund 7,326 Competing RPGs, or 1,648 less than estimated for the FY 2017 Annualized CR. It also supports 24,499 Noncompeting RPGs, 96 fewer than the FY Annualized CR level. In addition, the projected Competing RPGs average cost of approximately $389,436 would be 19.7% below the FY 2017 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2018 President's Budget would provide $703 million for SBIR/STTR program grants, which is $165 million below the FY 2017 Annualized CR level. The minimum set-aside requirement is 3.65% in FY 2018.

Research Centers
The FY 2018 President's Budget would provide $2.1 billion for Research Centers, which is $417 million less than the FY 2017 Annualized CR level. It would fund 1,234 grants, 48 fewer than the FY 2017 Annualized CR level.

Other Research
The FY 2018 President's Budget would provide $1.7 billion for this mechanism, which is $420 million less than the FY 2017 Annualized CR level. It would fund 5,795 grants, which is 614 fewer than the FY 2017 Annualized CR level.

Training
The FY 2018 President's Budget would provide $738 million for training, which is $106 million below the FY 2017 Annualized CR level. It would fund 14,279 Full-Time Trainee Positions (FTTPs), which is 1,640 fewer than the FY 2017 Annualized CR level. Stipend rates would remain at the FY 2017 Annualized CR level.

Research & Development (R&D) Contracts
The FY 2018 President's Budget would provide $2.5 billion for R&D contracts, which is $423 million less than the FY 2017 Annualized CR level. It would fund an estimated 1,965 contracts, which are 544 fewer than the FY 2017 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2018 President's Budget includes a $62 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement is 3.65% in FY 2018.

Intramural Research (IR)
The FY 2018 President's Budget would provide $3.1 billion for IR, which is $609 million less than the FY 2017 Annualized CR level.

Research Management and Support (RMS)
The FY 2018 President's Budget would provide $1.6 billion for RMS, which is $142 million less the FY 2017 Annualized CR level.

Office of the Director (OD)
The FY 2018 President's Budget would provide $1.5 billion for OD, which is $168 million less than the FY 2017 Annualized CR level.

- **Other than Common Fund**
  The $777 million allocated for OD elements other than the Common Fund or the Office of Research Infrastructure Programs is a net increase of $127 million above the FY 2017 Annualized CR level. This is due to an increase in funding authorized by the 21st Century Cures Act managed by OD, from $52 million to $110 million; the transition of the *All of Us* Research Program ($130 million in FY 2017) out of the Common Fund; and assumption by OD of funding and activities remaining from the Fogarty International Center that is proposed for elimination.

- **Common Fund (CF)**
  Approximately $454 million is allocated for CF-supported programs. This amount is $220 million below the FY 2017 Annualized CR level, due in part to the transition of the *All of Us* Research Program out of CF.

Buildings & Facilities (B&F)
The FY 2018 President's Budget provides $109 million for infrastructure sustainment projects associated with the B&F program, which is $36 million below the FY 2017 Annualized CR level. This amount includes $10 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Superfund Research Program
The FY 2018 President's Budget would provide $60 million, which is $18 million less than the FY 2017 Annualized CR level.

Type 1 Diabetes
The FY 2018 President's Budget would provide $150 million in mandatory funding for Type 1 Diabetes research grants, which is $10 million higher than the FY 2017 Annualized CR level (reduced due to sequestration). The FY 2018 Budget proposes a two year extension for this program with funding at $150 million in FY 2018 and FY 2019.

Patient-Centered Outcomes Research Trust Fund (PCORTF)
The FY 2018 President's Budget would provide $107 million in mandatory funding; PCORTF is proposed within NIH to accompany the National Institute for Research on Safety and Quality.

Program Evaluation Financing
The FY 2018 President's Budget would provide $780 million for Program Evaluation Financing purposes, which is the same as the FY 2017 Annualized CR level.

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OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
SRO-1.1 By 2016, explore biological or bio behavioral pathways through which physical activity and weight control may affect cancer prognosis and survival. (Output)	FY 2016: NIH supported the evaluation of a number of interdisciplinary strategies, including 4 key strategies to refine our understanding of the associations between obesity and specific cancers, the mechanisms underlying these associations and their potential reversibility, and to support behavioral research to help overcome obesity at the individual and population levels. These strategies include the ASA24, FLASHE, a lifestyle intervention study in patients with early-stage breast cancer, and a program announcement entitled, Physical Activity and Weight Control Interventions Among Cancer Survivors: Effects on Biomarkers of Prognosis and Survival. Target: Evaluate promising strategies for obesity prevention and treatment in real-world settings, and harness technology and tools to advance obesity research, and to improve health and survival among cancer patients. (Target Met)	N/A	N/A	N/A
SRO-1.2 By 2016, compare the effectiveness of two treatments for over active bladder syndrome among women. (Outcome)	FY 2016: The entire study was completed, finding that surgical and injection treatments were equally effective for urinary incontinence in women. Quality of life and treatment preference results were similar across treatments.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	Target: Analysis completed for Overactive Bladder Questionnaire Short form and Treatment Satisfaction Survey. (Target Met)			
SRO-1.3 By 2017, complete testing of the hypothesized mechanism of treatment effect of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (e.g., pilot studies or efficacy trials). (Output)	FY 2016: Initiated testing of 30 hypothesized mechanisms of treatment effect of novel interventions; completed testing of 14. Of the 14, 10 progressed to pilot studies of clinical effect. Target: Initiate testing of hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical testing. (Target Exceeded)	Complete testing of the hypothesized mechanism of treatment of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (pilot study or efficacy trial).	N/A	N/A
SRO-1.4 By 2016, advance a novel drug candidate for a disease that affects the nervous system to the point of preparedness for human studies. (Output)	FY 2016: The Blueprint Neurotherapeutics Network team filed an Investigational New Drug (IND) application with the Food and Drug Administration (FDA) in FY 2016. Target: File an Investigational New Drug application with the FDA for a Blueprint Neurotherapeutics Network project. (Target Met)	N/A	N/A	N/A
SRO-1.5 By 2020, increase our understanding of cancer trends and outcomes in the context of disparities and population subgroups	(Will begin reporting in December 2018)	N/A	Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
through expansion of coverage and representation of the US population in the Surveillance, Epidemiology and End Results (SEER) Program registries. (Outcome)			changing US population.	
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)	(Will begin reporting in December 2018)	N/A	Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy.	N/A
SRO-2.1 By 2023, develop, optimize, and evaluate the effectiveness of nano-enabled immunotherapy (nano-immunotherapy) for one cancer type. (Output)	(Will begin reporting in December 2018)	N/A	Optimize properties of 3 nanoformulations for effective delivery and antigen-specific response in immune cells.	N/A
SRO-2.2 By 2019, assess the efficacy of one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	FY 2016: The target was not met; however, enrollment was completed with 176 subjects, which was found to be statistically powered to complete the study aims. Follow-up visits are ongoing. Target: Complete enrollment of 200 subjects and conduct follow-up visits. (Target Not Met)	Conduct follow-up visits of enrolled subjects.	Complete follow-up visits of re-enrolled subjects and data analysis.	N/A
SRO-2.3 By 2018, evaluate the impact of two community-level combination prevention packages (which include	FY 2016: Participants enrolled in year 1 were seen for follow-up visits. Additional participants were enrolled in year 2.	Complete additional annual follow-up visits of all participants and	Perform data analyses and evaluate the impact of two community-level combination	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
universal HIV testing and intensified provision of HIV antiretroviral therapy and care) on population-level HIV incidence in the developing world. (Outcome)	Target: Complete first annual follow-up visits of participants enrolled in the first year of the study. (Target Met)	HIV incidence evaluations.	prevention packages on population-level HIV incidence.	
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 2016: NIH-supported scientists are recruiting patients for a clinical trial to determine whether tympanostomy tube placement compared with nonsurgical management will meaningfully improve children's experience with a common and painful type of ear infection (acute otitis media) over the succeeding 2 years. Target: Initiate testing one new potential treatment option for a hearing disorder. (Target Met)	Initiate testing one new potential treatment option for a hearing disorder.	Initiate testing one new potential treatment option for a speech and language disorder.	N/A
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	(Will begin reporting in December 2018)	N/A	Develop prototypes for four imaging technologies based on adaptive optics in animal models.	N/A
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these	FY 2016: Six exposures were studied but breeding problems occurred and not all generations were produced, which resulted in the target being missed. Target: Assess transgenerational effects of 6 exposures in 3 generations of animals.	Analyze the impact of how 2-6 distinct/individual environmental exposures alter epigenetic processes in animal models.	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
changes can be inherited. (Output)	(Target Not Met)			
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)	(Will begin reporting in December 2017)	Complete preclinical work to test safety and efficacy of the clinical product in animal models.	Submit IND application with the FDA to launch phase I clinical trial upon approval.	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)	(Will begin reporting in December 2018)	N/A	Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets.	N/A
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	(Will begin reporting in December 2017)	Strategy 1: Continue enrolling participants into two studies to test the safety, tolerability, and effectiveness of VRC01 as an intravenous prevention strategy.	Strategy 2: Analyze primary results of a Phase 2a study examining the long-acting injectable, cabotegravir, for the prevention of HIV.	N/A
SRO-2.10 By 2021, develop methods for the regeneration of functional tissues of the human dental, oral, and craniofacial complex to enable initiation of human Phase I clinical trials. (Outcome)	(Will begin reporting in December 2018)	N/A	Establish a centralized Resource Center that is fully operational to develop, optimize, and validate tools and strategies for dental, oral, and craniofacial tissue regeneration.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
SRO-2.11 By 2016, conduct studies of young children to determine whether the plant estrogens in soy formula produce hormone-like effects. (Outcome)	FY 2016: Two papers using IFED data were published in 2016. Data analyses continued throughout FY 16 and an additional manuscript has been drafted and circulated to authors for final review. Target: Continue analyses of IFED datasets and prepare a draft manuscript regarding the estrogenic effects of soy formula on infant development. (Target Met)	N/A	N/A	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)	(Will begin reporting in December 2018)	N/A	Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level.	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 toward the point of preparedness for phase 1 human studies. (Output)	(Will begin reporting in December 2018)	N/A	Initiate lead optimization studies to identify a pre-clinical candidate for 4-7 therapeutic candidates	N/A
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	(Will begin reporting in December 2018)	N/A	Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
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)	(Will begin reporting in December 2018)	N/A	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.	N/A
SRO-3.8 By 2016, determine the optimal tailored treatment regimen for patients with early stage breast cancer that maximizes the benefits of chemotherapy while minimizing the side-effects of unnecessary treatment. (Outcome)	FY 2016: The number of patients exhibiting recurrence were reported, resulting in the determination that the 21-gene expression assay has been successful in identifying breast cancer patients who may be safely spared adjuvant chemotherapy. Target: During the patient monitoring phase (N=7,000), the number of patients who exhibit recurrence will be reported. Any actions taken by program based on the recommendations of the independent data monitoring committee (IDMC) following their analysis of interim statistical data will also be reported. (Target Met)	N/A	N/A	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2016: Researchers have identified genetic mutations that cause Haploinsufficiency of A20 (HA20), an early-onset systemic inflammatory disorder resembling Behçet's disease; and demonstrated that the NFκB-dependent signaling pathway is a potential therapeutic target.	Design a clinical study testing an agent for a disorder of the immune system that affects children.	Identify at least one molecular pathway based on genetic analysis suitable for therapeutic targeting in a cohort of patients with an immune-mediated disease that affects children.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	Target: Identify at least one molecular pathway based on genetic analysis suitable for therapeutic targeting in a pediatric cohort of patients with an immune-mediated disease. (Target Met)			
SRO-3.10 By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY 2016: NIH completed a Phase 2 clinical trial of ABT-436, a novel vasopressin 1b receptor antagonist, for the treatment of alcohol use disorder. Target: Complete phase 2 clinical studies of a candidate compound. (Target Met)	Conduct one human laboratory study on a candidate compound.	N/A	N/A
SRO-3.11 By 2017, advance the discovery of high need cures through innovations in the therapeutics discovery and development process, by developing 3-D human tissue chips that accurately model the structure and function of human organs. (Outcome)	FY 2016: NIH funded scientists collaborated to combine tissue chips into several integrated systems that can mimic the complex functions of the human body, including an integrated heart-liver-vascular system, a female reproductive tract system, and an integrated in vitro model of solid tumor and cardiac tissue. Target: Complete integration of organ chip systems (Target Met)	Demonstrate that integrated organ chip systems model the structure and function of human organs	N/A	N/A
SRO-4.1 By 2018, enable 1-3 Bridging Interventional Development Gaps (BrIDGs) projects to have sufficient pre-clinical data for therapeutic agents in order to apply	FY 2016: The BrIDGs program acquired drug material and conducted dose range finding toxicology studies for 2 projects selected in 2014. Target: Acquire drug	Acquire Good Manufacturing Practice (GMP)-compliant drug material and conduct formal Good Laboratory Practice (GLP)	Generate data to enable IND application on the 1-3 compounds for the projects that were selected.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
for Investigational New Drug (IND) approval from the FDA. (Output)	material for and complete dose range finding toxicology studies for 1-3 projects. (Target Met)	toxicology studies for 1-3 projects.		
SRO-4.2 By 2017, develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in Native American (NA) populations that are culturally appropriate and promote the adoption of healthy lifestyles. (Outcome)	FY 2016: NIH supported the testing of three interventions in Native American communities in FY 2016, including an intervention to enhance colorectal cancer screening, an intervention to reduce tobacco use during pregnancy, and a web-based smoking cessation intervention. Target: Test three interventions in NA communities using rigorous study designs to test the effectiveness or efficacy of interventions. (Target Met)	Continue to develop, adapt, and test the effectiveness of culturally appropriate health promotion and disease prevention interventions in NA populations. Begin analyzing preliminary data from testing interventions in NA communities, and adapt community interventions based on initial finding.	N/A	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)	(Will begin reporting in December 2018)	N/A	Identify the cellular/genetic components of 3 common cancer types.	N/A
SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)	FY 2016: The molecular bases of 42 rare diseases were discovered. Target: Discover the molecular bases of an additional 15 rare diseases (Target Exceeded)	Discover the molecular bases of an additional 10 rare diseases	Discover the molecular bases of an additional 10 rare diseases	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
SRO-4.5 By 2016, test a targeted nanoparticle for imaging and drug delivery to atherosclerotic plaque in animal models. (Output)	FY 2016: Pig studies have been completed, data has been analyzed, and manuscript is in an advanced state of preparation. Target: Extend the studies into a pre-clinical pig model to assess targeted delivery and efficacy in reducing inflammation. (Target Met)	N/A	N/A	N/A
SRO-4.6 By 2016, use animal models to identify 3 new targets and/or molecular mechanisms that could be used in the development of interventions that enhance male fertility. (Output)	FY 2016: Identification of the molecule for activating sperm was achieved. This finding could aid in the development of contraception and infertility treatments. Target: Identify one epigenetic mechanism regulating spermatogenesis. (Target Met)	N/A	N/A	N/A
SRO-4.7 By 2016, determine the safety and effectiveness of two first-in-class treatments for nonalcoholic fatty liver disease in adults and children. (Outcome)	FY 2016: Analysis of data form the pediatric and adult NAFLD trials was completed. Target: Analyze data from pediatric and adult NAFLD treatment trials. (Target Met)	N/A	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	(Will begin reporting in December 2017)	Launch the main Brazil transfusion recipient study in Sao Paulo to identify cases of probable transfusion-transmitted ZIKV, chikungunya virus (CHIKV), and	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
safety of the blood supply. (Output)		dengue virus (DENV).		
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	(Will begin reporting in December 2018)	N/A	Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment.	N/A
SRO-4.10 By 2020, design and develop novel dental composite resins that that demonstrate superiority over the currently used restorative materials. (Output)	(Will begin reporting in December 2018)	N/A	Full material properties characterization of one novel resin will be achieved.	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)	(Will begin reporting in December 2018)	N/A	Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D.	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic outcomes in response to treatment of adolescents with severe obesity. (Outcome)	(Will begin reporting in December 2018)	N/A	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.	N/A
SRO-4.13 By 2020, complete analysis from the oral insulin trial for the prevention of type 1 diabetes in relatives at risk for the disease. (Outcome)	(Will begin reporting in December 2018)	N/A	Begin final outcomes assessment for the oral insulin trial.	N/A
SRO-4.14 By 2020, identify a total of three effective strategies to	(Will begin reporting in December 2018)	N/A	Identify 3 health risk reduction strategies to reduce modifiable	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
reduce modifiable health risk factors associated with premature mortality in people with serious mental illness (SMI) and adolescents and youths with serious emotional disturbance (SED). (Outcome)			health risks associated with premature mortality in adults with SMI.	
SRO-5.1 By 2020, develop and test the effectiveness of two strategies for translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	(Will begin reporting in December 2017)	Develop 2 strategies for translating validated basic knowledge, clinical interventions, or behavioral interventions to diverse communities and clinical practice through establishing partnerships to Advance Cancer Health Equity between Minority Serving Institutions (MSI) and NCI-designated Cancer Centers (CC).	Develop and support 2 partnerships to test validated basic cancer knowledge, clinical or behavioral interventions to diverse communities in clinical practice.	N/A
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 2016: Investigators recently met for a Disease Progression Workshop to discuss analyses of different predictors of disease progression. One predictor is current disease status. Those with mild COPD have the fastest progression. Another predictor appears to be emphysema subtype – certain patterns of emphysema, observable by CT, predict speed of disease progression. A third predictor relies on a principal components	Complete exome chip genotyping of 10,171 COPDGene subjects and identify 1 to 5 new rare and common genetic determinants of COPD.	Identify 1-5 genomic loci that correlate with specific lung patterns of emphysema.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	analyses, which predicts a group of COPD patients with high mortality. These results are being prepared for publication. Target: Analyze longitudinal data for the first 2000 five-year follow-up visits to identify 1-3 predictors of disease progression. (Target Met)			
SRO-5.3 By 2020, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease. (Output)	FY 2016: Sample selection/sequencing Discovery Extension phases completed (4,000 additional whole genomes). Data analysis for Extension Phase initiated. Genomic Center for Alzheimer's Disease funded (all ADSP quality control and data harmonization). Target: Begin confirmation of genomic regions of interest identified in the Discovery Phase using samples from the Replication phase. Begin harmonization of data from Discovery phase datasets with data from Replication Phase for confirmation of regions of interest. (Target Met)	Continue confirmation of genomic regions of interest in the Discovery and Replication phase datasets. Continue harmonization of Discovery Phase and Replication Phase datasets.	Continue confirmation of genomic regions of interest in the Discovery using samples from the Replication phase. Continue harmonization of Discovery Phase and Replication Phase datasets. Begin analysis of genomic regions of interest in the genomes of minority cohorts.	N/A
SRO-5.4 By 2017, address the growing public health problem of antimicrobial resistance by discovering four to six new therapeutic candidates and assessing two novel approaches/ regimens designed to	FY 2016: Two new candidate therapeutics for infections where resistance poses a significant public health threat were discovered. Target: Discover two additional new candidate therapeutics for infections	Assess two novel approaches/regimens designed to preserve existing antimicrobials.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
preserve existing antimicrobials. (Output)	where resistance poses a significant public health threat. (Target Met)			
SRO-5.5 By 2018, complete pre-commercial development of a point-of-care technology targeted for use in primary care setting. (Output)	FY 2016: Completed pilot clinical studies of 2 prototype devices. This phase of development includes testing and evaluating performance of prototype devices in simulated clinical environments and clinical laboratories. Target: Complete pilot clinical studies on 1 to 2 prototype devices. (Target Met)	Support research on continued development of one or two prototype devices that will begin to initiate the regulatory process.	Support research on refinement of one or two devices for use in primary care that includes end-user feedback.	N/A
SRO-5.6 By 2017, develop, evaluate, refine, and/or promote strategies for preventing prescription drug abuse and its consequences. (Output)	FY 2016: NIH studies showed that a naloxone spray was a simple and effective means for delivering the appropriate dose of naloxone. Another NIH study demonstrated co-prescribing naloxone to chronic pain patients was associated with positive behavioral changes and reduced ED visits Target: Develop, test or disseminate strategies to enhance the use of naloxone for overdose prevention (Target Met)	In basic research: identify new targets or refine existing ones in the endocannabinoid system for the development of treatments of chronic pain without development of tolerance or dependence. In clinical research: develop, evaluate, and/or refine two to four treatment strategies that target co-morbid opioid addiction and chronic pain; in translation research identify the impact of state level prescription	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
		monitoring programs (PMP) on prescriber behavior and patient outcomes.		
SRO-5.7 By 2016, the members of the National Dental Practice-based Research Network will contribute to the scientific basis for common dental procedures and improve the quality of dental care in community practices by conducting research studies in dental practices. (Output)	FY 2016: Evidence gathered in the six practice-based studies completed or implemented by the midpoint of the project (January 2016) was disseminated in three peer-reviewed publications and thirteen peer-reviewed conference presentations. Ten additional studies were developed and are in various stages of review or implementation. Target: By 2016, contribute to clinical decision-making based on evidence gained by the NPBRN studies. (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)	(Will begin reporting in December 2018)	N/A	Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population.	N/A
SRO-5.9 By 2017, determine the potential contributions of infectious agents to the underlying etiology of urologic chronic pelvic pain syndromes (UCPPS). (Outcome)	FY 2016: Analyses of differences in the urologic microbiome of UCPPS patients and controls were completed. Target: Complete analyses of differences in the urologic microbiome of UCPPS patients/controls by sex and according to stratification based on symptom profiles, correlations of flare events, and profiles of inflammatory markers.	Determine the potential contributions of infectious agents to the underlying etiology and symptom profiles for urologic chronic pelvic pain syndromes in males and females.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	(Target Met)			
SRO-5.10 By 2020, assess the effectiveness of five to seven interventions that focus on eliminating health disparities by utilizing community partnerships to conduct intervention research that will foster sustainable efforts at the community level that will impact disparate conditions. (Output)	FY 2016: The planning phase (Phase I) of the CBPR Initiative is complete and the intervention phase (Phase II) is underway. The 19 Phase II projects have begun interventions and are identifying adaptive strategies and collecting first year assessment variables. Target: Identify adaptive strategies and collect first year assessment variables. (Target Met)	Assess intervention progress and collect second year assessment variables.	Assess intervention progress and collect third year assessment variables.	N/A
SRO-5.11 By 2018, develop and test three to five strategies for symptom management that reduce the effects of acute and chronic illness. (Output)	FY 2016: An NIH-supported study found that cognitive behavioral therapy (CBT) focused on depressive symptoms improved related symptoms in patients after cardiac surgery. Target: Test one novel strategy for managing symptom clusters and that improves health outcomes such as HRQoL. (Target Met)	Assess the efficacy of one strategy that improves health outcomes through symptom self-management.	Test three strategies for symptom management that improve health outcomes across multiple illness trajectories.	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)	(Will begin reporting in December 2017)	Develop and/or characterize a mouse model that can be used to improve understanding of the in vivo conditions required for skin stem cell maintenance.	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	(Will begin reporting in December 2018)	N/A	Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment.	N/A
SRO-5.14 By 2020, evaluate the effectiveness of one intervention to reduce death and/or neurodisability in pre-term or in full term infants with life-threatening conditions. (Outcome)	(Will begin reporting in December 2017)	Complete follow-up on 168 subjects enrolled in a study of term or late preterm infants with brain injury due to low oxygenation.	Complete enrollment in study of preterm infants undergoing incubator treatment.	N/A
SRO-5.15 By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations. (Outcome)	FY 2016: NIH promoted and disseminated the College Alcohol Intervention Matrix (*CollegeAIM*), and disseminated the youth screening guide through print and electronic media. Target: Disseminate the newly released College Alcohol Interventions Matrix (CollegeAIM) and continue to disseminate the youth screening guide. (Target Met)	Continue to promote the College Alcohol Intervention Matrix (CollegeAIM)	Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e. American Indian, Alaska Native).	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)	(Will begin reporting in December 2017)	Submit one proposed label change to FDA.	Complete one Phase I/II clinical trial on a prioritized drug.	N/A
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	(Will begin reporting in December 2018)	N/A	Initiate development of new strategies for patient- and caregiver-centered decision-making in	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
			end-of-life and palliative care.	
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2016: Over 2200 participants had been enrolled in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Trial. Target: Enroll at least 2200 participants in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (Target Exceeded)	Complete enrollment for at least one Restore Insulin Secretion protocol.	Complete at least one Restoring Insulin Secretion protocol	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)	(Will begin reporting in December 2018)	N/A	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.	N/A
SRO-7.1 By 2016, assess the efficacy of a novel microbicide delivery system for the prevention of HIV. (Output)	FY 2016: The results of ASPIRE (A Study to Prevent Infection with a Ring for Extended Use) were published and announced on February 22, 2016. Target: Complete data analysis on the safety and/or efficacy of a novel microbicide delivery system and release results publicly. (Target Met)	N/A	N/A	N/A
SRO-7.2 By 2018, develop an evidence-based, online resource to help people who have	FY 2016: Researchers identified factors associated with recurrent pain after nonoperative treatment for	Integrate the individualized outcome models into an outcomes	Develop an evidence-based, online resource to help people who	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	disc herniation or the need for subsequent operations for spinal stenosis. Target: Develop individualized models of patient outcomes following surgical or non-operative treatment for common causes of surgery for low back pain (e.g., intervertebral disc herniation, lumbar spinal stenosis, and degenerative spondylolisthesis) (Target Met)	calculator and assess its use in a web-based environment	have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options	
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 2016: Five interventions utilizing HIT, including mobile health technology, addressing five research priority areas were developed. All interventions were found to be feasible and will undergo additional revision and efficacy testing in preparation for broad dissemination and implementation. Target: Identify next steps for testing or deployment of 2-4 substance abuse treatment or medication adherence interventions using mobile technology (Target Exceeded)	Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings	Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities	N/A
SRO-8.2 By 2017, identify circuits within the brain that mediate reward for 1) drugs, 2) non-drug rewards such as food or palatable substances, and 3) aversion to drug effects, and 4) determine the degree of overlap	FY 2016: Highlights of FY16 findings include identification of molecular pathways that regulate circuits involved in developing habitual behavior, retention of aversive memories, and opioid dependence, as well as identification of a	Identify morphological and functional neuroplastic modifications due to drugs at the level of dendritic spines and electrophysiologic al indices and their	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
between these circuits. (Output)	potential new treatment for cocaine use disorder. Target: Support research to compare and contrast rewarding versus aversive pathways in response to substances of abuse (Target Met)	persistence during the development of drug dependence (or during repeated intermittent drug administration).		
SRO-8.7 By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems. (Outcome)	FY 2016: NIH researchers tested hypothesized mechanisms of treatment effects, and novel implementation strategies. One study evaluated strategies for implementing trauma-focused cognitive behavioral therapy (TF-CBT). Findings indicated that a novel training approach resulted in higher rates of completed trauma screening of adolescents, higher rates of treatment completion, and significantly more therapists completing TF-CBT with fidelity. This approach combined a web-based component, an in-person workshop, and twice monthly phone consultation. This novel intervention is expected to progress further to clinical testing. Target: Initiate testing of hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical testing. (Target Met)	Establish one research-practice partnerships to improve dissemination, implementation, and continuous improvement of evidence-based mental health care services.	Identify three implementation strategies that improve the sustainability and uptake of evidence-based practices in large public services settings, such as child welfare and mental health agencies.	N/A
SRO-9.2 By 2018, identify culturally	FY 2016: Patient follow-up was completed in a study	Complete data analysis for a	Initiate dissemination and	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
appropriate, effective stroke prevention/intervention programs in minority communities. (Outcome)	testing a clinical program for improved blood pressure control in racial/ethnic minority populations, and analysis of the results is underway Target: Complete patient follow-up in a study testing a clinical program for improved blood pressure control in racial/ethnic minority populations. (Target Met)	study that tested culturally tailored interventions to address major contributors to stroke disparities in racial/ethnic minority populations.	implementation (D&I) data analyses to identify scalable components of successful disparities intervention programs.	
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2016: Award rate to comparison group reached 12% Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2016: Award rate to comparison group reached 15% and exceeded the target by 5%. Target: N ≥ 10% (Target Exceeded)	N ≥ 10%	N ≥ 10%	N/A
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying, and maintaining business modules. (Output)	FY 2016: MAINTENANCE NBS R12 Technical Upgrade transitioned to an operational maintenance steady state in November 2015. Target: (Maintenance [Mat]) Maintain deployed business modules. * Planned - Oracle 12i [Dep.2016] (Target Met)	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud	N/A
CBRR-3 By 2016, develop diagnostic definitions and outcome	FY 2016: At least 5 clinical studies have implemented the Task Force guidelines and	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
measures for use in clinical research studies on chronic lower back pain (cLBP). (Output)	are in the process of testing proposed outcome measures. In addition, the Task Force report continues to produce a significant influence on clinical research in cLBP. Target: Test standardized research diagnostic measures for cLBP. (Target Met)			
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)	(Will begin reporting in December 2017)	Deliver phenotyping on 300 knockout (KO) juvenile lines of genetically modified mice.	Deliver phenotyping on 500 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)	(Will begin reporting in December 2018)	N/A	Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and Recruitment Innovation Centers.	N/A
CBRR-6 By 2019, launch and establish a Biomedical Citizen Science Hub to serve as an online collaboration space for biomedical citizen science research efforts in cancer biology. (Output)	(Will begin reporting in December 2018)	N/A	Complete development & launch the Biomedical Citizen Science Hub	N/A
CBRR-7 By 2017, expand the scope and	FY 2016: eyeGENE International collaborations	Increase the number of	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENE®), a national genetics research resource for rare inherited ocular diseases, by adding new patient records to the database, augmenting and refining the phenotypic data collected, and by increasing the number of registered researchers to 900. (Output)	in 3 foreign countries (Canada, Japan, Italy) increased patient participant pool and data sharing among investigators. Target: Create international collaborations for Network, extending into 3 foreign countries. (Target Met)	registered eyeGene users to 900.		
CBRR-8 By 2017, characterize the three-dimensional atomic structure of 400 proteins of biomedical interest related to infectious agents. (Output)	FY 2016: 201 three-dimensional structures were characterized to enhance the biomedical research community's understanding of these proteins and to assist with the development of structure-based vaccines, diagnostics, and therapeutics. Target: Characterize the three-dimensional structure of an additional 100 protein targets or other molecules of biomedical interest with regard to bacterial, viral, and eukaryotic pathogens (Target Exceeded)	Characterize the three-dimensional structure of an additional 100 protein targets or other molecules of biomedical interest with regard to bacterial, viral, and eukaryotic pathogens.	N/A	N/A
CBRR-9 By 2020, enroll a total of 1,946 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	(Will begin reporting in December 2017)	Enroll 1,046 cumulative participants in GenomeConnect.	Enroll 1,346 cumulative participants in GenomeConnect.	N/A
CBRR-10 By 2020, enroll 180 children into the Pediatric Heart Network (PHN) to support a research resource for investigators	(Will begin reporting in December 2018)	N/A	Enroll 50 children with complex congenital heart	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
conducting research in congenital heart disease across the age spectrum. (Output)			disease in a clinical research study.	
CBRR-11 By 2016, collect and make available for distribution 600 well-characterized, high-quality human cell lines for use in genetic and genomic research. (Output)	FY 2016: One hundred fifty-two new human cell lines were accepted by the NIH Human Genetic Cell Repository in FY 2016. Target: Accept and make available to scientific researchers an additional 200 new human cell lines. (Target Not Met)	N/A	N/A	N/A
CBRR-12 By 2017, produce x-ray diffraction data for new protein structures that will enhance an existing x-ray resource for understanding basic biological processes. (Output)	FY 2016: X-ray crystallographic data provided for 209 new structures. Target: Provide x-ray crystallographic data for 180 new structures of macromolecules of biomedical relevance to researchers worldwide (Target Exceeded)	Provide x-ray crystallographic data for 170 new structures of macromolecules of biomedical relevance to researchers worldwide.	N/A	N/A
CBRR-13 By 2017, archive and annotate new protein structures to support research in human health and disease and drug development. (Output)	FY 2016: During FY 2016, 9,424 structures were archived and annotated at the Protein Data Bank and made available to the community, just missing the target. Target: Annotate and archive 9,500 new protein structures (Target Not Met)	Annotate and archive 9,200 new protein structures.	N/A	N/A
CBRR-14 By 2018, establish and utilize a national clinical network to conduct five stroke clinical trials using shared infrastructure and	FY 2016: Enrollment began in April 2016 for the Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3 (DEFUSE 3) trial,	To broaden the network's scope across stroke research, initiate one new trial in stroke prevention	Complete enrollment in 1 to 3 trials being conducted within the stroke network.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
efficient processes. (Output)	which was the first trial to be developed explicitly for implementation within the NIH StrokeNet. Target: Initiate the first new trial to be conducted in the Stroke Network. (Target Met)	or stroke treatment within the stroke network.		
CBRR-15 By 2016, establish a resource database and tissue bank of 30 reference tissues (e.g., liver, skin, heart, bone) in which the relationship between genetic variation and gene expression is quantified and 3 additional molecular analyses are performed. (Output)	FY 2016: Tissue samples of multiple parts of the body (e.g., liver, skin, heart, bone) were collected from 544 donors. Target: Enroll 300 donors annually. (Target Exceeded)	N/A	N/A	N/A
CBRR-16 By 2016, demonstrate the use of an efficient, cost-effective pipeline characterizing (phenotype) 2500 genetically modified mice. (Outcome)	FY 2016: All KOMP2 centers have completed their production goals. KOMP generated 2500 knockout lines. Target: Complete phenotyping the 2500 knockout lines. (Target Met)	N/A	N/A	N/A
CBRR-17 By 2017, take steps to improve the quality and availability of information to inform decisions about the size of the NIH training programs and the number of people in training to address future needs for the nation's biomedical research workforce. (Output)	FY 2016: Instructions for training grant applications and progress reports have been modified to collect information on graduate students closely associated with NIH-supported training programs and their career outcomes. Target: Implement the collection of information	Adopt a system for reporting training grant data and trainee outcomes electronically	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	from grantees on career outcomes for graduate students closely associated with training grants. (Target Met)			
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	(Will begin reporting in December 2018)	N/A	Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample.	N/A
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)	(Will begin reporting in December 2018)	N/A	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	N/A
CBRR-20 By 2020, advance the preclinical development of ten candidate products (e.g., vaccines, therapeutics) to combat infectious diseases. (Outcome)	(Will begin reporting in December 2018)	N/A	Advance the preclinical development of three vaccine and/or therapeutic candidate products.	N/A
CBRR-21 By 2020, establish and implement a national collaborative Pilot and Feasibility (P&F) program that utilizes specialized equipment, and expertise in nonmalignant hematology that are available through the	(Will begin reporting in December 2018)	N/A	Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
Cooperative Centers of Excellence in Hematology (CCEH). (Output)				
CBRR-22 By 2020, establish a reference map that will serve as the framework to understand the development of the human urinary tract. (Outcome)	(Will begin reporting in December 2018)	N/A	Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and prostate.	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)	(Will begin reporting in December 2018)	N/A	Support at least 50 studies in a project management pipeline from application development and review to laboratory and data analysis.	N/A
CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)	(Will begin reporting in December 2018)	N/A	Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5%.	N/A
CBRR-25 Increase the total number of mentored research career development experiences for trainees from underrepresented backgrounds to promote individual student development and to prepare them for a range of research-related careers. (Output)	(Will begin reporting in December 2018)	N/A	3556 career experiences across all career stages.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
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)	(Will begin reporting in December 2018)	N/A	Sustain the number of undergraduate mentored research experiences from 2017 level	N/A
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	(Will begin reporting in December 2018)	N/A	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	N/A
CBRR-28 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting research on brain and behavior. (Output)	(Will begin reporting in December 2018)	N/A	Collect brain tissue from 80 new donors and distribute tissue samples or data derived from tissue to 15 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)	(Will begin reporting in December 2018)	N/A	Begin developing a core set of small vessel VCID clinical data elements.	N/A
CTR-1 By 2018, increase the number of SBIR/STTR outreach	(Will begin reporting in December 2017)	Complete three outreach events with either a	Complete four outreach events with either a minority-	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
events that are targeted to groups that are currently underrepresented in the NIH SBIR/STTR portfolio. (Output)		minority-targeted organization or program, or a women-targeted organization or program.	targeted organization or program, or a women-targeted organization or program.	
CTR-2 By 2017, reach 500,000 visits to the website Genome: Unlocking Life's Code. (Outcome)	FY 2016: As of October 1, 2016, ULC reached 340,564 visits and 1,183,073 page views. Target: By 2016, reach 300,000 total visits (Target Exceeded)	By 2017, reach 2.5 million total page views.	N/A	N/A
CTR-3 By 2016, partner with 20 state and local mental health nonprofit organizations to facilitate awareness among the general public about the brain, mental health disorders, research-tested interventions and findings, and clinical trials research. (Outcome)	FY 2016: Partnered with 55 state and local mental health organizations to educate the public about the role of basic, translational, and clinical research in the prevention, treatment, and recovery and, ultimately, a cure for mental illness, and make the public aware of opportunities to participate in clinical research. Target: Support 20-25 state and local mental health organizations to educate the public about the role of basic, translational, and clinical research in the prevention, treatment, recovery and, ultimately, a cure for mental illness, and make the public aware of opportunities to participate in clinical research. (Target Exceeded)	N/A	N/A	N/A
CTR-4 By 2017, expand and implement the broad use of Common Data Elements for 17	FY 2016: A NINDS CDE Project Study Start-up Tutorial has been developed to help investigators access	Develop collaborative model to enable implementation of	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
neurological disorders among investigators conducting clinical research. (Output)	CDEs and utilize the tools provided for implementation in their research study. Target: Develop a clinical research training module on utilization of Common Data Elements tools. (Target Met)	the CDE project as a long-term sustainable resource for the clinical research community.		
CTR-5 By 2018, increase the number of computer-indexed MEDLINE journals by 469 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	FY 2016: The number of computer-indexed MEDLINE journals was increased by 128 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 121 titles over the previous year. (Target Exceeded)	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year.	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 60 titles over the previous year.	N/A
CTR-6 By 2018, improve NIH's ability to identify outcomes that result from NIH funded research projects and report to the public on research outcomes. (Outcome)	FY 2016: The NIH Research Performance Progress Report began collecting structured information on products that can be used by NIH staff for reporting purposes. Target: By 2016, expand NIH's electronic infrastructure to support grantees' reporting of products and research results that result from NIH research grants. (Target Met)	By 2017, establish an electronic closeout process for NIH research grants which includes a Project Outcomes Report for the general public summarizing the project outcomes or findings that expand fundamental knowledge, enhance health, lengthen life, reduce illness and disability, and otherwise fulfill the programmatic	By 2018, implement system improvements to collect inclusion data (i.e. race, gender, etc.) at award closeout in a structured format.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
		goals of the research activity.		
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)	(Will begin reporting in December 2017)	Complete development and begin dissemination of a national COPD action plan.	Conduct annual implementation progress webinars/meetings with stakeholders.	N/A
CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform agency funding decisions, and promote transparency regarding the agency's funding strategies. (Output)	(Will begin reporting in December 2018)	N/A	By 2018, develop a metric that captures the unique number of individuals who apply for and receive NIH funding over a five-year time period.	N/A
MPO-1 By 2016, decrease by 10% the costs associated with trans-NIH recruitment strategies for intramural research group leaders. (Efficiency)	FY 2016: NIH completed the phasing out of print advertisements in scientific journals for the Earl Stadtman Investigator search. This allowed NIH to meet its goal of reducing the overall trans-NIH recruitment budget by 2%. Target: A 2% decrease in the budget and a minimum of 400 applicants in the combined programs of the Earl Stadtman Investigator search, the Lasker Clinical Research Scholars, and the Early Independent Scientist program.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	(Target Met)			
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Ongoing) (Output)	FY 2016: NIH implemented further recommendations from the study as they revised the Administrative Training Committee Charter and Committee scope to establish maximum sizes of 6 at-large members, added term limits to subcommittees, and streamlined intern activities to match the smaller intern/fellows pool. NIH explored mixed At-Large and designated funding models, and incorporated quarterly updates to the Deputy Director of Management (DDM). With these changes, the latest survey of graduates showed 92 percent of interns were satisfied or very satisfied with their overall experience, which was a five percent increase from the previous year. Target: Assess [AS] results of implementation Implement recommendations from study of NIH's administrative intern and fellows program [EX 2014/ IM 2015] (Target Met) FY 2016: Webinars were successfully incorporated into the Mid-Level Leadership Program and Women in Leadership Workshops, and WebEx and iPads were also successfully incorporated into targeted	Examine [EX] key area to enhance leadership skills *NIH will examine best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019] Implement [IM] recommendation from prior year assessments *NIH will implement the recommendations from prior year assessments of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/ AS 2018] Assess [AS] results of implementation * Assess best practices and review the literature	Examine [EX] key area to enhance leadership skills NIH workforce trends to target junior-level programs to job series with the largest anticipated risk in filling future leadership positions.[IM 2019/ AS 2020] Implement [IM] recommendation from prior year assessments *NIH will implement best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019] Assess [AS] results of implementation *NIH will assess the outcomes of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/ AS 2018]	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	leadership programming and the Senior Leadership Program (SLP) role-play activities. Target: Implement [IM] recommendation from prior year assessments * Assess best practices and review the literature regarding incorporating the latest technologies into leadership development programs to determine which are most effective and practicable to create efficiencies and/or enhance learning [EX 2015 /AS 2017] (Target Met) FY 2016: An external research team evaluated the 2010-2014 Executive Leadership Programs. The comparative analysis and interviews produced overwhelmingly positive results, and recommendations will be implemented in the revised program, including changing the program to run biennially to maintain selectiveness, encourage more networking, re-introduce an off-site location, and offer more immersive NIH experiences. Target: Examine [EX] key area to enhance leadership skills *NIH will examine 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]	regarding incorporating the latest technologies into leadership development programs to determine which are most effective and practicable to create efficiencies and/or enhance learning [EX 2015 /AS 2017]		

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	(Target Met)			
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2016: NIH/OHR supported the Indian Health Services, per a request from HHS/ASA to help find talent in the greater plains area. IHS had to shut down several field hospitals due to not being able to staff them appropriately. Target: Implement [IM] key area to enhance recruitment *Increase the use of Community Recruitment Efforts. [AS 2017] (Target Met) FY 2016: OHR recruited for HR Specialists through Pathways to enhance OHR's succession planning efforts and to develop a talent pipeline. This will provide a steady stream of talent to complement our seasoned team members. Target: Implement [IM] key area to enhance recruitment *Launch a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [AS 2017] (Target Met) FY 2016: OHR expanded the Pathways program to include the following STEM positions: Engineering Technician, PMF Public Health Analyst, and a PMF Health Specialist.	Examine [EX] key area to enhance recruitment *Examine a way to create a comprehensive program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019] Implement [IM] key area to enhance recruitment *Implement an expansion of the Pathways Program to STEM career path for focused students and supporting of succession planning efforts. [IM 2017] [AS 2018] Assess [AS] results of implementation *Assess the results on launching a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [AS 2017] Assess [AS] results of implementation	Examine [EX] key area to enhance recruitment *NIH will examine HR CARDS to determine whether it is effective in meeting program goals and streamlining the efficient use of standard HR packages. [IM 2019/AS 2020] Implement [IM] key area to enhance recruitment *Implement the creation of a program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019] Assess [AS] results of implementation *Assess the expansion of the Pathways Program to STEM career path for focused students and in support of succession planning efforts. [IM 2017] [AS 2018]	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
	Target: Examine [EX] key area to enhance recruitment *Expansion of the Pathways Program to STEM career path for focused students and supporting of succession planning efforts. [IM 2017] [AS 2018] (Target Met)	*Assess the results of implementation on the Increase use of Global Recruitments. [AS 2017]		
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2016: 25% of Principal Investigators were reviewed resulting in 25% of resources recommended to be reallocated Target: Conduct BSC reviews of 25% of Principal Investigators to access quality of science in order to prioritize resources. (Target Met)	Conduct BSC reviews of 25% of Principal Investigators to access quality of science in order to 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 and Efficiency)	FY 2016: The condition of the facilities portfolio reached a CIwa of 83.6. Target: CIwa = 79.39 (Target Exceeded)	CIwa = 78.40	CIwa=80.86	N/A
MPO-6 By 2017, maintain the annual condition of buildings and facilities portfolio so that no less than 95% of occupied gross square feet (GSF) will have a CI greater than 65. (Output and Efficiency)	FY 2016: 88.9% of the occupied gross square (GSF) reached a CI greater than 65. Target: Target = 85.7% (Target Exceeded)	Target = 85.68%	N/A	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final	FY 2016: Eleven (11) of the fifteen (15) active projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively	16 Active Projects	15 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
approved project cost. (Ongoing) (Output)	managed to ensure completion within 100% of the final approved project cost. 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 2016: The design and construction for thirteen (13) of the fifteen (15) active projects in the portfolio was managed effectively under this target goal that focuses on ensuring that no more than 10% of the portfolio incorporated a plus or minus 10% adjustment of the approved scope. Target: 15 Active Projects (Target Not Met)	16 Active Projects	15 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2016: Obligated 47% of eligible service contracting dollars to PBC. Target: Obligate the FY 2016 NIH goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2017 goal of eligible service contracting dollars to PBC.	Obligate the FY 2018 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)	(Will begin reporting in December 2017)	Identify historical measures of peer review quality and efficiency.	Design and test measures of peer review quality and efficiency.	N/A
MPO-11 Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported	(Will begin reporting in December 2018)	N/A	70% of the awarded state-of-the-art instruments are acquired and	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
research institutions across the nation. (Output)			installed at NIH-supported research institutions 18 months after award	
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)	(Will begin reporting in December 2018)	N/A	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.	N/A

GRANT AWARDS TABLE

	FY 2016 Final	FY 2017 [3] Annualized CR	FY 2018 [3,4] President's Budget
Number of Awards	43,139	43,040	40,432
Average Award (in Whole $s)	$519,989	$524,512	$445,200
Range of Awards (in Whole $s) [1,2]	$1,000 to $32,196,477	$1,000 to $31,079,385	$1,000 to $29,962,293

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

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

[3] Includes 21st Century Cures Act funding.

[4] Includes funding for NIRSQ and excludes funding for FIC.

BUDGET REQUEST BY INSTITUTE AND CENTER (SUMMARY TABLE)

(Dollars in Thousands)	FY 2016 Final[1]	FY 2017 Annualized CR	FY 2018 President's Budget
NCI	$5,206,292	$5,504,788	$4,474,222
NHLBI	$3,109,221	$3,109,615	$2,534,803
NIDCR	$412,821	$414,792	$320,749
NIDDK[2]	$1,963,793	$1,954,550	$1,599,534
NINDS	$1,692,832	$1,692,915	$1,355,998
NIAID	$4,749,897	$4,621,127	$3,782,670
NIGMS[3]	$2,508,960	$2,508,780	$2,185,509
NICHD	$1,338,348	$1,337,255	$1,032,029
NEI	$707,007	$714,542	$549,847
NIEHS[4]	$769,922	$769,585	$593,144
NIA	$1,596,031	$1,597,149	$1,303,541
NIAMS	$540,912	$541,110	$417,898
NIDCD	$422,351	$422,227	$325,846
NIMH	$1,516,530	$1,545,447	$1,244,901
NIDA	$1,049,059	$1,075,440	$864,998
NIAAA	$466,798	$466,811	$361,356
NINR	$145,709	$146,207	$113,688
NHGRI	$512,509	$517,969	$399,622
NIBIB	$343,026	$346,136	$282,614
NIMHD	$280,293	$279,186	$214,723
NCCIH	$129,760	$130,540	$101,793
NCATS	$684,468	$684,114	$557,373
FIC[5]	$70,019	$70,313	---
NLM	$395,138	$393,913	$373,258
B&F	$128,863	$128,618	$98,615
NIRSQ[6]	---	---	$378,546
OD[5]	$1,570,791	$1,620,213	$1,452,433
TOTAL, NIH Program Level	**$32,311,350**	**$32,593,342**	**$26,919,710**
Mandatory Type 1 Diabetes Research	-$150,000	-$139,650	-$150,000
PHS Program Evaluation	-$780,000	-$780,000	-$780,000
PCORTF Mandatory			-$106,546
Interior Budget Authority	-$77,349	-$77,202	-$59,607
Total, NIH Labor/HHS Budget Authority	**$31,304,001**	**$31,596,490**	**$25,823,557**

[1]Excludes Ebola-related and Zika-related supplemental appropriations.

[2]Includes Mandatory Type 1 Diabetes Research funding.

[3]Includes Program Evaluation financing of $780 million in FY 2016, FY 2017, and FY 2018.

[4]Includes Interior Appropriation for Superfund research.

[5]FIC eliminated in FY 2018, remaining funding/activities shift to OD.

[6]Formerly the Agency for Healthcare Research and Quality, proposed for consolidation with NIH in FY 2018.

APPROPRIATIONS ADJUSTMENT TABLE

(Dollars in Thousands)	FY 2016 Enacted	FY 2016 HIV/AIDS Transfer	FY 2016 Zika Transfer	FY 2016 Operating Level
NCI	$5,214,701	-$1,192	-$7,217	$5,206,292
NHLBI	$3,115,538	-$2,005	-$4,312	$3,109,221
NIDCR	$415,582	-$2,186	-$575	$412,821
NIDDK[1]	$1,968,357	-$2,047	-$2,517	$1,963,793
NINDS	$1,696,139	-$959	-$2,348	$1,692,832
NIAID	$4,629,928	$85,769	$34,200	$4,749,897
NIGMS	$2,512,073	$364	-$3,477	$2,508,960
NICHD	$1,339,802	-$1,454	---	$1,338,348
NEI	$715,903	-$7,905	-$991	$707,007
NIEHS[2]	$771,051	-$169	-$960	$769,922
NIA	$1,600,191	-$1,945	-$2,215	$1,596,031
NIAMS	$542,141	-$479	-$750	$540,912
NIDCD	$423,031	-$95	-$585	$422,351
NIMH	$1,548,390	-$29,717	-$2,143	$1,516,530
NIDA	$1,077,488	-$26,938	-$1,491	$1,049,059
NIAAA	$467,700	-$255	-$647	$466,798
NINR	$146,485	-$573	-$203	$145,709
NHGRI	$518,956	-$5,729	-$718	$512,509
NIBIB	$346,795	-$3,289	-$480	$343,026
NIMHD	$279,718	$962	-$387	$280,293
NCCIH	$130,789	-$848	-$181	$129,760
NCATS	$685,417	---	-$949	$684,468
FIC	$70,447	-$330	-$98	$70,019
NLM	$394,664	$1,020	-$546	$395,138
OD	$1,571,200	---	-$410	$1,570,790
B&F	$128,863	---	---	$128,863
Total, NIH Program Level	**$32,311,349**	---	---	**$32,311,349**
Less funds allocated from different sources:				
Mandatory Type 1 Diabetes Research	-$150,000			-$150,000
PHS Program Evaluation	-$780,000			-$780,000
Total, NIH Discretionary Budget Authority	**$31,381,349**	---	---	**$31,381,349**
Interior Budget Authority	-$77,349			-$77,349
Total, NIH Labor/HHS Budget Authority	**$31,304,000**	---	---	**$31,304,000**

[1] Includes Mandatory Type 1 Diabetes Research funding.

[2] Includes Interior Appropriation for Superfund research.

BUDGET MECHANISM TABLE

(Dollars in Thousands)	FY 2016 Final[1,3]		FY 2017 Annualized CR[1,3,4]		FY 2018 President's Budget[1,4,10]	
	No.	Amount	No.	Amount	No.	Amount
Research Projects:						
Noncompeting	23,528	$11,726,633	24,595	$12,535,005	24,499	$10,531,990
Administrative Supplements	*(1,832)*	281,273	*(1,456)*	173,272	*(955)*	100,722
Competing:						
Renewal	1,641	925,443	1,400	755,198	1,108	439,836
New	8,689	4,071,994	7,558	3,589,996	6,204	2,409,846
Supplements	34	21,342	16	5,403	14	3,322
Subtotal, Competing	10,364	$5,018,779	8,974	$4,350,597	7,326	$2,853,005
Subtotal, RPGs	33,892	$17,026,685	33,569	$17,058,875	31,825	$13,485,717
SBIR/STTR	1,689	810,307	1,780	868,456	1,578	702,996
Research Project Grants	35,580	$17,836,992	35,349	$17,927,331	33,403	$14,188,712
Research Centers:						
Specialized/Comprehensive	1,053	$1,812,218	1,044	$1,769,290	1,011	$1,524,921
Clinical Research	67	406,678	67	377,967	67	282,432
Biotechnology	98	179,563	96	173,920	87	132,574
Comparative Medicine	47	120,096	48	118,451	51	100,132
Research Centers in Minority Institutions	23	56,759	27	56,651	18	39,656
Research Centers	1,288	$2,575,314	1,282	$2,496,279	1,234	$2,079,715
Other Research:						
Research Careers	3,618	$642,441	3,626	$666,150	3,554	$591,562
Cancer Education	74	23,261	76	23,261	74	20,901
Cooperative Clinical Research	345	404,684	327	397,967	298	343,564
Biomedical Research Support	107	67,235	109	69,949	112	55,907
Minority Biomedical Research Support	272	105,494	271	104,885	265	93,799
Other	1,855	776,404	2,000	889,189	1,492	626,150
Other Research	6,271	$2,019,519	6,409	$2,151,400	5,795	$1,731,883
Total Research Grants	43,139	$22,431,826	43,040	$22,575,010	40,432	$18,000,310
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs	
Individual Awards	3,282	$148,181	3,445	$160,074	3,076	$136,690
Institutional Awards	12,446	656,284	12,474	683,217	11,203	600,818
Total Research Training	15,728	$804,466	15,919	$843,291	14,279	$737,508
Research & Develop. Contracts	2,716	$2,915,277	2,509	$2,911,704	1,965	$2,489,201
(SBIR/STTR) (non-add)[2]	*(114)*	*(66,841)*	*(118)*	*(71,943)*	*(76)*	*(61,829)*
Intramural Research	6,884	$3,684,875	6,986	$3,672,888	7,009	$3,064,128
Res. Management & Support	5,410	1,653,326	5,762	1,718,144	5,947	1,576,596
Res. Management & Support (SBIR Admin) (non-add)[2]		*(3,427)*		*(6,187)*		*(26,285)*
Office of the Director - Appropriation[2,5]		*(1,570,790)*		*(1,620,212)*		*(1,452,433)*
Office of the Director - Other		599,368		650,485		777,199
ORIP (non-add)[2,5]		*(295,784)*		*(295,373)*		*(220,811)*
Common Fund (non-add)[2,5]		*(675,639)*		*(674,355)*		*(454,423)*
Buildings and Facilities[6]		144,863		144,618		108,615
Appropriation		*(128,863)*		*(128,618)*		*(98,615)*
Type 1 Diabetes[7]		-150,000		-139,650		-150,000
Program Evaluation Financing[8]		-780,000		-780,000		-780,000
Subtotal, Labor/HHS Budget Authority		**$31,304,000**		**$31,596,489**		**$25,823,557**
Interior Appropriation for Superfund Research		77,349		77,202		59,607
Total, NIH Discretionary B.A.		**$31,381,349**		**$31,673,691**		**$25,883,164**
Type 1 Diabetes and PCORTF[9]		150,000		139,650		256,546
Total, NIH Budget Authority		**$31,531,349**		**$31,813,341**		**$26,139,710**
Program Evaluation Financing		780,000		780,000		780,000
Total, Program Level		**$32,311,349**		**$32,593,341**		**$26,919,710**

1 All Subtotal and Total numbers may not add due to rounding.
2 All numbers in italics and brackets are non-add.
3 Excludes Ebola-related and Zika-related supplemental appropriations.
4 Includes 21st Century Cures Act funding.
5 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as a non-add. The Office of the Director - Appropriations also is noted as a non-add because the remaining funds are accounted for under OD - Other.
6 Includes B&F appropriation and funds for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
7 Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/ HHS Budget Authority.
8 Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.
9 Patient-Centered Outcomes Research Trust Fund included in FY 2018.
10 Includes funding for the National Institute for Research on Safety and Quality; does not include funding for the Fogarty International Center.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING TYPE 1 DIABETES

(Dollars in Thousands)

Object Classes[1]	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Personnel Compensation			
Full-Time Permanent (11.1)	$970,208	$1,019,972	$49,764
Other Than Full-Time Permanent (11.3)	513,855	527,274	13,419
Other Personnel Compensation (11.5)	37,284	37,897	613
Military Personnel (11.7)	19,634	20,335	701
Special Personnel Services Payments (11.8)	168,106	160,094	-8,012
Subtotal Personnel Compensation (11.9)	**$1,709,088**	**$1,765,572**	**$56,484**
Civilian Personnel Benefits (12.1)	496,048	517,663	21,614
Military Personnel Benefits (12.2)	12,195	12,465	270
Benefits to Former Personnel (13.0)	0	1,401	1,401
Total Pay Costs	**$2,217,332**	**$2,297,101**	**$79,769**
Travel & Transportation of Persons (21.0)	52,935	32,559	-20,376
Transportation of Things (22.0)	5,080	2,905	-2,175
Rental Payments to GSA (23.1)	22,601	17,763	-4,838
Rental Payments to Others (23.2)	670	575	-95
Communications, Utilities & Misc. Charges (23.3)	26,024	17,986	-8,038
Printing & Reproduction (24.0)	553	563	11
Consultant Services (25.1)	165,798	120,171	-45,627
Other Services (25.2)	1,129,791	789,382	-340,409
Purchase of goods and services from government accounts (25.3)	3,105,529	2,662,063	-443,465
Operation & Maintenance of Facilities (25.4)	214,987	166,880	-48,107
R&D Contracts (25.5)	1,457,191	1,256,380	-200,811
Medical Care (25.6)	33,662	20,614	-13,048
Operation & Maintenance of Equipment (25.7)	117,081	80,194	-36,887
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services (25.0)	**$6,224,039**	**$5,095,685**	**-$1,128,354**
Supplies & Materials (26.0)	212,378	114,274	-98,104
Equipment (31.0)	168,253	97,180	-71,073
Land and Structures (32.0)	145	133	-13
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	22,805,793	18,296,501	-4,509,292
Insurance Claims & Indemnities (42.0)	25	25	0
Interest & Dividends (43.0)	310	306	-4
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$29,518,807**	**$23,676,456**	**-$5,842,352**
Total Budget Authority	**$31,736,139**	**$25,973,557**	**-$5,762,583**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related and Zika-related supplemental appropriations, Program Evaluation Financing, and Patient-Centered Outcomes Research Trust Fund.

BUDGET AUTHORITY BY OBJECT CLASS INCLUDING SSF AND MF

(Dollars in Thousands)

Object Classes[1]	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Personnel Compensation			
Full-Time Permanent (11.1)	$1,328,462	$1,385,211	$56,750
Other Than Full-Time Permanent (11.3)	581,024	595,753	14,729
Other Personnel Compensation (11.5)	62,428	63,506	1,078
Military Personnel (11.7)	28,623	29,519	896
Special Personnel Services Payments (11.8)	174,105	166,198	-7,907
Subtotal Personnel Compensation (11.9)	**$2,174,642**	**$2,240,187**	**$65,545**
Civilian Personnel Benefits (12.1)	640,409	665,288	24,879
Military Personnel Benefits (12.2)	18,764	19,165	401
Benefits to Former Personnel (13.0)	1,105	2,506	1,401
Total Pay Costs	**$2,834,920**	**$2,927,146**	**$92,227**
Travel & Transportation of Persons (21.0)	56,149	35,774	-20,376
Transportation of Things (22.0)	6,511	4,336	-2,175
Rental Payments to GSA (23.1)	85,594	80,756	-4,838
Rental Payments to Others (23.2)	91,695	91,600	-95
Communications, Utilities & Misc. Charges (23.3)	144,362	136,324	-8,038
Printing & Reproduction (24.0)	558	568	11
Consultant Services (25.1)	187,613	141,986	-45,627
Other Services (25.2)	1,838,991	1,494,773	-344,218
Purchase of goods and services from government accounts (25.3)	1,007,001	558,062	-448,939
Operation & Maintenance of Facilities (25.4)	304,753	256,646	-48,107
R&D Contracts (25.5)	1,457,691	1,256,875	-200,816
Medical Care (25.6)	42,782	29,549	-13,233
Operation & Maintenance of Equipment (25.7)	268,138	230,701	-37,437
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services (25.0)	**$5,106,969**	**$3,968,592**	**-$1,138,377**
Supplies & Materials (26.0)	338,692	238,703	-99,989
Equipment (31.0)	211,256	140,182	-71,073
Land and Structures (32.0)	147	134	-13
Investments & Loans (33.0)	0	0	0
Grants, Subsidies & Contributions (41.0)	22,858,785	18,348,944	-4,509,842
Insurance Claims & Indemnities (42.0)	30	30	0
Interest & Dividends (43.0)	472	468	-4
Refunds (44.0)	0	0	0
Subtotal Non-Pay Costs	**$28,901,220**	**$23,046,410**	**-$5,854,809**
Total Budget Authority	**$31,736,139**	**$25,973,557**	**-$5,762,583**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related and Zika-related supplemental appropriations, Program Evaluation Financing, and Patient-Centered Outcomes Research Trust Fund.

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Classes[1]	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Personnel Compensation			
Full-Time Permanent (11.1)	$970,208	$1,019,972	$49,764
Other Than Full-Time Permanent (11.3)	513,855	527,274	13,419
Other Personnel Compensation (11.5)	37,284	37,897	613
Military Personnel (11.7)	19,634	20,335	701
Special Personnel Services Payments (11.8)	168,106	160,094	-8,012
Subtotal Personnel Compensation (11.9)	**$1,709,088**	**$1,765,572**	**$56,484**
Civilian Personnel Benefits (12.1)	496,048	517,663	21,614
Military Personnel Benefits (12.2)	12,195	12,465	270
Benefits to Former Personnel (13.0)	0	1,401	1,401
Total Pay Costs	**$2,217,332**	**$2,297,101**	**$79,769**
Travel & Transportation of Persons (21.0)	52,935	32,559	-20,376
Transportation of Things (22.0)	5,080	2,905	-2,175
Rental Payments to Others (23.2)	670	575	-95
Communications, Utilities & Misc. Charges (23.3)	26,024	17,986	-8,038
Printing & Reproduction (24.0)	553	563	11
Other Contractual Services:			
Consultant Services (25.1)	163,067	118,121	-44,946
Other Services (25.2)	1,129,791	789,382	-340,409
Purchase of goods and services from government accounts (25.3)[2]	2,290,328	1,966,018	-324,310
Operation & Maintenance of Facilities (25.4)	198,987	156,880	-42,107
Operation & Maintenance of Equipment (25.7)	117,081	80,194	-36,887
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$3,899,254**	**$3,110,595**	**-$788,659**
Supplies & Materials (26.0)	212,378	114,274	-98,104
Subtotal Non-Pay Costs	**$4,196,894**	**$3,279,458**	**-$917,436**
Total Salaries and Expense / Administrative Costs	**$6,414,226**	**$5,576,559**	**-$837,667**

[1] Excludes the Superfund Research account under the jurisdiction of the Interior & Related Agencies Appropriations Subcommittee, Ebola-related and Zika-related supplemental appropriations, Program Evaluation Financing, and Patient-Centered Outcomes Research Trust Fund.

[2] 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 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
NCI	2,991	3,047	3,047
NHLBI	931	962	962
NIDCR	228	235	235
NIDDK	643	663	663
NINDS	520	532	532
NIAID	1,943	1,963	1,963
NIGMS	180	184	184
NICHD	546	557	557
NEI	256	273	273
NIEHS	642	662	662
NIA	403	434	434
NIAMS	227	227	227
NIDCD	137	140	140
NIMH	533	563	563
NIDA	383	382	382
NIAAA	234	238	238
NINR	96	96	96
NHGRI	346	349	349
NIBIB	97	102	102
NCATS	142	167	167
NCCIH	72	73	73
NIMHD	64	68	68
FIC	62	61	---
NLM	772	741	764
OD	686	781	799
NIRSQ[4]	---	---	247
OD - CS	865	841	841
CC	1,840	1,844	1,864
CSR	394	417	417
CIT	263	257	257
ORS	536	539	539
ORF	691	707	707
Central Services[1]	4,589	4,605	4,625
Total	**17,723**	**18,105**	**18,352**
PHS Trust Fund (non-add)[2]	*4*	*4*	*4*
CRADA (non-add)[3]	*5*	*5*	*5*
PCOR Trust Fund[4]	---	---	*13*
Grand Total	**17,723**	**18,105**	**18,365**

[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] FTE associated the discretionary component of NIRSQ are identified only in FY 2018, consistent with the timing of the reorganization. FTE associated with mandatory component of the NIRSQ budget are identified to the Patient Centered Outcomes Research (PCOR)Trust Fund.

HISTORY OF OBLIGATIONS BY INSTITUTE AND CENTERS

(Dollars in Thousands)	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015 [1]	FY 2016 Final	FY 2017 Annualized CR [6,7,8]	FY 2018 President's Budget [6,7,8]
NCI	$4,966,927	$5,098,147	$5,058,105	$5,062,763	$4,789,014	$4,932,368	$4,953,028	$5,206,169	$5,504,788	$4,474,222
NHLBI	$3,014,552	$3,093,501	$3,069,550	$3,073,302	$2,903,768	$2,988,415	$2,995,865	$3,109,062	$3,109,615	$2,534,803
NIDCR	$402,011	$412,527	$409,549	$409,947	$387,309	$397,833	$397,700	$412,788	$414,792	$320,749
NIDDK[2]	$1,911,795	$1,958,905	$1,942,155	$1,943,706	$1,837,027	$1,884,377	$1,899,140	$1,963,738	$1,954,550	$1,599,534
NINDS	$1,590,781	$1,633,568	$1,622,001	$1,623,344	$1,533,793	$1,588,899	$1,604,607	$1,692,830	$1,692,915	$1,355,998
NIAID	$4,400,398	$4,515,426	$4,478,595	$4,482,369	$4,235,094	$4,401,185	$4,417,558	$4,749,884	$4,621,127	$3,782,670
NIGMS[3]	$1,994,426	$2,048,112	$2,033,663	$2,425,522	$2,293,044	$2,366,429	$2,372,301	$2,508,868	$2,508,780	$2,185,509
NICHD	$1,292,929	$1,327,349	$1,317,682	$1,318,943	$1,246,140	$1,283,314	$1,286,869	$1,338,280	$1,337,255	$1,032,029
NEI	$687,350	$705,792	$700,781	$701,407	$657,055	$675,551	$676,764	$707,002	$714,542	$549,847
NIEHS[4]	$746,107	$774,008	$762,602	$763,225	$721,331	$743,002	$744,682	$769,730	$769,585	$593,144
NIA	$1,079,004	$1,108,208	$1,100,445	$1,120,391	$1,040,565	$1,171,656	$1,197,523	$1,596,005	$1,597,149	$1,303,541
NIAMS	$523,887	$538,028	$534,260	$534,791	$505,206	$520,314	$521,528	$540,874	$541,110	$417,898
NIDCD	$406,516	$418,001	$415,104	$415,500	$392,540	$404,237	$405,207	$422,311	$422,227	$325,846
NIMH	$1,454,377	$1,493,510	$1,477,257	$1,477,516	$1,396,006	$1,419,632	$1,433,651	$1,516,325	$1,545,447	$1,244,901
NIDA	$1,039,561	$1,066,909	$1,050,519	$1,051,410	$993,404	$1,017,957	$1,015,705	$1,048,971	$1,075,440	$864,998
NIAAA	$449,524	$461,544	$458,257	$458,665	$433,247	$446,282	$447,153	$466,713	$466,811	$361,356
NINR	$141,660	$145,420	$144,369	$144,500	$136,516	$140,553	$140,852	$145,701	$146,207	$113,688
NHGRI	$507,210	$524,131	$511,469	$512,258	$483,650	$498,076	$498,677	$512,486	$517,969	$399,622
NIBIB	$307,701	$316,028	$313,787	$337,728	$319,062	$326,989	$327,243	$342,997	$346,136	$282,614
NIMHD	$205,616	$211,194	$209,693	$275,927	$260,671	$268,439	$270,969	$280,264	$279,186	$214,723
NCRR	$1,224,629	$1,267,021	$1,257,641	---	---	---	---	---	---	---
NCCAM	$125,265	$128,615	$127,706	$127,820	$120,767	$124,368	$124,062	$129,760	$130,540	$101,793
NCATS	---	---	---	$574,297	$542,598	$633,571	$632,710	$684,366	$684,114	$557,373
FIC	$68,607	$69,957	$69,413	$69,493	$65,627	$67,575	$67,634	$69,996	$70,313	---
NLM[5]	$337,814	$348,467	$344,860	$373,087	$325,088	$334,383	$337,324	$393,074	$393,913	$373,258
ORIP	---	---	---	$303,525	$290,042	$294,486	$294,665	$295,783	$295,373	$220,811
Common Fund	$541,133	$544,028	$543,017	$544,930	$513,461	$531,146	$545,639	$675,628	$544,602	$454,423
OD - Other	$706,295	$632,966	$623,887	$608,713	$608,584	$477,293	$573,430	$599,263	$780,238	$777,199
B&F	$88,815	$203,056	$62,161	$125,308	$106,676	$88,880	$128,863	$79,883	$128,618	$98,615
NIRSQ Total	…	…	…	…	…	…	…	…	---	$378,546
Total, NIH Program Level	**$30,214,890**	**$31,044,418**	**$30,638,528**	**$30,860,387**	**$29,137,284**	**$30,027,205**	**$30,311,349**	**$32,258,751**	**$32,593,341**	**$26,919,710**
Less funds allocated from different sources:										
Mandatory Type 1 Diabetes Research	-$150,000	-$150,000	-$150,000	-$150,000	-$142,350	-$139,200	-$150,000	-$150,000	-$139,650	-$150,000
PHS Program Evaluation	-$8,200	-$8,200	-$8,200	-$8,200	-$8,200	-$8,200	-$715,000	-$780,000	-$780,000	-$780,000
NIRSQ Mandatory Financing										-$106,546
Total, NIH Discretionary Budget Authority	**$30,056,690**	**$30,886,218**	**$30,480,328**	**$30,702,187**	**$28,986,734**	**$29,879,805**	**$29,446,349**	**$31,328,751**	**$31,673,691**	**$25,883,164**
Interior Budget Authority	-$78,070	-$79,201	-$79,045	-$78,928	-$74,864	-$77,345	-$77,349	-$77,252	-$77,202	-$59,607
Total, NIH Labor/HHS Budget Authority	**$29,978,620**	**$30,807,017**	**$30,401,283**	**$30,623,259**	**$28,911,870**	**$29,802,460**	**$29,369,000**	**$31,251,499**	**$31,596,489**	**$25,823,557**

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

[2] Includes Mandatory Type 1 Diabetes Research funding.

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

[4] Includes Interior Appropriation for Superfund research.

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

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

[7] Includes projected awards funded from resources in FY 2017 and FY 2018 under the 21st Century Cures Act.

[8] FIC awards are included in FY 2017 and prior. NIRSQ awards are included in FY 2018.

HISTORY OF OBLIGATIONS BY TOTAL MECHANISM

(Dollars in Thousands)[1]	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual[3]	FY 2016 Actual[3]	FY 2017 Annualized C.R.[3]	FY 2018 President's Budget[3]
Research Project Grants	$15,688,339	$16,124,554	$16,501,300	$16,428,047	$16,550,486	$15,445,463	$16,168,246	$16,441,843	$17,836,992	$17,927,331	$14,188,712
Research Centers	$2,946,346	$3,018,710	$3,082,914	$3,009,480	$3,040,375	$2,708,744	$2,723,203	$2,663,064	$2,573,314	$2,496,279	$2,079,715
Other Research	$1,779,990	$1,775,387	$1,794,148	$1,802,937	$1,808,138	$1,783,481	$1,846,841	$1,802,719	$2,019,519	$2,151,400	$1,731,883
Subtotal, Research Grants	$20,414,675	$20,918,651	$21,378,362	$21,240,464	$21,398,999	$19,937,688	$20,738,290	$20,907,625	$22,431,825	$22,575,009	$18,000,310
Research Training	$770,480	$776,193	$775,186	$771,766	$761,934	$733,524	$738,429	$758,017	$804,466	$843,291	$737,508
R & D Contracts	$2,934,858	$3,069,412	$3,143,929	$2,996,640	$2,937,188	$2,927,077	$2,990,037	$2,826,971	$2,915,277	$2,911,704	$2,489,201
Intramural Research	$3,091,240	$3,222,852	$3,306,312	$3,330,815	$3,401,506	$3,247,193	$3,373,601	$3,409,362	$3,684,875	$3,672,888	$3,064,128
Res. Mgt. & Support	$1,372,225	$1,428,138	$1,509,287	$1,517,630	$1,530,874	$1,485,575	$1,527,131	$1,619,784	$1,653,326	$1,718,144	$1,576,596
Office of the Director	$523,798	$616,639	$632,966	$623,887	$609,530	$608,584	$477,293	$573,328	$599,368	$650,485	$777,199
Subtotal	**$29,107,276**	**$30,031,885**	**$30,746,042**	**$30,481,202**	**$30,640,031**	**$28,939,641**	**$29,844,781**	**$30,095,088**	**$32,089,137**	**$32,371,521**	**$26,644,942**
Buildings & Facilities[2]	$135,147	$96,735	$210,975	$70,081	$133,228	$114,580	$96,880	$123,464	$144,863	$144,618	$108,615
Interior- Superfund	$77,531	$78,070	$79,201	$79,045	$78,928	$74,864	$77,345	$77,332	$77,349	$77,202	$59,607
PCORTF[4]	---	---	---	---	---	---	---	---	---	---	$106,546
Total	**$29,319,954**	**$30,206,690**	**$31,036,218**	**$30,630,328**	**$30,852,187**	**$29,129,085**	**$30,019,005**	**$30,295,884**	**$32,311,349**	**$32,593,341**	**$26,919,710**

[1] Obligations for actual years exclude lapse. Amounts for all years include special Type 1 Diabetes.

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

[3] Amounts include use of Program Evaluation financing resources that totaled $715.0 million in FY 2015 and $780.0 million in FY 2016, FY 2017, and FY 2018.

[4] Patient Centered Research Trust Fund (PCORTF) is included in FY 2018 consistent with reorganization of AHRQ within the NIH as an Institute.

PROGRAMS PROPOSED FOR ELIMINATION

John E. Fogarty International Center for Advanced Study in the Health Sciences

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.
Budget Authority (BA):

	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$69,996,000	$70,313,000	$0	-$70,313,000
FTE	62	61	0	-61

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

Program Descriptions and Accomplishments

The Fogarty International Center (FIC) supports and facilitates global health research conducted by U.S. and international investigators. FIC-supported programs encompass a wide range of diseases and needs, including HIV/AIDS; emerging infectious diseases, such as Ebola and Zika; non-communicable diseases, such as neurological disorders; and trauma and injury.

FIC supports research and research training programs for U.S. and low- and middle-income country (LMIC) scientists. Currently, FIC supports over 500 research and research training programs involving 100 universities. In FY 2016, FIC supported a total of 244 extramural grants, including 48 Research Project Grant (RPG) awards and 196 in Other Research grants. FIC's extramural program will support an estimated total of 312 grants in FY 2017, which includes approximately 62 RPG awards and 250 Other Research grants.

FIC's Research and Management Support (RMS) provides administrative, budgetary, logistical, and scientific support to review, award, and monitor research grants, training awards and, contracts. It encompasses strategic planning, coordination, and evaluation of FIC's programs; regulatory compliance; international coordination; international science policy; and liasions with other Federal agencies, Congress, and the public. Specific functions include an in-house epidemiology program performing mathematical modeling of infectious diseases; international program officers developing partnerships between U.S. scientists and institutions and their counterparts abroad to advance scientific research and training; identification of collaborative opportunities with foreign science funding agencies; support for all NIH international travel by issuing and tracking official government passports and international visas; review and approval of Notice of Foreign Travel requests; and the creation and coordination of office travel cables to U.S. Embassies.

Funding History

Fiscal Year	Amount
FY 2014	$67,577,000
FY 2015	$67,786,000
FY 2016	$69,996,000
FY 2017 CR	$70,313,000
FY 2018	$0

Budget Request

The FY 2018 Budget Request is $0.0, a decrease of $70.313 million from the FY 2017 Annualized CR. To help focus resources on the highest priority research and reorganize federal activities in a more effective manner, the Budget eliminates the Fogarty International Center. Approximately $25 million within the Office of the Director will be dedicated to coordinating global health research across the NIH, including issues regarding workforce development and engagement with NIH's international biomedical research partners.

National Institute for Research on Safety and Quality -- Health Information Technology Research Portfolio

Authorizing Legislation: Title III and IX and Section 947(c) of the Public Health Service Act.
Budget Authority (BA)[1]:

	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$21,500,000	$21,459,129	$0	-$21,459,129

[1]For this and all other tables related to Agency for Healthcare Research and Quality , the FY 2016 and FY 2017 columns contain information for the Agency for Healthcare Research and Quality and are provided for convenience and transparency. The FY 2018 President's Budget consolidates AHRQ's activities into NIH, and the FY 2018 column represents the request for the National Institute for Research on Safety and Quality.

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

Program Description and Accomplishments

In FY 2016, the Health IT portfolio within AHRQ funded $19.0 million in research grants to increase understanding of the ways health IT can improve health care quality. Early research efforts built the evidence base regarding facilitators and barriers to health IT adoption and the value of health IT implementation. Recent years' research grants included a focus on understanding how health IT can make care safer and how to ensure health IT safety and usability. Additionally, the Health IT portfolio supported the development and evaluation of health IT innovations ranging from mobile health applications to patient portals. Finally, $2.5 million in contract funds were used to support dissemination of health IT evidence.

In FY 2017, AHRQ's Health IT portfolio continued $19.0 million in grant funding to focus on supporting patient engagement. Another initiative for 2017 is exploring how health IT can improve health care quality and outcomes by enabling effective population health management and patient-centered care delivery and coordination; these grants will focus on applying data to facilitate bringing research evidence seamlessly into clinical practice to support shared decision making by patients and clinicians. Finally, FY 2017 funding will continue to disseminate health IT evidence at both healthit.ahrq.gov and healthit.gov, the HHS official website for health IT information.

Funding History within AHRQ

Fiscal Year	Amount
FY 2014	$29,572,000
FY 2015	$28,170,000
FY 2016	$21,500,000
FY 2017 CR	$21,459,129
FY 2018	$0

Budget Request

The FY 2018 Budget does not consolidate this activity of AHRQ's in NIH. The FY 2018 Budget Request is $0.0 million, a decrease of $21.459 million from AHRQ's FY 2017 Annualized CR. The goal of the reorganization is to focus resources on the highest priority research, reorganize federal activities in a more effective manner, and provide increased coordination on health services research activities and patient safety. The FY 2018 President's Budget ends dedicated funding for health IT. Instead, health IT research will compete for funding opportunities within patient safety and health services research to ensure the highest priority research is funded.

PHYSICIAN'S COMPARABILITY ALLOWANCE WORKSHEET

		FY 2016 Actual	FY 2017 Estimate	FY 2018 Estimate
1) Number of Physicians Receiving PCAs		161	147	147
2) Number of Physicians with One-Year PCA		23	19	19
3) Number of Physicians with Multi-Year PCA		138	128	128
4) Average Annual Physician Pay (without PCA payment)		$153,267	$152,320	$155,290
5) Average Annual PCA Payment		$11,909	$8,459	$8,624
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position			
	Category II Research Position	158	145	145
	Category III Occupational Health			
	Category IV-A Disability Evaluation			
	Category IV-B Health and Medical Admin.	3	2	2

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

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

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

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

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

In FY 2016, there was a total of 161 PCA recipients across NIH. In FY 2017 and beyond, a critical need will continue 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.

STATISTICAL DATA: DIRECT AND INDIRECT COST 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 2006	$15,219,138	$5,781,293	72.5%	27.5%	-1.3%	-0.2%
FY 2007	$15,387,745	$5,876,060	72.4%	27.6%	1.1%	1.6%
FY 2008	$15,295,950	$5,903,730	72.2%	27.9%	-0.6%	0.5%
FY 2009	$15,683,872	$6,027,543	72.2%	27.8%	2.5%	2.1%
FY 2010	$16,040,991	$6,193,567	72.1%	27.9%	2.3%	2.8%
FY 2011	$15,849,082	$6,173,769	72.0%	28.0%	-1.2%	-0.3%
FY 2012	$15,978,032	$6,182,900	72.1%	27.9%	0.8%	0.2%
FY 2013	$14,915,599	$5,755,617	72.2%	27.8%	-6.7%	-6.9%
FY 2014	$15,568,553	$5,908,275	72.5%	27.5%	4.4%	2.7%
FY 2015	$15,645,282	$6,020,843	72.2%	27.8%	0.5%	1.9%
FY 2016	$16,791,158	$6,445,133	72.3%	27.7%	7.3%	7.1%
FY 2017 Annualized CR [1,2]	$16,922,673	$6,495,627	72.3%	27.7%	0.8%	0.8%
FY 2018 President's Budget [1,2,3]	$16,882,774	$1,855,044	90.1%	9.9%	-0.2%	-71.4%

[1] FY 2017 and FY 2018 data represent estimates and will change as actual data is received.

[2] Includes 21st Century Cures Act funding.

[3] Includes funding for NIRSQ and excludes funding for FIC.

RESEARCH PROJECT GRANTS – TOTAL NUMBER OF AWARDS AND FUNDING

(Dollars in Thousands)	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016 Final	FY 2017 [2] Annualized CR	FY 2018 [2,3] President's Budget
No. of Awards:										
Competing	9,121	9,386	8,706	8,986	8,234	9,168	9,540	10,364	8,974	7,326
Noncompeting	26,217	25,738	26,166	25,631	25,140	23,504	23,261	23,528	24,595	24,499
Subtotal	35,338	35,124	34,872	34,617	33,374	32,672	32,801	33,892	33,569	31,825
SBIR/STTR	1,740	1,685	1,494	1,642	1,466	1,660	1,578	1,689	1,780	1,578
Total	**37,078**	**36,809**	**36,366**	**36,259**	**34,840**	**34,332**	**34,379**	**35,580**	**35,349**	**33,403**
Average Annual Cost:										
Competing	$427	$417	$427	$421	$418	$489	$452	$484	$485	$389
Total RPGs [1]	$438	$450	$453	$459	$444	$474	$479	$502	$508	$424
Percent Change over prior year										
Average Costs:										
Competing RPGs	13.2%	-2.4%	2.5%	-1.5%	-0.8%	17.0%	-7.5%	7.2%	0.1%	-19.7%
Total RPGs [1]	5.8%	3.0%	0.5%	1.4%	-3.3%	6.7%	1.2%	4.8%	1.2%	-16.6%
Average Length of Award in Years	**3.8**	**3.8**	**3.7**	**3.5**	**3.5**	**3.5**	**3.5**	**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] Includes 21st Century Cures Act funding.

[3] Includes funding for NIRSQ and excludes funding for FIC.

MANAGEMENT FUND

General Statement

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

Budget Authority by Activity
(Dollars in thousands)

	FY 2016 Final		FY 2017 Annualized CR		FY 2018 President's Budget		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:								
Clinical Center	1,839	$450,182	1,843	$482,936	1,863	$482,936	20	$0
Center for Scientific Review	394	127,402	417	144,016	417	129,614	0	(14,402)
Research Support and Administrative Services, OD 1/	60	29,380	0	0	0	0	0	0
Office of Research Services, Facilities, Development & Operations	543	68,412	539	82,075	539	73,868	0	(8,207)
TOTAL	**2,836**	**$675,376**	**2,799**	**$709,027**	**2,819**	**$686,418**	20	($22,609)

1/ The OD no longer has a MF Account in FY 2017.

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Management Fund

Detail of Positions

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	4	3	3
Total, ES Salary	$740,000	$567,998	$573,306
GM/GS-15	123	125	125
GM/GS-14	301	307	307
GM/GS-13	416	395	395
GS-12	501	496	496
GS-11	468	465	465
GS-10	26	26	26
GS-9	136	133	133
GS-8	122	121	121
GS-7	204	222	222
GS-6	53	55	55
GS-5	22	24	24
GS-4	11	11	11
GS-3	15	15	15
GS-2	9	9	9
GS-1	1	1	1
Subtotal	2,408	2,405	2,405
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	6	6	6
Senior Grade	22	22	22
Full Grade	19	19	19
Senior Assistant Grade	18	18	18
Assistant Grade	16	16	16
Subtotal	82	82	82
Ungraded	499	499	499
Total permanent positions	2,449	2,438	2,438
Total positions, end of year	2,993	2,989	2,989
Total full-time equivalent (FTE) employment, end of year	2,836	2,799	2,819
Average ES salary	185,100	189,333	191,102
Average GM/GS grade	11.5	11.3	11.4
Average GM/GS salary	94,980	97,145	98,095

SERVICE AND SUPPLY FUND

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

Budget Authority by Activity
(Dollars in thousands)

	FY 2016 Final		FY 2017 Annualized CR		FY 2018 President's Budget		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Detail:								
Research Support and Administrative	805	$961,286	841	$1,017,910	841	$916,119	0	($101,791)
Office of Research Facilities Development & Operations	684	457,279	707	484,143	707	435,729	0	(48,414)
Information Technology	263	352,216	257	372,996	257	335,696	0	(37,300)
Clinical Center	1	107	1	113	1	113	0	0
TOTAL	**1,753**	**$1,770,888**	**1,806**	**$1,875,162**	**1,806**	**$1,687,657**	0	($187,505)

1/ The OD no longer has a MF Account in FY 2017.

Detail of Positions

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	4	5	5
Total, ES Salary	$709,329	$894,960	$897,050
GM/GS-15	85	88	88
GM/GS-14	262	277	277
GM/GS-13	504	532	532
GS-12	265	291	291
GS-11	105	109	109
GS-10	2	2	2
GS-9	92	94	94
GS-8	30	31	31
GS-7	68	67	67
GS-6	13	15	15
GS-5	13	16	16
GS-4	19	14	14
GS-3	19	16	16
GS-2	6	6	6
GS-1	4	2	2
Subtotal	1,487	1,560	1,560
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	7	4	4
Senior Grade	3	3	3
Full Grade	6	5	5
Senior Assistant Grade	2	3	3
Assistant Grade	0	0	0
Subtotal	18	15	15
Ungraded	321	355	355
Total permanent positions	1,783	1,882	1,882
Total positions, end of year	1,830	1,935	1,935
Total full-time equivalent (FTE) employment, end of year	1,753	1,806	1,806
Average ES salary	177,332	178,992	179,410
Average GM/GS grade	11.8	11.8	11.8
Average GM/GS salary	96,092	96,986	98,199

COMMON FUND (CF)

	Final	Annualized CR	President's Budget
4D Nucleome	**24,680**	**27,940**	**19,476**
Technology Development, Biological Validation, Modeling and Pilot Mapping	9,968	10,169	7,955
Nucleomic, Imaging, and Computational Tool Development	9,968	9,991	6,912
4D Nucleome Coordination and Integration	4,744	7,779	4,608
Big Data to Knowledge (BD2K)	**62,666**	**74,136**	**34,855**
Extracellular RNA (ExRNA) Communication	**29,281**	**28,227**	**3,546**
Data Management and Resource/Repository (DMRR)	2,513	2,497	181
Reference Profiles of Human Extracellular RNA	4,074	4,043	3,223
Extracellular RNA Biogenesis, Biodistribution, Uptake, and Effector Function	7,533	7,223	48
Clinical Utility of Extracellular RNAs as Biomarkers and Therapeutic Agents	15,160	14,465	95
Gabriella Miller Kids First Pediatric Research	**13,128**	**12,970**	**12,944**
Health Care Systems Research Collaboratory	**11,774**	**11,335**	**4,528**
NIH-HMORN Coordinating Center	1,945	1,615	1,355
Expansion Activities	9,829	9,720	3,173
High-Risk, High-Reward Research	**163,432**	**153,465**	**153,804**
NIH Director's Pioneer Award	19,162	24,528	24,528
NIH Director's New Innovator Award Program	94,878	90,274	90,613
Transformative Research Award	28,566	17,557	17,557
NIH Director's Early Independence Award Program	20,826	21,106	21,106
Human BioMolecular Atlas Project (HuBMAP)	**0**	**0**	**5,680**
Illuminating the Druggable Genome (IDG)	**5,740**	**846**	**7,560**
Knowledge Management Network	3,219	560	1,307
Technology Development	2,521	15	0
Data and Resource Generation Centers	0	216	5,812
Dissemination and Outreach Hub	0	55	441
Metabolomics	**19,431**	**10,381**	**9,920**
Comprehensive Metabolomics Research Cores	9,176	5,840	9,920
Interdisciplinary Training in Metabolomics	3,274	15	0
Metabolomics Technology Development	1,995	30	0
Metabolomics Reference Standards Synthesis	1,929	1,946	0
Metabolomics Data Sharing and Program Coordination Core	3,057	2,550	0
Molecular Transducers of Physical Activity in Humans	**225**	**3,899**	**21,033**
Study Coordination and Data Management	180	1,542	3,127
Molecular Transducers of Physical Activity in Humans – Clinical Study	0	1,380	7,786
Chemical Analysis of Biological Samples	45	854	8,976
Characterization of Human Molecular Transducers of Physical Activity in Model Systems	0	123	1,144
Protein Capture Reagents	**207**	**1,005**	**2,000**
Antigen Production	50	0	0
Production of anti-TF antibodies	96	1,000	2,000
New Reagent Technology Development and Piloting	60	5	0
Regenerative Medicine Program (RMP)	**7,971**	**7,250**	**5,250**
NIH Center for Regenerative Medicine (NCRM)	54	0	0
Cell Therapy Projects	1,748	1,250	0
Stem Cell Translation Laboratory (SCTL)	6,169	6,000	5,250
Science of Behavior Change (SOBC)	**5,949**	**9,085**	**8,448**
Stimulating Peripheral Activity to Relieve Conditions (SPARC)	**21,267**	**42,068**	**37,781**
Functional and Anatomical Mapping of Five Organ Systems	14,960	21,890	15,855
Next Generation Tools	4,512	10,174	9,671
Off-Label Use of Existing Market-Approved Technology for Small Markets	1,713	7,866	7,385
Data Coordination	83	2,140	4,871
Strengthening the Biomedical Research Workforce	**6,602**	**6,684**	**2,447**
Transformative High Resolution Cryo-Electron Microscopy (CryoEM)	**0**	**0**	**6,080**
Undiagnosed Diseases Network (UDN)	**30,799**	**29,600**	**24,640**
Undiagnosed Diseases Program Network	29,899	28,785	24,640
Training in the Use of Contemporary Genomic Approaches to Rare Disease Diagnostics	900	815	0

Common Fund by Initiative
(Dollars in Thousands)

(Dollars in Thousands)	FY 2016 Final	FY 2017 Annualized CR	FY2018 President's Budget
Enhancing the Diversity of the NIH-Funded Workforce	**51,751**	**53,004**	**41,275**
BUILD Initiative	46,949	49,340	38,324
National Research Mentoring Network (NRMN)	1,434	2,436	1,963
Coordination and Evaluation Center (CEC)	3,368	1,228	988
Epigenomics	**4,322**	**4,000**	**73**
Genotype-Tissue Expression (GTEx)	**4,113**	**1,251**	**0**
Global Health	**13,303**	**15,530**	**12,741**
Medical Education Partnership Initiative (MEPI)	3,000	3,000	2,410
Human Heredity and Health in Africa (H3Africa)	8,478	10,182	8,493
Household Air Pollution Investigation Network (HAPIN)	1,825	2,348	1,838
Glycoscience	**19,836**	**20,552**	**17,319**
Health Economics	**5,317**	**3,406**	**54**
Changing Incentives for Consumers, Insurers, and Providers	84	146	41
Science of Structure, Organization, and Practice Design in the Efficient Delivery of Healthcare	2,427	1,567	0
Economics of Prevention	2,392	1,177	0
Data Infrastructure to Enable Research on Health Reform	415	517	14
Human Microbiome Project	**154**	**158**	**0**
Knockout Mouse Phenotyping Program	**8,000**	**11,000**	**8,850**
Data Coordination	1,262	1,262	1,011
Production, Characterization, Cryopreservation, Phenotyping, and Data Release	6,738	9,738	7,839
All of Us **Research Program** [1]	**130,000**	**129,753**	**0**
Single Cell Analysis	**14,330**	**45**	**0**
Pilot Studies to Evaluate Cellular Heterogeneity	6,026	22	0
Exceptionally Innovative Tools and Technologies for Single Cell Analysis	2,924	0	0
Accelerating the Integration and Translation of Technologies to Characterize Biological Processes at the Single Cell Level	5,380	23	0
Single Cell Analysis Challenges	0	0	0
Library of Integrated Network-Based Cellular Signatures (LINCS)	**9,964**	**9,964**	**7,999**
Nanomedicine	**25**	**0**	**0**
Regulatory Science	**4,000**	**0**	**0**
Strategic Planning Funds	7,372	6,800	6,120
Subtotal Common Fund	675,639	674,355	454,423
New Initiatives in Common Fund	0	0	0
Total Common Fund	675,639	674,355	454,423

[1] Requested in the Office of the Director but outside the Common Fund in FY 2018.

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 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$675,639,000	$674,355,000	$454,423,000	-$219,932,000
FTE	0	0	0	0

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

Overview

The NIH Common Fund (CF) supports research in areas of emerging scientific opportunities, rising public health challenges, and knowledge gaps that deserve special emphasis; that would benefit from strategic coordination and planning across NIH Institutes and Centers (ICs); and that are designed to address specific, high-impact goals and milestones within a 5- to 10-year timeframe.[70] Collectively, these programs represent strategic investments aimed at solving problems or building resources to affect research throughout the entire biomedical research enterprise. CF programs attempt to change the way science is conducted through the establishment of new scientific fields or paradigms, the development of new and innovative technologies that change the way scientists approach their work, or the generation of comprehensive data sets or other resources that catalyze all research and enable discovery.

Many CF programs support the NIH Director's priority themes for FY 2018:

1. Fundamental Science
2. Treatments and Cures
3. Health Promotion and Disease Prevention
4. Enhancing Stewardship

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 freed as programs end, move to other sources of support, or require decreased support as indicated by evaluative data will be available in FY 2018 for new challenges and opportunities.

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

Overall Budget Policy: The FY 2018 President's Budget Request for the CF is $454.423 million, a decrease of $219.932 million compared to the FY 2017 Annualized Continuing Resolution level. This decrease reflects an overall budget reduction in accordance with the President's Budget, and the transition of the *All of Us* Research Program out of the CF but still within the Office of the Director. The CF will continue to support high-priority research with trans-NIH relevance in FY 2018. As mature programs transition out of the CF, new programs are being established through strategic planning activities that identify potentially transformative areas of research where limited-term CF investment can have a catalytic impact.

Selected Program Descriptions and Accomplishments

CF supports approximately 30 programs, most of which consist of a series of integrated initiatives that collectively address a set of goals that aim 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. In accordance with the President's Budget Request, FY 2018 budgets for some CF programs are reduced by approximately 20 percent compared to the FY 2017 Annualized Continuing Resolution. Highlighted below are programs that exemplify the science to be supported in FY 2018, and/or which involve budget reductions significantly greater or less than 20 percent compared to FY 2017. Also included are CF programs that have achieved the goals set when program plans were originally developed, and have now identified additional scientific challenges and opportunities that will be addressed in a second stage of support. Several CF programs are planning to receive their final year of support in FY 2017, and thus are not requesting funds in FY 2018. These programs include Epigenomics[71], Genotype-Tissue Expression (GTEx)[72], and Health Economics[73]. Information on these programs and their accomplishments can be found on their program websites.

4D Nucleome

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 may not be randomly arranged within the nucleus. Research suggests that nuclear organization may play a role in cell function, but 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[74]. This program is developing technologies, resources, and data to enable the study of the 4D Nucleome. These include novel tools to explore the dynamic nuclear architecture and its role in gene expression, models to examine the relationship between nuclear organization and function in both normal

[71] https://commonfund.nih.gov/epigenomics/index
[72] https://commonfund.nih.gov/GTEx/index
[73] https://commonfund.nih.gov/Healtheconomics/index
[74] http://commonfund.nih.gov/4Dnucleome/index

development and disease, and reference maps of nuclear architecture in a variety of cells and tissues.

Big Data to Knowledge (BD2K)

As biomedical tools and technologies rapidly improve, researchers are producing and analyzing an ever-expanding amount of complex biological data called "big data." As one component of an NIH-wide strategy, CF, in concert with NIH ICs, is supporting the Big Data to Knowledge (BD2K) program[75]. The program goal is to facilitate broad use of biomedical big data, develop and disseminate analysis methods and software, enhance training in techniques associated with big data usage, and establish a network of collaborating centers of excellence. The expectation is that implementation of BD2K will result in sweeping cultural changes in the way the biomedical research community shares, accesses, queries, cites, and analyzes data. The program is working to make big data software innovations available and more user-friendly. It is also supporting innovative approaches to advance biomedical science using crowdsourcing and interactive digital media. In FY 2018, the program will enter a second stage, and will pilot making NIH-funded large datasets and associated computational tools findable, accessible, interoperable, and reusable in a shared space that multiple scientists can access remotely, such as the cloud.

Extracellular RNA (ExRNA) Communication

Ribonucleic acid (RNA) was once thought to exist in a stable form only inside cells, where it regulates gene expression by serving as an intermediate product in the process by which cells translate the information coded in genes into proteins that carry out all cellular functions. However, research indicates that RNAs can play a role in a variety of complex functions, including mechanisms of cell-to-cell communication via RNAs that are exported from the cell. The impact of these extracellular RNAs, or exRNAs, is currently unknown. The CF's Extracellular RNA Communication program capitalized on the opportunity to understand entirely new paradigms of information exchange based on the release, transport, uptake, and regulatory role of exRNAs[76]. The Extracellular RNA Communication program supported awards with the following aims: 1) to determine the biological principles that guide exRNA generation, secretion, uptake, and function; 2) to develop a catalogue of exRNAs found in healthy human body fluids; 3) to identify exRNA biomarkers that can be used to diagnose and monitor disease progression and response to therapy; 4) to develop and demonstrate the potential for clinical utility of exRNAs as therapeutic agents; and 5) to develop a community-wide resource for exRNA standards, protocols, and data. In FY 2018, the success of several of the initiatives will allow them to transition to IC support while profiling and data coordination efforts will be maintained within the CF.

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

[75] https://commonfund.nih.gov/bd2k/index
[76] https://commonfund.nih.gov/Exrna/index

community[77]. The Kids First program will support a data resource that will integrate data from patients with childhood cancer or structural birth defects, conditions which have profound, lifelong effects on patients and their families. The fields of pediatric oncology and developmental biology, which studies disorders like birth defects, have made major discoveries that have advanced our understanding of disease and development. However, while we know that genetic mutations can lead to cancer and can also lead to birth defects, we do not know how these mutations lead to disease. By sequencing the genomes of patients along with their parents, we will have a full picture of the genetic contributions to these conditions. This genetic information, in combination with other clinical data, will help researchers understand how genetic mutations lead to birth defects or to cancer, as well as understanding whether there are shared contributions to both conditions. There is considerable scientific evidence that examining childhood cancer and structural birth defects data together will uncover new connections between them that would not have been discovered if they were examined independently. Having these data sets together in a single, widely accessible resource is anticipated to facilitate new discoveries and novel ways of thinking about these conditions. Importantly, the Kids First Data Resource will aggregate Kids First-generated data together with many additional existing data sets, thus increasing researchers' ability to detect rare genetic changes that contribute to these conditions. In FY 2018, the program intends to support activities to establish and grow the Kids First Data Resource. This includes additional sequencing of genomes of participants in childhood cancer or structural birth defect research cohorts as well as support for the DNA sequencing center. It also includes an initiative to develop, build, and maintain a user-friendly interface that will facilitate data mining and analysis by the scientific community.

Health Care Systems Research Collaboratory

The Health Care Systems (HCS) Research Collaboratory program aims to strengthen the national capacity to implement cost-effective, large-scale research studies that engage health care delivery organizations as research partners[78]. This program will provide a framework of implementation methods and best practices that will enable the participation of many health care systems in clinical research. These methods and practices are being tested and honed within the context of pragmatic clinical trials, which measure the effectiveness of treatments in real world settings. A Coordinating Center serves as the central resource for the development of guidelines and best practices for the effective conduct of research studies in partnership with health care systems. The HCS Research Collaboratory also supports efficient, large-scale pragmatic clinical trials focused on the management of patients with multiple chronic health conditions. The pragmatic trials must address questions of major public health impact and test interventions that can be applied broadly to the patient population and are suitable for use in many health care systems, with the broad goal of determining whether the interventions improve health outcomes of patients with multiple chronic conditions. In FY 2018, CF support for HCS Research Collaboratory decreases with the planned ramping down of current pragmatic clinical trial efforts. IC support for a new round of pragmatic clinical trials will begin in FY 2018. Lessons learned from these trials will be disseminated to the broad biomedical research community.

[77] https://commonfund.nih.gov/KidsFirst
[78] https://commonfund.nih.gov/hcscollaboratory/index

High-Risk, High-Reward Research

Research that aims to transform science is inherently difficult and risky but necessary to accelerate the pace of scientific discovery and advance human health. While all CF programs encourage risk-taking to overcome significant challenges in biomedical research, most programs designate funds for particular high-risk objectives or methods. The High-Risk, High-Reward Research (HRHR) program takes a different approach by supporting exceptionally creative scientists proposing innovative and transformative research in any scientific area within the NIH mission through four complementary initiatives: the Pioneer Award, New Innovator Award, Transformative Research Award, and Early Independence Award.[79] 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.

Partially as a response to an evaluation of the Pioneer program that demonstrated high levels of innovation and impact, we initiated a budget policy for the HRHR program in 2013 in which Pioneer and Transformative Research Awards were co-funded between the CF and ICs. This led to a gradual decrease in the CF HRHR budget as ICs paid non-competing commitments on new awards. Although this policy reflected enthusiasm voiced by IC Directors about these initiatives, the budget policy has been difficult to implement in practice since the work supported by these grants often falls at the interface of multiple ICs. In addition, some ICs have developed their own person-based awards to support outstanding researchers. To stabilize the HRHR budget, the Common Fund began in FY 2016 to once again fully fund Pioneer and Transformative Research Awards. As new awards are issued each year, costs for each cohort will build on top of commitments from prior year awards.

[79] https://commonfund.nih.gov/highrisk/index

Program Portrait: Human BioMolecular Atlas Project (HuBMAP)

FY 2017 Level: $0.000 million
FY 2018 Level: $5.680 million
Change: +$5.680 million

This program is set to launch in FY 2018 using funds made available by the planned ending, or scaling-down, of other Common Fund programs.

Cells are the fundamental unit of life, but until recently, they could only be studied in large groups. New technologies now provide the opportunity to analyze individual cells and how they interact with each other to form a healthy or diseased tissue. Cells that were thought to be the same are now known to be different, which could have profound impact on disease diagnostics and treatment. These observations suggest that more in-depth analyses of individual cells in tissues are necessary to understand normal biology and disease processes, and ultimately provide targeted diagnostic and therapeutic approaches. Anticipated to launch in FY 2018, the Human BioMolecular Atlas Project (HuBMAP) program will involve partnerships within the NIH and with other funding organizations, including the Chan Zuckerberg Initiative (CZI) and the Wellcome Trust, to establish an international effort to analyze the human body at a single cell level. The HuBMAP contribution to this effort will support data generation and technology development to explore the relationship between cellular location and function and the variability in tissue organization at the level of individual cells. Data from the Common Fund-supported awards and from other efforts will be integrated through a data platform to be developed in partnership with the CZI.

Illuminating the Druggable Genome (IDG)

The overarching goal of the Illuminating the Druggable Genome (IDG) program is to improve knowledge of the properties and functions of understudied proteins that are related to known drug targets, and are thus likely candidates to be drug targets themselves.[80] This program is focusing on hundreds of understudied proteins within select protein families that are commonly targeted for drug development. Designed as a two-stage program, the pilot stage of the program created a data resource that will catalog known information about these protein families and establish strategies for obtaining further information about the function of these proteins so that investigators can determine whether a given protein is a likely target for a disease or condition of interest. In FY 2018, IDG will launch a second stage that will capitalize on the information gathered and technologies developed in the pilot stage to elucidate the function of three key families of uncharacterized proteins – G-protein-coupled receptors, ion channels, and protein kinases. Ultimately, this program will catalyze discovery of previously unknown processes that occur within cells to change their function, potentially leading to new candidates for therapeutic development.

Metabolomics

Metabolites are small molecules that are produced or consumed in the chemical reactions that take place in the body and sustain life. The sum of all metabolites at any given moment – the metabolome – is a form of big data "chemical read out" of the state of health of the cell or system, and provides a wealth of information about nutrition, effects of the environment, infection, health, and disease status. Recent advances in metabolomics technology have yielded important clues about disease mechanisms which suggest new opportunities for treatment

[80] https://commonfund.nih.gov/idg/index

strategies. However, the use of these technologies is limited by the number of research centers that have the necessary equipment and expertise to conduct the studies, and the lack of standards for identifying the vast number of unknown metabolites. The Metabolomics program is intended to establish the needed resources, training, and technology development to catalyze the field of metabolomics to advance basic scientific discovery and its use in clinical practice.[81] It also facilitates the dissemination of data generated by the program through an informatics component and by working with the international community. This will ensure that CF investments are also leveraging investments in other countries, resulting in increased data sharing, a uniform system to name metabolites, reduced redundancy of effort, and faster translation toward improvements in health. In FY 2018, a second stage of the Metabolomics program will begin. As the research facilities established in the first stage move to a fee-for-service model of sustainability, the Common Fund investments in the second stage will focus on establishing the data infrastructure for metabolomics data sharing. A data hub will be established with the goal of making all NIH-supported metabolomics data publicly available, and computational tools will facilitate analysis and interpretation of the complex data sets.

Molecular Transducers of Physical Activity in Humans

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[82]. 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. After a planning year in FY 2017, the awardees will ramp up their efforts significantly in FY 2018.

Protein Capture Reagents

The Protein Capture Reagents program is developing resources and tools necessary to better understand the critical roles proteins within cells play in development, health, and disease[83]. Monoclonal antibodies are currently used to capture proteins so they can be studied, but many monoclonal antibodies do not target a single specific protein, are not reliably reproduced, and only represent a small subset of all human proteins. A renewable resource of protein capture reagents is needed to advance the study of human proteins and fuel biomedical research. To

[81] https://commonfund.nih.gov/metabolomics/index
[82] https://commonfund.nih.gov/MolecularTransducers
[83] https://commonfund.nih.gov/proteincapture/index

have the maximum benefit, such reagents would need to be high quality, affordable, reliable, and represent the wide range of possible proteins within cells and tissues. The Protein Capture Reagents program piloted an effort focused on producing such reagents for an important class of proteins called human transcription factors, and tested renewable, next generation capture technologies. The effort produced needed reagents and established a community resource capable of generating protein capture reagents for future research. Currently, the program is focused on validating the generated human transcription factor reagents and making them available to the research community.

Regenerative Medicine Program (RMP)

The Regenerative Medicine Program (RMP) aims to work through scientific and regulatory hurdles to the development of induced pluripotent stem cells (iPSCs) for clinical use[84]. iPSCs are generated by coaxing adult cells into reverting back to an embryonic stem cell-like state, which then can generate many different cell types for use in screening or developing therapies. The goal of RMP is to serve as a national resource for stem cell science to accelerate the development of new medical applications and cell-based therapies. RMP is pursuing this goal through two initiatives. In the first initiative, RMP is supporting a Therapeutic Challenge award to advance efforts to develop iPSCs as therapy for age-related macular degeneration, a leading cause of blindness in the elderly. Additionally, in the second initiative, RMP is supporting the Stem Cell Translation Laboratory (SCTL) at the National Center for Advancing Translational Science. The SCTL will establish quality control standards, methods, and reagents to enable the research community to generate and study iPSCs, moving the field of iPSC research closer to therapeutic applications.

Science of Behavior Change (SOBC)

Unhealthy human behaviors, such as smoking, drug and alcohol abuse, over-eating, and failure to exercise, all contribute to negative health outcomes and common diseases. However, it is extremely difficult not only to implement healthy behavior changes, but to maintain positive changes over an extended period of time. Uncovering the basic foundations of how motivation changes across a broad array of health-related behaviors can lead to more effective and efficient approaches to behavioral interventions, with the ultimate goal of improving the Nation's health. The first stage of the Science of Behavior Change (SOBC) program aimed to improve understanding of the basic mechanisms of human behavior change across a broad range of health-related behaviors and use this knowledge to develop more effective behavioral interventions[85]. Research funded by the first stage led to the identification of three broad classes of intervention targets that are highly relevant to understanding the mechanisms of behavior change: self-regulation, stress reactivity and resilience, and interpersonal and social processes. The second stage of the SOBC program, which began in FY 2015, is developing measures and techniques that afford a more mechanistic, experimental medicine approach to behavior change. Interventions are designed to engage the specific targets identified in the first stage of the program, and engagement of those targets is assessed via reliable and validated assays. This approach provides a more reliable way to develop behavioral interventions, as well as a more

[84] https://commonfund.nih.gov/stemcells/index
[85] https://commonfund.nih.gov/behaviorchange/index

robust way to measure their effectiveness. The program includes a focus on adherence to medical regimens, a problem area that could benefit from this target engagement approach. In FY 2018, existing SOBC awardees will begin to disseminate information about validated targets and assays to the greater behavioral research community, and new awards will enable researchers to incorporate this rigorous approach across a wide range of behavioral health studies.

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

Bioelectronic medicine, which refers to neuromodulation of peripheral nerve signals to control organ function, has been recognized as a potentially powerful way to treat many diseases and conditions, such as hypertension, heart failure, gastrointestinal disorders, type II diabetes, inflammatory disorders, and more. However, neural control of end-organ function is poorly understood. Consequently, efficacy of neuromodulation therapies has been inconsistent and side effects are difficult to predict. The Stimulating Peripheral Activity to Relieve Conditions (SPARC) program is a high-risk, goal-driven basic research endeavor to develop foundational knowledge and technologies for an entirely new class of therapeutic devices that have the potential to precisely treat a wide variety of diseases and conditions.[86] Launched in FY 2015, the SPARC program supports interdisciplinary teams of investigators to deliver neural circuit maps that illustrate how peripheral nerves control organ function, along with technologies to isolate, measure, and manipulate nerve-organ interactions and their functions. Because these activities are driven by an end goal to catalyze development of next-generation neuromodulation therapies, all SPARC comprehensive mapping projects involve validation in human tissues. The program is designed to be iterative and dynamic, with the novel technologies informing mapping efforts, and mapping results defining new technology requirements. This program uses Other Transaction Authority for selected initiatives, which allows high levels of flexibility, responsiveness to adjust program components, and ability to engage with non-traditional partners as needed to address specific, high-risk goals within this complex, interdisciplinary, and rapidly evolving area of science. While distinct from the NIH BRAIN initiative and DARPA's ElectRx program, SPARC shares approaches with BRAIN and ElectRx so that all three programs will likely benefit from innovations made in the others. These initiatives are therefore being closely coordinated with NIH and DARPA staff. In FY 2018, SPARC will continue to progress toward its goals, investing in technology development, anatomical and functional mapping, exploring the utility of existing neuromodulation technologies for new purposes, leveraging partnerships with industry and physicians to learn from clinical studies in humans, and launching a publicly available online resource through which research tools and advancements will be shared.

Strengthening the Biomedical Research Workforce

The Strengthening the Biomedical Research Workforce program aims to enhance training opportunities for early career scientists to prepare them for a variety of career options in the dynamic biomedical research workforce landscape[87]. This program is supporting the Broadening Experiences in Scientific Training (BEST) awards to develop innovative approaches to complement traditional research training in biomedical sciences. Awardee institutions are collaborating with non-academic partners to ensure that experts from a broad spectrum of

[86] https://commonfund.nih.gov/sparc/index
[87] https://commonfund.nih.gov/workforce/index

research and research-related careers contribute to coursework, rotations, internships, and other forms of exposure for trainees. Awardee institutions are working together to define needs and share best practices so that proven approaches can be broadly disseminated and adopted by the biomedical research training community. NIH is taking an active role in evaluating the approaches developed by this program by conducting an evaluation across all BEST sites in order to share this evidence base with the training community. The first cohort of grantees from the Workforce program will receive their final year of funding in FY 2017, leaving the remaining cohort of grantees to receive their final year of funding in FY 2018.

Program Portrait: Transformative High Resolution Cryo-Electron Microscopy (CryoEM)

FY 2017 Level: $0.000 million
FY 2018 Level: $6.080 million
Change: +$6.080 million

This program is set to launch in FY 2018 using funds made available by the planned ending, or scaling-down, of other Common Fund programs.

Structure determines function in biology. Therefore, knowing the structures of biological molecules is essential to understanding how they work normally to confer health and how they go awry to produce disease. Recent advances in a technology called high resolution cryo-electron microscopy (cryoEM) have revolutionized the field of structural biology. CryoEM allows visualization of frozen biological samples without using dyes or fixatives that can alter the structure of molecules, enabling researchers to get a more accurate picture of these molecules and better understand their function. The structure determination of proteins and protein complexes once thought to be too daunting have now become feasible. However, adoption of cryoEM in the US, and therefore the ability of the US to stay at the forefront in structural biology, is limited by access to the necessary high-end cryo-electron microscopes and by the expertise to use them effectively. The Transformative High Resolution Cryo-Electron Microscopy (CryoEM) program works to build the national capacity and infrastructure for cryoEM through the development of comprehensive resource centers and by creating training opportunities to develop a large expert workforce in the most recent cryoEM advances. The program also will invest in improving technologies to make them more sensitive, practical and affordable.

Undiagnosed Disease Network (UDN)

It is estimated that rare diseases affect 25 to 30 million Americans. Often times, because their diseases are so uncommon or have never been described before, these individuals go for long periods of time without a diagnosis, as do those with rare variants of common diseases. To aid in the diagnosis of rare and new diseases, the CF's Undiagnosed Diseases Network (UDN) established clinical and research sites at academic centers across the country.[88] The UDN builds upon the experience and expertise of the NIH intramural Undiagnosed Diseases Program, established in 2008, and its cross-disciplinary approach to diagnosing both rare and new diseases. This Network is catalyzing the field of rare disease research by bringing state of the art medical and genomic approaches to bear on a myriad of diseases, bringing together basic and clinical researchers to elucidate underlying biological mechanisms, identify treatments and disease management strategies, and train the next generation of clinical researchers to use these approaches in disease diagnosis. The insights gained from understanding rare diseases may provide important clues about the pathology and potential treatments of a host of common diseases as well. In FY 2017, funding for the successful first stage of the UDN ended. In the

[88] https://commonfund.nih.gov/Diseases/index

second stage of the program, starting in FY 2018, the program will test additional diagnostic approaches and evaluate the long term sustainability of those approaches.

Strategic Planning and Evaluation

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

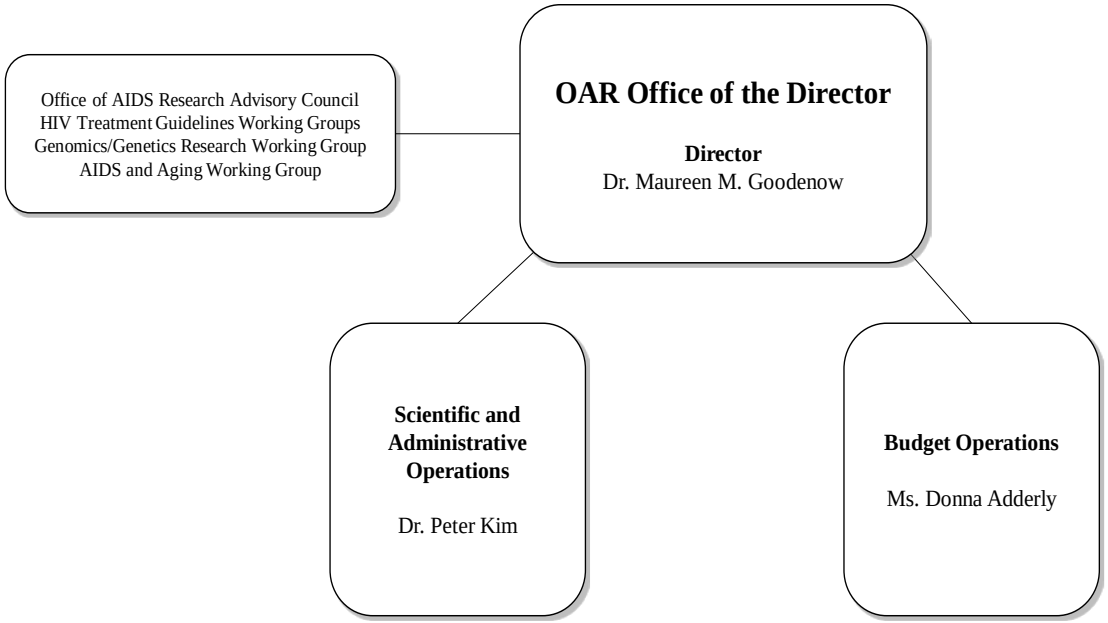
Since CF programs are goal driven, evaluation is critical and increasingly important as more programs near the end of their support period. Evaluation is conducted as a partnership between DPCPSI/OSC and the ICs, and it includes both formal and informal evaluative activities. Informal evaluation involves convening grantees and NIH-wide teams to review progress, discuss new challenges, and develop strategies to adapt as part of routine program management. It also involves gathering input from external consultants and using their input, together with internal analysis, to help guide the implementation of the program. Formal evaluations involve the development of baseline data for new programs and the development of multiple metrics of outcomes. The utility of data, resources, technologies, and other program outputs is assessed through surveys, expert opinion, and the analysis of bibliometric data such as citation analyses.

Funds Available for New Programs

As mature initiatives end or transition out of the CF, or as information gathered through evaluations indicates a need for decreased support of existing programs, funds are available to address new challenges. As described above, three existing CF programs are planning to launch a second stage of support beginning in FY 2018 (Illuminating the Druggable Genome, Metabolomics, and the Undiagnosed Disease Network). Additionally, two new programs, the Human BioMolecular Atlas Project (HuBMAP) and Transformative High Resolution Cryo-Electron Microscopy (CryoEM), are planned to launch in FY 2018. These programs were identified through the strategic planning process as being high priority for the NIH as a whole.

OFFICE OF AIDS RESEARCH

Trans-NIH HIV/AIDS Research Budget


Office of AIDS Research Advisory Council
HIV Treatment Guidelines Working Groups
Genomics/Genetics Research Working Group
AIDS and Aging Working Group
OAR Office of the Director
Director
Dr. Maureen M. Goodenow
Scientific and Administrative Operations
Dr. Peter Kim
Budget Operations
Ms. Donna Adderly

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

Institute / Center	FY 2016 Actual	FY 2017 Annualized Continuing Resolution	FY 2018 President's Budget	FY 2018 +/- FY 2017
NCI	$266,422	$267,105	$195,382	-$71,723
NHLBI	67,020	68,894	54,724	-14,170
NIDCR	18,015	20,163	14,167	-5,996
NIDDK	29,471	31,458	21,832	-9,626
NINDS	46,536	47,405	35,021	-12,384
NIAID	1,663,823	1,575,054	1,420,164	-154,890
NIGMS	53,194	52,730	41,273	-11,457
NICHD	144,736	145,912	113,339	-32,573
NEI	925	8,813	-	-8,813
NIEHS	5,342	5,501	4,201	-1,300
NIA	5,637	7,568	6,003	-1,565
NIAMS	4,587	5,056	3,607	-1,449
NIDCD	1,878	1,969	1,477	-492
NIMH	161,289	190,643	127,284	-63,359
NIDA	294,244	320,571	217,324	-103,247
NIAAA	28,404	28,604	22,336	-6,268
NINR	12,180	12,729	9,578	-3,151
NHGRI	1,531	7,246	722	-6,524
NIBIB	395	3,677	182	-3,495
NIMHD	21,674	20,673	15,865	-4,808
NCCIH	777	1,622	611	-1,011
NCATS	-	-	-	-
FIC	24,083	24,367	-	-24,367
NLM	8,822	7,787	6,938	-849
OD				
OAR	62,256	61,805	58,348	-3,457
ORIP	76,820	77,006	69,802	-7,204
Subtotal, OD	139,076	138,811	128,150	-10,661
TOTAL, NIH	**$3,000,061**	**$2,994,358**	**$2,440,180**	**-$554,178**

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

Overarching Priorities	FY 2014 Actual	FY 2015 Actual	FY 2016 Actual	FY 2017 Annualized Continuing Resolution	FY 2018 Presidents Budget	FY 2018 +/- FY 2017
Vaccine Research and Reducing the Incidence of HIV/AIDS	$1,057,257	$1,015,701	$1,042,552	$1,026,913	$860,412	-$166,501
Next Generation Therapies	535,391	587,432	478,335	487,255	380,097	-107,158
Research and Devlop a Cure for HIV/AIDS [1/]	---	161,045	230,653	212,250	192,608	-19,642
Improve Treatments for HIV-associated Comorbidities and Co-infections	600,646	585,909	564,094	570,327	467,596	-102,731
Crosscutting--Basic Research, Health Disparities, and Research Training	784,285	649,974	684,427	697,613	539,467	-158,146
Total	$2,977,579	$3,000,061	$3,000,061	$2,994,358	$2,440,180	-$554,178

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

Justification of Budget Request

Office of AIDS Research

Trans-NIH AIDS Research Budget Justification

(see also: OAR section in Office of the Director/DPCPSI)

Budget Authority (BA):

FY 2016 Actual	FY 2017 Annualized Continuing Resolution	FY 2018 President's Budget	FY 2018+/- FY 2017
$3,000,061,000	$2,994,358,000	$2,440,180,000	-$554,178,000

Director's Overview

Since the first discovery of the human immunodeficiency virus (HIV) as the cause of the acquired immunodeficiency syndrome (AIDS) in the 1980s, the HIV epidemic represents the most serious health crisis of our time, a critical and ongoing risk to the health of Americans and populations around the world. In the U.S., more than 1.2 million people are living with HIV infection, and approximately 108 new diagnoses of HIV infection are made daily. More than 36 million people globally live with HIV infection. HIV infection destroys the body's immune system and debilitates its ability to control infections, inflammatory syndromes, and cancer. HIV infection affects people of all ages, gender, and races, and also accelerates the risk of diseases often associated with aging such as heart and neurodegenerative diseases. Investment in HIV/AIDS research to date has led to unprecedented success in the development of diagnostics and multi-drug regimens that can effectively suppress HIV infection and reduce transmission. Additionally, HIV/AIDS research has stimulated significant advances in other related fields such as cancer, hepatitis, neurology, and molecular diagnostics. Unfortunately, despite the scientific advances, there is still no cure for HIV infection, rendering it a chronic disease requiring life-long, daily treatment. Drug-based strategies for the prevention of infection have proven successful, but a vaccine to prevent infection remains elusive. These challenges are reflected in the study of HIV/AIDS both domestically and globally.

HIV/AIDS Research and Translating Findings to Address Emerging Priorities: The U.S. investment in HIV/AIDS research through NIH spans the full spectrum of medical research from basic science to clinical trials, and has led to significant and dramatic advances, which have decreased new infections and saved millions of lives. According to the *HIV Surveillance Report* released by the CDC in 2015, between 2005-2014, the number of new HIV diagnoses in the U.S. declined 19 percent, which may be attributed to prevention efforts based on NIH-funded research. Despite this accomplishment, new infections continue, and by the end of 2014 an estimated 9,731 youth aged 13 to 24 were diagnosed with HIV. That same age group accounted for an estimated 22 percent of all new HIV diagnoses in the U.S., and has caused a change in the

demographics of the epidemic that will last for at least the next 10 years.[89] Inevitably, the youth and growing numbers of other people living with HIV in the U.S. and abroad require treatment for the rest of their lives.

NIH will continue to explore novel ideas and develop basic research discoveries from multiple biomedical and behavioral research fields, build on the scientific advances and knowledge that have been gained, and capitalize on the unique scientific opportunities, to improve the health of those infected with HIV. Through this exploration, NIH intends to aid in successfully developing a safe and effective HIV vaccine, as well as a cure for infection, which will ultimately lead to the end of the HIV/AIDS pandemic.

Priorities for NIH-Funded HIV/AIDS Research: A series of key HIV/AIDS research priorities and cross-cutting research areas that underpin these priorities were developed in 2015 to serve as a guide for the investment in the NIH HIV/AIDS research over the next three to five years.

The overarching priorities for NIH HIV/AIDS research reflected in this Trans-NIH HIV/AIDS research budget request are:

- Vaccine research and other modalities to reduce the incidence of HIV/AIDS
- Next generation of HIV therapies with better safety and ease of use
- Research toward sustained viral remission and develop a cure
- HIV-associated coinfections, comorbidities, and complications

The priority areas are linked by crosscutting areas focused on basic research, research to reduce health disparities, behavior and social science research, and research training.

Enhancing Stewardship within NIH-Funded HIV/AIDS Research: The OAR develops an annual Trans-NIH Plan for HIV-Related Research (Strategic Plan) to ensure that the Trans-NIH AIDS research budget is used to fund the overarching HIV/AIDS research priorities. It provides a roadmap for the NIH HIV/AIDS research effort, which is carried out by nearly all of the NIH Institutes and Centers. The Plan shapes the NIH investment in building on the most recent scientific progress and opportunities to develop a safe and effective AIDS vaccine, generate a cure for HIV/AIDS, and ultimately achieve an end to the AIDS pandemic. The Plan also serves as a resource to inform the public, the scientific community, Congress, and HIV/AIDS-affected communities about the NIH HIV/AIDS research agenda. It is developed through a collaborative process involving broad input from NIH intramural and extramural scientists and other stakeholders.

Starting in FY 2015, the OAR implemented new review processes to align investment of NIH HIV/AIDS dollars with projects in the highest priority areas (overarching priorities) of HIV/AIDS research. These processes include trans-NIH planning, budgeting, and encouragement of increased collaboration and partnerships across ICs. NIH developed and implemented a recurring annual comprehensive portfolio review process to assess all grants, contracts, and intramural projects supported with HIV/AIDS funding. As a result of the

[89] Centers for Disease Control and Prevention: HIV Among Youth. (2016, April 27). https://www.cdc.gov/hiv/group/age/youth/

evaluation processes, OAR has and will continue to allocate and redirect resources across NIH ICs and across the key areas of science to address high research priorities.

Overall Budget Policy: The FY 2018 President's Budget estimate for the trans-NIH AIDS research program is $2,440.180 million, a decrease of $554.178 million compared to the FY 2017 Annualized Continuing Resolution level. The OAR is authorized to allocate all dollars associated with this area of research across the entire NIH. Now that the NIH HIV/AIDS research budget is more tightly focused on high priority HIV/AIDS research, this total amount of funding will support only the highest priority HIV/AIDS research. This includes: 1) discovery, translation, and development of new prevention and treatment modalities for HIV/AIDS including vaccines, monoclonal antibodies, and new drugs, 2) clinical trials to test and develop these new products, 3) enhancing research for achieving a cure or sustained HIV remission , 4) exploring new opportunities for basic scientific research on HIV interactions with cells and the immune responses to the virus and its components and 5) co-morbidities and co-infections associated with HIV/AIDS. In addition, these resource alignment practices have opened opportunities to incorporate improved risk-assessment tools and to enhance better study designs to deliver effective interventions for prevention and treatment of HIV/AIDS.

Program Descriptions and Accomplishments

Vaccine research and reducing the incidence of HIV/AIDS: The best long-term strategy for controlling the HIV/AIDS pandemic is the development of safe, effective, and affordable HIV vaccine(s) that may be used in combination with other prevention strategies. NIH supports a broad research portfolio encompassing basic, preclinical, and clinical research to prevent infection, including studies to identify and understand protective immune responses in HIV-positive individuals and studies of improved animal models for the preclinical evaluation of vaccine candidates. NIH has supported unprecedented collaborative investigations to identify how specific immune responses may protect against HIV acquisition. The OAR is committed to providing resources for the advancement of existing vaccine concepts, as well as supporting innovative basic HIV vaccine research studies that may prevent HIV infection more efficiently than vaccines already tested. New discoveries in HIV vaccine research have radically changed our thinking concerning the design of novel immunogens and strategies to employ them.

A large clinical trial of a promising vaccine candidate, launched in FY 2017 by the HIV Vaccine Trials Network (HVTN) 702, is the first study of its kind in many years and represents the culmination of wide ranging, multidisciplinary efforts to improve upon a vaccine candidate that showed modest success in 2009. In addition to the HVTN 702 study, additional novel HIV vaccine approaches are currently under investigation to maximize the chance for success in this critical field. These approaches include the latest discoveries in human immunology and vaccinology to effect a powerful and long lasting anti-HIV response and to develop antibodies that neutralize HIV. Lastly, these scientific advances are being undergirded by investments in biologic manufacturing infrastructure to ensure that progress is not impeded by delays in production capacity.

NIH has made dramatic advances in research and development related to HIV prevention in both adults and infants. A recently completed trial ((HIV Prevention Trials Network) HPTN 052) demonstrated that early treatment of HIV-infected individuals to achieve full viral suppression before immune decline resulted in a 93 percent reduction of HIV transmission between sexual partners. Another trial showed that an antiretroviral (ARV)-based intravaginal ring was up to 70 percent effective in preventing sexually-transmitted HIV infection in women who used the ring. In addition, the large Promoting Maternal and Infant Survival Everywhere (PROMISE) trial completed in 2016 demonstrated that HIV positive women, who were treated successfully with ARV during their pregnancy and while breastfeeding, prevented nearly all HIV infections in their infants.

New developments in the HIV prevention field are currently being tested in clinical trials and have the potential to develop safer and more effective prevention strategies. Discoveries by scientists at NIH and elsewhere have led to the development of broadly neutralizing antibodies (bNAbs) that may prevent HIV infection, a concept under evaluation in a pair of trials called "AMP" for Antibody-Mediated Prevention. Another study is evaluating a new injectable drug—Long Acting Cabotegravir—opening the possibility that future prevention modalities will be effective with monthly, rather than daily dosing.

While these breakthroughs are significant and substantial, many challenges remain. For example, prevention products may not be used by individuals on a consistent basis, thereby decreasing their effectiveness. These challenges demonstrate that further research is needed to better understand human behavior and to develop prevention tools and strategies that are effective for all high risk populations.

Next generation of HIV therapies: Antiretroviral (ARV) treatment (ART) has resulted in remarkable immune recovery and physiologic function in HIV-infected individuals who can consistently take prescribed HIV treatment regimens and tolerate occasional side effects or toxicities. Combination ART with several classes of anti-HIV drugs has simplified treatment regimens, delayed the progression of HIV infection to AIDS, prolonged viral suppression, delayed the development of viral resistance, and reduced HIV-associated comorbidity and comortality from other infections (e.g., hepatitis, TB, and pneumonia), chronic diseases, cancers, and neurologic and mental health complications. Despite these treatment advances many challenges remain including: 1) identifying new virus and cell targets to suppress viral replication and to overcome resistance to existing drugs 2) maintaining long-term treatment adherence to keep HIV replication suppressed, thus improving immune competence and prolonging the time to the development of drug resistance, and 3) overcoming the persistent disparities in HIV treatment outcomes across race, gender, and socioeconomic status.

To address the challenges of developing and testing HIV treatments, NIH-funded researchers are engaged in a wide array of research to improve current remedies. Efforts are underway to develop and test HIV treatments that are longer acting, less toxic with fewer side effects and complications, and easier to take, thus improving adherence. In the near future, individuals with HIV may be able to receive a once monthly injection instead of taking one or more pills every day. Basic and clinical researchers are evaluating therapeutic vaccines that have the potential to effect long term viral remission without the need for additional drugs. Epidemiologists are investigating the spread of drug resistance and strategies to prevent disease progression from one place to another. Behavioral and social scientists are studying novel approaches to get treatment

started as soon as an HIV diagnosis is made, as well as how to keep HIV-infected patients in these services to achieve optimal prevention and treatment responses.

Research and develop a cure for HIV/AIDS: The mechanisms by which HIV persists in hidden reservoirs within cells and tissues in the body are not well understood and represents the largest hurdle to finding a cure for HIV. Significant advances to understand the biology of reservoir formation, the ability of a virus to remain dormant within a cell, and viral persistence have been made, but continued research is fundamental to further understand and overcome this barrier. A 2016 breakthrough from NIH researchers showed that some monkeys infected with Simian immunodeficiency virus (SIV)—a virus that is a close relative to HIV—were able to control the virus without continued ART for as long as nine months after a two-step treatment with antiretroviral drugs and a monoclonal antibody that blocks a receptor on immune cells. The mechanism behind this finding is unclear, but research is already initiated to capitalize on this unexpected, seminal breakthrough. Initial human clinical studies to confirm and extend these animal model findings are underway.

In addition, a wide array of basic, preclinical, and clinical research are ongoing to facilitate progress in developing new therapeutic strategies that reliably and reproducibly induce sustained remission of viral replication or viral eradication without antiretroviral treatment (ART). Multiple strategies are in progress in large consortia funded by NIH, including: 1) "kicking" the virus out of its hidden/latent state and "killing" any cells that start producing the virus when ART is not present; 2) creating immune cells that are resistant to HIV infection by manipulating genes so that the virally resistant cells have a survival advantage, and; 3) inducing immune responses that can control HIV.

HIV-associated comorbidities and coinfections: HIV directly and indirectly causes a complex array of health problems that are unresolved by current ART. Immune deficiency and underlying inflammation caused by the virus increases susceptibility to many diseases and amplifies the effects of these diseases. Ongoing basic and observational research continues to shed light on the interaction of HIV with other infections, such as tuberculosis (TB) and hepatitis, and the impact a dysfunctional immune system has on diseases traditionally not regarded as immune-mediated. Critical research on the central nervous system continues to shed light on the impact of HIV infection on cognitive function and neurologic disorders.

These findings are actively being translated into clinical trials of new drugs and diagnostics so as to accelerate improvement in the health outcomes of people living with HIV/AIDS. NIH is currently funding a host of trials evaluating drugs to prevent and/or treat heart disease, TB disease, hepatitis and other opportunistic infections, underlying inflammation, and neurologic complications.

Crosscutting Areas

A major proportion of HIV/AIDS research has relevance to not one, but all of the overarching NIH HIV/AIDS priority research areas. This includes basic research, health disparities research, behavior and social sciences research, training and capacity building, and information dissemination.

- **Basic Research**: Major gaps remain in our understanding of the basic biology of HIV transmission and pathogenesis; development of immune dysfunction and chronic inflammation; host microbiome, genetic determinants and innate immunity that may either prevent or accelerate disease; and other fundamental issues that underpin the development of high-priority strategies for the prevention, treatment, and cure of HIV and related co-morbidities and coinfections.

- **Epidemiological Research**: The lifetime risk of being diagnosed with HIV in the U.S. is greater for people living in the South, including the District of Columbia, than in other regions of the country.[90] Understanding causes, patterns, and social phenomenon that have led to higher rates of HIV infection in the South and Midwest of the U.S. is key to rapidly identifying and preventing HIV outbreaks such as the one that recently occurred in Indiana. With a surging opioid epidemic, particularly in youth in the U.S., methodology to detect infection clusters early and prevent future outbreaks has become a cross-cutting and cross-discipline priority.

- **Behavioral and Social Science Research:** HIV/AIDS-related behavioral and social science research is integrated within all of the high-level priorities for HIV/AIDS research including prevention and treatment of HIV infection, developing a cure, and research on comorbidities and co-infections. Behavioral and social science research findings continue to reveal a wide range of individual, interpersonal, social, structural, and other factors that contribute to and drive the HIV/AIDS pandemic.

- **Research to Reduce Health Disparities:** The disproportionate rate of infections in racial and ethnic minorities, especially young men who have sex with men (MSM) of color, as well as the disturbing trends in treatment outcomes of those living with HIV/AIDS, supports the ongoing research funding to discover ways to resolve these disparities. Defining where the gaps occur and the immediate causes will go a long way to addressing biologic, genetic, epidemiologic risk and behavioral differences that can systematically be addressed to change the course of HIV infection in these populations.

- **Training, Infrastructure, and Capacity Building:** Training of the biomedical, behavioral, and social science workforce required to conduct high-priority HIV/AIDS research has long been a goal of the OAR office. NIH provides support for infrastructure and capacity building as integral components of its commitment to carry out highly productive HIV-related research that is both scientifically and ethically sound.
  Equipment, shared instrumentation, and tissue and specimen repositories are examples of the research infrastructure and capacity building support that NIH provides to strengthen the conduct of HIV/AIDS research.

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

- **Information Dissemination:** NIH supports innovative initiatives to enhance the dissemination of research findings. The diversity of communities makes it imperative that dissemination approaches address the different levels of scientific literacy and how information is accessed. Tailoring the scientific information for each community is a priority. NIH research findings are used to develop state-of-the-art U.S. HIV/AIDS treatment and prevention guidelines. The OAR coordinates the development, update, and distribution of U.S. guidelines for HIV/AIDS treatment. The need to effectively and rapidly translate HIV/AIDS research into practice requires new and innovative approaches to reach diverse stakeholders including research investigators, health providers, policy makers, the public, and HIV-infected and -affected individuals.

Benefits of AIDS Research to Other Areas: NIH investment in HIV/AIDS research has resulted in critical scientific accomplishments that benefit not only the nearly 37 million HIV-positive individuals around the world, but also has contributed knowledge to the prevention, diagnosis, and treatment of many other diseases and conditions. HIV/AIDS research has driven the overall understanding of immunology, virology, microbiology, molecular biology, and the impact of genetics on human health. HIV/AIDS research is helping to unravel the mysteries surrounding other diseases because of the pace of discovery and the unique nature of HIV, i.e., the way the virus enters a cell, causes infection, affects every organ system, and involves a broad range of opportunistic infections, comorbidities, cancers, and other complications.

HIV/AIDS research continues to make discoveries that can be applied to other infections and conditions such as cancer, neurologic, autoimmune, and metabolic diseases, as well as to the complex issues of aging and dementia. HIV research initially benefitted from prior NIH-funded research on viruses that cause cancer, and now paves the way with new areas of basic research that applies to other diseases and conditions. Some of the benefits and discoveries as a result of HIV/AIDS research include:

- HIV/AIDS research has advanced the understanding of the relationships between viruses, immune regulation, and cancer.
- HIV/AIDS research has directly led to new treatments for cancer that transform a patient's immune system to fight the cancer directly.
- Research on HIV-associated neurologic and cognitive manifestations similarly may benefit millions of individuals with Alzheimer's disease and other aging and dementia issues.
- HIV/AIDS treatment research has led to more effective drugs for multiple bacterial, mycobacterial, and fungal diseases and fostered significant improvements in drug design and delivery technologies that can improve adherence.
- The treatment of hepatitis B and hepatitis C infections, which currently affect more than 185 million people globally, has been revolutionized and curative regimens are now available because of the development of specific drugs that directly interfere with virus replication.
- Blood supplies are safe from multiple infectious disease agents, because of nucleic acid tests and test concepts that were developed, refined, and implemented to prevent HIV-contaminated blood from being used for transfusions.
- HIV/AIDS research has led to the development of new models to test treatments for other diseases in faster, more efficient, and more inclusive clinical trials.

Conclusion: The NIH investment in HIV/AIDS research continues to produce significant groundbreaking scientific advances, unprecedented scientific opportunities, as well as new challenges. NIH's leadership and commitment to build on these advances and strategically allocate funds to the highest priorities are essential to successfully develop a safe and effective HIV/AIDS vaccine, reduce the incidence of new infections, develop strategies for sustained viral remission, and ultimately bring an end to the HIV pandemic.

DRUG CONTROL PROGRAMS

	Budget Authority (in millions)		
	FY 2016 Final	FY 2017 Annualized CR	FY 2018 Request
Drug Resources by Budget Decision Unit and Function:			
Decision Unit 1: National Institute on Drug Abuse			
Research and Development: Prevention	$356.650	$365.650	$294.099
Research and Development: Treatment	$692.321	$709.790	$570.899
Total, Decision Unit 1	$1,048.971	$1,075.440	$864.998
Decision Unit 2: National Institute on Alcohol Abuse and Alcoholism			
Research and Development: Prevention	$48.783	$48.783	$37.763
Research and Development: Treatment	$6.394	$6.394	$4.950
Total, Decision Unit 2	$55.177	$55.177	$42.713
Total Funding	$1,104.148	$1,130.617	$907.711
Drug Resources Personnel Summary			
Total FTEs (direct only)	383	382	382
Drug Resources as a Percent of Budget			
Total Agency Budget (in Billions)	$32.31	$32.59	$26.92
Drug Resources percentage	3.42%	3.47%	3.37%

Program Summary

MISSION

The NIDA and the NIAAA, two of the twenty-seven Institutes and Centers of the NIH, support the *Strategy*: NIDA, by funding research on the prevention and treatment of drug use, addiction, and its harmful consequences; and NIAAA, by funding research on the prevention and treatment of underage drinking and its harmful consequences.

The societal impact of the misuse of illicit drugs in 2007 was estimated at $193 billion in health care, crime-related, and productivity losses[91]. Knowledge is the foundation of the transformative agenda needed to strike at the heart of this stubborn and costly challenge. To provide a comprehensive public health response, NIDA will continue to build on science advances from the Institute's investments in genetics, neuroscience, pharmacotherapy, and behavioral and health services research that have led to innovative strategies for preventing and treating substance use disorders (SUDs) in this country and worldwide.

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

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

[91] U.S. DOJ National Drug Intelligence Center. The Economic Impact of Drug Use in American Society. April 2011

individuals with AUD and with co-occurring conditions, as well as to disseminate research-based information to health care providers, researchers, policy makers, and the public.

METHODOLOGY

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

The prevention and treatment components of NIAAA's underage drinking research program are scored as a part of the national drug control budget. Underage drinking research is defined as research that focuses on alcohol use by youth (individuals under the legal drinking age of 21), as well as the negative consequences of underage alcohol use (e.g., alcohol-related injuries, impact on adolescent development, including on the developing brain, and risk for AUD). It includes basic research, epidemiological studies, behavioral research, screening and intervention studies, and the development and testing of preventive interventions. NIAAA's methodology for developing budget estimates for the *Budget and Performance Summary* is a two-step process. First, NIAAA identifies its underage drinking projects using NIH's automated, electronic text mining system for research, condition, and disease categorization. Once all underage drinking projects are identified through this process, NIAAA conducts a manual review of the project listing and identifies only those projects and amounts that are relevant to prevention and treatment. This is used to generate the NIAAA drug control budget estimate.

BUDGET SUMMARY

The FY 2018 President's Budget request for drug-related activities at NIH is $907.711 million ($864.998 million for NIDA and $42.7 million for NIAAA), a decrease of $222.906 compared with the FY 2017 Annualized CR level.

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

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

National Institute on Drug Abuse

FY 2018 Request: $864.998 million

($210.4 million below the FY 2017 Annualized CR level)

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

Neuroscience and Behavior Research

FY 2018 Request: $286.3 million

($73.3 million below the FY 2017 Annualized CR level)

The Neuroscience and Behavior portfolio seeks to expand our understanding of the fundamental neurological, genetic/epigenetic, and behavioral processes that underlie SUDs. Central to this goal are efforts to tease apart the multiple factors that contribute to drug use and addiction risk, with particular emphasis on individual differences in risk and responses to drugs. NIDA is working to expanding our basic understanding of the brain from the molecular to the behavioral level. NIDA is supporting research to develop advanced technologies that improve our ability to study the organization and function of the living brain that will help us to better understand the interactions of complex neural circuits including those that mediate reward, aversion to drug effects, and related decision making; and develop novel strategies to therapeutically influence SUD-relevant brain circuits including transcranial magnetic stimulation (TMS), transcranial direct current stimulation (tDCS), deep brain stimulation (DBS), and neurofeedback. Other key projects are investigating the effects of drugs on gene expression and brain development and function; the interactions of an individual's genes with environmental conditions, such as stress and early exposure to drugs, that influence risk for addiction; the role of epigenetic changes that can influence long-term patterns of gene expression in specific brain cells (neuron and glia) without changing DNA sequence; basic processes underlying resilience against SUDs in childhood and adolescence; and exploring gender-related differences in these effects. NIDA is also working to develop the capacity 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 perspective on effects of drugs on multiple biological systems to improve our understanding of the basic neural and genetic mechanisms that underlie drug use and addiction.

In addition, under the Collaborative Research on Addiction at the NIH (CRAN) initiative, NIDA and NIAAA, along with other components of NIH and the Centers for Disease Control and Prevention, are supporting a longitudinal study to examine the neurodevelopmental consequences of substance use. The Adolescent Brain Cognitive Development (ABCD) study will follow the biological and behavioral development of more than 11,000 children beginning at ages 9-10 through adolescence into early adulthood. Over the course of the next decade, scientists will use advanced brain imaging, interviews, and behavioral testing to determine how childhood experiences interact with each other and with a child's changing biology to affect brain development and—ultimately—social, behavioral, academic, health and other outcomes. Understanding these relationships may help reveal the biological and environmental building

blocks that contribute to successful and resilient young adults. This enhanced knowledge also may lead to ways to predict potential developmental problems including mental illness and SUD so that they can be prevented or reversed. Families that volunteer will be part of groundbreaking research that promises to inform future substance use prevention strategies, educational priorities, child development innovations, research priorities, and public health interventions.

Epidemiology, Services, and Prevention Research

FY 2018 Request: $263.6 million

($67.5 million below the FY 2017 Annualized CR level)

This NIDA Division supports integrated approaches to understanding and developing strategies to address the interactions between individuals and environments that contribute to drug use and related problems. With a focus on research to inform public health, the Division supports the annual Monitoring the Future survey, which tracks drug use and related attitudes among teens, as well as surveillance networks to monitor local and national drug trends. NIDA's National Drug Early Warning System (NDEWS) monitors emerging trends related to illicit drug use, including designer synthetic compounds and fentanyl, around the country so that rapid, informed, and effective public health responses can be developed and implemented precisely where and when they are needed. NIDA's Division of Epidemiology, Services, and Prevention Research also supports research related to more effectively integrating prevention and treatment services into healthcare and community systems. For example, NIDA research is exploring treatment of SUDs in the criminal justice system, including studies on implementation of medication-assisted treatment (MAT) and seek, test, treat, and retain (STTR) strategies for people with SUDs 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.

Therapeutic and Medical Consequences

FY 2018 Request: $145.9 million

($37.4 million below the FY 2017 Annualized CR 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 their development has rested largely with NIDA. To most effectively leverage NIDA resources, this program encourages the formation of alliances between strategic partners (pharmaceutical and biotechnology companies as well as academic institutions) with the common goal of advancing medications through the development pipeline toward FDA approval in a timely manner. NIDA conducts research to decrease the risks associated with medications development to make it more appealing for pharmaceutical companies to complete costly phase IIb and III clinical studies. An example of such a project is a partnership with AstraZeneca to explore a novel medication that modulates the activity of glutamate – an excitatory neurotransmitter – to treat drug addiction.

Preclinical studies with this class of molecule indicate that it could be effective for treating nicotine and cocaine use disorders. Another example is the partnership with Lightlake Pharmaceuticals and Adapt Pharma that led to the successful development of Nasal Narcan®, the only FDA approved intranasal naloxone product to treat opioid overdose. Further, US World Meds, funded in part through NIDA grants, is in late stage development of lofexidine, a medication for the treatment of opioid withdrawal symptoms that might also hold promise for the treatment of other addictions. NIDA has also invested in research supporting the development of vaccines and monoclonal antibodies for the treatment of SUDs. For example, an ongoing collaboration with Selecta Biosciences is working to develop a novel nicotine vaccine and another with InterveXion Therapeutics is working to develop a monoclonal antibody to treat methamphetamine addiction. The latter program is currently in clinical trials**.**

Clinical Trials Network

FY 2018 Request: $35.2 million

($9.0 million below the FY 2017 Annualized CR level)

The CTN comprises 13 research nodes, two research coordinating centers, and more than 240 community treatment programs and/or medical settings in over 40 States plus the District of Columbia and Puerto Rico. Current initiatives are emphasizing research to develop and test strategies for the integration of SUD treatment, particularly for opioid use disorder (OUD), into mainstream general medical settings, embedding research in clinical practice, and enhancing capacity to leverage electronic health record data in research studies. Through collaborations with clinical investigators, the CTN evaluates research based strategies needed for the integrated management of patients with substance misuse/SUD in general medical settings and linked specialty care treatment settings. The CTN develops and tests the feasibility and effectiveness, as well as implementation strategies and health system approaches for addressing SUDs and related disorders, such as comorbid mental health disorders and HIV, in diverse patient populations. The CTN is currently conducting studies that: 1) compare Vivitrol® (extended-release naltrexone) to Suboxone® (buprenorphine and naloxone) Sublingual Film for patients addicted to heroin or other opioids, including prescription pain relievers; 2) evaluate a linkage-to-care intervention for HIV/HCV co-infected patients with SUDs; and 3) incorporate common data elements for SUD screening and assessment into a widely used electronic health record system. Research under development includes a trial to investigate the effectiveness and safety of a combination therapy of Vivitrol® plus Wellbutrin XL® (bupropion hydrochloride, extended-release tablets) for treatment of methamphetamine use disorder, as well as three studies to evaluate strategies for integrating OUD screening and treatment interventions into routine practice in emergency departments, primary care clinics, and pharmacies, respectively.

Intramural Research Program

FY 2018 Request: $75.4 million

($16.7 million below the FY 2017 Annualized CR level)

In addition to funding extramural scientists, NIDA also conducts research in high priority areas through our IRP. Intramural research at NIDA focuses on conducting cutting-edge research within a coordinated multidisciplinary framework to: 1) elucidate the nature of the addictive process; 2) evaluate the potential of emerging new therapies for SUDs, including pharmacological and non-pharmacological (e.g. psychosocial, biofeedback, brain stimulation technologies); and 3) describe the long-term consequences of drug use on systems and organs, with particular emphasis on the brain and its development, maturation, function, and structure. For example, the IRP is furthering SUD research by collaborating with pharmaceutical industry partners to study a potential medication that can decrease methamphetamine craving and by collaborating with researchers in Italy to study the efficacy of TMS for treatment of cocaine use disorders. In addition, the IRP is working to understand the impact of long lasting deficits in the prefrontal cortex – an area of the brain that mediates decision making – caused by cocaine and heroin use. In an animal model, scientists can reverse this deficit by hyper-stimulating the prefrontal cortex for brief periods. This intervention is being developed as a possible therapy for addiction. The IRP is also working to develop clinically useful indicators (biomarkers) of addiction severity or treatment efficacy that will support the development of more effective treatments and discovery of novel treatment targets. IRP scientists are also working to better understand factors that contribute to cravings and relapse. Memories of items, people, or environments that are present when addicted individuals take drugs become powerful cues that trigger them to relapse again and again. Scientists have shown that these memories are stored in specific patterns of neurons called neuronal ensembles in the brain. Researchers have been successful in inactivating these drug-related ensembles and related memories in animal models, and are developing similar procedures that might be used in humans to selectively impair harmful addiction memories. In addition, IRP scientists are developing a mobile health toolbox to collect data on the daily-life reality of addiction. These tools can support intensive assessments to help identify individual and environmental influences on drug craving and to understand when people are most vulnerable to relapse. One of the goals of this research is to deploy a mobile intervention that will automatically predict imminent drug use and deliver help just when a person needs it.

Research Management and Support

FY 2018 Request: $58.5 million

($6.5 million below the FY 2017 Annualized CR level)

RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. Additionally, the functions of RMS encompass strategic planning, coordination, and evaluation of NIDA's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. NIDA currently oversees more than 1,300 research grants and more than 70 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 2018 Request: $42.7 million

($12.5 million below the FY 2017 Annualized CR level)

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

Reducing alcohol misuse among college students, many of who are underage, continues to be a high priority for NIAAA. Binge drinking (drinking 4 or more drinks for women and 5 or more drinks for men, in approximately two hours) and extreme binge drinking (drinking at levels two or more times the binge drinking threshold) are especially pervasive among college students; these practices are particularly troubling as they increase risks for alcohol-related blackouts, alcohol overdoses, sexual assault, sexually transmitted diseases, AUD, and other detrimental consequences. To assist college and university officials in addressing alcohol misuse on their campuses, NIAAA developed the College Alcohol Intervention Matrix (*CollegeAIM*), a user-friendly guide and website that rates nearly 60 evidence-based alcohol interventions in terms of effectiveness, costs, and other factors. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address harmful and underage student drinking.

NIAAA's investment in underage drinking research also includes studies to understand how alcohol affects the developing brain. For example, NIAAA supports the National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA), an accelerated longitudinal study

of more than 800 youth ages 12-21 to assess the vulnerability of the adolescent brain to alcohol exposure. NCANDA has laid the methodological foundation for the NIH Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of brain development and child health in the United States. Over 11,000 9- to 10-year olds are being invited to participate in the ABCD study, which will use brain imaging and neuropsychological and behavioral assessments to track the biological and behavioral development of youth before and after they start to use alcohol and/or other addictive substances. These two studies are expected to illuminate the neurobiological, cognitive, and behavioral precursors of alcohol and other drug misuse and ultimately inform preventive and treatment strategies. Complementing NCANDA and ABCD, NIAAA's Neurobiology of Adolescent Drinking in Adulthood initiative is enabling investigators to examine, in animal models, the molecular, cellular, and circuit-level mechanisms by which adolescent drinking affects brain structure and function in the short- and long-term and how the changes observed during this critical period persist into adulthood.

PERFORMANCE

Information regarding the performance of the drug control efforts of NIH is based on agency GPRMA documents and other information that measures the agency's contribution to the *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. All performance results reported were achieved in FY 2016.

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

One of these measures, led by NIAAA and supported by NIDA, is SRO-5.15: "By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations." This measure, which began in FY 2014, is indicative of NIDA's and NIAAA's efforts to support research to foster the development and implementation of prevention-based strategies for reducing substance misuse and addiction. NIH's prevention portfolio encompasses a broad range of research on the efficacy and cost effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to misuse or addiction—and how these programs can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of substance use or SUDs.

NIDA created and leads SRO-7.3: "By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification,

treatment delivery and adherence for substance use disorders and related health consequences." This measure began in FY 2014 and has been updated to reflect NIDA's current focus in exploring and leveraging technological advances to improve the efficiency and quality of health care delivery for SUDs.

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

National Institute on Drug Abuse		
Selected Measures of Performance	**FY 2016 Target**	**FY 2016 Achieved**
» Scientific Research Outcome-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.	Assess the efficacy/ effectiveness of brief interventions to prevent substance use and other risk behaviors in a variety of settings.	41 research articles were published examining the efficacy of a variety of prevention interventions to protect youths from initiation or escalation of substance use and associated negative health outcomes.
» 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.	Identify next steps for testing or deployment of 2-4 substance abuse treatment or medication adherence interventions using mobile technology.	Five interventions utilizing HIT, including mobile health technology, addressing five research priority areas were developed. All interventions were found to be feasible and will undergo additional revision and efficacy testing in preparation for broad dissemination and implementation.

Prevention – Scientific Research Outcome-5.15

NIDA continues to fund a robust prevention portfolio that builds upon solid epidemiological findings and insights from genetics and neuroscience and applies this knowledge to develop effective strategies to prevent initiation of drug use and escalation of use to addiction in underage youth. The performance target for SRO-5.15 was met for FY 2016. Prevention of the initiation of drug use and escalation to addiction continues to be one of NIDA's primary strategic goals (see NIDA's Strategic Plan).

NIH's prevention portfolio encompasses a broad range of research to increase our understanding of factors that enhance or mitigate an individual's propensity to initiate drug use or to escalate from use to SUDs across different developmental stages. Information about these contributors to substance use and addiction and the different ways biological, psychosocial, and environmental factors operate across individuals is critical to designing more effective prevention messages. NIH's growing knowledge about substance use and addiction (including tobacco, alcohol, illicit, and nonmedical prescription drug use) is helping to inform the development of prevention strategies that are evidence-based and rooted in a growing understanding of the biological (e.g., genetics, neurobiology), psychosocial (e.g., support systems, stress resilience), and environmental (e.g., socioeconomic, cultural) factors that influence risk for substance use and

related disorders. NIH-supported research is building the scientific knowledge base needed to advance our goal of developing effective tailored prevention strategies for youth.

A number of genetic markers have been identified that influence risk for addiction and recent research has shown that genetic risk factors can influence the effectiveness of school based prevention interventions.[92] In addition, individual differences seen in response to medications for nicotine and AUD suggest that genetic predictors of treatment response could lead to more efficacious and cost-effective relapse prevention strategies.[93] This information can be harnessed for improving prevention by personalizing interventions for optimal benefit. Such strategies would enable substance use prevention programs to target programs more precisely based on individual or group vulnerability markers, ultimately increasing their impact and cost-effectiveness. Combined with improved educational efforts to increase an individual's awareness of his or her personal risk, this preemptive prevention approach can empower people to make decisions that ultimately prevent substance use from starting or escalating.

The information gained from research on the factors that influence risk and resilience to SUDs will lay the foundation for improved and tailored prevention efforts in the future. As personalized risk factors for substance use and addiction vulnerability (or protection) are identified, NIH will encourage researchers to use that information to better understand how biological factors, combined with environmental ones, contribute to substance use disorder vulnerability, thereby enhancing its prevention portfolio. NIH will also encourage the scientific community to use this knowledge to develop and test targeted prevention interventions for populations with differing vulnerabilities to improve our Nation's intervention efforts, similar to the strategy now being used to prevent substance use in high sensation-seeking youth.

The efficacy and cost-effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to substance use disorders—including their severest form, addiction—can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of taking drugs or becoming addicted. For example, prevention programs designed for sensation-seeking youth are effective for these youth, but not for their peers who do not demonstrate a high level of sensation seeking. High levels of sensation-seeking, and other traits known to be risk factors for substance misuse, may be identified early using genetic markers.

From FY 2016 to the present (FY 2017), multiple studies have been funded to develop and test interventions to prevent drug use, drug use problems, and risk behaviors and to improve the implementation of these evidence-based interventions. NIDA is supporting research to test culturally and developmentally appropriate strategies to prevent drug use and addiction across the lifespan: for all developmental stages, from birth through adulthood and older age; for diverse racial/ethnic populations, targeted to various settings such as family, school, community, and health care settings; and for high risk populations, such as LGBT, homeless, child welfare involved, juvenile justice system involved, criminal justice involved, individuals with comorbid conditions, and populations at risk for HIV/AIDS.

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[92] Vandenbergh DJ, Schlomer GL, Cleveland HH et al. *An adolescent substance prevention model blocks the effect of CHRNA5 genotype on smoking during high school.* Nicotine Tob Research. 2016;18(2):212-20.
[93] Sturgess JE, George TP, Kennedy JL, Heinz A, Muller J. *Pharmacogenetics of alcohol, nicotine, and drug addiction treatments.* Addict Biol. 2011;16(3):357-76.

In FY 2016, 41 studies examining the efficacy of prevention interventions within adolescent populations were published. One recent study examined the efficacy of the Family Check-Up (FCU) intervention on conduct problems (CPs) and antisocial behavior (AB) in children living in high risk, deprived neighborhoods—characterized by poverty, violence, deviant peers and adults, toxic air, and lack of community resources—that are associated with increased risk for poor health outcomes including substance use disorders.[94] FCU is an annual, three-session, family-centered intervention that motivates parents to promote positive child adjustment and to participate in parent management training that is adapted for their specific needs. CPs and AB were identified from school-based teacher reports. The study found that for most families eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) that were not seeking help for CP with their children, FCU resulted in significant reductions in CP; however, these results did not extend to children living in the most deprived neighborhoods. It was observed, however, that caregivers and children living in extremely deprived neighborhoods that developed particularly positive relationships during early childhood (toddler years) received fewer reports of CP from teachers. Researchers suggested that one reason FCU may not have provided more long-term efficacy for families living in extremely deprived neighborhoods could be linked to their inability to access mental health services. Although continued research is needed, these findings suggest that there is hope for delivering effective preventive interventions to children and families living in vulnerable environments by using innovative methods to reach families isolated by their economic status.

Implementation of effective prevention interventions within community settings is very low due to a variety of factors including community readiness or resistance to change, lack of infrastructure and technical support, as well as poor fidelity to evidence-based prevention interventions (EBPIs).[95,96,97,98] A recent study examined the implementation of PROmoting School-community-university Partnerships to Enhance Resilience (PROSPER)—a delivery model designed to support dissemination and sustained implementation of evidence based practices that prevent substance misuse and promote healthy adolescent development through the creation of partnerships between a land-grant university's Cooperative Extension System (CES) and local community organizations. The PROSPER model has demonstrated multiple positive impacts on youth and their families which include reduced rates of substance use[99] and problem behaviors[100], as well as improved family bonding and parenting quality.

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[94] Shaw, D.S., et al., *The long-term effectiveness of the Family Check-Up on school-age conduct problems: Moderation by neighborhood deprivation.* Dev Psychopathol, 2016. 28(4pt2): p. 1471-1486.

[95] Bumbarger, B. and D. Perkins, *After randomised trials: Issues related to dissemination of evidence-based interventions.* Journal of Children's Services, 2008. 3(2): p. 55-64.

[96] Akerlund, K.M., *Prevention program sustainability: The state's perspective.* Journal of Community Psychology, 2000. 28(3): p. 353-362.

[97] Fixsen, D.L., et al., *Implementation research: A synthesis of the literature.* . 2005, The National Implementation Research Network: Tampa, FL.

[98] Spoth, R., et al., *Longitudinal Effects of Universal Preventive Intervention on Prescription Drug Misuse: Three Randomized Controlled Trials With Late Adolescents and Young Adults.* American Journal of Public Health, 2013. 103(4): p. 665-672.

[99] Spoth, R., et al., *Substance-use outcomes at 18 months past baseline - The PROSPER community-university partnership trial.* American Journal of Preventive Medicine, 2007. 32(5): p. 395-402.

[100] Spoth, R.L., et al., *PROSPER partnership delivery system: Effects on adolescent conduct problem behavior outcomes through 6.5 years past baseline.* J Adolesc, 2015. 45: p. 44-55.

The current study compared implementation of PROSPER in two states eight years after the discontinuation of grant funding[101] and examined the methods used by 14 community teams in two different states (Iowa and Pennsylvania, seven teams per state) to effectively implement and disseminate EBPIs using the PROSPER model as well as to achieve sustained financial independence for their programs. While successful implementation of EBPIs can be achieved by a variety of methods, this study demonstrated that the sustainability of PROSPER was significantly tied to streamlined fundraising efforts that built long-term partnerships with school districts, social service agencies and other partners, and increasing state-level financial resources over time. A striking difference between the diffusion of EBPIs in Iowa and Pennsylvania can be attributed to the Pennsylvania Commission on Crime and Delinquency (PCCD). The PCCD provides grants and implementation support to promote successful community-based dissemination of EBPIs, and consequently PROSPER teams in Pennsylvania were able to achieve sustained, state-based funding and Pennsylvania communities were able to more successfully implement EBPIs.

In addition, the infrastructure provided by the PCCD altered PROSPER team dynamics: Iowa team leaders were much more focused on securing funding than were Pennsylvania team leaders. Ongoing technical assistance in the form of access to expertise in marketing, communications, grant writing, program evaluation, and dissemination skills was also critical for enabling communities to transition from seed funding to sustained financial independence. Overall this study demonstrates that effective dissemination and implementation of EBPIs can be achieved with high quality if community teams actively plan for it, community and state-level resources are available to support it, and teams receive ongoing technical assistance.

Universal prevention programs, while effective, do not work for everyone. NIDA-funded researchers investigated whether particular gene variations associated with nicotine sensitivity influenced the efficacy of universal prevention programs delivered using the PROSPER model to prevent smoking in high school students.[102] Nicotine produces its addictive effects by binding to nicotinic acetylcholine receptors in the brain. Individuals with specific genetic variants in the nicotine receptor allele (rs16969968) exhibit a heightened sensitivity to nicotine, and are at increased risk of becoming daily smokers. This study analyzed 424 DNA samples from a subset of adolescents participating in school-delivered and in-home prevention interventions to determine if their genotype influenced their smoking behavior or the efficacy of universal prevention interventions to prevent smoking. Students with the risk allele smoked more than students that lacked this allele, but surprisingly, the universal prevention programs were equally effective at preventing smoking regardless of the presence of the risk allele. These results suggest that the effect of this prevention intervention lie in reducing smoking initiation rather than smoking escalation because those who possess the risk allele would experience enhanced nicotine sensitivity and would be predicted to be more likely to continue smoking.

Collectively these findings demonstrate strategies for effective dissemination and implementation of evidence-based substance use prevention programs and further support key prevention lessons and principles that have emerged from NIDA-funded studies: prevention

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[101] Welsh, J.A., et al., *Pathways to Sustainability: 8-Year Follow-Up From the PROSPER Project.* J Prim Prev, 2016. 37(3): p. 263-86.

[102] Vandenbergh, D.J., et al., *An Adolescent Substance Prevention Model Blocks the Effect of CHRNA5 Genotype on Smoking During High School.* Nicotine Tob Res, 2016. 18(2): p. 212-20.

interventions implemented in early childhood can have positive effects into young adulthood; universal interventions can protect higher risk, vulnerable youth; and universal substance use prevention interventions are effective in individuals with high-risk genotypes.

Treatment—Scientific Research Outcome-7.3

SRO-7.3 is focused on developing and testing treatment interventions using HIT tools to improve patient identification, treatment delivery, or adherence to treatment for substance use disorders and related health problems. This goal contributes to NIDA's long-term strategy for improving drug use disorder treatment nationwide, thereby contributing to the National Drug Control Strategy's Goals of: Seeking Early Intervention Opportunities in Health Care (Chapter 2) by supporting screening for substance use and substance use disorders in healthcare settings using mobile technologies; and Increasing Access to Treatment and Supporting Long Term Recovery (Chapter 3) by supporting innovative research to develop and test mobile technologies to support the delivery of treatment and recovery services.

Addiction is a complex but treatable disorder that affects brain function and behavior. Unfortunately, we have a significant and ongoing treatment gap in our Nation. Among those who need treatment for a SUD, few receive it. In 2015, 21.7 million Americans needed treatment for a SUD, but less than 11% received specialty treatment.[103] Further, many treatment programs do not deliver current evidence based practices—for example, less than 50% provide access to medication assisted treatment for opioid use disorders, and they typically do not coordinate care with the patient's general health care providers. In addition, patients receiving treatment for SUD or related health conditions—such as HIV or mental health disorders—often do not fully adhere to the treatment plan recommended by their doctor. NIDA is committed to supporting health services and implementation research to develop and test technologies that aim to reduce these gaps.

NIH's health services research portfolio encompasses a broad array of studies exploring the use of HIT tools to deliver evidence based treatments, support coordination of care, improve the organization and delivery of treatment services, educate patients to prevent common comorbidities such as HIV or Hepatitis C, improve adherence to treatment for both substance use disorders and comorbid health conditions, increase treatment engagement, and provide recovery support. Research in this area will lay the foundation for leveraging technology to improve health outcomes related to substance use and substance use disorders. As these technologies advance, NIH will continue to encourage innovative research to determine how they can best be applied to address gaps in access to and quality of care as well as treatment engagement to improve public health.

An unacceptable gap also separates scientific discoveries from their implementation into community health care settings. A scientific approach must be brought to bear on effectively testing and disseminating research-based treatments and understanding how health service systems and settings influence treatment implementation. Ultimately, NIH strives to make research-based treatments user friendly, cost effective, and available to a broad range of

[103] *2015 National Survey on Drug Use and Health: Detailed Tables.*, C.f.B.H.S.a. Quality, Editor. 2016, Substance Abuse and Mental Health Services Administration: Rockville, MD.

practitioners and their patients. HIT tools, including mobile technologies, represent one promising mechanism to achieve this goal.

The last few years have seen tremendous advances in the development and implementation of HIT tools that have great promise for improving the efficiency and quality of health care delivery for substance use disorders – ranging from electronic health records, telehealth, wearable sensors, and mobile health technologies. These advances are revolutionizing health services research and presenting new opportunities to deliver innovative treatment and recovery interventions. HIT has the power to drive new treatment delivery models by supporting more effective integration of care, extending the reach of the SUD treatment workforce, enabling real-time patient monitoring and support, and engaging patients who are hesitant to participate in traditional behavioral health treatment systems. NIH-supported research is exploring how technology can best be leveraged to increase access to and quality of care to improve patient outcomes.

The FY 2016 target for SRO-7.1 was met. NIDA funds a broad portfolio of research on the potential of HIT tools to improve health care delivery and health outcomes related to SUDs as described in over 12 publications released in FY 2016. Research findings leveraging HIT to address five NIDA research priority areas are reported below:

Improving medication adherence using mHealth technologies – A recent NIDA-funded study examined the efficacy of a bidirectional text messaging intervention (TEXT) to improve antiretroviral medication (ART) adherence, improve attendance at health care visits, and reduce substance use among people living with HIV.[104] Text messaging is an ideal platform to collect and deliver real time health information because it can reach patients living in remote areas even when cellular service is weak. The automated TEXT intervention can send daily queries to patients checking on medication dosing, mood, and substance use, and can generate appropriate intervention messages based on patient responses. The pilot randomized clinical trial demonstrated that TEXT improved ART adherence and reduced missed HIV care visits; however, TEXT did not significantly improve substance use behaviors as compared to individuals receiving treatment as usual. Study authors are now considering utilizing mobile applications instead of text messages to provide enhanced privacy.

Integration of SUD treatment within broader health care management using health IT – Individuals with SUDs have high rates of medical and psychiatric comorbidities and exhibit poor uptake of health services, resulting in poor treatment compliance. Integration of SUD treatment within general health care not only improves overall health outcomes, including SUD outcomes, but also lowers overall health care costs. The NIDA supported LINKAGE Clinical Trial examined the feasibility and efficacy of a linkage intervention that utilizes patient portals to facilitate SUD patients' engagement with specialized health care providers to treat comorbid health conditions.[105] The LINKAGE intervention educates patients receiving SUD treatment how to proactively engage in their own health care management by using patient portals, accessing online treatment programs (e.g., coping with pain), obtaining medical information, and

[104] Ingersoll, K.S., et al., *Pilot RCT of bidirectional text messaging for ART adherence among nonurban substance users with HIV.* Health Psychol, 2015. 34 Suppl: p. 1305-15.
[105] Weisner, C.M., et al., *Examination of the Effects of an Intervention Aiming to Link Patients Receiving Addiction Treatment With Health Care: The LINKAGE Clinical Trial.* JAMA Psychiatry, 2016. 73(8): p. 804-14.

scheduling appointments. Although there were no significant differences at six months regarding SUD and depression outcomes between patients receiving the LINKAGE intervention compared to those receiving treatment as usual, it is expected that the LINKAGE intervention will demonstrate superior health benefits at later time points allowing patients more time to fully benefit from the intervention.

Preventing substance use using health IT – RealTeen is a gender-specific, web-based substance use prevention intervention tailored to meet the specific concerns of 13-14 year old adolescent girls to delay onset and reduce overall rates of substance use.[106] The intervention consists of nine sessions that address body image, decision making, peer pressure, drug knowledge, communication, and assertiveness. The intervention has undergone initial feasibility testing and is currently being revised to include hypothetical scenarios to allow users to practice skills acquisition in addition to improving enhanced content delivery for the web. Once complete, the intervention will be tested for acceptability with the target audience, feasibility, and efficacy for SUD prevention in adolescent girls.

Utilizing mHealth to improve smoking cessation interventions – My Mobile Advice Program (MyMAP) is a mobile optimized website accessed via smartphone, but designed to be accessible on a variety of mobile platforms to improve medication adherence and provide tailored advice to manage symptoms to help users quit smoking.[107] An initial pilot study determined that MyMAP is a feasible, acceptable, and potentially effective means to support varenicline use to quit smoking. Future studies are planned to determine the efficacy of this intervention for smoking cessation.

Improving health outcomes in people living with HIV using mHealth – African-American adolescent girls are disproportionately at risk for HIV infection. While HIV prevention interventions exist, dissemination and effective implementation remain limited and are often inaccessible to this high risk population. SiHLE*Web* is an internet version of the evidence-based, culturally informed HIV prevention program traditionally delivered to female African-American adolescents in an in-person group format that has been adapted for the web to overcome accessibility barriers. A recent pilot study determined that SiHLE*Web* improved knowledge, was easy to use, and generally attractive; however, users reported some difficulties with website navigation.[108] Further work is underway to improve this prevention intervention and determine the efficacy in preventing HIV infection within this vulnerable population.

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[106] Schwinn, T.M., J.E. Hopkins, and S.P. Schinke, *Developing a Web-Based Intervention to Prevent Drug Use among Adolescent Girls.* Res Soc Work Pract, 2016. 26(1): p. 8-13.
[107] McClure, J.B., et al., *Evaluating an Adaptive and Interactive mHealth Smoking Cessation and Medication Adherence Program: A Randomized Pilot Feasibility Study.* JMIR Mhealth Uhealth, 2016. 4(3): p. e94.
[108] Danielson, C.K., et al., *SiHLEWeb.com: Development and usability testing of an evidence-based HIV prevention website for female African-American adolescents.* Health Informatics J, 2016. 22(2): p. 194-208.

National Institute on Alcohol Abuse and Alcoholism		
Selected Measures of Performance	**FY 2016 Target**	**FY 2016 Achieved**
» Scientific Research Outcome-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.	Disseminate the newly released College Alcohol Intervention Matrix (CollegeAIM) and continue to disseminate the youth screening guide.	NIAAA promoted and disseminated the College Alcohol Intervention Matrix (CollegeAIM), and disseminated the youth screening guide through print and electronic media.
» Scientific Research Outcome-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems.	Continue to encourage alcohol screening for all youth, and referral to treatment for those who need it, by disseminating the youth screening guide. Continue to support online training on the use of the guide that allows healthcare providers to earn continuing medical education credits.	NIAAA encouraged youth alcohol screening and referral to treatment by supporting and promoting continuing medical education training on the use of the guide, organizing or participating in symposia addressing youth alcohol screening, and supporting studies to evaluate the youth screening guide in various settings and populations.

Prevention – Scientific Research Outcome-5.15

NIAAA embarked on a multifaceted effort to promote and disseminate the College Alcohol Intervention Matrix (CollegeAIM) throughout FY 2016. To introduce *CollegeAIM* to college and university officials, NIAAA senior staff and selected researchers from the *CollegeAIM* development team made numerous presentations, including at meetings of: the National Prevention Network; the Student Affairs Administrators in Higher Education, the American College Health Association; Community Anti-Drug Coalitions of America; Higher Education Center for Alcohol and Drug Misuse, Prevention, and Recovery; and the Campus Safety National Forum. NIAAA also collaborated with the NIAAA College Presidents Working Group to Address Harmful and Underage Drinking to organize two regional workshops which introduced *CollegeAIM* to college staff and offered step by step instructions on using the guide and website.

Treatment – Scientific Research Outcome-8.7

NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide* was devised to help health care providers identify alcohol use and AUD in children and adolescents, as well as identify risk for alcohol use, especially in younger children. It includes a brief two-question screener and support materials about brief intervention and referral to treatment that are designed to help surmount common obstacles to youth alcohol screening in primary care. To encourage youth alcohol screening and referral to treatment, NIAAA partnered with Medscape to develop an online continuing medical education (CME) training course based on the guide to familiarize clinicians with the screening and brief intervention process and increase their skill and comfort level with it. NIAAA promoted this CME training and organized or participated in symposia addressing youth alcohol screening at professional meetings. In addition, NIAAA has supported six studies to evaluate the effectiveness of its youth guide as an initial screen for drug use and other behavioral health problems primary care, emergency department, juvenile justice setting, and school settings, as well as with youth who have a chronic health condition (e.g., asthma, diabetes).

Research Highlights

Alcohol Screening Among Youth with Chronic Conditions.[109] In a recent NIAAA-funded study, investigators compared the use of NIAAA's two question youth screening tool with a standard 53 question instrument for assessing alcohol use and substance use disorders—the Diagnostic Interview Schedule for Children (DISC)—with children aged 9-18 who were being treated for Type 1 diabetes, asthma, cystic fibrosis, inflammatory bowel disease, or juvenile idiopathic arthritis at a large children's hospital. They found that NIAAA's youth alcohol screening tool is highly efficient for detecting alcohol use and AUD among these populations.

Screening for Underage Drinking and Alcohol Use Disorder in Rural Primary Care Practice.[110] This NIAAA-funded study used a computer-administered assessment to examine alcohol involvement, including patterns of alcohol consumption and presence of AUD in a large sample of adolescents seen in rural primary care settings. The study found that 10 percent of these youth over age 14 years had past-year AUD. When they examined various alcohol use patterns in this population as a screen for AUD, the researchers found that a single question on past year drinking frequency as recommended in NIAAA's youth guide was effective at identifying youth at moderate risk for AUD and those at the highest risk. These and other studies demonstrating the utility of the youth screening guide are expected to encourage further adoption of youth alcohol screening in healthcare and other appropriate settings.

[109] Levy S, Dedeoglu F, Gaffin JM, Garvey KC, Harstad E, MacGinnitie A, Rufo P, Huang Q, Ziemnik RE, Wisk LE, Weitzman ER. *A Screening Tool for Assessing Alcohol Use Risk among Medically Vulnerable Youth.* PLOS One. 2016. Doi:10.1371/journalpone.0156240

[110] Clark DB, Martin CS, Chung T, Gordon AJ, Fiorentino L, Tootell M, Rubio DM. Screening for Underage Drinking and *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* Alcohol Use Disorder in Rural Primary Care Practice. J Pediat. 2016; 173:214-20. doi: 10.1016/j.jpeds.2016.02.047.