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.

AUTHORIZING LEGISLATION

| TICTHORIZING ELGIDENTION | | | |
|--|--------------------------|------------------------------|---|
| (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 | | | |
| 21 st 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 |

¹See NIRSQ chapter for Authorizing Legislation on NIRSQ.

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APPROPRIATIONS HISTORY

| Fiscal Year | Budget Request | House | Senate | | |
|---------------|---------------------|------------------|--------------------|------------------|---|
| riscai Tear | to Congress | Allowance | 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.

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.

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

Allocation Methods: Competitive Grants; Contract; Intramural; Other

 $^{^2}$ 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.

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.

<u>Heart Diseas</u>e

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

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. 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.

 $[\]underline{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. 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. 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

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

⁴³ Nelson CE, et al. *Science* 2015; epub ahead of print. PMID: 26721684 http://www.ncbi.nlm.nih.gov/pubmed/26721684

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. 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. 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. In further support of these findings, other studies have shown that brain tissue of patients with schizophrenia has an altered neuronal structure. 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

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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. 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. 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. 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. 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.

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. 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. 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.

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. 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. 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. 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 Rico⁶⁰, and is linked to a steep increase in the number of babies born with microcephaly, a very

https://clinicaltrials.gov/ct2/show/NCT02848131?term=senolytic+drugs&rank=1

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

⁵⁶Clinical Trial: Senescence in Chronic Kidney Disease

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

⁶²Tang 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. 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. These results will pave the way for advancing liquid biopsies to test for a range of acute and chronic conditions.

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 $[\]frac{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 |
| 2014 ² | \$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 million 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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|--|--|-------------------|-------------------|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|---|---|--|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 | Conduct follow-up visits of enrolled subjects. | Complete follow-up visits of re-enrolled subjects and data analysis. | N/A |
| | of 200 subjects and conduct follow-up visits. (Target Not Met) | | | |
| 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 | FY 2017 | FY 2018 | FY 2018 |
|---|---|--|--|--------------------------|
| | Result / Target for Recent Result / (Summary of Result) | Target | Target | 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 longacting 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 |

OVERALL APPROPRIATIONS

| 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/recordin g 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 preclinical 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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|---|---|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target +/-FY 2017 Target |
|--|--|--|---|---|
| | (Summary of Result) 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 | FY 2017 | FY 2018 | FY 2018 |
|--|--|---|--|--------------------------------|
| | Result / Target for Recent Result / (Summary of Result) | Target | Target | 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) analyses, which predicts a group of COPD patients with high mortality. These results are being prepared for publication. | FY 2017 Target | FY 2018 Target | FY 2018 Target +/-FY 2017 Target |
|---|--|---|---|---|
| | 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/regime ns designed to preserve existing antimicrobials. | N/A | N/A |

| Measure | Year and Most Recent Result / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|--|--|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 coprescribing 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 | FY 2017 | FY 2018 | FY 2018 |
|---|---|--|--|----------------------|
| | Result / | Target | Target | Target |
| | Target for Recent Result / (Summary of Result) | | | +/-FY 2017 Target |
| between these circuits. | potential new treatment for | persistence during | | |
| (Output) | Target: Support research to compare and contrast rewarding versus aversive pathways in response to substances of abuse (Target Met) | 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 webbased component, an inperson 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, | FY 2016: Patient follow-up | Complete data | Initiate | N/A |
| identify culturally | was completed in a study | analysis for a | dissemination and | |

| Measure | Year and Most Recent Result / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|--|--|--|--|----------------------|
| | Target for Recent Result / (Summary of Result) | Zuzgev | Tunget | +/-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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|--|--|--|----------------------|
| | Target for Recent Result / (Summary of Result) | Ü | U | +/-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 |

| reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENE®), a national genetics research resource for rare inherited | Year and Most Recent Result / Target for Recent Result / (Summary of Result) in 3 foreign countries (Canada, Japan, Italy) increased patient participant pool and data sharing among investigators. Target: Create international | registered eyeGene users to 900. | FY 2018 Target | FY 2018 Target +/-FY 2017 Target |
|--|--|--|---|---|
| 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) | collaborations for Network, extending into 3 foreign countries. (Target Met) | | | |
| 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) from grantees on career outcomes for graduate students closely associated with training grants. (Target Met) | FY 2017 Target | FY 2018 Target | FY 2018 Target +/-FY 2017 Target |
|--|---|-------------------|---|---|
| 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 Cooperative Centers of Excellence in Hematology (CCEH). | 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-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 |

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| Measure | Year and Most Recent Result / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|--|--|--|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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) | (Summary of Result) | 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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|--|--|--|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 |

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| 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 | FY 2017 | FY 2018 | FY 2018 |
|--|--|---|---|----------------------|
| | Result / | Target | Target | Target |
| | Target for Recent Result / (Summary of Result) | | | +/-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 | FY 2017 | FY 2018 | FY 2018 |
|---------|---|------------------------------------|---------|------------|
| Measure | Result / | Target | Target | Target |
| | | | Ü | |
| | Target for Recent Result / | | | +/-FY 2017 |
| | (Summary of Result) | | | Target |
| | leadership programming and | regarding | | |
| | the Senior Leadership | incorporating the | | |
| | Program (SLP) role-play | latest technologies | | |
| | activities. | into leadership | | |
| | Target: Implement [IM] | development programs to | | |
| | recommendation from prior | determine which | | |
| | year assessments * Assess | are most effective | | |
| | best practices and review the | and practicable to | | |
| | literature regarding incorporating the latest | create efficiencies and/or enhance | | |
| | technologies into leadership | learning [EX 2015 | | |
| | development programs to | /AS 2017] | | |
| | 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] | | | |

| Measure | Year and Most Recent | FY 2017 | FY 2018 | FY 2018 |
|---|--|---|--|----------------------|
| | Result / | Target | Target | Target |
| | Target for Recent Result / (Summary of Result) | | | +/-FY 2017 Target |
| | (Summary of Result) | | | |
| | (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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|---|--|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 / | FY 2017 Target | FY 2018 Target | FY 2018 Target |
|---|---|--|---|----------------------|
| | Target for Recent Result / (Summary of Result) | | | +/-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 |

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| research institutions across the nation. (Output) | Year and Most Recent Result / Target for Recent Result / (Summary of Result) | FY 2017 Target | installed at NIH-supported research institutions 18 months after award | FY 2018 Target +/-FY 2017 Target |
|---|--|-------------------|---|---|
| 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 | \$1,000 to | \$1,000 to |
| | \$32,196,477 | \$31,079,385 | \$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.