#### APPROPRIATIONS LANGUAGE

#### NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [\$5,214,701,000]\$5,097,287,000, of which up to [\$16,000,000]\$50,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

#### NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, [\$3,115,538,000]\$3,069,901,000.

#### 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, [\$415,582,000]\$404,560,000.

## 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, [\$1,818,357,000]\$1,786,086,000.

#### 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, [\$1,696,139,000]\$1,659,416,000.

#### NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to allergy and infectious diseases, [\$4,629,928,000]\$4,700,548,000.

#### NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [\$2,512,073,000]\$2,434,144,000, of which [\$780,000,000]\$847,489,000 shall be from funds available under section 241 of the PHS Act [: *Provided*, That not less than \$320,840,000 is provided for the Institutional Development Awards program].

# EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [\$1,339,802,000]\$1,316,607,000.

### NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [\$715,903,000]\$687,249,000.

#### NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [\$693,702,000]\$681,613,000.

#### 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, \$77,349,000.

#### NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, [\$1,600,191,000]\$1,265,133,000.

# 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, [\$542,141,000]\$532,753,000.

# NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

For carrying out section 301 and title IV of the PHS Act with respect to deafness and other communication disorders, [\$423,031,000]\$416,146,000.

#### NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [\$146,485,000]\$143,942,000.

#### 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, [\$467,700,000]\$459,578,000.

#### NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [\$1,077,488,000]\$1,020,459,000.

#### NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [\$1,548,390,000]\$1,459,700,000.

#### NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [\$518,956,000]\$509,762,000.

## NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, [\$346,795,000]\$334,025,000.

#### NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to complementary and integrative health, [\$130,789,000]\$126,673,000.

#### 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, [\$279,718,000]\$279,680,000.

#### JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart 2 of part E of title IV of the PHS Act), [\$70,447,000]\$69,175,000.

#### NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [\$394,664,000]\$395,110,000: *Provided*, That of the amounts available for improvement of information systems, \$4,000,000 shall be available until September 30, [2017]2018: *Provided further*, That in fiscal year [2016]2017, the National Library of Medicine may enter into personal services contracts for the provision of services in facilities owned, operated, or constructed under the jurisdiction of the National Institutes of Health (referred to in this title as "NIH").

#### NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, [\$685,417,000]\$660,131,000: Provided, That up to \$25,835,000 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network [: Provided further, That at least \$500,000,000 is provided to the Clinical and Translational Sciences Awards program].

# OFFICE OF THE DIRECTOR (INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, [\$1,558,600,000]\$1,432,859,000, of which up to [\$30,000,000]\$40,000,000 may be used to carry out section [215]213 of this Act: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: [Provided further, That \$165,000,000 shall be for the National Children's Study Follow-on: Provided further, That NIH shall submit a spend plan on the next phase of the study in the previous proviso to the Committees on Appropriations of the House of Representatives and the Senate not later than 90 days after the date of enactment of this Act:] Provided further, That [\$663,039,000]\$553,039,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: Provided further, That of the funds provided, \$10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director of the NIH may spend up to \$8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act: Provided further, That up to [\$130,000,000]\$20,000,000 of the funds provided to the Common Fund are available to support the trans-NIH Precision Medicine Initiative: [Provided further, That of the amount provided to the NIH, the Director of the NIH shall enter into an agreement with the National Academy of Sciences, as part of the studies conducted under section 489 of the PHS Act, to conduct a comprehensive study on policies affecting the next generation of researchers in the United States:] Provided further, That, [of the funds from Institute, Center, and Office of the Director accounts within "Department of Health and Human

Services, National Institutes of Health,"] in order to strengthen privacy protections for human research participants, NIH shall require investigators receiving NIH funding, from amounts appropriated in this Act to NIH accounts, for new and competing research projects designed to generate and analyze large volumes of data derived from human research participants to obtain a certificate of confidentiality: Provided further, That the Director may direct up to 1 percent of the total made available in this or any other Act to all National Institutes of Health discretionary appropriations to activities that the Director may so designate: Provided further, That no such appropriation shall be decreased by more than 1 percent by any such transfers and that the Congress is promptly notified of the transfer.

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

#### **BUILDINGS AND FACILITIES**

For the study of, construction or demolition of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, \$128,863,000, to remain available through September 30, [2020]2021.

## LANGUAGE ANALYSIS

Language Provision	Explanation/Justification
NATIONAL CANCER INSTITUTE For carrying out section 301 and title IV of the PHS Act with respect to cancer, \$4,950,396,000, of which up to [\$8,000,000]\$50,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center (FFRDC) in Frederick, Maryland. (Department of Health and Human Services Appropriations Act, 2017.)	NIH requests the NCI repairs and improvement cap for the Fort Detrick campus be increased to \$50 million. In recent years, NCI has allocated a larger share of its overall appropriations to meet the needs of the Fort Detrick campus. The increase would allow NCI to complete priority projects, maintain FFRDC operations, and provide high-value support to the NCI mission, the research community, and to patients diagnosed with cancer.
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES [Provided, That not less than \$273,325,000 is provided for the Institutional Development Awards program.]	NIH requests this specific language be removed because it is no longer needed.
NATIONAL LIBRARY OF MEDICINE Provided, That of the amounts available for improvement of information systems, \$4,000,000 shall be available until September 30, [2017]2018:	NIH requests this language change to ensure continuation of two-year funding availability. The proposed language change helps to clarify that the \$4 million level is meant to be a ceiling only for the purposes of the two-year funding availability.
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES [Provided further, That at least \$500,000,000 is provided to the Clinical and Translational Sciences Awards program]	NIH requests this specific language be removed because it is no longer needed.
OFFICE OF THE DIRECTOR  Provided further, that the Director may direct up to 1 percent of the total made available in this or any other Act to all National Institutes of Health discretionary appropriations to activities that the Director may so designate: Provided further, That no such appropriation shall be decreased by more than 1 percent by any such transfers and that the Congress is promptly notified of the transfer.	NIH requests this specific language in order to provide clarity regarding the NIH Director's ability to use the one percent transfer authority, as provided in authorizing language.

Language Provision	Explanation/Justification
BUILDINGS AND FACILITIES For the study of, construction <i>or demolition</i> of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, \$128,863,000, to remain available through September 30, [2020]2021.	NIH requests that the word 'demolition' be added to the appropriations language.

# **AUTHORIZING LEGISLATION**

(Dollars in Thousands)	FY 2016 Amount Authorized	FY 2016 Appropriations Act	FY 2017 Amount Authorized	FY 2017 President's Budget
National Institutes of Health:				S
Section 3330B(b)(2)(C) of the PHS Act	\$32,311,349	\$32,311,349	\$33,136,349	\$33,136,349
Section 330B(b)(2) of the PHS Act <sup>1</sup>	\$150,000	\$150,000	\$150,000	\$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	\$77,349	\$77,349	\$77,349	\$77,349

<sup>&</sup>lt;sup>1</sup> This represents a mandatory appropriation under Public Law 114-10, the Medicare Access and CHIP Reauthorization Act of 2015 that was extended through 2017.

#### APPROPRIATIONS HISTORY

Fiscal Year	Budget Request	House	Senate	
riscai Teai	to Congress	Allowance	Allowance	Appropriation 1
FY 2008	\$28,849,675,000	\$29,899,004,000	\$30,129,004,000	\$29,312,311,000 2
FY 2008 Supp.				\$150,000,000
FY 2009	\$29,457,070,000	\$30,607,598,000	\$30,404,524,000 3	\$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 4
FY 2011	\$32,136,209,000		\$31,989,000,000	\$30,935,000,000 5
FY 2012	\$31,979,000,000		\$30,630,423,000	\$30,852,187,000 6
FY 2013				
Base	\$30,852,187,000		\$30,810,387,000	\$30,929,977,000 7
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 8
FY 2016	\$31,311,349,000 °	\$31,411,349,000	\$32,311,349,000	\$32,311,349,000 10
FY 2017	\$33,136,349,000 11			

<sup>&</sup>lt;sup>1</sup> Does not include comparability adjustments. Superfund and Type 1 Diabetes are included except where indicated.

<sup>&</sup>lt;sup>2</sup> Reflects: a) \$2,928,345,000 appropriated to the ICs for HIV research, b) NIH share of the Government-wide rescission of \$520,929,000, c) transfer of \$294,759,000 to the Global Fund.

<sup>&</sup>lt;sup>3</sup> Excludes funding for Superfund Research activities for which the Appropriations Committee did not mark up a figure.

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup> Reflects: \$3,059,277,000 appropriated to the ICs for HIV research; \$998,000 transfer from HHS to the Interagency Autism Coordinating Committee.

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> Reflects: Full-year continuing resolution base. Does not include Section 3004 OMB 0.2 percent across-the-board

<sup>&</sup>lt;sup>8</sup> Excludes Ebola-related funding. Includes Program Evaluation Financing of \$715,000,000.

<sup>&</sup>lt;sup>9</sup> Includes Program Evaluation Financing of \$847,489,000.

<sup>&</sup>lt;sup>10</sup> Includes Program Evaluation Financing of \$780,000,000. Excludes Ebola-related funding.

<sup>&</sup>lt;sup>11</sup> Includes Program Evaluation Financing of \$847,489,000. Includes mandatory financing.

## NARRATIVE BY ACTIVITY TABLE

				FY 2017 Request
(Dollars in Millions)			FY 2017	+/- <b>FY 2016</b>
	FY 2015 Actual <sup>1</sup>	FY 2016 Enacted <sup>1</sup>	President's Budget	Enacted
Program Level <sup>2</sup>	\$30,311	\$32,311	\$33,136	\$825
FTE	17,824	18,000	18,000	0

<sup>&</sup>lt;sup>1</sup> Excludes Ebola-related funding.

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

Allocation Methods: Competitive Grants; Contract; Intramural; Other

 $<sup>^2</sup>$  Includes Mandatory Type 1 Diabetes and Superfund in FY 2015, FY 2016, and FY 2017; NIGMS Program Evaluation funding of \$715 million in FY 2015, \$780 million in FY 2016, and \$847 million in FY 2017, and mandatory financing in FY 2017.

# PROGRAM DESCRIPTION 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 2010, the life expectancy of the average American increased by 7.9 years. Older Americans are not just living longer; they are staying healthy and active longer. Rates of reported risk factors for chronic disease (uncontrolled LDL or high blood pressure, smoking, etc.) have dropped by more than 10 percent since 1999. At age 65, Americans today can expect to live 19.2 more years, or 40 percent longer than in 1950, and the vast majority of these adults continue to live without any activity limitations, a major improvement in just the past 30 years. The largest growing demographic group in the United States consists of individuals living beyond the age of 85. We can attribute these remarkable improvements, in part, to NIH research. NIH-funded projects have made many contributions that have advanced health care and enhanced public health. The following are some selected examples.

#### **Heart Disease**

At the outset of the 20<sup>th</sup> 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.<sup>23</sup> 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 3,000 publications. This research, along with NIH-supported clinical trials, has led to 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 the 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

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<sup>&</sup>lt;sup>21</sup> Calculated from Health, United States, 2013: with Special Feature on Socioeconomic Status and Health, http://www.cdc.gov/nchs/data/hus/hus13.pdf

<sup>&</sup>lt;sup>22</sup> Calculated from Health, United States, 2010: with Special Feature on Death and Dying http://www.cdc.gov/nchs/data/hus/10.pdf and National Vital Statistics Reports Deaths: Preliminary Data for 2011 Vol. 61, Number 6 http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61\_06.pdf.

<sup>&</sup>lt;sup>23</sup> National Vital Statistic Reports, Volume 64, Number 2. Forthcoming. Deaths: Final Data for 2013. http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64\_02.pdf.

now living longer and healthier lives. Between 1969 and 2013, the death rate among adults with diabetes declined by 16.5 percent, 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. These remarkable improvements are due largely to clinical trials supported by NIH. In addition, basic science research 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 type 1 diabetes, progress toward the development of a fully reliable artificial pancreas provides 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 due to both 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. 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 both men and women. NIH-funded research has contributed to the

<sup>&</sup>lt;sup>24</sup> Ma, Jiemin et al. "Temporal Trends in Mortality in the United States, 1969-2013" JAMA. 2015;314(16):1731-1739. http://jama.jamanetwork.com/article.aspx?articleid=2466136&linkid=18099832

<sup>&</sup>lt;sup>25</sup> Gregg EW, Li Y, Wang J, Burrows NR, Ali MK, Rolka D, et al. Changes in diabetes-related complications in the United States, 1990-2010. N Engl J Med 2014 http://www.ncbi.nlm.nih.gov/pubmed/24738668
<sup>26</sup> http://www.cdc.gov/nchs/fastats/stroke.htm

<sup>&</sup>lt;sup>27</sup> Jauch, EC et al. Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2013 Mar;44(3):870-947. http://www.ncbi.nlm.nih.gov/pubmed/23370205

<sup>&</sup>lt;sup>28</sup> Bankhead C. Clot-busting drugs used more often in stroke. *MedPage Today*. August 23, 2013. http://www.medpagetoday.com/Cardiology/Strokes/41156

decrease in mortality, lowering the death rate by 20 percent from 1990 to 2010.<sup>29</sup> 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 1 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 it to live for many years. As a result, death rates dropped more than 50 percent between 1987 and 2010, and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s. 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 1994-2013, 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. <sup>32</sup> 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, this bacterium was the leading cause of meningitis and acquired mental retardation in children less than 5 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 ~20,000 cases annually in the early 1980s to less than 30 per year today. <sup>33</sup> The CDC has estimated that Hib vaccination has prevented 361,000 illnesses, 334,000 hospitalizations, and 13,700 deaths.

<sup>&</sup>lt;sup>29</sup> http://www.cdc.gov/cancer/lung/statistics/

<sup>30</sup> http://www.cdc.gov/hiv/pdf/statistics\_surveillance\_hiv\_mortality.pdf

<sup>&</sup>lt;sup>31</sup> Samji et al "Closing the gap: increases in life expectancy among treated HIV-positive individuals in the United States and Canada." PLoS One. 2013 Dec 18;8(12):e81355 http://www.ncbi.nlm.nih.gov/pubmed/24367482 <sup>32</sup> Whitney, MMWR, 2014

<sup>&</sup>lt;sup>33</sup> CDC MMWR 2014: Prevention and Control of *Haemophilusinfluenzae* TypebDisease Recommendations of the Advisory Committee on Immunization Practice

#### **Breast Cancer**

Primarily because of NIH-supported research, multiple breast cancer susceptibility genes have now been identified, including BRCA1, BRCA2, TP53, and PTEN/MMAC1. Genetic testing now allows for tailored, safer, and more efficient treatments. Recent research studies also 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 in 2012. 34.

#### **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 1990 and 2010, prostate cancer deaths per 100,000 men dropped from 38.4 to 21.9, with a 5-year survival rate approaching 99 percent. <sup>35</sup> Current research focuses on increasing understanding of the epidemiology and genetics of prostate cancer and improving treatment and diagnostic options.

#### **Cervical Cancer**

Cervical cancer is a deadly cancer in women. It is usually a slow-growing cancer that may or may not have symptoms, but it can be detected during routine gynecologic examinations. Nearly all cervical cancer is caused by human papillomavirus (HPV). Due to groundbreaking NIH research, two FDA-approved vaccines (Cervarix and Gardasil) are now available to prevent infection by HPV types 16 and 18, which cause about 70 percent of cervical cancer. In the first few years of HPV vaccine use, the prevalence of the types of HPV covered by the vaccine decreased from 11.5 percent to 5.1 percent among 14-19 year old women. Ongoing efforts to scale up the use of the vaccines both in the United States and abroad are underway.

### **Roots of Precision Medicine**

NIH-supported research has built an understanding of the processes underlying health and disease that enable us to think beyond decades-old models of organ systems. Thanks to a deep understanding of biology and behavior from the molecule to society, we can now begin to

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<sup>&</sup>lt;sup>34</sup> NCI Surveillance, Epidemiology, and End Results Program (SEER).

http://seer.cancer.gov/statfacts/html/breast.html

<sup>&</sup>lt;sup>35</sup> NCI Surveillance, Epidemiology, and End Results Program (SEER). http://seer.cancer.gov/statfacts/html/prost.html

<sup>&</sup>lt;sup>36</sup> Markowitz L et al. Reduction in HPV prevalence among young women following HPV vaccine introduction in the United States, National Health and Nutrition Examination Surveys, 2003-2010. *J Infect Dis.* 2013 Aug 1;208(3):385-93. http://www.ncbi.nlm.nih.gov/pubmed/23785124

approach disease treatment in a more precise way. Approved by the FDA in 2001, an early hallmark of this new approach is Gleevec® (imatinib), a highly effective treatment for the rare cancer chronic myelogenous leukemia (CML). Using DNA sequencing methods and molecular biology techniques to isolate the underlying genetic cause of CML, Gleevec® was developed in large part through NIH funding to target the specific, mutated signaling molecule (a tyrosine kinase) that causes the cancerous CML cells to grow uncontrollably. By inhibiting the tyrosine kinase, the cancerous cells cease to grow and die. The result is a remarkable change in prognosis for those diagnosed with CML. Prior to the development of Gleevec®, overall survival of patients was less than 50 percent with available treatment. With Gleevec®, five year survival rates exceed 89 percent, with minimal relapses or side effects, and patients with a new diagnosis of CML are now expected to live 30 years post-diagnosis, essentially a normal lifespan. Gleevec® now has been approved to treat several other cancers, including GIST (gastrointestinal stromal tumor); together, more than 100,000 patients with CML or GIST have received Gleevec®. Gleevec®'s effectiveness paved the way for a new industry of drugs; by the end of 2014, more than 39 drugs targeting different kinds of kinases were approved by the FDA.

#### **Infant Health**

In 1960, 26 of every 1,000 babies born in the United States died before their first birthday. By 2010, the infant mortality rate was 6.1 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.

#### **Adolescent Risk Behavior**

In the last three decades, biological, epidemiological, and social science discoveries funded by NIH have produced a detailed understanding of the risks and mechanisms that lead to drug abuse and addiction in adolescents. This knowledge in turn has informed several new science-based prevention approaches. Today, the rate of cigarette smoking by teenagers is at its lowest point since the NIH-funded Monitoring the Future survey began tracking drug use and attitudes of teens in 1975. Alcohol use by teenagers also has steadily declined since the 1970s, and continued to decline in 2014. 38,39

## **Age-Related Macular Degeneration (AMD)**

A major cause of blindness and the leading cause of new cases of blindness in people over age 65, AMD was largely untreatable prior to the 1990s. In 1991, an NIH-funded clinical trial established the value of laser treatment for advanced AMD to stabilize the condition. In 2001, NIH researchers announced that a daily dietary regimen of antioxidant vitamins and minerals

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<sup>&</sup>lt;sup>37</sup> http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/InfantMortality.htm#note1

<sup>38</sup> http://monitoringthefuture.org/pressreleases/14drugpr.pdf

<sup>&</sup>lt;sup>39</sup> http://www.drugabuse.gov/news-events/news-releases/2014/12/teen-prescription-opioid-abuse-cigarette-alcohol-use-trends-down

may delay the onset of advanced AMD by 25 percent. In 2012, a clinical trial supported by NIH showed that long-term treatment of AMD with either the drug Avastin or the drug Lucentis resulted in dramatic and lasting improvement in vision, such that two-thirds of patients had driving vision (20/40 vision or better). More recently, researchers have begun to understand epigenetic changes that can occur in individuals and to identify genes that result in an increased risk of AMD. Scientists are also developing new technologies to improve imaging methods for diagnosis.

#### **Hearing Loss**

As a result of NIH efforts that led to statewide screening for hearing loss in newborns and infants, nearly all infants born in U.S. hospitals in 2010 were screened for hearing loss, up from as few as one-tenth of infants screened in 1993. NIH-supported research also has driven the development of hearing aids from the first electronic hearing devices invented in the 1950s to the sophisticated digital devices available today. Innovative collaborations between NIH, the Department of Veterans Affairs, and the National Aeronautics and Space Administration have significantly improved hearing aid technology over the past 20 years. In addition to amplifying sound, today's hearing aids are able to address the challenges of understanding speech, localizing sound, and hearing in noisy environments. Furthermore, many children born with congenital deafness can now be successfully treated with cochlear implants, giving them a lifetime of hearing. According to the FDA, approximately 324,000 cochlear implants have been implanted worldwide, including about 58,000 U.S. adults and 38,000 U.S. children. Studies have shown that screening and implantation before the age of 18 months allows more than 80 percent of children with hearing loss to join mainstream classes with their normal-hearing peers, and saves society more than \$30,000 per child.

#### **Burns and Traumatic Injury**

NIH funded research on fluid resuscitation, wound cleaning, skin replacement, infection control, and nutritional support has greatly improved 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.

<sup>40</sup> http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx

<sup>&</sup>lt;sup>41</sup> Semenov et al. Age-Dependent Cost-Utility of Pediatric Cochlear Implantation. *Ear Hear*. 2013 Jul-Aug; 34(4): 402–412.

#### Alzheimer's Disease

Alzheimer's disease is a progressive, irreversible brain disease that slowly destroys memory and thinking skills, and eventually even the ability to carry out the simplest tasks of daily living. Alzheimer's disease is currently the sixth leading cause of death in the United States and affects as many as 5 million Americans age 65 and older. As recently as 30 years ago, very little was known about Alzheimer's disease, but research supported by NIH and other organizations has greatly expanded knowledge and understanding of brain function, risk factors, treatment, and prevention. NIH-supported imaging studies have provided dramatic insights into disease pathogenesis, and the need to initiate clinical trials at the earliest stages of disease (ideally even before symptoms have appeared) has become increasingly clear. While much more remains to be discovered in each of these areas, recent research has led to more than 90 drugs in clinical trials for Alzheimer's disease with many more in the pipeline awaiting FDA approval to enter human testing. In addition, the Accelerating Medicines Partnership, an NIH-led public-private partnership to transform and accelerate drug development, recently launched a new Alzheimer's Big Data portal for use by the research community.

#### Parkinson's Disease

Parkinson's disease is a neurodegenerative disorder, caused by the death of dopamine-producing brain cells that affect the ability of individuals to move. As many as one million Americans and an estimated 7-10 million people worldwide are living with Parkinson's, with ~60,000 Americans diagnosed with a new case every year. Though there is currently no cure for Parkinson's disease, a variety of medications exist that can provide relief for the symptoms, though the effectiveness of these drugs varies from case to case. In cases where the disease does not respond to drugs, NIH has supported the development of a therapy called Deep Brain Stimulation (DBS), in which electrodes are implanted directly into the brain to stimulate some of the affected areas. DBS can provide relief from many of the symptoms of Parkinson's, and in some cases can even reduce the need for other drugs, allowing patients to avoid the burden of those drugs' side effects. DBS has been FDA-approved for Parkinson's disease since 2002, and NIH continues to support research into understanding how to improve the process of both selecting appropriate patients and providing the best possible treatment.

## **Chronic Obstructive Pulmonary Disease (COPD)**

COPD is a progressive disease which includes two main conditions that coexist: emphysema and chronic bronchitis. COPD, which in many cases may be undiagnosed, is the third leading cause of death in the United States and a major cause of disability. The majority of COPD sufferers are current or former smokers over 40 years old. Large, multi-center NIH-funded clinical trials are evaluating the efficacy of several treatments in order to reduce the disability and costs associated with COPD. In addition, new studies are examining the genetic contributions,

43 http://www.ninds.nih.gov/disorders/parkinsons\_disease/parkinsons\_disease.htm

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<sup>42</sup> http://www.pdf.org/en/parkinson\_statistics

<sup>&</sup>lt;sup>44</sup> Weaver et al. Bilateral Deep Brain Stimulation vs Best Medical Therapy for Patients With Advanced Parkinson Disease: A Randomized Controlled Trial. *JAMA*. 2009;301(1):63-73.

<sup>45</sup> http://www.cdc.gov/copd/index.html

susceptibility factors, and disease progress of COPD, as well as attempting to understand the mechanisms that link COPD to cardiovascular health.

#### **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.

### Drug Re-purposed for Alzheimer's Disease

Drugs that are being developed or have been approved for use to treat particular symptoms or diseases may have usefulness for entirely new, and often unexpected, diseases. However, drugs that are in development but do not show positive early results may be shelved and forgotten. As a result of a unique public-private partnership supported by NIH, scientists are "rescuing" these drugs and testing them for potential use to treat other diseases. One such rescued drug is saracatinib, which was developed to treat cancer but did not progress well in clinical trials. Now, NIH-funded researchers, in partnership with AstraZeneca, the maker of the drug, have shown promising results using saracatinib to treat animal models of Alzheimer's disease. Researchers found that mice treated with the experimental drug had a complete reversal of spatial learning and memory loss, and the brains of the mice showed a restoration of the synapse loss typically seen in Alzheimer's disease. Clinical trials have commenced, and early results show that the drug is safe in humans. Additional clinical trials are underway to begin testing the efficacy of the drug to treat Alzheimer's disease.

### **Promising Results with a New Ebola Vaccine**

The outbreak of Ebola Virus Disease (EVD) in West Africa was devastating, not only because of its toll on human life but also because of the rapidity of its spread. In response to this crisis, NIH accelerated its long-standing support for EVD vaccine development. Two vaccines emerged: cAd3-EBOZ, which uses a chimpanzee-derived cold virus to deliver genetic material from the Ebola virus to generate immunity, and VSV-ZEBOV, which uses an animal virus that affects cattle (vesicular stomatitis virus) to carry the Ebola virus gene segment. Because the vaccines do not contain the entire Ebola virus, they are not capable of causing the disease. However, using pieces of the Ebola virus in the vaccine can stimulate the human immune system to create anti-Ebola antibodies that will protect the patient from the disease. Both vaccines proved to be safe in early phase clinical trials, and the vaccines are being tested in controlled clinical trials in Liberia with results expected in late 2015.

#### **Two New Medical Devices Enable Personalized Drug Testing in Patients**

For the promise of personalized medicine to become reality, biomedical science must join with technology to produce solutions that address each individual patient's specific needs. One step along this road is to eliminate the guesswork and lost time due to failed cancer treatments. Two NIH-funded research groups recently developed devices to allow doctors to try multiple treatments simultaneously on the same tumor. One device, called CIVO, includes up to eight needles arranged in an array, and each can be loaded with a different drug or drug combination.

The needles are injected into solid tumors that are near the skin's surface, and pieces of the tumor can be removed a few days later to examine the tissue around each injection site to see which treatment had the most profound effect. This device has been tried successfully in animals and a trial in four lymphoma patients demonstrated feasibility in humans and reported no adverse events.

A second device about the size of a rice grain can be implanted in a tumor to study the tumor's response to various anticancer treatments simultaneously. The device contains many tubes that can release micro doses of up to 16 drugs or drug combinations into a tumor. The tumor response is then assessed a day or two later via a minimally invasive biopsy of a small region of the tumor. This device has been tested successfully in mice thus far. These two devices could help optimize drug therapies before a full treatment regimen begins, improve drug response prediction, or even gather efficacy data on new drug compounds.

## **Digging Up New Antibiotics**

Manufacturing antibiotics began about 75 years ago, and bacteria have been evolving to evade these efforts ever since. Antibacterial resistance is a growing public health threat, with antibiotic-resistant infections claiming the lives of 23,000 Americans each year. NIH-funded scientists recently made progress in the battle against antibiotic resistance with the discovery of a new class of antibiotic drugs developed from ordinary soil – one of the most fertile places for the discovery of new antibiotics. Researchers used a new technology called a microfluidic "iChip," an apparatus roughly the size of a standard microscope slide which can assay approximately 10,000 different species of bacteria for antimicrobial activity at once. Using the iChip, researchers discovered the new antibiotic teixobactin, which was then used successfully to combat 19 types of bacteria in test tube experiments as well as to treat two different antibiotic-resistant infections in mice. Teixobactin uses a different mechanism to kill bacteria than other kinds of antibiotics, and scientists were unable to create strains of bacteria that would resist this drug. This promising development is just one angle of NIH's efforts to fight antibiotic-resistant infections.

## Peanut Allergies: Prevention by Early Exposure?

A growing number of parents and schools are contending with children with peanut allergies. In the United States, peanut allergies have quadrupled over the past 13 years and now affect more than 2 percent of Americans. Many parents have been advised not to introduce peanuts into their child's diet until at least two years of age. But in a recent NIH-funded study, researchers found that adding peanut-based foods to an infant's diet reduced the risk of peanut allergy between 70 and 80 percent. Feeding infants peanut-rich foods helped their immune system learn to tolerate peanuts and avoid an allergy later in life. Researchers did not report any adverse events from the study, indicating that the method is relatively safe. A second study, which dovetails with this work, involves a search for genes that increase the risk of peanut allergy. In this NIH-funded study, investigators examined the DNA of more than 2,700 individuals — including parents and children with and without clearly defined food allergies — and discovered

that a region on chromosome 6 harbors genetic risk factors for peanut allergy. <sup>46</sup> These findings represent long-awaited developments in understanding the causes and the potential means of prevention for peanut allergy.

#### **Insights into Energy-Burning Fat Cells**

White fat, one of two main types found in humans, tends to be located under the skin and around internal organs, and it stores excess calories. Too much white fat is characteristic of obesity and increases the risk of several metabolic disorders. In contrast, the second main type, brown fat, burns energy to create heat and help maintain body temperature. The darker color of brown fat is due to the presence of energy-generating mitochondria. Recently, researchers identified a third type of fat cell in humans called beige fat cells, which appear within white fat in response to triggers such as cold. The beige fat cells burn energy rather than store it, but it is not yet clear whether these cells are generated by a conversion of white cells into a more brown-like state or if they are newly produced in response to a stimulus (or a combination). Because beige and brown cells can burn calories, the finding may lead to new targets for therapies or new ways to engineer fat cells to fight obesity and its associated disorders.

#### 3-D Lasers Used to 'Print' New Airways

On the cutting edge of medical technology and regenerative medicine, doctors used a 3-D laser printer to create custom-made plastic airway splints to help three small children with a rare condition called tracheobronchomalacia, which causes weak, constantly collapsing airways. The printed splints, developed by NIH-funded researchers and made from materials that will be absorbed by the body over time, were attached to the children's tracheas, enabling them to breathe on their own. The splints are fitted precisely to each child, and they will expand as the children grow until they are reabsorbed by the body in about three years, by which time the children's airways will be able to function on their own. The pioneering device and procedure will now be tested on a variety of patients to gauge its breadth of applicability. This could be the first of many medical needs met by the new techniques made possible by 3-D printing technology.

#### Human Tissue-specific Networks Provide Comprehensive View of Disease Biology

Big data analyses are opening new doors in understanding how diseases work. Most studies of disease concentrate on understanding the disease process only in the affected cell type, but the advent of genomic sequencing provides new opportunities to explore other interactions that may play an important role. Investigators from seven institutions across the country collaborated in an NIH-funded study to combine big data from numerous disease and normal tissue sources to understand how genes work together to carry out functions in 144 different tissue and cell types. The researchers first pinpointed functional genetic interconnections for specific tissue types and then combined that information with the DNA-based genome-wide association studies from the

<sup>&</sup>lt;sup>46</sup> Hong X et al. Genome-wide association study identifies peanut allergy-specific loci and evidence of epigenetic mediation in U.S. children. *Nature Communications* 2015 Feb 24;6:6304. http://www.ncbi.nlm.nih.gov/pubmed/25710614

relevant disease. This cross-referencing technique, called a network-guided association study, or NetWAS, allowed researchers to identify associations between genes and diseases that were undetectable with previous methods. The resulting functional gene interaction networks for the kidney, brain, and other organs could provide maps for scientists looking to better understand the underlying causes of diseases or for possible drug targets or pathways. The researchers also produced an online resource that allows other scientists to explore interacting genes in hundreds of human tissues and cell types.

#### Nanotechnology Provides Means to Identify and Treat Brain Tumors

Neurological symptoms can be similar for different diseases, and standard techniques such as X-rays and MRI may not be sufficient to distinguish between one diagnosis and another. In cases such as brain tumors, a biopsy for definitive diagnosis may be risky or impossible. Realizing that a more accurate image of the tumor could aid diagnosis, an international consortium of NIH-funded academic investigators and industry representatives created a novel type of nano-imaging agents. They created the imaging agent by chemically attaching an MRI tracer molecule, which allows visualization, to microscopic nano-beads capable of crossing into the brain. This enabled the group to generate an "MRI virtual biopsy" that specifically targets tumor cells for efficient imaging. Using this non-invasive method, the investigators were able to use the same targeting agents in a therapeutic way by attaching the imaging agents to a treatment molecule that could be delivered directly to the tumor site. This novel method allows for the diagnosis and treatment of tumors without the necessity of biopsy in those cancers where biopsy is difficult to perform.

## **Early Detection of Pancreatic Cancer**

Pancreatic cancer is one of the most deadly forms of cancer—of the nearly 50,000 Americans diagnosed in 2015, only 7 percent are expected to survive after 5 years. <sup>47</sup> Part of what makes this disease so lethal is that it is very difficult to detect at a stage that is early enough for effective treatment. In July 2015, NIH-funded researchers published the results of a search for markers in the blood that could act as an early warning for pancreatic cancer. One protein in particular, called Glypican-1, was found at high levels in patients with both breast cancer and pancreatic cancer, and patients with more severe, later-stage disease tended to have more of this protein in their blood. This research presents a promising opportunity for physicians to diagnose some of the most deadly cancers before the disease has a chance to turn deadly, and uses a simple, non-invasive blood test to do so. If confirmed, these results would allow for earlier diagnosis and treatment that could increase survival rates for pancreatic cancer.

#### Lymphatic Vessels Discovered in Central Nervous System

For years, textbooks have described the brain as the only major organ lacking a direct connection to the lymphatic system, which carries immune cells and other cells or molecules (including proteins, bacteria, and fats) that occupy the space between tissues throughout the body. Given the widespread availability of advanced imaging techniques, the assumption that

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<sup>&</sup>lt;sup>47</sup> http://seer.cancer.gov/statfacts/html/pancreas.html

human anatomy has long been mapped, and a lack of evidence to the contrary, it came as quite a surprise when NIH-funded researchers discovered a pathway that carries fluid and immune cells from cerebrospinal fluid in the brain to nearby lymph nodes. These lymphatic vessels lay next to larger blood vessels that previously had obscured them from view. This discovery reveals a gap in our understanding of the human body that could have significant health implications, particularly for neurological diseases that are associated with immune system dysfunction, including Alzheimer's diseases, meningitis, and multiple sclerosis.

#### **Big Potential in Tiny 3D Heart Chambers**

The heart is essential to keeping human beings alive, and defects in the development of the heart can cause serious problems in children. However, the development of the heart is difficult to study in isolation, both because it is a complex, three-dimensional, moving structure and because it is required for life. Recently, a group of NIH-funded scientists created a model for studying the human heart in miniature. Using skin cells from adult patients, the researchers genetically reprogrammed them into induced pluripotent stem cells and then used those cells to produce cardiac tissue. While previous studies had succeeded in producing cardiac tissue, this group introduced a 3D structure that caused the cells to form tiny, pulsating microchambers that beat very similarly to the chambers of a full-size heart, and with a similar cellular organization. The researchers also showed that drugs which cause cardiac birth defects in children can cause similar defects in their miniature model heart, suggesting that this method may be useful for screening drugs for cardiac side effects in the future. This new "heart in a dish" model allows scientists to study the development of human heart cells more accurately than before, without having to use animal models, and could lead to a better understanding of how current and future drugs might affect the heart of a developing fetus.

#### **CRISPR** Used in Wide-Ranging Applications

CRISPR (clustered regularly interspaced short palindromic repeats) is a genome-editing technique hailed as the 2015 Breakthrough of the Year by Science magazine. Using a DNA-cutting enzyme called Cas9, it can make sequence-specific edits – a vast improvement on the precision, speed and throughput of the technology. This transformative development is having a huge impact on a wide range of research studies, and is revealing new targets for therapy and clinical trials related to genetic abnormalities.

## Non-invasive Glioblastoma Characterization to Help Predict Patient Outcomes

Glioblastoma is a highly lethal brain cancer and the most common brain cancer in adults. One of the inherent challenges in treating glioblastoma is the lack of non-surgical options for predicting the success of treatment. Magnetic resonance imaging (MRI) provides clinicians with the location and size of a tumor; however, multiple biopsy samples must be taken in order to truly assess a patient's specific disease state. Seeking to develop a non-invasive diagnostic approach, scientists attempted to detect MR image-based biomarkers to identify different types of glioblastoma. Building off of work from previous groups that have linked imaging features with gene expression data, this NIH-funded team was able to classify tumors into three distinct categories. These encouraging findings point the way for future non-invasive methods for identifying particular subtypes of disease, which could inform targeted therapies for

glioblastoma. This technique also could expand options to monitor disease progression and treatment response, thus enabling a more tailored approach to treating glioblastoma.

## 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 enabled voluntary leg movement through physiotherapy plus a noninvasive method called trans-cutaneous spinal stimulation, in which electrodes are strategically placed on the skin of the lower back. By the end of the study, 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 and regain autonomic functions that were lost due to paralysis. These advances offer options for patients that may not be able to endure additional surgery to implant a stimulation device and are helping to change the outlook for spinal cord injuries.

## **FUNDING HISTORY**

Fiscal Year	Amount <sup>1</sup>
2013 <sup>2</sup>	
Base	\$30,695,855,975
Sequestration	-\$1,552,593,211
Total Post-Sequestration	\$29,143,262,764
2014 <sup>3</sup>	\$30,061,862,000
2015 Actual <sup>4</sup>	\$30,311,349,000
2016 Fnacted <sup>4</sup>	\$32,311,349,000
2017 Budget Request <sup>5</sup>	\$33,136,349,000

<sup>&</sup>lt;sup>1</sup> 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; also includes NLM Program Evaluation (\$8.20 million) in FY 2014, and NIGMS Program Evaluation financing of \$715 mllion in FY 2015, \$780 million in FY 2016, and \$847.489 million in FY 2017.

 $<sup>^2</sup>$  FY 2013 appropriation includes the effect of sequestration, 0.2 percent across-the-board rescission, and Secretary's Transfers.

 $<sup>^3</sup>$  FY 2014 appropriation includes the effect of Secretary's Transfers, and it also reflects sequestration of the mandatory funding for Type 1 Diabetes.

<sup>&</sup>lt;sup>4</sup> Excludes Ebola-related funding.

<sup>&</sup>lt;sup>5</sup> Includes mandatory financing.

## SUMMARY OF THE REQUEST NARRATIVE

The FY 2017 President's Budget request would provide \$33.1 billion to NIH, which is \$0.8 billion above the FY 2016 Enacted level. It would include \$30.3 billion in discretionary funding, \$0.8 billion in Program Evaluation financing, and \$2.0 billion in mandatory funding.

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 (including the Special Type 1 Diabetes account), and National Institute of General Medical Sciences funding under Section 241 of the Public Health Service Act.

#### **Research Project Grants (RPGs)**

The FY 2017 President's Budget would provide \$18.2 billion for RPGs, which is \$386 million more than the FY 2016 Enacted level estimate. This amount would fund 9,946 Competing RPGs, or 807 less than estimated for the FY 2016 Enacted level. It also supports 24,608 Noncompeting RPGs, 1,241 more than the FY 2016 Enacted level. To sustain the maximum practicable number of new awards, the Competing RPG average cost of approximately \$469,000 for FY 2017 is essentially the same as the average cost reflected in the FY 2016 Enacted level.

• Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR). The FY 2017 President's Budget would provide \$863 million for SBIR/STTR program grants, which is \$58 million above the FY 2016 Enacted level. The statutory minimum set-aside requirement will increase from 3.45 percent in FY 2016 to 3.65 percent in FY 2017.

#### **Research Centers**

The FY 2017 President's Budget would provide \$2.6 billion for Research Centers, which is \$56 million less than the FY 2016 Enacted level. It would fund 1,354 grants, which is 27 less than the FY 2016 Enacted level.

#### **Other Research**

The FY 2017 President's Budget would provide slightly under \$2.1 billion for this mechanism, which is \$73 million more than the FY 2016 Enacted level. It would fund 6,856 grants, which is 109 more than the FY 2016 Enacted level.

## **Training**

The FY 2017 President's Budget would provide \$849 million for training, which is \$18 million more than the FY 2016 Enacted level. A two-percent increase to stipend rates is proposed to maintain the stipend's purchasing power and offset the effects of anticipated inflation. It would fund 16,421 Full-Time Trainee Positions (FTTPs), which is 225 more than the FY 2016 Enacted level.

### Research & Development (R&D) Contracts

The FY 2017 President's Budget would provide \$3.2 billion for R&D contracts, which is \$258 million more than the FY 2016 Enacted level. It would fund an estimated 2,281 contracts, which is 18 more than the FY 2016 Enacted level.

• Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR). Approximately \$91 million is identified within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts consistent with NIH adherence to applicable statutory threshold targets.

#### **Intramural Research (IR)**

The FY 2017 President's Budget would provide \$3.6 billion for IR, which is \$33 million more than the FY 2016 Enacted level. It accommodates required pay cost increases for Federal civilian employees and military personnel as well as employer-paid health insurance premium adjustments.

## **Research Management and Support (RMS)**

The FY 2017 President's Budget would provide \$1.7 billion for RMS, which is \$34 million above the FY 2016 Enacted level. The amount covers mandatory pay cost increases for Federal civilian employees and military personnel attributable to the same factors described for the IR mechanism, such as the proposed 2017 pay raise and projected growth in health insurance premium costs.

#### Office of the Director (OD)

The FY 2017 President's Budget would provide \$1.7 billion for OD, which is \$145 million more than the FY 2016 Enacted level.

#### • Other than Common Fund

The \$930 million allocated for OD elements other than the Common Fund is \$45 million more than the FY 2016 Enacted level, due to an increase for the BRAIN initiative.

#### Common Fund (CF)

Approximately \$776 million is allocated for CF-supported programs. This amount is \$100 million more than the FY 2016 Enacted level, due to an increase for the PMI Cohort Program, and represents about 2.6 percent of NIH total FY 2017 discretionary budget authority (exclusive of program evaluation financing resources).

#### **Building & Facilities (B&F)**

The FY 2017 President's Budget provides \$179 million for infrastructure sustainment projects associated with the B&F program, which is \$34 million above the FY 2016 Enacted level. This amount includes \$50 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

#### **Superfund Research Program**

The FY 2017 President's Budget would provide \$77 million which is the same amount as the FY 2016 Enacted level.

## **Type 1 Diabetes**

The FY 2017 President's Budget would provide \$150 million in mandatory funding for Type 1 Diabetes research grants, which is the same as the FY 2016 Enacted level.

## **Program Evaluation Financing**

The FY 2017 President's Budget would provide \$847 million for Program Evaluation Financing purposes, which is \$67 million above the FY 2016 Enacted level.

# **OUTPUTS AND OUTCOMES**

Measure	Year and Most Recent Result /	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	Target for Recent Result /			+/-FY 2016 Target
	(Summary of Result)			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 2015: NIH supported several studies (1) to identify potential pathways through which physical activity interventions, weight control interventions, or a combination of these interventions affect cancer prognosis among cancer survivors, and (2) to test these effects on relevant biomarkers.  Target: Identify potential pathways through which physical activity interventions, weight control interventions, or a combination of these interventions affect cancer prognosis among cancer survivors, or conduct intervention studies to test these effects on relevant biomarkers.  (Target Met)	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.	N/A	N/A
SRO-1.2 By 2016, compare the effectiveness of two treatments for over active bladder syndrome among women. (Outcome)	FY 2015: 250 women in this study have been randomly assigned to receive either an injection of Botox A® into the bladder or the Interstim® device. All women are being asked to complete bladder symptom diaries and questionnaires, and to undergo examinations every 6 months for 2 years after treatment.  Target: Evaluate any changes in urine biomarker levels in approximately 250 women that may be associated with one of the two treatments.  (Target Met)	Analysis completed for Overactive Bladder Questionnaire Short form and Treatment Satisfaction Survey.	N/A	N/A
SRO-1.3 By 2017,	FY 2015: Identified 14	Initiate testing of	Complete testing	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
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)	hypothesized mechanisms of treatment effect for novel interventions from emerging neuroscience or basic behavioral science of mental disorders.  Target: Identify one hypothesized mechanism of treatment effect for novel interventions that is based on emerging neuroscience or basic behavioral science of mental disorders.  (Target Exceeded)	hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical 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).	
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 2015: The Blueprint Neurotherapeutics Network team initiated three preclinical studies to enable filing Investigational New Drug (IND) applications with the Food and Drug Administration (FDA) in FY 2015.  Target: Initiate toxicology studies enabling an Investigational New Drug (IND) application for a Blueprint Neurotherapeutics Network project.  (Target Met)	File an Investigational New Drug application with the FDA for a Blueprint Neurotherapeutics Network project.	N/A	N/A
SRO-2.1 By 2015, evaluate islet transplantation in combination with immune modulation strategies for the treatment of type 1 diabetes in clinical trials. (Outcome)	FY 2015: Confirmed the efficacy of Purified Human Pancreatic Islet product transplant for treatment of severe hypoglycemia and achievement of tight glycemic control in patients with type 1 diabetes and severe hypoglycemic events.  Target: Evaluate islet transplantation in combination with immune modulation strategies for the treatment of type 1 diabetes in clinical trials.	N/A	N/A	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
SRO-2.2 By 2019, assess the efficacy of one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	(Target Met)  FY 2015: Cumulative enrollment of 160 patients was achieved and follow-up visits are being conducted.  Target: Achieve cumulative enrollment of 140 patients and conduct follow-up visits.	Complete enrollment of 200 subjects and conduct follow-up visits.	Conduct follow- up visits of enrolled subjects.	N/A
SRO-2.3 By 2018, evaluate the impact of two community-level combination prevention packages (which include universal HIV testing and intensified provision of HIV antiretroviral therapy and care) on population-level HIV incidence in the developing world. (Outcome)	(Target Exceeded)  FY 2015: Enrollment for the study, Population Effects of Antiretroviral Therapy to Reduce HIV Transmission, also known as "PopART," ended in March 2015 with a total of 38,382 participants.  Target: Complete target enrollment of 52,500 in the population cohort.	Complete first annual follow-up visits of participants enrolled in the first year of the study.	Complete second annual follow-up visits for Year 1 participants and first annual visits for those enrolled in Year 2.	N/A
SRO-2.4 By 2020, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding one new treatment option per year. (Outcome)	(Target Not Met)  FY 2015: An NIH-supported clinical trial has begun recruiting patients to test a new treatment for balance problems.  Target: Initiate testing one new potential treatment option for a balance disorder.  (Target Met)	Initiate testing one new potential treatment option for a hearing disorder.	Initiate testing one new potential treatment option for a communication disorder.	N/A
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these changes can be inherited.	FY 2015: Epigenomic maps were generated for three cell types, exposed to four environmental chemicals.  Target: Generate epigenomic maps of three cell types, exposed to four environmental chemicals.  (Target Met)	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.	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /			+/-FY 2016 Target
	(Summary of Result)			
(Output)				
SRO-2.9 By 2015, advance understanding of social determinants of health and health disparities using multilevel, transdisciplinary team science approaches by developing intervention models of how various factors affect individual health outcomes and their distribution in populations. (Outcome)	FY 2015: NIH implemented intervention models for reducing health disparities/inequities in various populations and is currently analyzing data to identify commonalities for interventions in various underserved populations.  Target: Implement intervention models for reducing health disparities/inequities in various populations and identify commonalities for interventions in various underserved populations.  (Target Not Met but	N/A	N/A	N/A
SRO-2.11 By 2016, conduct studies of young children to determine whether the plant estrogens in soy formula produce hormone-like effects. (Outcome)	Improved)  FY 2015: 16 datasets were finalized including: Ultrasound, Anthropometrics and Physical exam, Maternal 2 and 12 week questionnaires after all data management tasks were completed. Analyses of the datasets are ongoing.  Target: Finalize 8 datasets (including ultrasound, anthropometry and physical exam data) and begin analyses of these datasets.  (Target Exceeded)	Continue analyses of IFED datasets and prepare a draft manuscript regarding the estrogenic effects of soy formula on infant development.	N/A	N/A
SRO-3.4 By 2015, evaluate an HIV vaccine candidate in a test of concept (phase IIB) efficacy trial in order to move towards an HIV/AIDS vaccine. (Outcome)	FY 2015: In February 2015, NIH initiated HVTN 100, a Phase I/II study to evaluate the safety and immunogenecity of a vaccine regimen consisting of ALVAC-HIV and a gp120 protein subunit.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/-FY 2016 Target
	Target: Initiate a suite of studies to support efficacy evaluation and licensure of an HIV vaccine.  (Target Met)			
SRO-3.8 By 2018, 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 2015: Hormone receptor scoring for 75% of all cases was completed.  Target: Complete hormone receptor scoring for 75% of all cases.  (Target Met)	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.	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.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system in children. (Outcome)	FY 2015: Researchers have completed a compassionate use study to evaluate treatment with Janus Kinase (JAK) inhibitors in pediatric patients with the immune disorder CANDLE.  Target: Complete a clinical pilot study in a cohort of pediatric patients with a disorder of the immune system.  (Target Met)	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.	Design a clinical study testing an agent for a disorder of the immune system in children.	N/A
SRO-3.10 By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY 2015: NIH initiated a Phase II clinical trial to test the effectiveness of an extended release formulation of gabapentin (HORIZANT®) in reducing heavy drinking in individuals with moderate to severe	Complete phase 2 clinical studies of a candidate compound.	Complete one human laboratory study on a new candidate compound.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/-FY 2016 Target
	alcohol use disorder.  Target: Conduct Phase 2 clinical testing of a novel compound.  (Target Met)			
SRO-3.11 By 2017, advance the discovery of high need cures through innovations in the therapeutics discovery and development process, by developing 3-D human tissue chips that accurately model the structure and function of human organs. (Outcome)	FY 2015: Eleven of the twelve organ platform teams advanced to the integration phase and are working within the Tissue Chip Consortium, which includes other NIH and DARPA investigators, on organ connection.  Target: Advance three projects to integration of individual organ or system chips into a multiple tissue chip or organ microsystem.  (Target Met)	Complete integration of organ chip systems.	Demonstrate that integrated organ chip systems model the structure and function of human organs.	N/A
SRO-4.1 By 2017, enable 1-3 Bridging Interventional Development Gaps (BrIDGs) projects to have sufficient pre-clinical data for therapeutic agents in order to apply for Investigational New Drug (IND) approval from the FDA. (Output)	FY 2015: The BrIDGs program has awarded two toxicology contracts for projects selected in 2014.  Target: Complete contracts for and initiate 1-3 projects that were selected.  (Target Met)	Acquire drug material for and complete dose range finding toxicology studies for 1-3 projects.	Generate data to enable IND application on the 1-3 compounds for the projects that were selected.	N/A
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 2015: NIH supported the identification, development, and adaptation of three interventions for testing in Native American communities in FY 2015.  Target: Identify, develop, and adapt three multilevel interventions for testing in Native American communities.	Test three interventions in NA communities using rigorous study designs to test the effectiveness or efficacy of interventions.	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	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
	(Target Met)		interventions in NA communities, and adapt community interventions based on initial finding.	
SRO-4.4 By 2016, discover the molecular basis for 30 rare diseases. (Output)	FY 2015: The molecular bases of 15 rare diseases were discovered.  Target: Discover the molecular bases of 15 rare diseases.  (Target Met)	Discover the molecular bases of an additional 15 rare diseases.	N/A	N/A
SRO-4.5 By 2016, test a targeted nanoparticle for imaging and drug delivery to atherosclerotic plaque in animal models. (Output)	FY 2015: Data are currently being analyzed to correlate imaging and histochemistry.  Target: Correlate rabbit inflammation imaging studies with histochemistry to confirm efficacy of nanoparticle treatment.  (Target Not Met)	Extend the studies into a pre-clinical pig model to assess targeted delivery and efficacy in reducing inflammation.	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 2015: Identification of one new pathway/mechanism that regulates spermatogenic stem cells in their decision making process governing cell renewal vs. cell differentiation.  Target: Identify one new pathway/mechanism that regulates spermatogenic stem cells in their decision making process governing cell renewal vs. cell differentiation.  (Target Met)	Identify one epigenetic mechanism regulating spermatogenesis.	N/A	N/A
SRO-4.7 By 2016, determine the safety and effectiveness of two first- in-class treatments for nonalcoholic fatty liver	FY 2015: NIH finished data collection in obeticholic acid treatment trial of adult patients with NASH.	Analyze data from pediatric and adult NAFLD treatment trials.	N/A	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)	~~~~	24.50	+/-FY 2016 Target
disease in adults and children. (Outcome)	Target: Finish data collection in obeticholic acid treatment trial of adult patients with NASH.  (Target Met)			
SRO-5.2 By 2018, (a) identify genetic factors that enhance or reduce the risk of development and progression of chronic obstructive pulmonary disease (COPD) and (b) validate new genetic and clinical criteria that may be added to COPD classification and contribute to better and/or earlier diagnosis or prognosis of the disease. (Output)	FY 2015: Identified four clusters that show robust associations with clinical characteristics of COPD and known COPD-associated genetic variants.  Target: Using analysis of genetic and clinical data from the original 10,000 subjects, identify 1-3 COPD sub-classes that can then be tested for prognostic potential.  (Target Met)	Analyze longitudinal data for the first 1000 five year follow-up visits to identify 1- 3 predictors of disease progression.	Complete exome chip genotyping of 10,171 COPDGene subjects and identify 1 to 5 new rare and common genetic determinants of COPD.	N/A
SRO-5.3 By 2020, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease. (Output)	FY 2015: Sample selection for whole genome sequencing on additional multiply affected families was initiated. Planning of the Replication Phase has begun.  Target: Initiate Replication Phase to validate genes / regions of interest identified from case-control and family sequencing in ~50,000 samples from well phenotyped individuals by targeted sequencing and/or genotyping.  (Target Met)	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.	Continue confirmation of genomic regions of interest in the Discovery and Replication phase datasets. Continue harmonization of Discovery Phase and Replication Phase datasets.	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 2015: Optimized treatment strategies to reduce the risk of antimicrobial resistance were evaluated.  Target: Evaluate optimized treatment strategies to reduce the risk of antimicrobial resistance.	Discover two additional new candidate therapeutics for infections where resistance poses a significant public health threat.	Assess two novel approaches/regim ens designed to preserve existing antimicrobials.	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /			+/-FY 2016 Target
preserve existing	(Summary of Result)			
antimicrobials. (Output)	(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 2015: Identified and established the feasibility of 3 technologies through preliminary testing for potential use as point of care technology in the primary care setting.  Target: Establish feasibility of use of 3 to 4 identified technologies through preliminary testing.	Complete pilot clinical studies on 1 to 2 prototype devices.	Support research on continued development of one or two prototype devices that will begin to initiate the regulatory process.	N/A
GDO 5 6 D 2017	(Target Met)	D 1	T 1 ' 1	NT/A
SRO-5.6 By 2017, develop, evaluate, refine, and/or promote strategies for preventing prescription drug abuse and its consequences. (Output)	FY 2015: Promising results were obtained from development of tools to overcome opioid overdoses, development of analgesics and compounds to block side effects from pain medication for cancer, assessment of vaporized cannabis for neuropathic pain from spinal cord injury, and the implementation of opioid therapy guidelines to improve primary care among providers.  Target: Develop, test or disseminate strategies to prevent prescription drug abuse, including the development of pain medications with reduced abuse potential.  (Target Met)	Develop, test or disseminate strategies to enhance the use of naloxone for overdose prevention.	In basic research identify new targets or refine existing ones in the endocannabinoid system for the development of treatments of chronic pain without development of tolerance or dependence; in clinical research develop, evaluate, and/or refine two to four treatment strategies that target co-morbid opioid addiction and chronic pain; in translation research identify the impact of state level prescription monitoring programs (PMP) on prescriber behavior and patient outcomes.	N/A
SRO-5.7 By 2016, the	FY 2015: Twenty studies	By 2016,	N/A	N/A
members of the National	nominated and approved by	contribute to		

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
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)	practitioners are completed, underway, or in progress.  Target: By 2015, design 10 studies nominated by practitioners as relevant to their practices.  (Target Exceeded)	clinical decision- making based on evidence gained by the NPBRN studies.		
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 2015: 150 biological samples were assessed through complementary methods to characterize urologic microbial profiles of UCPPS patients and control subjects, and, through linking to associated clinical data, the profiles were related to patient characteristics, including symptoms and risk factors.  Target: Assess 150 biological samples through complementary methods to characterize urologic microbial profiles of UCPPS patients and control subjects and through linking to associated clinical data relate profiles to patient characteristics, including symptoms and risk factors.  (Target Met)	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
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	FY 2015: Phase I is underway and the 33 projects in the planning phase are building strong partnerships, generating baseline data, and completing pilot interventions. In 2015, NIH solicited applications for the intervention phase and 28 of the 33 participants applied.	Identify adaptive strategies and collect first year assessment variables.	Assess intervention progress and collect second year assessment variables.	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /	~g.v		+/-FY 2016 Target
	(Summary of Result)			
community level that will impact disparate conditions. (Output)	Target: Initiate the implementation of the Phase I plan and pilot, including baseline data.  (Target Met)			
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)	(Target Met)  FY 2015: NIH-supported research developed: strategies to reduce insomnia in patients with heart failure and relieve pain after cardiac surgery, and a new instrument for the measurement of fatigue.  Target: Develop one novel strategy for managing symptom clusters and that improves health outcomes such as HRQoL.	Test one novel strategy for managing symptom clusters and that improves health outcomes such as HRQoL.	Assess the efficacy of one strategy that improves health outcomes through symptom self-management.	N/A
SRO-5.13 By 2015, establish and evaluate a process to prioritize compounds that have not yet been adequately tested for more in-depth toxicological evaluation. (Outcome)	(Target Met)  FY 2015: A formal process for evaluating HTS results for use in prioritization of compounds for additional testing has been developed, and a model was developed to evaluate the estrogenic potential of chemicals and has been proposed for use.  Target: A formal process of prioritizing compounds for more extensive toxicological testing will be evaluated and used.  (Target Met)	N/A	N/A	N/A
SRO-5.15 By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance use, abuse, addiction and their consequences in underage populations. (Outcome)	FY 2015: NIH supported six studies to evaluate the effectiveness of the youth guide for alcohol screening and brief intervention in a variety of settings.  Target: Evaluate the effectiveness of screening	Disseminate the newly released College Alcohol Interventions Matrix (CollegeAIM) and continue to disseminate the youth screening	Promote existing resources and develop new resources to address underage substance use, abuse, and addiction in subpopulations of	N/A

Measure	Year and Most Recent Result / Target for Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target +/-FY 2016
	(Summary of Result)			Target
	and brief intervention for alcohol and other drug use in a variety of settings.  (Target Met)	guide.	youth.	
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2015: The data on complications in the Diabetes Prevention Program Outcomes Study was analyzed.  Target: Analyze data on complications in the Diabetes Prevention Program Outcomes Study.  (Target Met)	Enroll at least 2200 participants in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study.	Complete enrollment for at least one Restore Insulin Secretion protocol.	N/A
SRO-6.4 By 2015, identify and characterize two molecular pathways of potential clinical significance that may serve as the basis for discovering new medications for preventing and treating asthma exacerbations. (Outcome)	FY 2015: Identified and characterized two molecular pathways of potential clinical significance that may serve as the basis for discovering new medications for preventing and treating asthma exacerbations.  Target: Identify and characterize two molecular pathways of potential clinical significance that may serve as the basis for discovering new medications for preventing and treating asthma exacerbations.  (Target Met)	N/A	N/A	N/A
SRO-6.6 By 2015, provide at least one new or significantly improved minimally-invasive treatment for clinical use in patients using imageguided interventions. (Outcome)	FY 2015: NIH-supported research has led to development of several image-guided interventions that reduce the risk of adverse outcomes, shorten patient recovery time, and improve precision of procedures, especially related to brain, spinal cord, and nerves.  Target: Support new or	N/A	N/A	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)	Target	Taiget	+/-FY 2016 Target
SRO-7.1 By 2016, assess	significantly improved human subject research for image-guided interventions to reduce the risk of adverse outcomes to structures such as the brain, spinal cord, or nerves that are within or near the operating field.  (Target Met)  FY 2015: The ASPIRE (A	Complete data	N/A	N/A
the efficacy of a novel microbicide delivery system for the prevention of HIV. (Output)	Study to Prevent Infection with a Ring for Extended Use) study completed participant follow-up of the phase III trial of a novel microbicide delivery system.  Target: Complete follow up of a phase III trial of a novel microbicide delivery system.  (Target Met)	analysis on the safety and/or efficacy of a novel microbicide delivery system and release results publicly.		
SRO-7.2 By 2018, develop an evidence- based, online resource to help people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	FY 2015: The benefits of surgery remain for up to 8 years for patients who have a herniated lumbar disc; the benefits of surgery for people who had surgery for spinal stenosis decrease with time.  Target: Collect data on pain and function from Spine Patient Outcomes Research Trial participants 8 years after joining the study.  (Target Met)	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).	Integrate the individualized outcome models into an outcomes calculator and assess its use in a web-based environment.	N/A
SRO-7.3 By 2016, develop and/or evaluate one to four interventions using mobile technology to improve treatment delivery and adherence for addiction and related health consequences. (Output)	FY 2015: Studies examined the efficacy of mobile technology-based treatments to enhance treatment for patients with mental illness, and for interactive treatment of patients with drug addiction; and the feasibility of improving HIV antiretroviral treatment adherence with cell phone	Identify next steps for testing or deployment of 2-4 substance abuse treatment or medication adherence interventions using mobile technology.	N/A	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
	reminders, counseling, and two-way personalized text messaging.  Target: Continue to develop and/or test substance abuse treatment or medication adherence interventions using mobile technology.  (Target Met)			
SRO-8.2 By 2017, identify circuits within the brain that mediate reward for 1) drugs, 2) non-drug rewards such as food or palatable substances, and 3) aversion to drug effects, and 4) determine the degree of overlap between these circuits. (Output)	FY 2015: NIH-funded researchers defined circuits and portions of circuits that are important for the perception of reward that are activated in the presence or absence of drugs of abuse.  Target: Identify non-drug activated reward circuits and compare with drug-activated reward circuits.  (Target Met)	Support research to compare and contrast rewarding versus aversive pathways in response to substances of abuse.	Identify morphological and functional neuroplastic modifications due to drugs at the level of dendritic spines and electrophysiologic al indices and their persistence during the development of drug dependence (or during repeated intermittent drug administration).	N/A
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 2015: NIH researchers identified three key factors that influence the scaling up of research-tested interventions across large services systems such as child welfare, primary care, specialty care and community practice. These key factors include the utilization of technological approaches to enhance validation and scale-up; optimization of treatment fidelity in the delivery of research-based treatment; and the development of research community partnerships to promote research-tested interventions.	Initiate testing of hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical testing.	Establish one research-practice partnerships to improve dissemination, implementation, and continuous improvement of evidence-based mental health care services.	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)	Taiget	Target	+/-FY 2016 Target
	Target: Identify three (3) key factors influencing the scaling up of research-tested interventions across large networks of services systems such as primary care, specialty care and community practice. (Outcome)  (Target Met)			
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/intervention programs in minority communities. (Outcome)	FY 2015: Recruitment was initiated in three studies (and completed in one of these) testing various culturally tailored interventions to reduce health disparities in stroke.  Target: Initiate enrollment in two studies testing culturally tailored interventions to reduce health disparities in stroke.  (Target Exceeded)	Complete patient follow-up in a study testing a clinical program for improved blood pressure control in racial/ethnic minority populations.	Complete data analysis for a study that tested culturally tailored interventions to address major contributors to stroke disparities in racial/ethnic minority populations.	N/A
SRO-9.5 By 2015, assess the efficacy of long-term oxygen treatment in patients with COPD and moderate hypoxemia. (Outcome)	FY 2015: A publication reporting the results of the trial was submitted to a major peer-reviewed journal in December 2015. A second publication reporting on the design of the trial is in an advanced state of preparation.  Target: Complete data analysis and prepare results for publication on the efficacy of long-term oxygen treatment in patients with COPD and moderate hypoxemia.  (Target Met)	N/A	N/A	N/A

**Functional Area: Communication and Transfer of Results (CTR)** 

Measure	ommunication and Transfer  Year and Most Recent	FY 2016	FY 2017	FY 2017
1v1CaSu1 C	Result /	Target	Target	Target
	Ttobale /	Turget	Turget	141.500
	Target for Recent Result /			+/-FY 2016
	(C CD II)			Target
CTD 2 Dec 2017 manufa	(Summary of Result)	D-: 2016	D-: 2017	NT/A
CTR-2 By 2017, reach 500,000 visits to the	FY 2015: As of July 30, 2015, ULC visits totaled	By 2016, reach 300,000 total	By 2017, reach 500,000 total	N/A
website Genome:	185,000.	visits.	visits.	
Unlocking Life's Code.	100,000.	, 151 <b>6</b> 5,	, 151 <b>6</b> 5,	
(Outcome)	Target: By 2015, reach			
	150,000 visits.			
	(Target Exceeded)			
CTR-3 By 2016, partner	FY 2015: Selected 48	Partner with 20-	N/A	N/A
with 20 state and local	Outreach Partner	25 state and	11/11	10/11
mental health nonprofit	organizations to conduct	local mental		
organizations to facilitate	science-based education and	health nonprofit		
awareness among the	outreach projects aimed at	organizations to		
general public about the brain, mental health	reaching the general public and a variety of targeted	facilitate awareness		
disorders, research-tested	audiences, including	among the		
interventions and	populations that experience	public about the		
findings, and clinical	mental health disparities.	role of basic,		
trials research. (Outcome)	Tangati Summant 20, 25 atata	translational, and clinical		
	Target: Support 20-25 state and local mental health	research, and		
	nonprofit organizations in	opportunities to		
	conducting science-based	participate in		
	education and outreach	clinical research.		
	projects addressing the needs of populations that			
	experience mental health			
	disparities as defined by race			
	or ethnicity, age, education			
	or income, disability status,			
	geographic location, and risk status related to sex and			
	gender.			
	(Target Exceeded)			
CTR-4 By 2017, expand	FY 2015: Two NIH-funded	Develop a	Develop	N/A
and implement the broad use of Common Data	stroke clinical trials, one focused on stroke prevention	clinical research training module	collaborative model to enable	
Elements for 17	and another on rehabilitation,	on utilization of	implementation	
neurological disorders	began using the NINDS	Common Data	of the CDE	
among investigators	Common Data Elements in	Elements tools.	project as a	
conducting clinical	FY 2015.		long-term	
research. (Output)	Target: Utilize common data		sustainable resource for the	
	elements in two new clinical		clinical research	
	trials.		community.	
			-	
	(Target Met)			

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)	J	J	+/-FY 2016 Target
CTR-5 By 2017, increase the number of computer-indexed MEDLINE journals by 409 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	FY 2015: The number of computer-indexed MEDLINE journals was increased by 149 titles, thereby increasing indexing efficiency for MEDLINE.  Target: Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year.  (Target Exceeded)	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 121 titles over the previous year.	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year.	N/A
CTR-6 By 2017, improve NIH's ability to identify outcomes that result from NIH funded research projects and report to the public on research outcomes. (Outcome)	FY 2015: NIH applicants can gather information from My Bibliography, eRA Commons, FastLane and ORCID into SciENcv to generate biosketches.  Target: By 2015, introduce ScienCV, an electronic repository where NIH grant applicants and grantees can gather and store personalized information about their professional accomplishments, and select information from their repository to generate biographical sketches that will be accepted by NIH.  (Target Met)	By 2016, expand NIH's electronic infrastructure to support grantees' reporting of products and research results that result from NIH research grants.	By 2017, establish an electronic closeout process for NIH research grants which includes a Project Outcomes Report for the general public summarizing the project outcomes or findings that expand fundamental knowledge, enhance health, lengthen life, reduce illness and disability, and otherwise fulfill the programmatic goals of the research activity.	N/A

Functional Area: Capacity Building and Research Resource (CBRR)

Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
Wiedsufe	Result /	Target	Target	Target
	Tresure /	1 urget	1 unget	Tunget
	Target for Recent Result /			+/-FY 2016
				Target
	(Summary of Result)	37. 400/	37. 400/	27/1
CBRR-1.1 Provide	FY 2015: Award rate to	$N \ge 10\%$	$N \ge 10\%$	N/A
research training for	comparison group reached 10%.			
predoctoral trainees and fellows that promotes	10%.			
greater retention and	Target: N ≥10%			
long-term success in	14194111 = 1070			
research careers. (Output)	(Target Met)			
CBRR-1.2 Provide	FY 2015: Award rate to	N ≥ 10%	N ≥ 10%	N/A
research training for	comparison group reached			
postdoctoral fellows that	14% and exceeded the target			
promotes greater	by 4%.			
retention and long-term	Tanget N > 100/			
success in research	Target: $N \ge 10\%$			
careers. (Output)	(Target Exceeded)			
CBRR-2 Promote data	FY 2015:	(Maintenance	(Development	N/A
sharing and provide	Completed integration for	[Mat]) Maintain	[Dev]) Initiate	1,71
information in real time	Oracle 12i Upgrade.	deployed	development of	
through the NIH Business		business	planned business	
System (NBS) by	Target: (Integration [Int])	modules. *	modules to build	
developing, integrating,	Complete integration	Planned - Oracle	capacity and	
deploying and	activities for full	12i [Dep.2016]	functionality of	
maintaining business modules. (Output)	functionality and usability of priority modules for		the NIH Business	
modules. (Output)	successful development		System. *	
	efforts within 3 years of		Planned - NBS	
	development. * Planned -		Hosting to	
	Oracle 12i Upgrade		Oracle Cloud	
	[Dev.2012, 2014-			
	15/Dep.2016]			
	(Target Met)			
	FY 2015: Completed			
	development for Oracle 12i			
	Upgrade.			
	- r <del>o</del>			
	Target: Development [Dev])			
	Initiate development of			
	planned business modules to			
	build capacity and			
	functionality of the NIH Business System. * Planned -			
	Oracle 12i Upgrade			
	[continuation from			
	2014/Int.2015-16]			
	(Target Met)			

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)	8	8	+/-FY 2016 Target
CBRR-3 By 2016, develop diagnostic definitions and outcome measures for use in clinical research studies on chronic lower back pain (cLBP). (Output)	FY 2015: Subsequent to the Task Force issuing its report on the NIH Pain Consortium website, the dissemination of the report, including the recommended minimum dataset for all subsequent clinical studies on chronic low back pain, has been accomplished through a total of 9 peer-reviewed journals.  Target: Disseminate information about development and validation of standardized research diagnostic measures for cLBP. (For example, report to NIH Pain Consortium and publication in peer reviewed journal.)	Test standardized research diagnostic measures for cLBP.	N/A	N/A
	(Target Met)			
CBRR-5 By 2015, implement and evaluate leadership forums in cancer control planning in select low and middle income countries.  (Outcome)	FY 2015: Developed, implemented, and began evaluation on leadership forums in 3 regions of the world in FY 2015.  Target: Organize, implement, and evaluate leadership forums in two regions of the world.  (Target Exceeded)	N/A	N/A	N/A
CBRR-7 By 2017 expand the scope and reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENE®), a national genetics research resource for rare inherited ocular diseases, by adding new patient records to the database, augmenting and refining the phenotypic data collected, and by increasing the number of	FY 2015: The eyeGENE network has collected detailed phenotypic data, including diagnostic imaging and/or electrophysiology results for 1900 patients to enable precision diagnostics.  Target: Collect comprehensive phenotyping data from 500 patients, by using precision diagnostic, imaging tools and electrophysiological methods.	Create international collaborations for Network, extending into 3 foreign countries.	Increase the number of registered eyeGene users to 900.	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /	Tunger	Turger	+/-FY 2016
	(Summary of Result)			Target
registered researchers to	(Summing of Result)			
900. (Output)	(Target Exceeded)			27/4
CBRR-8 By 2017, characterize the three-dimensional atomic structure of 400 proteins of biomedical interest related to infectious agents. (Output)	FY 2015: 134 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.	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.	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
	(Target Exceeded)			
CBRR-10 By 2015, make freely available to researchers the results of 400 high-throughput biological assays screened against a library of 300,000 unique compounds, and the detailed information on the molecular probes that are developed through that screening process. (Outcome)	FY 2015: The Molecular Libraries Program (MLP) completed 448 HTS assays screened against a library of 300,000 compounds and generated 382 small molecule probes. The information on the probes and assays was deposited in PubChem.  Target: Make freely available to researchers the results of 400 high-throughput biological assays screened against a library of 300,000 unique compounds, and the detailed information on the molecular probes that are developed through that screening process.	N/A	N/A	N/A
CBRR-11 By 2016,	(Target Exceeded) FY 2015: Four hundred and	Accept and	N/A	N/A
collect and make available for distribution 600 well-characterized, high-quality human cell	eighty-eight new human cell lines were accepted by the NIH Human Genetic Cell Repository in FY 2015.	make available to scientific researchers an additional 200	IV/M	IVA

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2016 Target
lines for use in genetic and genomic research. (Output)	Target: Accept and make available to scientific researchers an additional 400 new human cell lines.  (Target Met)	new human cell lines.		
CBRR-12 Produce x-ray diffraction data for new protein structures that will enhance an existing x-ray resource for understanding basic biological processes.  (Output)	FY 2015: During FY 2015, 172 x-ray data sets from protein crystal structures were measured at the GM/CA beamlines, exceeding the target.  Target: Provide x-ray crystallographic data for 160 new structures of macromolecules of biomedical relevance to researchers worldwide.	Provide x-ray crystallographic data for 180 new structures of macromolecules of biomedical relevance to researchers worldwide.	Provide x-ray crystallographic data for 190 new structures of macromolecules of biomedical relevance to researchers worldwide.	N/A
CBRR-13 By 2017, archive and annotate new protein structures to support research in human health and disease and drug development. (Output)	(Target Exceeded)  FY 2015: During FY 2015, 9211 protein structures were archived and annotated at the Protein Data Bank and made available to the community, exceeding the target.  Target: Annotate and archive 9,000 new protein structures.  (Target Exceeded)	Annotate and archive 9,500 new protein structures.	Annotate and archive 9,500 new protein structures.	N/A
CBRR-14 By 2018, establish and utilize a national clinical network to conduct five stroke clinical trials using shared infrastructure and efficient processes. (Output)	FY 2015: To date, NIH StrokeNet has contributed 30% of the subject enrollment in the MISTIE 3 stroke trial, and is also assisting with recruitment in two additional NIH-funded stroke trials (CREST 2 and iDEF).  Target: Use the network's Regional Coordinating Centers for patient recruitment in a stroke trial.  (Target Exceeded)	Initiate the first new trial to be conducted in the Stroke Network.	To broaden the network's scope across stroke research, initiate one new trial in stroke prevention or stroke treatment within the stroke network.	N/A

Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	Target for Recent Result /			+/-FY 2016
	(Summary of Result)			Target
CBRR-15 By 2016,	FY 2015: GTEx Expression	Enroll 300	N/A	N/A
establish a resource	Quantitative Trait Loci	donors annually.	14/11	14/11
database and tissue bank	(eQTL) data from blood	,		
of 30 reference tissues	samples were compared to			
(e.g., liver, skin, heart,	results from previously			
bone) in which the	published studies and GTEx			
relationship between	demonstrated that a greater			
genetic variation and gene expression is	than 75% consensus list of replicated eQTLs were			
quantified and 3	significant in multiple GTEx			
additional molecular	tissues.			
analyses are performed.				
(Output)	Target: Demonstrate that at			
	least 75% of a consensus list			
	of replicated eQTLs are			
	significant in at least 1 GTEx tissue.			
	ussue.			
	(Target Met)			
CBRR-16 By 2016,	FY 2015: All KOMP2	Complete	N/A	N/A
demonstrate the use of an	centers have completed their	phenotyping the		
efficient, cost-effective	production goals. KOMP	2500 knockout		
pipeline characterizing (phenotype) 2500	generated 2500 knockout lines and phenotyped 1500	lines.		
genetically modified	lines.			
mice. (Outcome)				
,	Target: By the end of FY15,			
	produce 2500 knockout lines			
	and phenotype 1500 lines.			
	(Target Met)			
CBRR-17 By 2017, take	FY 2015: Progress report	Implement the	Adopt a system	N/A
steps to improve the	instructions have been	collection of	for reporting	1,112
quality and availability of	modified to direct NIH	information	training grant	
information to inform	grantees to report on whether	from grantees on	data and trainee	
decisions about the size	their institution uses	career outcomes	outcomes	
of the NIH training	Individual Development	for graduate	electronically.	
programs and the number of people in training to	Plans to manage the training of graduate students and	students closely associated with		
address future needs for	postdoctorates, and if so, to	training grants.		
the nation's biomedical	describe how.	6 6		
research workforce.				
(Output)				
	Target: Communicate widely			
	the expectation for grantees			
	to develop an institutional			
	policy requiring Individual Development Plans (IDP) be			
	implemented for every			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/-FY 2016 Target
	graduate student and post- doctorate supported by any NIH grant, and reportable on the grant progress report. (Target Met)			

**Functional Area: Management and Program Oversight (MPO)** 

	anagement and Program O		EX7.0015	EX. 2015
Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	T4 6 D4 D14 /			. / EX 2016
	Target for Recent Result /			+/-FY 2016
	(C			Target
150 15 2011	(Summary of Result)		27/1	27/
MPO-1 By 2016,	FY 2015: There was a 2%	A 2% decrease	N/A	N/A
decrease by 10% the	decrease in the budget	in the budget		
costs associated with	(comparing FY13 to FY14)	and a minimum		
trans-NIH recruitment	and there were over 530	of 400		
strategies for intramural	applications for the	applicants in the		
research group leaders.	combined programs.	combined		
		programs of the		
(Efficiency)	Target: A 2% decrease in the	Earl Stadtman		
	budget and a minimum of	Investigator		
	400 applicants in the	search, the		
	combined programs of the	Lasker Clinical		
	Earl Stadtman Investigator	Research		
	search, the Lasker Clinical	Scholars, and		
	Research Scholars, and the	the Early		
	Early Independent Scientist	Independent		
	program.	Scientist		
		program.		
	(Target Met)			
MPO-2 Provide	FY 2015: NIH's leadership	Examine [EX]	Examine [EX]	N/A
opportunities for	development programs have	key area to	key area to	
enhanced leadership	been evaluated for their	enhance	enhance	
skills to meet the	effectiveness and to identify	leadership skills	leadership skills	
challenges of workforce	specific technological			
management and/or	improvements to increase	NIH will	NIH will	
individual advancements.	access for students and	examine the	examine best	
(Ongoing)	improve engagement and	outcomes of the	practices in	
	retention. These include	Executive	supervisory	
	iPads, online meeting tools,	Leadership	onboarding to	
	and audience response	Program (ExLP)	determine how	
	systems.	to determine	to best prepare	
	Toronti Evamina (EVI las	whether it is	new NIH	
	Target: Examine [EX] key	effective in	supervisors for	
	area to enhance leadership	meeting its long-	their roles and	
	skills * Assess best practices	term goals, and	ensure that they	

Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	Target for Recent Result /			+/-FY 2016 Target
	(Summary of Result)			Target
	and review the literature	validate whether	are engaged and	
	regarding incorporating the	the program	committed to	
	latest technologies into	should continue	NIH. [IM 2018/	
	leadership development	with its current	AS 2019]	
	programs to determine which are most effective and	content [IM	Implement [IM]	
	practicable to create	2017/ AS 2018]	Implement [IM] recommendation	
	efficiencies and/or enhance	Implement [IM]	from prior year	
	learning [IM 2016/ AS 2017]	recommendation	assessments	
		from prior year		
	(Target Met)	assessments *	NIH will	
	EX 2015 NHP	Assess best	examine the	
	FY 2015: NIH's administrative intern and	practices and review the	outcomes of the	
	fellowship programs have	literature	Executive	
	been designed to implement	regarding	Leadership Program (ExLP)	
	rotations based on identified	incorporating	to determine	
	"future" competencies for	the latest	whether it is	
	development from previously	technologies	effective in	
	conducted evaluations and	into leadership	meeting its long-	
	literature review.	development programs to	term goals, and	
	Target: Implement [IM]	determine which	validate whether	
	recommendation from prior	are most	the program should continue	
	year assessments *	effective and	with its current	
	Implement recommendations	practicable to	content [IM	
	from study of NIH's	create	2017/ AS 2018]	
	administrative intern and	efficiencies		
	fellows program [EX 2014/ AS 2016]	and/or enhance learning [EX	Assess [AS]	
	110 2010]	2015 /AS 2017]	results of implementation	
	(Target Met)		* Assess best	
		Assess [AS]	practices and	
	FY 2015: To ensure the NIH	results of	review the	
	Training Center is providing	implementation	literature	
	NIH executive employees with valuable coaching	* Implement recommendation	regarding	
	experiences, a multi-level	s from study of	incorporating	
	evaluation approach has been	NIH's	the latest technologies	
	implemented in the executive	administrative	into leadership	
	coaching program. Mid-point	intern and	development	
	check-ins with the coach and	fellows program	programs to	
	employee ensures objectives	[EX 2014/ IM	determine which	
	are met and a closeout survey at the end of the engagement	2015]	are most	
	helps to evaluate the overall		effective and	
	effectiveness of the		practicable to create	
	engagement. This data is		efficiencies	
	used continuously to assess		and/or enhance	
	the program's executive			

Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	Target for Recent Result /			+/-FY 2016
	(Summary of Result)			Target
	coaches.		learning [EX	
	coaches.		2015 /AS 2017]	
	Target: Assess [AS] results		2013 /110 2017]	
	of implementation * Assess			
	results from implementing			
	best practices in			
	implementing and evaluating			
	executive coaching programs			
	in the federal sector. [IM			
	2014/EX2013]			
	(Target Met)			
MPO-3 Address diverse	FY 2015: NIH has utilized	Examine [EX]	Examine [EX]	N/A
workforce recruitment	the Pathways Program to hire	key area to	key area to	
needs to ascertain highly	a cohort of individuals who	enhance	enhance	
qualified staff to conduct	are provided rotational	recruitment	recruitment *Create a	
or support biomedical research. (Ongoing)	opportunities throughout the organization. They are	*Expansion of the Pathways	comprehensive	
research. (Ongoing)	provided extensive training,	Program to	program that	
	knowledge assessments and	STEM career	incorporates	
	research assignments.	path for focused	SMEs during the	
		students and	recruitment	
	Target: Examine [EX] key	supporting of	process, as	
	area to enhance recruitment	succession	appropriate. [IM	
	*Launch a robust OHR	planning efforts.	2018] [AS 2019]	
	succession planning effort to ensure OHR staff are	[IM 2017] [AS	Implement [IM]	
	available to meet the	2018]	Implement [IM] key area to	
	recruitment needs of NIH.	Implement [IM]	enhance	
	[IM 2016] [AS 2017]	key area to	recruitment	
		enhance	*Expansion of	
	(Target Met)	recruitment	the Pathways	
		*Launch a	Program to	
	FY 2015: Increased outreach	robust OHR	STEM career	
	efforts within the	succession	path for focused	
	Washington Metro area disabilities organizations to	planning effort to ensure OHR	students and supporting of	
	promote the NIH	staff are	succession	
	opportunities.	available to meet	planning efforts.	
	rr	the recruitment	[IM 2017] [AS	
	Target: Examine [EX] key	needs of NIH.	2018]	
	area to enhance recruitment	[AS 2017]		
	*Increase the use of		Assess [AS]	
	Community Recruitment	Implement [IM]	results of	
	Efforts. [IM 2016] [AS 2017]	key area to	implementation	
	(Target Met)	enhance recruitment	*Launch a robust OHR	
	(Target Wiet)	*Increase the	succession	
	FY 2015: NIH established an	use of	planning effort	
	in depth process for	Community	to ensure OHR	

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
		Target	Target	
	Target for Recent Result /			+/-FY 2016 Target
	(Summary of Result)			
	exhausting Title V prior to utilizing Title 42. A number of peer and pay review provisions were established as well to meet HHS requirements and ensure pay alignment between pay systems.  Target: Assess [AS] results of implementation *Establish increased oversight and review of Title 42 recruitment. [IM 2014]  (Target Met)  FY 2015: NIH hired 201 Interns, 43 Recent Grads, and 9 PMFs. NIH continues to effectively utilize the Pathways Program to support succession planning efforts which resulted in 37 conversions to permanent and/or term positions in FY 2015.  Target: Assess [AS] results of implement Pathways Program to establish a focused student and entry level recruitment plan that supports succession planning efforts at NIH. [IM 2014]  (Target Met)  FY 2015: NIH increased membership to a total of 24 people. Conducted 10 specific recruitment /outreach events to underrepresented communities to promote scientific training and careers at the NIH.  Target: Assess [AS] results	Recruitment Efforts. [AS 2017]	staff are available to meet the recruitment needs of NIH. [AS 2017]  Assess [AS] results of implementation *Increase the use of Global Recruitments. [AS 2017]	

Measure	Year and Most Recent	FY 2016	FY 2017	FY 2017
	Result /	Target	Target	Target
	Target for Recent Result /			+/-FY 2016 Target
	(Summary of Result)			Target
	of implementation *Create			
	the Scientific and Medical Recruitment Forum (SMRF)			
	to attract world-class			
	scientists and medical			
	professionals to drive			
	discovery and innovation at NIH. [IM 2014]			
MDO 4 P. II	(Target Met)	G 1 PGG	G 1 PGG	N/4
MPO-4 Reallocate laboratory resources	FY 2015: 25% of Principal Investigators were reviewed	Conduct BSC reviews of 25%	Conduct BSC reviews of 25%	N/A
based on external reviews	resulting in 25% of resources	of Principal	of Principal	
by Boards of Scientific	recommended to be	Investigators to	Investigators to	
Counselors. (Ongoing)	reallocated.	access quality of science in order	access quality of science in order	
	Target: Conduct BSC	to prioritize	to prioritize	
	reviews of 25% of principal	resources.	resources.	
	Investigators to assess			
	quality of science in order to prioritize resources.			
	prioritize resources.			
) (D) (T) (C) (T)	(Target Met)	GI 70.20	CT 70.40	27/4
MPO-5 Improve facility conditions in order to	FY 2015: The condition of the facilities portfolio	CIwa = 79.39	CIwa = 78.40	N/A
reach and maintain a	reached a CIwa of 82.5.			
Condition Index (CI)				
weighted average of 85 or above (CIwa=85).	Target: CIwa = 79.9			
(Ongoing)	(Target Exceeded)			
MPO-6 By 2017,	FY 2015: 82.8% of occupied	Target = 85.7%	Target = 85.68%	N/A
maintain the annual condition of buildings	gross square feet (GSF) reached a CI greater than 65.			
and facilities portfolio so	reactied a C1 greater than 65.			
that no less than 95% of	Target: 73.5%			
occupied gross square	(Torget Eveneded)			
feet (GSF) will have a CI greater than 65.	(Target Exceeded)			
(Output)				
MPO-7 Manage all	FY 2015: One (1) of the two	15 - Active	16 - Active	N/A
Buildings and Facilities	(2) active Recovery Act	Projects	Projects	
(B&F) line item projects so it is completed within	funded projects at the Facility Project Approval			
100% of the final	Agreement (FPAA) level			
approved project cost.	was managed effectively to			
(Ongoing)	ensure completion within			

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /	Turget	Turget	+/-FY 2016 Target
	(Summary of Result)			
	100% of the final approved project cost.			
	Target: 2 Active RA Project			
	(Target Not Met)			
	FY 2015: Nine (9) of the original eleven (11) active non-Recovery Act projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100% of the final approved project cost.			
	Target: 11 - Active Projects			
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)	(Target Not Met)  FY 2015: The design and construction of one (1) of the two (2) active Recovery Act funded projects was managed effectively so that no more than 10% of the portfolio incorporated a plus or minus 10% adjustments of the approved scope.  Target: 2 Active RA Project  (Target Not Met)  FY 2015: The design and construction of ten (10) of the initial eleven (11) 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: 11 - Active Projects  (Target Not Met)	15 - Active Projects	16 - Active Projects	N/A

Measure	Year and Most Recent Result /	FY 2016 Target	FY 2017 Target	FY 2017 Target
	Target for Recent Result /			+/-FY 2016 Target
MPO-9 Utilize performance-based contracting (PBC). (ongoing)	(Summary of Result)  FY 2015: Awarded 47% of eligible service contracting dollars employing the performance-based contracting principle.  Target: Obligate the FY 2015 OMB/OFPP goal of eligible service contracting dollars to PBC.  (Target Met)	Obligate the FY 2016 NIH goal of eligible service contracting dollars to PBC.	Obligate the FY 2017 goal of eligible service contracting dollars to PBC.	N/A
MPO-10 By 2015, report the percent of extramural construction projects that are in compliance with the post award 20 year usage requirement to conduct research.	FY 2015: 99% of the extramural construction projects were in compliance with the post award 20 year usage requirement.  Target: 95% of 212 projects are in compliance.  (Target Met)	N/A	N/A	N/A