APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$4,950,396,000] *$5,098,479,000*, of which up to [$8,000,000]*$16,000,000* may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, [$2,997,870,000]*$3,071,906,000*.

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, [$399,886,000]*$406,746,000*.

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, [$1,749,681,000]*$1,788,133,000*.

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, [$1,605,205,000]*$1,660,375,000*.

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, [$4,358,841,000]*$4,614,779,000*.

[For an additional amount for National Institute of Allergy and Infectious Diseases to prevent, prepare for, and respond to Ebola domestically and internationally, including expenses related to carrying out section 301 and title IV of the PHS Act, $238,000,000, to remain available until September 30, 2016: Provided, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.]

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [$2,371,476,000]*$2,433,780,000*, of which [$715,000,000]*$847,489,000* shall be from funds available under section 241 of the PHS Act[: Provided, That not less than $273,325,000 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, [$1,286,571,000]*$1,318,061,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [$684,191,000]*$695,154,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [$667,502,000]*$681,782,000*.

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, [$1,199,468,000]*$1,267,078,000*.

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, [$521,665,000]*$533,232,000*.

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, [$405,302,000]*$416,241,000*.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [$140,953,000]*$144,515,000*.

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, [$447,408,000]*$459,833,000*.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [$1,028,614,000]*$1,047,397,000*.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [$1,463,036,000]*$1,489,417,000*.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [$499,356,000]*$515,491,000*.

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, [$330,192,000]*$337,314,000*.

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, [$124,681,000]*$127,521,000*[: Provided, That these funds may be used to support the transition enacted in section 224 of this Act].

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, [$269,154,000]*$281,549,000*.

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), [$67,786,000]*$69,505,000*.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [$336,939,000]*$394,090,000*: Provided, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2016]*2017*: Provided further, That in fiscal year [2015]*2016*, 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, [$635,230,000]*$660,131,000*: Provided, That up to [$9,835,000]*$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 $474,746,000 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, [$1,401,134,000]*$1,430,028,000*, of which up to [$25,000,000]*$30,000,000* may be used to carry out Section [213]*212* 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 (NCS) or research related to the Study's goals and mission, and any funds in excess of the estimated need shall be transferred to and merged with the accounts for the various Institutes and Centers to support activity related to the goals and objectives of the NCS: Provided further, That NIH shall submit a spend plan on the NCS's next phase 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

[$533,039,000]*$553,039,000* shall be available for the Common Fund established under section 402A(c)(l) 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 NIH shall contract with the National Academy of Sciences for a Blue Ribbon Commission on Scientific Literacy and Standing: Provided further, That NIH shall submit to Congress an NIH-wide 5-year scientific strategic plan as outlined in sections 402(b)(3) and 402(b)(4) of the PHS Act no later than 1 year after enactment of this Act]*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 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]*$128,863,000*, to remain available [through September 30, 2019]*until expended*.

DIVISION G, TITLE II
GENERAL PROVISIONS

[SEC. 224. Title IV of the PHS Act is amended by: (1) Striking “National Center for Complementary and Alternative Medicine” in each place it appears and replacing it with “National Center for Complementary and Integrative Health”; (2) Striking “alternative medicine” in each place it appears and replacing it with “integrative health”; (3) Striking all references to “alternative and complementary medical treatment” or “complementary and alternative treatment” in each place either appears and inserting “complementary and integra1tive health”; (4) Striking references to “alternative medical treatment” in each place it appears and inserting “integrative health treatment”; and (5) Striking section 485D(c) and inserting: “(c) In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration of new and non-traditional approaches to health care treatment and consumption, including but not limited to nontraditional treatment, diagnostic and prevention systems, modalities, and disciplines.”.]

SEC. 225. In addition to amounts provided herein, payments made for research organisms or substances, authorized under section 301(a) of the PHS Act, shall be retained and credited to the appropriations accounts of the Institutes and Centers of the NIH making the substance or organism available under section 301(a). Amounts credited to the account under this authority shall be available for obligation through September 30, [2016] *2017*.

[SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan, as required under section 2(d)(2) of Public Law 111–375.]

[SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan, as required under section 2(d)(2) of Public Law 111–375.]

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]*$16,000,000* 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, 2015.)	NIH requests the NCI repairs and improvement cap for the Fort Detrick campus be increased to $16 million. The increase would allow NCI to complete priority facilities projects that will help, 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 not necessary to set-aside a specific amount in appropriations language, as NIGMS justification identifies the level of resources planned to be devoted to this program in FY 2016.
NATIONAL LIBRARY OF MEDICINE Provided, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2016]*2017*:	NIH requests this language change to ensure continuation of two-year funding availability.
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES [Provided further, That at least $474,746,000 is provided to the Clinical and Translational Sciences Awards program]	NIH requests this specific language be removed because it is not necessary to set-aside a specific amount in appropriations language, as NCATS justification identifies the level of resources planned to be devoted to this program in FY 2016.
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 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 *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, 2019] *until expended.*	NIH requests that the word 'demolition' be added to the appropriations language. In addition, NIH requests that language reverts back to previous language in the Consolidated Appropriations Act, 2012 (P.L.112-74) … by adding back 'until expended' to provide NIH maximum flexibility to administer these resources.
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES [For an additional amount for National Institute of Allergy and Infectious Diseases to prevent, prepare for, and respond to Ebola domestically and internationally, including expenses related to carrying out section 301 and title IV of the PHS Act, $238,000,000, to remain available until September 30, 2016: Provided, That such amount is designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.]	NIH requests that this specific language be removed because it was provided as one-time emergency funding for this program.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2015 Amount Authorized	FY 2015 Appropriations Act	FY 2016 Amount Authorized	FY 2016 President's Budget
National Institutes of Health:				
Section 301 and Title IV of the PHS Act	$29,369,000	$29,369,000	$30,236,511	$30,236,511
Section 330B(b)(2) of the PHS Act[1]	$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

[1] This represents a mandatory appropriation, for which FY 2015 was authorized and appropriated in the Protecting Access to Medicare Act of 2014 (P.L. 113-93), and for which reauthorization is proposed for FY 2016.

APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2007	$28,578,417,000	$28,479,417,000 [2]	$28,779,081,000 [2]	$29,030,004,000 [3]
FY 2008	$28,849,675,000	$29,899,004,000	$30,129,004,000	$29,312,311,000 [4]
FY 2008 Supp.				$150,000,000
FY 2009	$29,457,070,000	$30,607,598,000	$30,404,524,000 [5]	$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 [6]
FY 2011	$32,136,209,000		$31,989,000,000	$30,935,000,000 [7]
FY 2012	$31,979,000,000		$30,630,423,000	$30,852,187,000 [8]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [9]
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 [10]
FY 2016	$31,311,349,000 [11]			

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

[2] Reflects funding levels approved by the Appropriations Committees.

[3] Reflects: a) $2,905,802,000 appropriated to the ICs for HIV Research, b) add-on for pay cost of $18,087,000, c) transfer of $99,000,000 to the Global Fund, and d) supplemental bill transfer of $99,000,000.

[4] 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.

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

[6] 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.

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

[8] 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.

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

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

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

NARRATIVE BY ACTIVITY TABLE

(Dollars in Millions)	FY 2014 Actual	FY 2015 Enacted[1]	FY 2016 President's Budget	FY 2016 Request +/- FY 2015 Enacted
Program Level[2]	$ 30,070	$ 30,311	$ 31,311	$ 1,000
FTE	18,048	18,150	18,150	0

[1] Excludes Ebola-related funding.

[2] Includes Mandatory Type 1 Diabetes and Superfund in FY 2014, FY 2015 and FY 2016; includes NLM Program Evaluation ($8.20 million) in FY 2014; also includes NIGMS Program Evaluation funding of $715 mllion in FY 2015 and $847.5 million in FY 2016.

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

Allocation Methods: Competitive Grants; Contract; Intramural; Other

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

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.[15] Older Americans are not just living longer; they are staying healthy and active longer. Rates of reported risk factors for chronic disease (e.g., uncontrolled low-density lipoprotein (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.[16] The fastest 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

Through research advances supported in large part by NIH, deaths from heart disease have fallen by more than 60 percent since 1970.[17] The identification of cardiac risk factors, such as smoking, high blood pressure, and high cholesterol by the Framingham Heart Study along with NIH-supported clinical trials, led to the development of effective pharmacological and behavioral interventions and prevention strategies, as well as 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, developing and understanding the value of new diagnostic and imaging tests, and enhancing device technologies for treatment.

Diabetes

In the recent past, adults diagnosed with diabetes during middle age lived on average 10 years less than adults without diabetes. Thanks to the development of early screening methods and treatments that enable better control of diabetes-related complications, adults with diabetes are now living longer and healthier lives. Between 1997 and 2006, the death rate among adults with diabetes declined by 23 percent for all causes of death and by an extraordinary 40 percent for cardiovascular disease.[18] 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

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[15] Calculated from Health, United States, 2011: with Special Feature on Socioeconomic Status and Health, http://www.cdc.gov/nchs/data/hus/hus11.pdf

[16] Calculated from Health, United States, 2010: with Special Feature on Death and Dying http://www.cdc.gov/nchs/data/hus/hus10.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.

[17] Calculated from Health, United States, 2011: with Special Feature on Socioeconomic Status and Health, http://www.cdc.gov/nchs/data/hus/hus11.pdf

[18] Gregg, E.W. et al. Diabetes Care 35, 1252–1257 (2012). CDC News: http://www.cdc.gov/diabetes/news/docs/cvd_2012.htm

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 70 percent since 1950 and by 33 percent since 1996 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 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 relatively soon after the onset of symptoms. Current estimates suggest that fewer than 10 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.[19,20] 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 decrease in mortality, lowering the death rate per 100,000 people by 20 percent between 1990 and 2010. 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.

HIV/AIDS

In the 30 years since HIV was first recognized, NIH has established the world's leading AIDS research program. Each year, 50,000 people in the United States become infected with HIV, the virus that causes AIDS. Currently, there are more than one million people in the United States and 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

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[19] Bankhead, C. Clot-busting drugs used more often in stroke. *MedPage Today*. August 23, 2013. http://www.medpagetoday.com/Cardiology/Strokes/41156

[20] Jauch, E.C., 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*. 44:870-947 (2013). http://stroke.ahajournals.org/content/44/3/870.full.pdf+html

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. In fact, death rates have dropped by more than 13 percent, and a 20-year-old HIV-positive adult living in the United States or Canada who receives these treatments is expected to live into their early 70s, nearly as long as someone in the general population.[21] These treatments, combined with advances toward the development of an HIV vaccine and research to find a cure, mean the eradication of AIDS is possible with sustained effort.

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 death rate from breast cancer per 100,000 women declined from 33.3 to 22.1 between 1990 and 2010.

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. 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. Ongoing efforts to scale up the use of the vaccines both in the United States and abroad are under way.

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 in reducing

[21] Samji H, Cescon A, Hogg RS, Modur SP, Althoff KN, Buchacz K, Burchell AN, Cohen M, Gebo KA, Gill MJ, Justice A, Kirk G, Klein MB, Korthuis PT, Martin J, Napravnik S, Rourke SB, Sterling TR, Silverberg MJ, Deeks S, Jacobson LP, Bosch RJ, Kitahata MM, Goedert JJ, Moore R, Gange SJ; North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) of IeDEA. Closing the gap: increases in life expectancy among treated HIV-positive individuals in the United States and Canada. PLoSOne. 2013 Dec 18;8(12):e81355.

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 (MTF) survey began tracking drug use and attitudes of teens in 1975. Alcohol use by teenagers also has declined steadily since the 1970s, and continued to decline in 2013.

Age-Related Macular Degeneration (AMD)

A major cause of blindness and the leading cause of new cases of blindness in people over age 65, age-related 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 delayed 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 also are 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 (VA), and the National Aeronautics and Space Administration (NASA) have improved significantly 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.

Burns and Traumatic Injury

NIH-funded research on fluid resuscitation, wound cleaning, skin replacement, infection control, and nutritional support has improved greatly the chances of surviving catastrophic burns and traumatic injuries. In the mid-1970s, burns that covered even 25 percent of the body were almost always fatal. Today, people with burns covering 90 percent of their bodies can survive, although often with some impairments. Between 1990 and 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 in large part due to research findings that have transformed clinical practice.

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 five 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 greatly expanded knowledge and understanding of brain function, risk factors, treatment, and prevention. One particular focus of research is in detecting the disease before symptoms appear, in the hope that treatment might be able to reverse the disease at this earlier stage. A recent study identified a set of 10 compounds in the blood that might be usable as risk factors for memory decline, opening up the possibility for doctors to measure dementia risk with a simple blood test. 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.

Chronic Obstructive Pulmonary Disease (COPD)

COPD is a progressive disease that includes two main conditions that coexist: emphysema and chronic bronchitis. COPD is the third leading cause of death in the United States and a major cause of disability, which in many cases may be undiagnosed. 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, susceptibility, and disease progression of COPD, as well as attempting to understand the mechanisms that link COPD to cardiovascular health.

Chronic Pain

Chronic pain is a debilitating symptom of many long-term diseases and a major cause of disability among Americans. The NIH Pain Consortium was established to enhance pain research and promote collaboration among researchers across NIH. NIH-funded research has led to many advances in understanding the mechanisms behind chronic pain, including genetic contributions and neurological pathways, as well as developing new ways to manage and treat chronic pain.

Science Advances from NIH Research

NIH-funded scientists report thousands of new findings every year across the spectrum of biomedical science, from basic research to clinical studies and beyond. Many of the basic science discoveries build over time until they can be pieced together and translated into diagnostics or treatments to improve health. A few of the many recent NIH research accomplishments are listed below.

Ebola Vaccine Research and Development

The on-going Ebola virus disease epidemic in West Africa reminds us that viruses remain a threat to human health and can emerge at any time with devastating consequences. The need for a fully protective vaccine to prevent Ebola transmission is a priority. While NIH has supported

the development of such a vaccine since 2001, the epidemic that arose in early 2014 refocused attention on this need and expedited the development process, resulting in potentially beneficial experimental vaccine candidates.

In September 2014, a Phase I clinical trial assessed the safety, efficacy, and immunogenicity of an intramuscular vaccine co-created by NIH and GlaxoSmithKline. The vaccine causes infected cells to express a specific Ebola protein that, in turn, prompts an immune response. Prior to human study, non-human primates inoculated with this vaccine developed both antibody and cellular (T-cell) responses sufficient to protect them from the Ebola virus. Results indicated this vaccine was well-tolerated and elicited anti-Ebola antibody responses in the healthy adult volunteers. Moving forward, NIH plans to conduct Phase II/III studies in Liberia to assess the efficacy and safety of this vaccine compared to other Ebola vaccine candidates prior to wider vaccine distribution.

Another promising vaccine candidate began Phase I trials in October 2014 in thirty-nine healthy volunteers. The vesicular stomatitis virus (VSV) Ebola vaccine studies are being conducted in collaboration with the U.S. Department of Defense and NewLink Genetics Corp. A parallel study is on-going at the Walter Reed Army Institute of Research to evaluate in real time the vaccine's safety when provided at different dosages and compare the immune responses induced by one injection to the response to two doses.

Atlas of the Developing Brain

NIH-supported scientists contributed to the first comprehensive 3-D atlas of gene expression in the developing human brain as part of a larger project to profile gene expression throughout the course of brain development. Scientists gathered the data using a variety of genomic and imaging techniques on intact human pre-natal brains. The results provide a powerful map to pin brain areas to genes tied to neurodevelopmental disorders and human-specific brain functions. This resource will help reveal the early roots of brain-based disorders, such as autism and schizophrenia.

Gut Microbes Linked to Autoinflammatory Disease

Rheumatoid arthritis is a chronic inflammatory disorder that causes pain, swelling, and stiffness in joints when the immune system mistakenly attacks the body's own tissue. The immune system is influenced by the microbiome, which consists of trillions of microbes – bacteria, fungi, and viruses – that live in and on the body. NIH-supported researchers found that 75 percent of people with new-onset, untreated rheumatoid arthritis had the bacterium *Prevotella copri* in their intestinal microbiome. To test whether *P. copri* could influence inflammation, the team administered the bacteria to healthy mice so that the bacteria became part of their gut microbiome. Mice were then given a chemical that induced colitis, a model of gut inflammation. Animals with *P. copri* developed more severe symptoms than the mice that had not received the bacteria. The finding provides further evidence for a potential role for bacteria in this autoimmune disease.

Another recent NIH-funded study revealed that diet-induced changes to intestinal bacteria can influence susceptibility to autoinflammatory disease. The results could help guide new, dietary approaches to treat autoinflammatory diseases in susceptible people.

Genetic Microsurgery

A new technology called CRISPR (clustered regularly interspaced short palindromic repeats) is allowing scientists to specifically target genes for deletion, addition, activation, or suppression in what amounts to performing their own genetic microsurgery. The method harnesses a protein (called Cas9) that is involved in a bacterium's adaptive immune response that works through precise targeting of DNA. Using this system, NIH-supported researchers have altered DNA in human cells, rats, mice, zebrafish, bacteria, fruit flies, yeast, nematodes, and crops. This wide-ranging applicability makes the technology valuable for numerous applications, including conducting large-scale genetic screens in mammalian cells (recently validated by NIH-funded scientists), as well as the promise of new treatments for genetic diseases. Furthermore, the recent discovery of the specific structure of the Cas9 protein opens up new possibilities to maximize the potential of the CRISPR technology to advance understanding of disease and accelerate development of treatments and cures.

Safe, Effective Gene Therapy for Hemophilia

Hemophilia is a rare bleeding disorder in which the blood fails to clot normally. Current treatments require a lifetime of frequent injections, often twice a week, of an expensive clotting factor called factor IX in order to restore normal clotting. A recent NIH-funded clinical trial used gene therapy to reprogram the body's own cells to produce factor IX using special viruses that have been engineered not to cause diseases. When adult men with hemophilia were given an intravenous dose of the therapy, patients with the higher dose improved markedly, with the effects lasting for the entire 4-year period of the study.

New Insights into Bariatric Surgery Outcomes

Researchers who followed adults and teens who have undergone bariatric surgery for severe obesity found that this type of treatment is both safe and effective. Adults who had undergone the procedure not only had substantial weight loss but also significant improvements in diabetes and cardiovascular disease risk factors after three years. Although weight loss did vary, and the maximum weight loss occurred during the first year, many individuals with diabetes before surgery experience partial remission, and significant improvements in blood pressure and lipid levels were seen in many patients.

A 3-D Scaffold Guides Stem Cells into Cartilage-Producing Cells

NIH-funded researchers developed a 3-D scaffold that guides the development of stem cells into specialized cartilage-producing cells, an approach that could allow for the creation of orthopedic implants to replace cartilage in patients with arthritis. The scientists applied human stem cells from adult bone marrow to a 3-D woven scaffold coated with viruses. The viruses were used to transfer the gene TGF-β3 gene into the cells. The TGF-β3 drives the cells to become chondrocytes, which are the type of cells found in cartilage. Cells within the artificial scaffold successfully differentiated into chondrocytes within two weeks and created a cartilage-like extracellular matrix within four weeks. This approach could allow for implants that restore function to a joint immediately and drive development of a mature, viable tissue replacement.

Nature-Inspired Surgical Glue Mends Hearts

Researchers developed a new biodegradable, biocompatible, and easily manipulated tissue adhesive that could allow for less invasive surgeries that do not require sutures or staples. Inspired by the footpad of insects and the thick, sticky secretions of slugs and sandcastle worms,

whose fluids can create bonds underwater, the research team set out to develop a similar gel-like material that could function as a stable, water-insoluble, and elastic surgical glue. The gel's base consisted of glycerol, a basic building block of lipids, as well as a naturally occurring fatty acid. When mixed with a special light-sensitive chemical, the resulting gel solidifies after being exposed to ultraviolet (UV) light for five seconds. The researchers found that the gel easily spread over a surface and adhered to tissues in wet conditions, and they tested the glue in several settings. The team demonstrated that the glue stayed attached to the beating hearts of rats and pigs without altering heart function. The glue also was able to seal a defect in the wall of a rat heart and to create a leak-proof seal in the carotid artery of pigs. The technology has been licensed to a company, and patents based on the study have been filed. Long-term experiments will be needed to further evaluate the gel before it can be tested in humans.

Blood Test for Solid Tumors

A simple blood test was shown to detect solid tumors rapidly and accurately, track their progression over time, and could possibly predict their response to treatment. Solid tumors include cancers of the brain, breast, colon, and other tissues and consist of abnormal masses of tissue that usually do not contain cysts or liquid areas. Cancers of the blood, like leukemia, usually do not form solid tumors. Lung cancer solid tumors are particularly difficult to detect. NIH-funded scientists used genetic data from the Cancer Genome Atlas (TCGA) database to develop a molecular signature for non-small-cell lung cancers. Using this signature and samples from patients with non-small-cell lung cancer, researchers designed a highly sensitive DNA-based blood test that accurately identified all patients with advanced lung cancer, as well as half of patients whose lung cancer was in its earliest stage. Efforts are now under way toward clinical trials to measure this technique and its potential to improve the detection of many different kinds of solid tumors. The technique also may be developed to monitor treatment progression and to predict disease outcome.

Isolating and Profiling the Cancer Cells that Cause Metastasis

One of the issues that makes treating cancer so difficult is that cells can shed from individual tumors and spread throughout the body in a process called metastasis. Often, these cells enter the bloodstream in low numbers and result in new cancerous growths that are resistant to treatment. A recent study invented a new method which, using microfluidic technology to manipulate tiny volumes of fluid, can isolate these circulating cancer cells from the bloodstream in patients with metastatic breast cancer. Isolating these cells from the blood will allow researchers to directly characterize the cells that cause metastasis, to discover both genetic changes that lead to metastasis and the treatments which might be more likely to target it successfully.

Structure of Hepatitis C Cell Surface Protein Important for Virus Entry

Hepatitis C is an infectious disease caused by a virus that attacks the liver, leading to inflammation. Most infections become chronic and, if left untreated, can cause severe liver disease or liver cancer. Some proteins on the surface of the hepatitis C virus (HCV) are constantly changing, which allows the virus to avoid the natural defenses of the body's immune system. Using X-ray crystallography, NIH-supported researchers have determined the structure of a protein on the surface of the HCV that allows it to bind to, and gain entry into, liver cells. This finding may help in developing a vaccine against HCV, as well as new inhibitors.

Using Tiny Sponges to Fight MRSA

Methicillin-resistant, Staphylococcus aureus bacteria, commonly known as MRSA, is a critical threat to public health. In the United States, MRSA causes more than 80,000 skin, lung, and blood infections and kills about 11,000 people each year. The bacteria cause their devastation by secreting a toxin that punches holes in the membranes of cells, causing their contents to leak and the cells to die. To prevent the toxin from weakening the cells, NIH-funded researchers developed a sponge that can trap and bind the MRSA toxin. These sponges were then injected into mice to evoke an immune system response that would protect the mice against future exposure to the MRSA toxin. This could be a new technique to fight bacterial infections without the use of antibiotics.

Toxin Kills HIV-Infected Cells

Researchers found that an HIV-specific poison can kill cells in mice in which the virus is still reproducing despite antiretroviral therapy. In an effort to identify a targeted poison that could complement antiretroviral therapy by killing HIV-infected cells, 3B3-PE38, a genetically designed, HIV-specific poison, was developed. This immunotoxin targets HIV-infected cells and, when taken inside cells, shuts down protein synthesis and triggers cell death. To test the poison, researchers infected 40 mice bioengineered to have a human immune system with HIV. After several months, the mice were given a combination of antiretroviral drugs for four weeks. Half the animals subsequently received a two-week dose of the immunotoxin in addition to the antiretrovirals, while the other half continued receiving antiretrovirals alone. The addition of the immunotoxin significantly reduced the number of cells with detectable virus in multiple organs. It also lowered the level of HIV in the blood. Additional research is needed before this can be tested in clinical trials.

Antibiotics to Treat Drug-Resistant Forms of Tuberculosis (TB)

Researchers designed and tested a class of new antibiotics to treat TB, a contagious disease caused by infection with *Mycobacterium tuberculosis* (Mtb) bacteria. TB is treated with antibiotic drugs, but the bacteria have evolved to become resistant to these medications. An NIH-funded research team set out to develop new drugs that could work against drug-resistant strains of Mtb but have minimal side effects. Researchers analyzed the structure of an existing antibiotic and made various chemical modifications to create a new class of agents that were active against both multidrug-resistant (MDR) and extensively drug-resistant (XDR) bacteria. These compounds were not toxic in laboratory assays or in animals, and a subset of the compounds was highly effective against TB infections in mice. This work represents an initial step in the development of a new class of drugs to treat TB.

Technique Directs Immune Cells to Target Leukemia

In targeted immunotherapy, which directs the patient's own immune system to attack cancer cells, researchers first remove immune cells known as T-cells from the patient. These cells are genetically modified to produce an artificial receptor that can latch onto cancerous cells and trigger their destruction. Using a form of targeted immunotherapy, NIH-funded clinician-scientists induced remission in adults with an aggressive form of leukemia who had relapsed – a situation with typically poor prognosis. Of 16 patients who received the therapy, 14 were in complete remission within weeks of the T-cell infusion. Additional studies by NIH researchers found that targeted immunotherapy can treat not only cancers of the blood, but also other hard-

to-treat cancers, such as cancers of the epithelial cells that line the surface of the body, which comprise more than 80 percent of all cancers.

Drug Delivery System from Grapefruit Juice

Microscopic pouches made of synthetic lipids can serve as a carrier to protect drug molecules within the body and deliver them to specific cells. However, these synthetic carriers can pose obstacles, including potential toxicity, environmental hazards, and the cost of large-scale production. A naturally derived tiny particle found in grapefruit juice can be used to make micro-capsules that can safely deliver drugs and biologic agents to humans. Researchers involved in this study were searching for sources of edible, non-toxic, and plant-derived sources for drug delivery. Using these sources instead of mammalian or artificial sources could pose fewer potential health risks and be produced at a much lower cost. The grapefruit-derived molecules proved to be a safe, effective way to deliver some chemotherapy drugs in mouse models with no signs of adverse effects or toxicity. A phase I clinical trial is under way to determine whether the grapefruit-derived molecules can deliver anti-inflammatory drugs or chemotherapy drugs to targeted cells.

Mining a Treasure Trove of Big Data

Biomedical researchers and clinicians are generating mountains of digital data through DNA sequencing, biomedical imaging, and electronic health records. The next era of biomedical research will leverage the power of Big Data to advance scientific discovery. For instance, one researcher used a database that catalogued the DNA variation in patients to find new links among genes, diseases, and detectable physical or behavioral characteristics, such as cholesterol levels or body weight. Once the genes were linked to diseases, researchers mined the data to find associations between the diseases and physical or behavioral traits. One surprising finding they made was a link between elevated prostate specific antigen (PSA) and lung cancer. Other studies are now doing targeted searches of the 1percent of the human genome that codes for proteins, allowing for the rapid detection of new disease-causing mutations in patients with suspected genetic diseases. Two 2014 studies found that as many as 25 percent of undiagnosed patients were able to get a diagnosis using these new techniques. In the future, these links may be used to predict whether an individual will develop a particular disease or to identify a common biological mechanism underlying many diseases.

In addition to the treasure trove of DNA data, NIH-funded researchers are assembling a massive amount of data on the proteins in the human body to look at how and where genes are expressed. A team of researchers funded by several NIH Institutes and Centers examined tissue from multiple ages, tissues, and cell types and sequenced the amino acids that make up the proteins in each tissue, resulting in a map of the human proteome. The results included known products of 17,000 human genes - 84 percent of the known protein-coding genes in the genome - and 193 novel proteins that previously had not been identified, as well as a few genes which were expressed in unexpected places or times. This study and others like it offer a new trove of data to help other scientists understand human health and disease.

Telemedicine Catches Blinding Disease in Premature Babies

Retinopathy of prematurity (ROP) appears in more than half of all infants born at 30 weeks pregnancy or younger, although only about 5 to 8 percent of cases are severe enough to require treatment. In ROP, blood vessels in the retina begin to grow abnormally, which can lead to

scarring and detachment of the retina. Early diagnosis and prompt treatment is the best prevention for vision loss from ROP; thus, routine screening by an ophthalmologist is recommended for all babies who are born at gestational age 30 weeks or younger or who weigh less than 3.3 pounds at birth. NIH-supported researchers recently piloted a telemedicine strategy that sent photos of babies' eyes to a distant image reading center for evaluation by non-physicians trained to recognize signs of severe ROP. In the study, the non-physician readers accurately identified 90 percent of infants that ophthalmologists referred for further evaluation and potential treatment. The approach, if adopted broadly, could help ease the strain on hospitals with limited access to ophthalmologists and lead to better care for infants in underserved areas of the country.

Expanding the Genetic Alphabet

DNA is comprised of four chemical bases that form two base pairs (adenine with thymine and cytosine with guanine). The order of these pairs defines genes and other essential information for cell function. Synthetic biology aims to redesign natural biological systems for new purposes, and scientists previously expanded the genetic alphabet to include several unnatural base pairs in DNA. New experiments conducted by NIH-supported researchers have created the first living organism that can grow and reproduce using DNA base pairs that are not found in nature. This step of incorporating unnatural base pairs into an organism marks a substantial leap in the field and eventually could aid development of novel protein therapeutics, diagnostics, and lab reagents to have specific functions.

Placental Microbiome

The placenta is a vital organ that develops during pregnancy to deliver food and oxygen to the growing fetus via the umbilical cord. Until recently, the placenta was thought to be germ-free and sterile to keep the baby safe from infection. However, that left scientists at a loss to explain the complex array of microbes in babies' guts just a week after birth. Recently, a research team led by a recipient of an NIH Director's New Innovator Award discovered that the placenta itself has its own microbes. They also found that the placental microbes from babies born earlier than 37 weeks (preterm births) had a significantly different collection of microbes compared to those of babies carried to full term. This observation could have clinical significance if further research indicates that specific microbes or predictable shifts in the bacterial community explain why some infants are more likely to be born preterm. If this is the case, then early diagnostic testing may help identify women at risk for preterm birth and possibly lead to ways to encourage full-term pregnancies.

Advances in the Treatment of Sickle Cell Disease

Sickle cell disease is a genetic blood disorder that causes defective hemoglobin, the protein in red blood cells that carries oxygen. It affects millions worldwide, including approximately 100,000 people in the United States. The disease disproportionately affects African Americans, and current treatments are largely ineffective. NIH-funded studies are addressing this need from multiple angles, and several therapies hold promise. A recent study showed that a stem cell transplant from a healthy relative could reverse the disease in 87 percent of patients. NIH research also is working towards a drug therapy for sickle cell disease. Through a collaborative agreement, researchers at the National Center for Advancing Translational Sciences' (NCATS) Therapeutics for Rare and Neglected Diseases (TRND) program and AesRx, a biopharmaceutical company, developed a drug candidate to treat sickle cell disease that

specifically targets the underlying disease mechanism. TRND and AesRx researchers worked together to develop Aes-103 through a Phase II clinical trial to evaluate safety and effectiveness. The success of this trial resulted in the recent acquisition of the drug by a pharmaceutical company that will advance the clinical development activities required for regulatory approval and commercialization.

FUNDING HISTORY

Fiscal Year	Amount[1]
2012[2]	$30,852,187,000
2013[3]	
Base	$30,695,855,975
Sequestration	-$1,552,593,211
Total Post-Sequestration	$29,143,262,764
2014 Actual [2]	$30,061,862,000
2015 Enacted [4]	$30,311,349,000
2016 Budget Request	$31,311,349,000

[1] Appropriated amounts include discretionary budget authority received from both Labor/HHS appropriations that fund ICs as well as the Interior, Environment & Related Agencies appropriation that supports NIH Superfund Research activities. Includes mandatory budget authority derived from the Special Type 1 Diabetes account; also includes NLM Program Evaluation ($8.20 million) in FY 2014, and NIGMS Program Evaluation financing of $715 mllion in FY 2015 and $847.5 million in FY 2016.

[2] FYs 2012 and 2014 appropriation includes the effect of Secretary's Transfers.

[3] FY 2013 appropriation includes the effect of sequestration, 0.2 percent across-the-board rescission, and Secretary's Transfers.

[4] Excludes Ebola-related funding.

SUMMARY OF THE REQUEST NARRATIVE

The FY 2016 President's Budget request would provide $31.3 billion to NIH, which is $1.0 billion above the FY 2015 Enacted level.

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

Research Project Grants (RPGs)

The FY 2016 President's Budget would provide $17.2 billion for RPGs, which is $873 million more than the FY 2015 Enacted level estimate. This amount would fund 10,303 Competing RPGs, or 1,227 more than estimated for the FY 2015 Enacted level. It also supports 23,303 Noncompeting RPGs, 130 less than the FY 2015 Enacted level. In addition, the Competing RPGs average cost of approximately $461,000 would be very similar to the FY 2015 Enacted level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR)** The FY 2016 President's Budget would provide $765 million for SBIR/STTR program grants, which is $49 million above the FY 2015 Enacted level. The minimum set-aside requirement increased from 3.30 percent in FY 2015 to 3.45 percent for FY 2016.

Research Centers

The FY 2016 President's Budget would provide $2.6 billion for Research Centers, which is $63 million less than the FY 2015 Enacted level. It would fund 1,399 grants, 42 more than the FY 2015 Enacted level.

Other Research

The FY 2016 President's Budget would provide $1.9 billion for this mechanism, which is $38 million more than the FY 2015 Enacted level. It would fund 6,527 grants, which is 337 more than the FY 2015 Enacted level.

Training

The FY 2016 President's Budget would provide $785 million for training which is $23 million more than the FY 2015 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 15,735 Full-Time Trainee Positions (FTTPs), which is 204 more than the FY 2015 Enacted level.

Research & Development (R&D) Contracts

The FY 2016 President's Budget would provide $2.9 billion for R&D contracts, which is $3.0 million less than the FY 2015 Enacted level. It would fund an estimated 2,095 contracts, which are 17 more than the FY 2015 Enacted level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR)** The FY 2016 President's Budget includes a $79 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement increased from 3.30 percent in FY 2015 to 3.45 percent for FY 2016.

Intramural Research (IR)

The FY 2016 President's Budget would provide $3.52 billion for IR, which is $95 million more than the FY 2015 Enacted level. It accommodates mandatory pay cost increases for Federal civilian employees and military personnel, including the proposed 2016 pay raise of 1.3 percent, health insurance premium adjustments, and higher agency contributions to the Federal Employee Retirement System (FERS).

Research Management and Support (RMS)

The FY 2016 President's Budget would provide $1.58 billion for RMS, which is $19.5 million above the FY 2015 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 2016 pay raise of 1.3 percent, growth in health insurance premiums and higher FERS contribution rates.

Office of the Director (OD)

The FY 2016 President's Budget would provide $1.44 billion for OD, which is $29 million more than the FY 2015 Enacted level.

- **Other than Common Fund**

  The $877 million allocated for OD elements other than the Common Fund is $9.0 million above the FY 2015 Enacted level. This segment includes $158 million for Strategic Pediatric Research, $13 million more than the FY 2015 Enacted level.

- **Common Fund (CF)**

  Approximately $566 million is allocated for CF-supported programs. This amount is $20 million above the FY 2015 Enacted level and represents at least 1.9 percent of NIH total FY 2016 discretionary budget authority. It also includes $12.6 million from the Pediatric Research Initiative Fund, the same as the FY 2015 Enacted level.

Building & Facilities (B&F)

The FY 2016 President's Budget provides $145 million for infrastructure sustainment projects associated with the B&F program, which is $8 million above the FY 2015 Enacted level. This amount includes $16 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Superfund Research Program

The FY 2016 President's Budget would provide $77 million which is the same amount as the FY 2015 Enacted level.

Type 1 Diabetes

The FY 2016 President's Budget would provide $150 million in mandatory funding for Type 1 Diabetes research grants, which is the same as the FY 2015 Enacted level.

Program Evaluation Financing

The FY 2016 President's Budget would provide $848 million for Program Evaluation Financing purposes, which is $132 million above the FY 2015 Enacted level.

EVIDENCE AND INNOVATION STRATEGIES

The American public has entrusted the NIH with the Nation's largest investment in biomedical research. As a steward of public funds, the NIH is responsible for using its resources effectively to address the many health challenges that face our nation and the world. The NIH uses a well-established, rigorous decision-making process that relies on scientific expertise and stakeholder input when reviewing proposed projects and setting research priorities, while it continually seeks to improve its ability to assess the value of the research it supports. By enhancing the understanding of the results of its activities, the NIH can continue to make informed decisions for future investments and further increase the value it provides to society.

Clearly linking public health improvements to NIH-funded research remains a challenge. By its nature, research is a long-term and accumulative endeavor. Research outcomes cannot be foreseen with certainty, and unplanned results are common, which often provide new information that increases our understanding and may lead to redirecting the course of research activities. In some cases, the downstream impact or application of research findings is not known without further development by other entities. Despite the inherent challenges in evaluating biomedical research programs, the NIH has long engaged in activities to build a strong evidence base for current and future programs.

The NIH uses portfolio analysis tools to enhance analytic capabilities to extract meaningful information about fields of science, characteristics of research portfolios, and the outputs of research funding. Such analyses can inform the NIH about research needs, opportunities, and priority setting both within and across the organization. The Agency is actively identifying and developing new tools that expand and advance NIH-wide efforts in portfolio analysis; applying and disseminating current and newly developed tools to analyze biomedical research funding and the resulting impact; and promoting trans-NIH coordination of portfolio analysis activities and enhancing collaboration and training on these efforts. Portfolio analysis efforts have already proven useful in decision-making. For instance, all concepts that are selected for potential funding by the Common Fund undergo portfolio analysis to understand the current state of the science in each field and identify the research goals and unique opportunities where a Common Fund investment can have the greatest impact. One example of portfolio analysis conducted in support of a new Common Fund program area is the 4D Nucleome program, launched in FY 2015. Analysis of the NIH's investment in related scientific areas revealed limited large-scale efforts in genome-wide analysis and computational analyses. The 4D Nucleome program initiatives are designed to fill these gaps, providing a strategic investment that aims to catalyze this emerging scientific area.

The NIH also relies on program evaluation to generate a broad range of information about program performance and its context to support decision-making. Depending on its focus, an evaluation may examine the operations and outputs of a program, the extent to which program goals have been achieved, the factors that have impeded or contributed to its success, or how it may be modified to be more efficient and effective. Evaluation results are used to develop recommendations to provide appropriate level of support to a program, restructure program components, modify program goals, and/or support other program activities. The NIH frequently engages outside experts, such as the National Academy of Sciences, to conduct objective evaluations and provide independent, credible reports that offer advice and strategies to inform future research studies and investments.

To better support a wide range of analytic and evaluation activities, the NIH is working to strengthen its data and information technology infrastructure. In 2013, the Research Portfolio Online Reporting Tools (RePORT) program and several other NIH program analysis and reporting infrastructure initiatives were organized into a single entity for a coordinated NIH-wide effort. The NIH has begun to build an infrastructure that integrates the Agency's administrative data on research programs with other sources of information to support evidence-based decision-making, including the long-term results of NIH-funded research found in research publications and patents. Some of this information has already been made publicly available in the RePORT Expenditures and Results database (RePORTER) at http://projectreporter.nih.gov. In 2014, the NIH led the way in extending its reporting capabilities to other agencies by creating Federal RePORTER (http://federalreporer.nih.gov), a single searchable database of research projects funded by science agencies across the Federal government. In 2015, the NIH will release proof-of-concept software that will allow the Agency's program administrators to simultaneously search multiple databases for long-term research outcomes relevant to their programs. Efforts are also underway to increase the data integration and informatics capabilities needed to support portfolio analysis projects.

In addition, the new Research Performance Progress Report (RPPR) was recently implemented at the NIH. The RPPR will be used by all Federal agencies that award research and development grants, and will collect data on scientific products such as publications, patents, databases, software, new animal models, curricula, protocols, clinical interventions, and other outputs that result from the NIH's research funding. This effort to develop a standard method for documenting research products across the NIH and across the Federal government not only reduces the burden for grantees, but also provides a better foundation for making linkages across datasets, and has the potential to produce outcomes reporting that enables cross-agency comparisons.

Both the generation of knowledge and the application of that knowledge to health, as well as the impacts of these pursuits on the broader society, are vital parts of the NIH's value. A better understanding of all aspects of the NIH's work will lead to increased efficiency and effectiveness of that work. In 2013, the NIH Director charged the Scientific Management Review Board (SMRB), one of the Agency's advisory groups, with identifying the best methods and strategies for assessing the value of NIH-supported research. The NIH is currently exploring strategies to implement the SMRB recommendations to employ a more comprehensive, systematic, and strategic approach for building the evidence base for biomedical research.

OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 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 2014: Result Expected Dec 31, 2014 Target: Develop trans-disciplinary teams on 3 research projects that bring together behavioral intervention expertise, cancer biology, and other basic and clinical science disciplines relevant to the pathways of interest. (In Progress)	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.	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
SRO-1.2 By 2016, compare the effectiveness of two treatments for over active bladder syndrome among women. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: Recruitment of over 300 women for the study. (In Progress)	Evaluate any changes in urine biomarker levels in approximately 250 women that may be associated with one of the two treatments.	Analysis completed for Overactive Bladder Questionnaire Short form and Treatment Satisfaction Survey.	N/A
SRO-1.3 By 2017, complete testing of the hypothesized mechanism of treatment effect of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (e.g., pilot studies or efficacy trials). (Output)	FY 2015: Result Expected Dec 31, 2015 Target: (FY15) Identify one hypothesized mechanism of treatment effect for novel interventions that is based on emerging neuroscience or basic behavioral science of mental disorders.	(FY15) Identify one hypothesized mechanism of treatment effect for novel interventions that is based on emerging neuroscience or basic behavioral science of mental disorders.	(FY16) Initiate testing of hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical testing.	N/A
SRO-1.4 By FY 2016, advance a novel drug candidate for a disease that affects the nervous system to the point of preparedness for human studies. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Complete medicinal chemistry optimization for one project (compound) in the Blueprint Neurotherapeutics Network. (In Progress)	Initiate toxicology studies enabling an Investigational New Drug (IND) application for a Blueprint Neurotherapeutics Network project.	File an Investigational New Drug application with the FDA for a Blueprint Neurotherapeutics Network project.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2014: Result Expected Dec 31, 2014 Target: Perform the primary endpoint analysis in CIT-07, which is a clinical trial of islet transplantation (alone) in Type 1 diabetes.	Evaluate islet transplantation in combination with immune modulation strategies for the treatment of type 1 diabetes in clinical trials.	N/A	N/A
SRO-2.2 By 2019, assess the efficacy of one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Develop trial protocol and begin patient enrollment. (In Progress)	Achieve cumulative enrollment of 140 patients and conduct follow-up visits.	Complete enrollment of 200 subjects and conduct follow-up visits.	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)	FY 2014: Result Expected Dec 31, 2014 Target: Initiate a trial of a combination prevention approach to preventing HIV infections on a population level in Zambia and South Africa (In Progress)	Complete target enrollment of 52,500 in the population cohort	Complete annual follow-up visits and HIV incidence evaluations	N/A
SRO-2.4 By 2020, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding one new treatment option per year. (Outcome)	FY 2015: Result Expected Dec 31, 2015 Target: Initiate testing one new potential treatment option for a balance disorder.	Initiate testing one new potential treatment option for a balance disorder.	Initiate testing one new potential treatment option for a TBD communication disorder.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these changes can be inherited. (Output)	FY 2015: Result Expected Dec 31, 2015 Target: Generate epigenomic maps of three cell types, exposed to four environmental chemicals.	Generate epigenomic maps of three cell types, exposed to four environmental chemicals.	Assess transgenerational effects of 6 exposures in 3 generations of animals.	N/A
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 2013: Teams of transdisciplinary scientists at NIH Centers for Population Health and Health Disparities have developed multilevel intervention strategies directed at more than just individual behavior change to prevent disease burden and improve public health. Target: Develop interventions directed at more than two factors (such as both individual level and social context) and more than just individual behavior change. (Target Met)	Implement intervention models for reducing health disparities/inequities in various populations and identify commonalities for interventions in various underserved populations.	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)	FY 2013: 1,255 Infant Phase visits were completed. Target: Complete 100 Infant Phase study visits. (Target Exceeded)	Finalize 8 datasets (including ultrasound, anthropometry and physical exam data) and begin analyses of these datasets.	Continue analyses of IFED datasets and prepare a draft manuscript regarding the estrogenic effects of soy formula on infant development.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2013: Researchers tested DNA/MVA vaccine in non-human primates and phase 1trials; showing the induction of durable CD4 and CD8 T-cell and binding antibody responses. Target: Advance at least one promising candidate vaccine so that it is ready to move forward into a phase II trial. Previous target: Advance at least one promising candidate vaccine into a phase II trial. (Target Met)	Initiate a suite of studies to support efficacy evaluation and licensure of an HIV vaccine.	N/A	N/A
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 2013: Due to major changes in the cooperative group trials network in FY 13, the first in 50 years, only 50% of the hormone receptors were done in 2013 as opposed to 60% (Target Not Met). The results from the ER testing will not be released until the definitive trial results have been obtained; this delay will not impact the timing of the reporting of the results. Target: Complete hormone receptor scoring for 60% of all cases. (Target Not Met)	Complete hormone receptor scoring for 85% of cases.	Complete hormone receptor scoring for 100% of cases.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system in children. (Outcome)	FY 2013: Researchers have identified a genetic variant that confers an increased risk of developing systemic juvenile idiopathic arthritis (sJIA) and that indicates the CD4+ T cell activation pathway as a therapeutic target. Target: Identify at least one molecular pathway suitable for targeting in the patient cohort by performing detailed genetic mapping and confirmatory analyses for markers and pathways identified through genome-wide association. Previous Target Identify at least one molecular pathway suitable for targeting in the patient cohort. (Target Met)	Complete a clinical pilot study in a cohort of pediatric patients with a disorder of the immune system	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.	N/A
SRO-3.10 By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY 2013: A pharmacogenetic study of the medication ondansetron revealed that variations in two different genes predict effectiveness in treating alcohol dependence. Target: Conduct pharmacogenetic studies to identify genetic variations that influence treatment response to one compound. (Target Met)	Conduct Phase 2 clinical testing of a novel compound	Complete phase 2 clinical studies of a candidate compound.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2013: All of the Tissue Chip for Drug Screening initiative grantees were funded for a second year, as they all either met or exceeded their milestones, and there was continued close collaboration with DARPA and FDA. Target: Initiate research on the therapeutics discovery and development process and "high need cures" projects. (Target Met)	Advance three projects to integration of individual organ or system chips into a multiple tissue chip or organ microsystem.	Completion of program towards integrated organ systems.	N/A
SRO-4.1 By 2016, 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 2014: Result Expected Dec 31, 2014 Target: Select 1-3 projects for which the BrIDGs program will generate pre-clinical data. (In Progress)	Complete contracts for and initiate 1-3 projects that were selected.	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 2014: Result Expected Dec 31, 2014 Target: Build partnerships with three NA communities to incorporate a community-based participatory research approach to adapt, develop, and test interventions. (In Progress)	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-4.4 By 2016, discover the molecular basis for 30 rare diseases. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Enroll patients with rare or undiagnosed diseases into studies (In Progress)	Discover the molecular bases of 15 rare diseases	Discover the molecular bases of an additional 15 rare diseases	N/A
SRO-4.5 By 2016, test a targeted nanoparticle for imaging and drug delivery to atherosclerotic plaque in animal models. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Demonstrate targeted delivery of statin-loaded HDL nanoparticles to atherosclerotic plaque in rabbits and assess inflammation using 18F FDG. (In Progress)	Correlate rabbit inflammation imaging studies with histochemistry to confirm efficacy of nanoparticle treatment.	Extend the studies into a pre-clinical pig model to assess targeted delivery and efficacy in reducing inflammation.	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 2014: Result Expected Dec 31, 2014 Target: Identify one new molecular pathway governing the generation of sperm and/or sperm function. (In Progress)	Identify one new pathway/mechanism that regulates spermatogenic stem cells in their decision making process governing cell renewal vs. cell differentiation.	Identify one epigenetic mechanism regulating spermatogenesis.	N/A
SRO-4.7 By 2016, determine the safety and effectiveness of two first-in-class treatments for nonalcoholic fatty liver disease in adults and children. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: Enroll target number of pediatric patients with NAFLD for cysteamine treatment trial. (In Progress)	Finish data collection in obeticholic acid treatment trial of adult patients with NASH.	Analyze data from pediatric and adult NAFLD treatment trials.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2014: Result Expected Dec 31, 2014 Target: Complete Genome-wide Association analysis of the original 10,000 subjects to discover 3 statistically significant genetic risk factors for COPD. (In Progress)	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.	Analyze longitudinal for the first 1000 five year follow-up visits to identify 1-3 predictors of lung function decline.	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 2014: Result Expected Dec 31, 2014 Target: Complete Discovery Phase whole genome sequencing and analysis of 582 family members from 111 families with late onset AD to identify genomic regions associated with increased risk of AD; sequencing of the coding regions of the DNA (whole exome sequencing) of 5,000 cases / 5,000 controls for both risk raising and protective loci; and whole exome sequencing and analysis of one individual from ~1,000 additional AD families to identify regions associated with increased risk for protection from AD (In Progress)	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.	Initiate analysis and confirmation of genes identified in the Discovery Phase	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-5.4 By 2017, address the growing public health problem of antimicrobial resistance by discovering four to six new therapeutic candidates and assessing two novel approaches/ regimens designed to preserve existing antimicrobials. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Discover two new candidate therapeutics for infections where resistance poses a significant public health threat. (In Progress)	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.	N/A
SRO-5.5 By 2018, complete pre-commercial development of a point-of-care technology targeted for use in primary care setting. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Identify 6 enabling technologies with potential clinical use in primary care setting. (In Progress)	Establish feasibility of use of 3 to 4 identified technologies through preliminary testing.	Complete pilot clinical studies on 1 to 2 prototype devices.	N/A
SRO-5.6 By 2017, develop, evaluate, refine, and/or promote strategies for preventing prescription drug abuse and its consequences. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Develop and disseminate medical education curricula on pain and substance abuse (In Progress)	Develop, test or disseminate strategies to prevent prescription drug abuse, including the development of pain medications with reduced abuse potential	Develop, test or disseminate strategies to enhance the use of naloxone for overdose prevention	N/A
SRO-5.7 By 2016, the members of the National Dental Practice-based Research Network will contribute to the scientific basis for common dental procedures and improve the quality of dental care in community practices by conducting research studies in dental practices. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: By 2014, expand the number of participating dental practitioners from 1500 to 3000. (In Progress)	By 2015, design 10 studies nominated by practitioners as relevant to their practices.	By 2016, contribute to clinical decision-making based on evidence gained by the NPBRN studies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2014: Result Expected Dec 31, 2014 Target: Obtain 300 biological samples and corresponding clinical data from UCPPS patients and control subjects suitable for the study of infectious agents, including potential contributions to disease etiology and symptom variation (e.g., flare). (In Progress)	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.	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.	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 community level that will impact disparate conditions. (Output)	FY 2015: Result Expected Dec 31, 2015 Target: Initiate the implementation of the Phase I plan and pilot, including baseline data.	Initiate the implementation of the Phase I plan and pilot, including baseline data.	Identify adaptive strategies and collect first year assessment variables	N/A
SRO-5.11 By 2018, develop and test three to five strategies for symptom management that reduce the effects of acute and chronic illness. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Initiate testing of one biological/genomic mechanism associated with symptoms or symptom clusters that has the potential to play a role in managing or assessing symptoms. (In Progress)	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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)	FY 2013: The 10,000 compound library was screened in 33 qHTS assays and data was analyzed on 179 compounds screened for cytotoxicity across 1086 human lymphoblastoid cell lines representing 9 racial groups to assess genetic diversity in response to toxicants. Target: Test 10,000 compound main library in 25 qHTS and test 180 compounds in densely sequenced human lymphoblastoid cell lines to assess genetic diversity in response to toxicants. (Target Met)	A formal process of prioritizing compounds for more extensive toxicological testing will be evaluated and used	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 2014: N/A Target: Develop materials to help academic officials address underage and harmful drinking and other substance use by their students. (In Progress)	Evaluate the effectiveness of screening and brief intervention for alcohol and other drug use in a variety of settings.	Develop interventions to prevent underage substance use, abuse and addiction in special populations.	N/A
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: Launch enrollment for two Restore Insulin Secretion protocols (In Progress)	Analyze data on complications in the Diabetes Prevention Program Outcomes Study	Enroll at least 2200 participants in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2013: The Severe Asthma Research Program is conducting investigations. Target: Conduct investigations to elucidate the dynamic, pathophysiologic phenotypes of severe asthma. (Target Met)	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.	N/A	N/A
SRO-6.5 By 2014, develop and evaluate two new interventions for the prevention and/or treatment of HIV disease utilizing the newly restructured HIV/AIDS clinical trials networks. (Outcome)	FY 2013: The Vaginal and Oral Interventions to control the Epidemic (VOICE) study (MTN 003) to compare the safety and acceptability and efficacy of oral pre-exposure prophylaxis (PrEP) and topical microbicides for prevention of sexual transmission of HIV in women was completed. Target: Complete the first study to compare the safety, acceptability and efficacy of oral pre-exposure prophylaxis (PrEP) and topical microbicides for prevention of sexual transmission of HIV in women. (Target Met)	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-6.6 By 2015, provide at least one new or significantly improved minimally-invasive treatment for clinical use in patients using image-guided interventions. (Outcome)	FY 2013: Development was completed on image guided interventions for assessing involvement of lymph nodes in cancer, skin cancer and for the treatment of cardiac arrhythmias. Target: Conduct one additional feasibility study on new IGI technologies for the diagnosis of lymph node cancer, treatment of skin cancer, and treatment of cardiac arrhythmias. (Target Met)	Support new or 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.	N/A	N/A
SRO-7.1 By 2016, assess the efficacy of a novel microbicide delivery system for the prevention of HIV. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Continue enrollment and follow up of a phase III trial of a novel microbicide delivery system. (In Progress)	Complete follow up of a phase III trial of a novel microbicide delivery system	Complete data analysis on the safety and/or efficacy of a novel microbicide delivery system	N/A
SRO-7.2 By 2018, develop an evidence-based, online resource to help people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	FY 2015: Result Expected Dec 31, 2015 Target: Collect data on pain and function from Spine Patient Outcomes Research Trial participants 8 years after joining the study.	Collect data on pain and function from Spine Patient Outcomes Research Trial participants 8 years after joining the study.	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)	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2014: Result Expected Dec 31, 2014 Target: Develop and/or test 2-4 substance abuse treatment or medication adherence interventions using mobile technology (In Progress)	Continue to develop and/or test substance abuse treatment or medication adherence interventions using mobile technology	Identify next steps for testing or deployment of 2-4 substance abuse treatment or medication adherence interventions using mobile technology	N/A
SRO-8.2 By 2017, identify circuits within the brain that mediate reward for (1) drugs, (2) non-drug rewards such as food or palatable substances, and (3) aversion to drug effects, and (4) determine the degree of overlap between these circuits. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Identify drug-activated reward circuits (In Progress)	Identify non-drug activated reward circuits and compare with drug-activated reward circuits	Support research to compare and contrast rewarding versus aversive pathways in response to substances of abuse	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2013: NIH researchers identified three influences on sustainability of research-tested interventions in service systems such as primary care, specialty care, and community practice: Community Development Teams in child mental health service systems; barriers and facilitators to evidence-based interventions to control blood pressure in community practice; and a set of factors to enhance sustainability of health care interventions across multiple settings. Target: Identify three key factors influencing the sustainability of research-tested interventions in service systems such as primary care, specialty care, and community practice. (Target Met)	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)	Initiate testing of hypothesized mechanism of treatment effect of one novel intervention, and determine whether the intervention should progress further to clinical testing.	N/A
SRO-8.9 By 2014, identify 12 pathogen and/or host factors critical for understanding the molecular and cellular basis of pathogenesis of Category A-C biodefense pathogens and/or pathogens causing emerging infectious diseases. (Outcome)	FY 2013: Twenty pathogens and/or host factors, including those that cause: dengue, hepatitis, TB, SARS, influenza, Marburg, E. coli, tularemia, Burkholderia infection, Rift Valley Fever, plague, arenavirus infection, Q fever, rabies, smallpox, botulism, were identified that are critical for understanding pathogenesis and show promise for the development of new therapeutics. Target: Identify three pathogens and/or host factors. (Target Exceeded)	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/intervention programs in minority communities. (Outcome and Efficiency)	FY 2013: Completed testing of a culturally tailored intervention in an underserved minority community and demonstrated an increased proportion of patients with acute stroke who arrived at the hospital rapidly and were treated with tissue plasminogen activator. Target: Complete testing of a culturally tailored intervention to improve stroke awareness and time to hospital arrival in order to increase utilization of tissue plasminogen activator (tPA) treatment in minority populations. (Target Met)	Initiate enrollment in two studies testing culturally tailored interventions to reduce health disparities in stroke.	Complete patient follow-up in a study testing a clinical program for improved blood pressure control in racial/ethnic minority populations.	N/A
SRO-9.4 By 2014, develop and evaluate the efficacy of neonatal screening for congenital cytomegalovirus (CMV) infection to permit identification of infants who will develop CMV-induced hearing loss in the first years of life. (Outcome)	FY 2013: An interim report on the longitudinal study of infants infected with CMV determined that 6.3% of infants born infected with CMV yet with no clinical symptoms will develop hearing loss in the first years of life. Target: Provide an interim report on how many children identified with neonatal asymptomatic CMV-infection have developed hearing loss. (Target Met)	N/A	N/A	N/A
SRO-9.5 By 2015, assess the efficacy of long-term oxygen treatment in patients with COPD and moderate hypoxemia. (Outcome)	FY 2013: LOTT recruited 643 participants. Target: Continue recruitment to 626 subjects. Previous target: Continue recruitment to 1134 subjects. (Target Met)	Complete data analysis and publish results of study assessing the efficacy of long-term oxygen treatment in patients with COPD and moderate hypoxemia.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2013: Award rate to comparison group reached 11%. Target: N ≥ 10% (Target Met)	N ≥10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2013: Award rate to comparison group reached 13% and exceeded the target by 3%. Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (By FY 2014, the NBS will be in an ongoing status) (Output)	FY 2013: Maintained post deployment support for Animal Procurement. Target: (Maintenance [Mat]) Maintain deployed business modules. * Planned - Service and Supply Activities Fund Module [Dep.2012] *Planned - Animal Procurement [Dep. 2013] (Target Met) FY 2013: Deployed Animal Procurement. Target: (Deployment [Dep]) Conduct priority deployment activities to enable user accessibility and skill development within 2 years from the onset of integration. * Planned - Animal Procurement (Target Met) FY 2013: Completed integration for Animal Procurement. Target: (Integration [Int]) Complete integration activities for full functionality and usability of priority modules for successful development efforts within 3 years of initiated development. * Planned - Animal Procurement [Dev.2013/Dep.2014] (Target Met) FY 2013: Initiated development of Animal Procurement. Target: (Development [Devl]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System.* Planned - Animal Procurement [Int.2013] (Target Met)	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] (Integration [Int]) Complete integration activities for full functionality and usability of priority modules for successful development efforts within 3 years of development. * Planned - Oracle 12i Upgrade [Dev.2012, 2014-15/Dep.2016]	(Integration [Int]) Complete integration activities for full functionality and usability of priority modules for successful development efforts within 3 years of development. * Planned - Oracle 12i Upgrade [Dev.2012, 2014-15/Dep.2016] (Deployment [Dep]) Conduct priority deployment activities to enable user accessibility and skill development within 2 years from the onset of integration.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 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 2014: Result Expected Dec 31, 2014 Target: Develop framework for standardized diagnostic definitions for use in clinical research studies on cLBP. (In Progress)	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
CBRR-5 By 2015, implement and evaluate leadership forums in cancer control planning in select low and middle income countries. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: Develop the content of 2 leadership forums that will serve as a basis for developing and implementing national cancer control plans. (In Progress)	Organize, implement, and evaluate leadership forums in two regions of the world.	N/A	N/A
CBRR-7 By 2017 expand the scope and reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENEÂ®), a national genetics research resource for rare inherited ocular diseases, by adding new patient records to the database, augmenting and refining the phenotypic data collected, and by increasing the number of registered researchers to 900. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Increase database and diagnostic genotyping to a total of 5,000 patient records. (In Progress)	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.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CBRR-8 By 2017, characterize the three-dimensional atomic structure of 400 proteins of biomedical interest related to infectious agents. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Characterize the three-dimensional structure of 100 protein targets or other molecules of biomedical interest with regard to bacterial, viral, and eukaryotic pathogens (In Progress)	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
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 2013: Established 570 primary biochemical, cell-based or protein-protein interaction assays that were miniaturized and automated as high throughput screens in the Molecular Libraries Program (MLP) Portfolio. Target: Establish 400 primary biochemical, cell-based or protein-protein interaction assays that can be miniaturized and automated as high throughput screens in the Molecular Libraries Program (MLP) Portfolio. (Target Exceeded)	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
CBRR-11 By 2016, collect and make available for distribution 1200 well-characterized, high-quality human cell lines for use in genetic and genomic research. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Accept and make available to scientific researchers 400 new human cell lines. (In Progress)	Accept and make available to scientific researchers an additional 400 new human cell lines.	Accept and make available to scientific researchers an additional 400 new human cell lines.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
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 2014: Result Expected Dec 31, 2014 Target: Provide x-ray crystallographic data for 150 new structures of macromolecules of biomedical relevance to researchers worldwide (In Progress)	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	N/A
CBRR-13 By 2017, archive and annotate new protein structures to support research in human health and disease and drug development. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Annotate and archive 8,500 new protein structures (In Progress)	Annotate and archive 9,000 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 2014: Result Expected Dec 31, 2014 Target: Finalize master trial agreement with 100% of the Regional Coordinating Centers and the National Clinical Coordinating Center. (In Progress)	Use the network's Regional Coordinating Centers for patient recruitment in a stroke trial.	Initiate the first new trial to be conducted in the Stroke Network.	N/A
CBRR-15 By 2016, establish a resource database and tissue bank of 30 reference tissues (e.g., liver, skin, heart, bone) in which the relationship between genetic variation and gene expression is quantified and 3 additional molecular analyses are performed. (Output)	FY 2015: Result Expected Dec 31, 2015 Target: Demonstrate that at least 75% of a consensus list of replicated eQTLs are significant in at least 1 GTEx tissue.	Demonstrate that at least 75% of a consensus list of replicated eQTLs are significant in at least 1 GTEx tissue.	Enroll 300 donors annually.	N/A
CBRR-16 By 2016, demonstrate the use of an efficient, cost-effective pipeline characterizing (phenotype) 2500 genetically modified mice. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: By the end of FY14, produce 1500 knockout lines and phenotype 500 lines. (In Progress)	By the end of FY15, produce 2500 knockout lines and phenotype 1500 lines.	Complete phenotyping the 2500 knockout lines.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CBRR-17 By FY 2017, take steps to improve the quality and availability of information to inform decisions about the size of the NIH training programs and the number of people in training to address future needs for the nation's biomedical research workforce. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Implement a process to collect information on all graduate students and postdoctorates supported by NIH-funded research projects. (In Progress)	Communicate widely the expectation for grantees to develop an institutional policy requiring Individual Development Plans (IDP) be implemented for every graduate student and post-doctorate supported by any NIH grant, and reportable on the grant progress report.	Implement the collection of information from grantees on career outcomes for graduate students closely associated with training grants.	N/A
CTR-1 By 2014, reduce the disparity between African American and white infants in back sleeping by 50% to further reduce the risk of sudden infant death syndrome (SIDS). (Outcome and Efficiency)	FY 2013: The NIH successfully conducted three meetings with up to nine federal agencies in attendance to determine outreach strategies to reduce the number African American infants who die from SIDS. Target: Convene two meetings with two or more federal agencies on how to coordinate efforts to reduce SIDS in African American communities across the nation. (Target Exceeded)	N/A	N/A	N/A
CTR-2 By 2017, reach 500,000 visits to the website Genome: Unlocking Life's Code. (Outcome)	FY 2015: Result Expected Dec 31, 2015 Target: By 2015, reach 150,000 visits	By 2015, reach 150,000 visits	By 2016, reach an additional 300,000 visits	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CTR-3 By 2016, partner with 20 state and local mental health nonprofit organizations to facilitate awareness among the general public about the brain, mental health disorders, research-tested interventions and findings, and clinical trials research. (Outcome)	FY 2014: Result Expected Dec 31, 2014 Target: Partner with 20-25 state and local mental health nonprofit organizations to disseminate science-based information about mental health disorders and research-tested interventions to the general public. (In Progress)	Support 20-25 state and local mental health nonprofit organizations in conducting science-based education and outreach 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.	Partner with 20-25 state and local mental health nonprofit organizations to facilitate awareness among the public about the role of basic, translational, and clinical research, and opportunities to participate in clinical research.	N/A
CTR-4 By 2017, expand and implement the broad use of Common Data Elements for 17 neurological disorders among investigators conducting clinical research. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Initiate development of one new set of disease-specific common data elements. (In Progress)	Utilize common data elements in two new clinical trials.	Develop a clinical research training module on utilization of Common Data Elements tools.	N/A
CTR-5 By 2016, increase the number of computer-indexed MEDLINE journals by 288 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	FY 2014: Result Expected Dec 31, 2014 Target: Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year.	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
CTR-6 By FY 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 2014: Result Expected Dec 31, 2014 Target: By 2014, establish proof-of-concept for a process to link the references cited in published reports about clinical guidelines and practice recommendations to NIH funded research projects. (In Progress)	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.	By 2016, 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
MPO-1 By 2016, decrease by 10% the costs associated with trans-NIH recruitment strategies for intramural research group leaders. (Efficiency)	FY 2014: Result Expected Dec 31, 2014 Target: A 7% decrease in the budget and a minimum of 400 applicants in the combined programs of the Earl Stadtman Investigator search, the Lasker Clinical Research Scholars, and the Early Independent Scientist program. (In Progress)	A 2% decrease in the budget and a minimum of 400 applicants in the combined programs of the Earl Stadtman Investigator search, the Lasker Clinical Research Scholars, and the Early Independent Scientist program.	A 2% decrease in the budget and a minimum of 400 applicants in the combined programs of the Earl Stadtman Investigator search, the Lasker Clinical Research Scholars, and the Early Independent Scientist program.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Ongoing) (Output)	FY 2013: NIH reviewed literature and benchmarked other organizations to determine best practices in delivering executive coaching programs in the public sector and determine principles around which to operate the internal program. Target: Examine [EX] key area to enhance leadership skills. * Study best practices in implementing and evaluating executive coaching programs in the federal sector. [IM 2014] (Target Exceeded) FY 2013: NIH implemented recommendations from the previous year to offer a multifaceted program of supervisory training geared towards meeting both the basic requirements of all new supervisors and the more varied needs of all existing supervisors. Target: Implement [IM] recommendation from prior year assessments. * Create and implement revised supervisory training. [EX.2012/AS.2014] (Target Exceeded) FY 2013: The Executive Onboarding Program analyzed the effectiveness of retaining employees. All new hires who participated remain at NIH, and every new executive continues to receive onboarding through the program. Target: Assess [AS] results of implementation. * Assess results from executive on-boarding program. [IM 2012] (Target Exceeded)	Assess [AS] results of implementation * Assess results from implementing best practices in implementing and evaluating executive coaching programs in the federal sector. [IM 2014/EX2013] Implement [IM] recommendation from prior year assessments * Implement recommendations from study of NIH's administrative intern and fellows program [EX 2014/ AS 2016] Examine [EX] key area to enhance leadership skills * Assess best practices and review the literature regarding incorporating the latest technologies into leadership development programs to determine which are most effective and practicable to create efficiencies and/or enhance learning [IM 2016/ AS 2017]	Examine [EX] key area to enhance leadership skills NIH will examine the outcomes of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/ AS 2018] Implement [IM] recommendation from prior year assessments * Assess best practices and review the literature regarding incorporating the latest technologies into leadership development programs to determine which are most effective and practicable to create efficiencies and/or enhance learning [EX 2015 /AS 2017] Assess [AS] results of implementation * Implement recommendations from study of NIH's administrative intern and fellows program [EX 2014/ IM 2015]	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2013: NIH developed a corporate recruitment strategy for FY13 enhancing partnerships, connecting talent, and streamlined pathways program recruitment. SMRF FY13 executed pilot "Career Experience Program" and Discover a Career initiative. Target: Implement [IM] key area to enhance recruitment *Develop corporate recruitment strategy to focus on diversity recruiting, student recruiting, and trans-NIH hiring. [EX 2012] [AS 2014] *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] [AS 2015] (Target Met) FY 2013: Expanded the use of Pathways recruitments for the scientific community. Implemented and managed automated register and applicant referral process for management selection of candidates. Target: Examine [EX] key area to enhance recruitment *Implement Pathways Program to establish a focused student and entry level recruitment plan that supports succession planning efforts at NIH. [IM 2014] [AS 2015] (Target Met) FY 2013: NIH has developed an action plan to identify ways to enhance oversight and management of Title 42 cases and new procedures for exhaustion. In addition NIH is developing training on preparing cases. Target: Examine [EX] key area to enhance recruitment *Establish increased oversight and review of Title 42 recruitment. [IM 2014] [AS 2015] (Target Met)	Assess [AS] results of implementation *Create Scientific and Medical Recruitment Forum (SMRF) to attract world-class scientists and medical professionals to drive discovery and innovation at NIH. [IM 2014] Assess [AS] results of implementation *Implement Pathways Program to establish a focused student and entry level recruitment plan that supports succession planning efforts at NIH. [IM 2014] Assess [AS] results of implementation *Establish increased oversight and review of Title 42 recruitment. [IM 2014] Examine [EX] key area to enhance recruitment *Increase the use of Global Recruitments. [IM 2016] [AS 2017] Examine [EX] key area to enhance recruit *Launch a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [IM 2016] [AS 2017]	Examine [EX] key area to enhance recruitment *Expansion of the Pathways Program to STEM career path for focused students and supporting of succession planning efforts. [IM 2017] [AS 2018] Implement [IM] key area to enhance recruit *Launch a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [AS 2017] Implement [IM] key area to enhance recruitment *Increase the use of Global Recruitments. [AS 2017]	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2013: 25% of Principal Investigators were reviewed resulting in 25% of resources recommended to be reallocated Target: Conduct BSC reviews of 25% of Principal Investigators to assess quality of science in order to prioritize of resources. (Target Met)	Conduct BSC reviews of 25% of principal Investigators to assess quality of science in order to prioritize resources.	Conduct BSC reviews of 25% of Principal Investigators to access quality of science in order to prioritize resources.	N/A
MPO-5 Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa=85). (Ongoing) (Output and Efficiency)	FY 2013: The condition of the facilities portfolio reached a CIwa of 80.96. Target: CIwa = 75.4 NIH has revised the FY2012 and FY 2013 targets to reflect a change in the way the CI figure is calculated. The new calculation methodology enables NIH to provide consistent results across multiple facility condition reports. Previous target: CIwa = 78.9 (Target Exceeded)	CIwa = 79.9	CIwa = 80.0	N/A
MPO-6 By 2017, maintain the annual condition of buildings and facilities portfolio so that no less than 95% of occupied gross square feet (GSF) will have a CI greater than 65. (Ongoing) (Output and Efficiency)	FY 2013: 73% of occupied gross square feet (GSF) reached a CI greater than 65. Target: Target = 69.6% (Target Exceeded)	73.5%	Target = 74.0%	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final approved project cost. (Ongoing) (Output)	FY 2013: Nine (9) of the twelve (12) active non-Recovery Act funded projects at the HHS Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100% of the final approved project cost. Target: 12 Active Projects Previous target: 6 Active Projects (Target Not Met) FY 2013: The eight (8) active Recovery Act funded projects at the HHS Facility Project Approval Agreement (FPAA) threshold were managed effectively to ensure completion within 100% of the final approved project cost. Target: (2013 RA) 8 Active Recovery Act projects Previous target: 4 Active Recovery Act projects (Target Met)	11 - Active Projects 1 Active RA Project	5 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-8 Manage design and construction of capital facility projects funded by B&F so that no more than 10% of the projects may incorporate plus or minus 10% adjustments of the approved scope. (Ongoing) (Output)	FY 2013: The design and construction of ten (10) of the twelve (12) active non-Recovery Act funded projects was managed effectively so that no more than 10% of the projects incorporated a plus or minus 10% adjustments of the approved scope. One (1) project was canceled and the work incorporated under another project for costs savings. Another project was delayed to support further analysis of the most viable programmatic and facilities solution. Target: 12 Active Projects Previous target: 6 Active Projects (Target Not Met) FY 2013: The design and construction of the eight (8) active reportable Recovery Act funded projects was managed effectively so that no more than 10% of the projects incorporated a plus or minus 10% adjustment of the approved scope. Target: (2013 RA) 8 Active Recovery Act funded Projects Previous target: 4 Active Recovery Act funded Projects (Target Met)	11 - Active Projects 1 Active RA Project	5 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 Target +/-FY 2015 Target
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2013: Obligated 38% of eligible service contracting dollars through performance-based contracting. Target: Obligate the FY 2013 OMB/OFPP goal of eligible service contracting dollars to PBC. (Target Not Met)	Obligate the FY 2015 OMB/OFPP goal of eligible service contracting dollars to PBC.	Obligate the FY 2016 OMB/OFPP 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. (Output)	FY 2013: 99% of the extramural construction projects were in compliance with the post award 20 years usage requirement. Target: 95% of 219 projects are in compliance. (Target Met)	95% of 212 projects are in compliance	N/A	N/A