

APPROPRIATIONS LANGUAGE**NATIONAL CANCER INSTITUTE**

For carrying out section 301 and title IV of the PHS Act with respect to cancer, \$5,226,312,000 of which up to \$20,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, \$3,112,032,000.

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, \$413,196,000.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301, section 330B, and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, 1,965,434,000, of which \$150,000,000, to remain available until expended, shall be for making grants under such section 330B.

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, \$1,781,056,000.

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, \$4,761,948,000.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, \$2,572,669,000, of which \$741,000,000 shall be from funds available under section 241 of the PHS Act.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, \$1,339,592,000.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, \$711,015,000.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, \$693,199,000.

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, \$53,967,000.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, \$1,988,200,000.

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, \$545,494,000.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

For carrying out section 301 and title IV of the PHS Act with respect to deafness and other communication disorders, \$423,992,000.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, \$145,842,000.

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, \$469,109,000.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, \$1,137,403,000.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, \$1,554,692,000.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, \$512,979,000.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, \$346,550,000.

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to complementary and integrative health, \$130,717,000.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

For carrying out section 301 and title IV of the PHS Act with respect to minority health and health disparities research, \$280,545,000.

JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart 2 of part E of title IV of the PHS Act), \$70,084,000.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, \$395,493,000: Provided, That of the amounts available for improvement of information systems, \$4,000,000 shall be available until September 30, 2020: Provided further, That in fiscal year 2019, the National Library of Medicine may enter into personal services contracts for the provision of services in facilities owned, operated, or constructed under the jurisdiction of the National Institutes of Health (referred to in this title as "NIH").

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, \$685,087,000: Provided, That up to 10 percent of the amount available under this heading shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network.

OFFICE OF THE DIRECTOR

For carrying out the responsibilities of the Office of the Director, NIH, \$1,795,706,000: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: Provided further, That \$586,181,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: Provided further, That of the funds provided, \$10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: Provided further, That the Office of AIDS Research within the Office of the Director

of the NIH may spend up to \$8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act.

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, \$200,000,000, to remain available through September 30, 2023.

NIH INNOVATION ACCOUNT

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the National Institutes of Health in this Act, \$711,000,000, to remain available until expended: Provided, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act and are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act: Provided further, That of the amount appropriated under this heading, \$400,000,000 shall be transferred to the "National Cancer Institute" for the purposes described in section 1001(b)(4)(C) of such Act, \$57,500,000 shall be transferred to the "National Institute of Neurological Disorders and Stroke" for the purposes described in section 1001(b)(4)(B) of such Act, and \$57,500,000 shall be transferred to the "National Institute of Mental Health" for the purposes described in section 1001(b)(4)(B) of such Act: Provided further, That remaining amounts may be transferred by the Director of the National Institutes of Health to any accounts of the National Institutes of Health: Provided further, That upon a determination by the Director that funds transferred pursuant to any of the previous provisos are not necessary for the purposes provided, such amounts may be transferred back to this account: Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

NATIONAL INSTITUTE FOR RESEARCH ON SAFETY AND QUALITY

For carrying out titles III and IX of the PHS Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, \$255,960,000: Provided, That section 947(c) of the PHS Act shall not apply in fiscal year 2019: Provided further, That in addition, amounts received from Freedom of Information Act fees, reimbursable and interagency agreements, and the sale of data shall be credited to this appropriation and shall remain available until expended.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

For carrying out titles II, III, and XVII of the PHS Act, sections 101, 102, 103, 201, 202, 203, 301, and 501 of the Federal Mine Safety and Health Act, section 13 of the Mine Improvement

and New Emergency Response Act, and sections 20, 21, and 22 of the Occupational Safety and Health Act, with respect to occupational safety and health, \$200,000,000.

***ENERGY EMPLOYEES OCCUPATIONAL ILLNESS
COMPENSATION PROGRAM***

For necessary expenses to administer the Energy Employees Occupational Illness Compensation Program Act, \$55,358,000, to remain available until expended: Provided, That this amount shall be available consistent with the provision regarding administrative expenses in section 151(b) of division B, title I of Public Law 106-554.

***NATIONAL INSTITUTE ON DISABILITY, INDEPENDENT LIVING, AND
REHABILITATION RESEARCH***

For carrying out title II (and section 14 with respect to such title) of the Rehabilitation Act of 1973, \$95,127,000.

BUDGET MECHANISM TABLE

(Dollars in Thousands) ¹	FY 2017 Final ^{3,4}		FY 2018 Annualized CR ^{3,4}		FY 2019 President's Budget ^{4,10}		FY 2019 +/- FY 2018	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	24,638	\$12,661,301	25,468	\$13,495,362	25,030	\$13,291,723	-438	-\$203,639
Administrative Supplements ²	(1,508)	225,445	(1,174)	157,514	(952)	112,473	(-222)	-45,041
Competing	10,123	\$5,283,732	8,656	\$4,486,448	9,084	\$4,571,486	428	\$85,038
Subtotal, RPGs	34,761	\$18,170,479	34,124	\$18,139,325	34,114	\$17,975,682	-10	-\$163,643
SBIR/STTR	1,807	923,162	1,796	926,988	1,835	918,846	39	-8,142
Research Project Grants	36,568	\$19,093,641	35,920	\$19,066,313	35,949	\$18,894,528	29	-\$171,785
Research Centers:								
Specialized/Comprehensive	1,004	\$1,766,720	979	\$1,706,013	1,082	\$1,709,109	103	\$3,096
Clinical Research	67	402,112	71	418,602	85	405,881	14	-12,721
Biotechnology	105	187,352	101	175,897	123	180,243	22	4,346
Comparative Medicine	48	121,663	47	118,807	51	127,634	4	8,827
Research Centers in Minority Institutions	24	58,462	24	64,388	22	59,851	-2	-4,537
Research Centers	1,248	\$2,536,309	1,222	\$2,483,707	1,363	\$2,482,718	141	-\$989
Other Research:								
Research Careers	3,712	\$672,622	3,792	\$688,038	4,226	\$752,342	434	\$64,304
Cancer Education	83	23,629	85	24,147	94	26,492	9	2,345
Cooperative Clinical Research	329	403,274	265	377,633	291	400,779	26	23,146
Biomedical Research Support	109	69,962	109	68,778	63	39,703	-46	-\$29,075
Minority Biomedical Research Support	281	104,119	281	103,454	357	110,179	76	6,725
Other	1,863	907,363	1,954	979,720	2,088	863,101	134	-116,619
Other Research	6,377	\$2,180,970	6,486	\$2,241,770	7,119	\$2,192,596	633	-\$49,174
Total Research Grants	44,193	\$23,810,919	43,628	\$23,791,790	44,431	\$23,569,842	803	-\$221,948
Ruth L. Kirchstein Training Awards:								
Individual Awards	3,599	\$157,826	3,554	\$159,393	3,488	\$157,910	-66	-\$1,483
Institutional Awards	12,419	669,571	12,471	680,412	12,282	652,676	-189	-\$27,736
Total Research Training	16,018	\$827,397	16,025	\$839,805	15,770	\$810,586	-255	-\$29,219
Research & Develop. Contracts	2,028	\$3,070,430	2,018	\$2,896,751	2,003	\$2,931,915	-15	\$35,164
(SBIR/STTR) (non-add) ²	(88)	(57,569)	(78)	(60,086)	(98)	(61,241)	(20)	(1,155)
Intramural Research		\$3,782,692		\$3,787,681		\$3,795,544		\$7,863
Res. Management & Support		1,747,769		1,765,098		1,757,337		-7,761
Res. Management & Support (SBIR Admin) (non-add) ^{2,11}		(5,695)		(0)		(0)		(0)
Office of the Director - Appropriation ^{2,5}		(1,728,603)		(1,706,132)		(2,004,306)		(298,174)
Office of the Director - Other		754,016		751,723		1,152,682		400,959
ORIP (non-add) ^{2,5}		(279,131)		(275,580)		(252,843)		(-22,737)
Common Fund (non-add) ^{2,5}		(695,456)		(678,829)		(598,781)		(-80,048)
Buildings and Facilities ⁶		158,567		157,784		220,000		62,216
Appropriation		(128,567)		(127,988)		(200,000)		(72,012)
National Institute for Occupational Safety and Health ⁹		---		---		200,000		200,000
National Institute on Disability, Independent Living, and Rehabilitation Research ⁹		---		---		95,127		95,127
Special type 1 Diabetes ⁷		-139,650		-150,000		---		150,000
Program Evaluation Financing ⁸		-824,443		-818,844		-741,000		77,844
Subtotal, Labor/HHS Budget Authority		\$33,187,697		\$33,021,788		\$33,792,033		\$770,245
Interior Appropriation for Superfund Research		77,349		76,824		53,967		-22,857
Total, NIH Discretionary BA		\$33,265,046		\$33,098,611		\$33,846,000		\$747,389
Special type 1 Diabetes		139,650		150,000		0		-150,000
Patient-Centered Outcomes Research Trust Fund (PCORTF)						124,349		124,349
Energy Employees Occupational Illness Compensation Program Act (EEOICPA)						55,358		55,358
Total, NIH Budget Authority		\$33,404,696		\$33,248,611		\$34,025,707		\$777,096
Program Evaluation Financing		824,443		818,844		741,000		-77,844
Total, Program Level		\$34,229,139		\$34,067,456		\$34,766,707		\$699,251

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

² All numbers in italics and brackets are non-add.

³ Excludes Ebola-related supplemental appropriations.

⁴ Includes 21st Century Cures Act funding.

⁵ Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as a non-add. The Office of the Director - Appropriations also is noted as a non-add because the remaining funds are accounted for under OD - Other.

⁶ Includes the Building & Facilities appropriation as well as funds identified for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

⁷ In FY 2017 and FY 2018 the number of grants and dollars for mandatory Special type 1 Diabetes Research account are distributed by mechanism above; therefore, type 1 Diabetes amounts are deducted to provide subtotals that align to the Labor/ HHS Budget Authority levels. In FY 2019, resources for Special type 1 Diabetes are incorporated in discretionary appropriations.

⁸ Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals that align to the Labor/ HHS Budget Authority levels.

⁹ National Institute for Occupational Safety and Health (NIOSH) and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) included in FY 2019 only and are not distributed by mechanism.

¹⁰ Includes funding for the National Institute for Research on Safety and Quality (formerly the Agency for Healthcare Research and Quality), NIOSH, and NIDILRR.

¹¹ SBIR administrative funds pilot program expired on September 30, 2017.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
National Institutes of Health:			
Section 301 and Title IV of the PHS Act	\$33,265,046		
Section 1001 (b)(3)(A) of the 21 st Century Cures Act	\$352,000	\$496,000	\$711,000
Section 402A(a)(1) of the PHS Act	\$34,229,139	\$34,851,000	\$35,585,871
Public Law 114-10, Medicare Access and CHIP Reauthorization Act of 2015.	\$139,650		
Public Law 115-123, Bipartisan Budget Act of 2018		\$150,000,000	
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	\$76,824	\$53,967
Title II of the Rehabilitation Act of 1973, as amended			\$119,608
Titles III and Title IX and Section 947(c) of the Public Health Service Act, as amended and Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003			\$255,960
Titles II, III, and XVII of the Public Health Service Act, sections 101, 102, 103, 201, 202, 203, 301, and 501 of the Federal Mine Safety and Health Act, section 13 of the Mine Improvement and New Emergency Response Act, and sections 20, 21, and 22 of the Occupational Safety and Health Act			\$200,000

APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation	
FY 2010	\$30,988,000,000	\$31,488,000,000	\$30,988,000,000	\$30,934,413,000	¹
FY 2011	\$32,136,209,000		\$31,989,000,000	\$30,935,000,000	²
FY 2012	\$31,979,000,000		\$30,630,423,000	\$30,852,187,000	³
FY 2013					
Base	\$30,852,187,000		\$30,810,387,000	\$30,929,977,000	⁴
Sequestration				-1,552,593,211	⁵
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	⁶
FY 2016	\$31,311,349,000 ⁷	\$31,411,349,000	\$32,311,349,000	\$32,311,349,000	⁸
FY 2017	\$33,136,349,000 ⁹	\$33,463,438,000	\$34,311,349,000	\$34,229,139,000	¹⁰
FY 2018	\$26,919,710,000 ¹¹	\$35,184,000,000	\$36,084,000,000	\$34,067,456,000	¹²
FY 2019 PB	\$34,766,707,000 ^{13,14}				

¹ Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special type 1 Diabetes Research mandatory funding included except for FY 2019.

² 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.

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

⁴ 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.

⁵ Reflects: Full-year continuing resolution base. Does not include Section 3004 OMB 0.2 percent across-the-board rescission.

⁶ Includes Program Evaluation Financing of \$715,000,000. Excludes Ebola-related funding.

⁷ Includes Program Evaluation Financing of \$847,489,000.

⁸ Includes Program Evaluation Financing of \$780,000,000. Excludes Ebola-related and Zika-related funding.

⁹ Includes Program Evaluation Financing of \$847,489,000. Includes mandatory financing.

¹⁰ Includes Program Evaluation Financing of \$824,443,000.

¹¹ Includes Program Evaluation Financing of \$780,000,000.

¹² Includes Program Evaluation Financing of \$818,844,000.

¹³ Includes Program Evaluation Financing of \$741,000,000.

¹⁴ Includes funding for NIRSQ, NIOSH, and NIDILRR associated with the proposed FY 2019 consolidation as well as PCORTF (NIRSQ) and EEOICPA (NIDILLR) mandatory accounts.

APPROPRIATIONS NOT AUTHORIZED BY LAW

Program	Last Year of Authorization	Authorization Level in Last Year of Authorization	Appropriations in Last Year of Authorization	Appropriations in FY 2018
Research on Health Costs, Quality, and Outcomes.....	FY 2005	Such Sums As Necessary	\$260,695,000	\$321,800,000

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 President's Budget +/- FY 2018 Annualized CR
Program Level ^{1,2}	\$34,229,139	\$34,067,456	\$34,766,707	\$699,251
FTE ³	18,018	18,105	19,456	1,351

¹ Excludes Ebola-related supplemental appropriations or transfers.

² Includes Interior appropriation's Superfund Research allocation (all years) and the Special type 1 Diabetes account resources-- mandatory through FY 2018 and discretionary in FY 2019. Also included is NIGMS Program Evaluation funding in FY 2017 (\$824 million), FY 2018 (\$819 million), and FY 2019 (\$741 million) as well as PCORTF (\$124 million) and EEOICPA (\$55 million) mandatory accounts associated with the proposed FY 2019 consolidation.

³ FTE in FY 2019 include staff consolidated from NIRSQ, NIOSH, and NIDILRR.

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

NIH Research Contributes to Improvements in Human 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 2015, the life expectancy of the average American increased by nearly nine years.³¹ Further, the yearly death rate for Americans from all causes dropped by 43 percent from 1969 to 2015.³² Older Americans are not just living longer; they are staying healthy and active longer. Rates of reported risk factors for chronic disease (uncontrolled cholesterol or high blood pressure, smoking, etc.) have dropped by more than ten percent since 1999. At age 65, Americans today can expect to live 19.4 more years, nearly 40 percent longer than in 1950.³³ We can attribute these remarkable improvements, in part, to NIH research advances that have helped us understand how to prevent disease or in some cases offered new treatments to cure it. NIH-funded projects have made numerous contributions that have advanced health care and improved human health, with the following as some selected examples.

Heart Disease

At the outset of the 20th Century, the three leading causes of death in the United States were pneumonia, tuberculosis, and infectious diarrhea, but by 1950, heart disease had surpassed all other maladies to become the leading cause of death. Through research advances supported in large part by NIH, deaths from heart disease decreased by approximately 67 percent between 1969 and 2015.^{34 35} The Framingham Heart Study, one of the first studies that followed a large cohort of individuals over time and begun by NIH in 1947, introduced the concept of risk factors, identifying factors that lead to heart disease, such as smoking, high blood pressure, and high cholesterol, and generating research findings that have led to more than 3,200 publications. NIH-supported clinical trials spurred the development of effective pharmacological and behavioral interventions and prevention strategies, including safe and effective surgical and catheter-based procedures to open clogged coronary arteries. While death rates have decreased in recent decades, heart disease remains the leading cause of death in the US, and so more work is required to capitalize on these advances and discover new approaches to detecting, preventing, and treating heart disease.

Diabetes

In the recent past, adults diagnosed with diabetes during middle age lived on average 10 years less than adults without diabetes. Thanks to the development of early screening methods and treatments that enable better control of diabetes-related complications, adults with diabetes are now living longer and healthier lives. Between 1969 and 2015, the death rate among adults with

³¹ <https://www.cdc.gov/nchs/data/hus/hus16.pdf>

³² Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. <https://www.cdc.gov/nchs/products/databriefs/db267.htm>

³³ <https://www.cdc.gov/nchs/data/hus/hus16.pdf>

³⁴ Ma J, Ward EM, Siegel RL, Jemal A. Temporal Trends in Mortality in the United States, 1969-2013. *JAMA J ...* 2015;314(16):1731-1739. doi:10.1001/jama.2015.12319. <http://jamanetwork.com/journals/jama/fullarticle/2466136>

³⁵ K Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. <https://www.cdc.gov/nchs/products/databriefs/db267.htm>

diabetes declined by 15.8 percent,^{36 37} and from 1990 to 2010 the rates of major diabetes complications dropped dramatically, particularly for heart attacks related to diabetes, which declined by 68 percent, and stroke related to diabetes, which declined by 53 percent.³⁸ These remarkable improvements are due largely to clinical trials supported by NIH. In addition, basic science research, including a recent international “big data” study that NIH helped support,³⁹ has unveiled genes that may be involved in the development and progression of diabetes. NIH research also is generating important insights into the prevention and management of diabetes, highlighting the importance of family support. Studies funded through the Diabetes Prevention Program also have shown that lifestyle changes, such as diet and physical activity, can lower the risk of developing type 2 diabetes by 58 percent in adults at high risk for the disease. Further research is investigating potential approaches to reversing type 2 diabetes, including remission after bariatric surgery. For individuals with type 1 diabetes, islet cell transplantation trials and progress toward the development of a fully reliable artificial pancreas provide hope for an end to the daily routine of finger sticks and insulin injections (see later section on Promising New Treatments for Type 1 Diabetes).

Stroke

Fewer people are dying of stroke today—the age-adjusted stroke mortality rate has decreased by 76 percent since 1969,⁴⁰ due to treatment and prevention strategies based on NIH-funded research. While much of this decrease is due to improvements in stroke diagnosis and prevention, NIH has also contributed to advances in stroke treatment. In 1995, an NIH-funded clinical trial established the first and only FDA-approved treatment for acute ischemic stroke, which makes up 87% of strokes in the U.S.⁴¹ The drug tissue plasminogen activator (tPA) reduces the risk of disability and maximizes the potential for patient recovery. However, tPA must be administered quickly after the onset of symptoms. Current estimates suggest that fewer than ten percent of stroke patients are treated with the drug. 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. 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.^{42,43} 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.

³⁶ Ma J, et al. *JAMA* 2015; 314(16):1731-1739. PMID: 26505597

<http://jama.jamanetwork.com/article.aspx?articleid=2466136&linkid=18099832>

³⁷ Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. <https://www.cdc.gov/nchs/products/databriefs/db267.htm>

³⁸ Gregg EW, et al. *N Engl J Med* 2014; 370(16):1514-23. PMID: 24738668
<http://www.ncbi.nlm.nih.gov/pubmed/24738668>

³⁹ Fuchsberger C, et al. *Nature* 2016; epub ahead of print. PMID: 27398621
<http://www.nature.com/nature/journal/vaop/ncurrent/full/nature18642.html>

⁴⁰ Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. NCHS Data Brief. 2016 Dec;(267):1-8. <https://www.cdc.gov/nchs/products/databriefs/db267.htm>

⁴¹ https://www.cdc.gov/stroke/types_of_stroke.htm

⁴² Jauch EC, et al. *Stroke* 2013; 44(3):870-947 PMID: 23370205
<http://www.ncbi.nlm.nih.gov/pubmed/23370205>

⁴³ <http://www.medpagetoday.com/Cardiology/Strokes/41156>

Lung Cancer

Lung cancer is the second most common cancer and is the primary cause of cancer-related death in both men and women in the United States. However, both incidence rates and mortality rates continue to decline for men and women. NIH-funded research has contributed to the decrease in mortality, lowering the death rate by 43 percent in men and 17 percent in women from 2002 to 2014.⁴⁴ Much of this decrease is due to prevention efforts targeting smoking, which has been estimated to cause 80% of deaths from lung cancer.⁴⁵ Many of these efforts to reduce smoking were developed and tested using NIH funding. The recent development of targeted cancer therapies, such as erlotinib and crizotinib, has led to dramatic responses in individuals whose lung cancers harbor particular genetic mutations. Advances in genetic screening techniques have helped NIH-funded researchers identify genes that may influence the risk for lung cancer development and genetic errors that cause lung cancer, and new precision medicine clinical trials are targeting some types of this disease.

HIV/AIDS

HIV, the virus that causes AIDS, was first recognized more than 30 years ago. In that time, NIH has established the world's leading AIDS research program. Each year, close to 40,000 people in the United States are still diagnosed with HIV.⁴⁶ Currently, there are more than one million people in the United States, and over 35 million people globally, who are living with HIV infection. In the early 1980s when the HIV/AIDS epidemic began, those infected with the virus were not likely to live longer than a few years. Now, thanks to research funded in large part by NIH, there are powerful treatments that can suppress the virus to undetectable levels, allowing those infected with HIV to live for many years. As a result, death rates dropped more than 80 percent between 1990 and 2015,⁴⁷ and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s.⁴⁸ NIH research also has informed the implementation of HIV testing and preventive interventions that have reduced the rate of mother-to-child infection by more than 90 percent in the United States.⁴⁹ Ongoing efforts seek to develop new and even more effective treatment approaches, including new research in primates that could prove useful in suppressing HIV in humans.⁵⁰ These treatments, combined with encouraging advances toward the development of an HIV vaccine and research to find a cure, mean that a future AIDS-free generation is possible with sustained effort.

⁴⁴ Siegel RL, Miller KD, Jemal A. Cancer statistics, 2017. *CA Cancer J Clin*. January 2017:n/a - n/a. 10.3322/caac.21387. <https://www.ncbi.nlm.nih.gov/pubmed/26742998>

⁴⁵ Siegel RL, et al. *JAMA Intern Med*. 2015;175:1574-1576. <https://www.ncbi.nlm.nih.gov/pubmed/26076120>

⁴⁶ <https://www.cdc.gov/nchs/data/hus/2016/034.pdf>

⁴⁷ <https://www.cdc.gov/nchs/data/hus/16.pdf>

⁴⁸ Samji H, et al. *PLoS One* 2013; Dec 18;8(12):e81355 PMID: 24367482

<http://www.ncbi.nlm.nih.gov/pubmed/24367482>

⁴⁹ <http://www.niaid.nih.gov/topics/HIVAIDS/Understanding/Prevention/Pages/perinatal.aspx>

⁵⁰ <https://www.nih.gov/news-events/nih-research-matters/dual-antibody-treatment-suppresses-hiv-virus-monkeys>

Breast Cancer

Primarily because of NIH-supported research, multiple breast cancer susceptibility genes have been identified, including BRCA1, BRCA2, TP53, and PTEN/MMAC1. Genetic testing now allows for tailored, safer, and more efficient treatments. Recent studies identified 55 genes linked to a tumor suppressor gene that can predict breast cancer survival as well as a natural compound that can attack human epidermal growth factor receptor 2 (HER2) positive breast cancer cells. Scientists also conducted studies in mice in which they found a protein that reduces the risk that breast cancer will spread. In addition, a new imaging technique to improve diagnosis in women with dense breast tissue has been developed. As a result of these and many other advances, breast cancer death rates for women declined by about 38 percent from 1989 to 2015,⁵¹ and the relative 5-year survival from breast cancer in women has increased from 74.8 percent in 1980 to greater than 91 percent, as of a 2015 CDC report.⁵²

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. NIH has also supported research to help understand genetic risk factors for the disease, and to develop and improve early screening for at-risk populations. The success of these advances has contributed to the significant decline in the death rate. Between 1993 and 2014, the prostate cancer death rate dropped by 51 percent,⁵³ with a 5-year survival rate approaching 99 percent.⁵⁴ Current research focuses on increasing understanding of the epidemiology and genetics of prostate cancer and improving treatment and diagnostic options.

Infant Health

In 1960, 26 of every 1,000 babies born in the United States died before their first birthday. By 2014, the infant mortality rate was below 6 per 1,000 births, considerably less than a generation before.⁵⁵ A sustained, long-term effort, informed in large part by NIH research to reduce preterm births, neonatal mortality, and other complications that increase the risk of infant death, contributed to these substantial improvements in the survival rates of infants born preterm and to advances in care for all newborns. For example, rates of Sudden Infant Death Syndrome have declined considerably, with the mortality rate in 2014 being one-third the rate of 1990,⁵⁶ and the

⁵¹ Samji H, Cescon A, Hogg RS, et al. Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada. Okulicz JF, ed. *PLoS One*. 2013;8(12):e81355. doi:10.1371/journal.pone.0081355. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3867319/>

⁵² <https://www.cdc.gov/nchs/data/hus/hus15.pdf>, Table 37

⁵³ Siegel RL, Miller KD, Jemal A. Cancer statistics, 2017. *CA Cancer J Clin*. January 2017:n/a - n/a. 10.3322/caac.21387. <https://www.ncbi.nlm.nih.gov/pubmed/26742998>

⁵⁴ Cancer of the Prostate - SEER Stat Fact Sheets. <http://seer.cancer.gov/statfacts/html/prost.html>

⁵⁵ <https://www.cdc.gov/nchs/nvss/deaths.htm>

⁵⁶ <https://www.cdc.gov/sids/data.htm>

death rate from Respiratory Distress Syndrome in infants has dropped 95%, from 2.2 deaths per 100,000 in 1980 to only 0.1 in 2015.⁵⁷

Burns and Traumatic Injury

NIH-funded research on fluid resuscitation, wound cleaning, skin replacement, infection control, and nutritional support has improved greatly the chances of surviving catastrophic burns and traumatic injuries. In the mid-1970s, burns that covered even 25 percent of the body were almost always fatal. Today, people with burns covering 90 percent of their bodies can survive, although often with some impairments. From 1990 to 2015, the death rate per 100,000 people from motor vehicle traffic injury decreased from 18.5 to 11.5,⁵⁸ and firearm fatalities dropped from 14.6 to 11.1.⁵⁹ These dramatic increases in survival rates, as well as increased health, functioning, and quality of life of survivors, are due in large part to research findings that have transformed clinical practice.

Science Advances from NIH Research:

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

CRISPR Used in Wide-Ranging Applications

Hailed as the 2015 Breakthrough of the Year by Science magazine, the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) system continues to facilitate groundbreaking scientific research. The system, which allows relatively easy and precise genome editing, has promise for use in a range of applications, from studying gene function to treating genetic diseases and developing therapeutics for clinical trials. In one study, NIH-funded researchers used CRISPR to stop the production of a particular protein in mouse models of Huntington's disease, reversing the disease process.⁶⁰ In another project, NIH-funded scientists isolated cells with two copies of the mutation that causes sickle cell disease and used CRISPR to remove one copy of the mutation. With only one copy of the gene, the cultured cells went on to produce healthy hemoglobin at a frequency that might be able to help patients.⁶¹ Early proof-of-concept studies have even shown the potential of CRISPR for such diverse applications as disrupting genes that cause high cholesterol, or removing HIV viral DNA from the genomes of infected cells.^{62,63} Researchers are also working to improve gene editing technology itself, including expanding its capabilities to target RNA, the intermediate step between DNA and the creation of

⁵⁷ CDC WONDER Mortality Database, <https://wonder.cdc.gov/>

⁵⁸ <https://www.cdc.gov/nchs/data/hus/2016/017.pdf>

⁵⁹ <https://www.cdc.gov/nchs/data/hus/2016/031.pdf>

⁶⁰ Yang S, et al. *J Clin Invest* 2017 Jun 30; 127(7):2719-2724. PMID: 28628038
<https://www.ncbi.nlm.nih.gov/pubmed/28628038>

⁶¹ DeWitt MA et al. *Sci Transl Med*. 2016 Oct 12;8(360):360ra134. PMID: 27733558
<https://www.ncbi.nlm.nih.gov/pubmed/27733558>

⁶² Yin H et al. *Nat Biotech* 2017 6 Nov 13. PMID: 29131148 <https://www.ncbi.nlm.nih.gov/pubmed/29131148>

⁶³ Kaminski R. et al. *Gene Ther*. 2016 Aug 23. PMID: 27194423 <https://www.ncbi.nlm.nih.gov/pubmed/27194423>

functional proteins.^{64,65} In one such study, researchers used novel RNA-targeted gene editing tools to eliminate RNA that leads to toxic proteins in a model of the degenerative disease myotonic dystrophy, providing a potential use for such expanded tools in humans.⁶⁶ In the future, this technology could potentially be applied to treat people affected by a variety of devastating diseases, many of which currently have no approved therapies.

Precision Oncology Leads to Targeted Therapies

In the field of oncology, immunotherapy has been used to enlist a patient’s own immune system to fight, and sometimes cure, cancer. However, immunotherapy does not work for all patients or types of cancer. Precision medicine has enormous potential to allow doctors and researchers to treat and prevent disease using strategies targeted for a patient’s individual biology, lifestyle, and environment. Such approaches can lead to the development and application of targeted drugs which address the specific genetic alterations in a patient’s cancer cells, and can also provide clues to which patients will respond better to immunotherapy, ensuring that the right patient gets the right drug (or combination of drugs) with the best chance of treating their cancer. In May 2017, the Food and Drug Administration (FDA) approved the use of the cancer immunotherapy pembrolizumab⁶⁷ to treat patients with any solid tumor with a particular genetic defect, regardless of location, making it the first treatment ever approved to treat cancer based on a specific genetic feature rather than the tumor’s location in the body. In addition, new breakthroughs are allowing doctors to re-engineer a patient’s own immune cells as a “living drug” that can target cancerous cells based on a tumor’s unique molecular signature. In August 2017, the FDA approved the first cell-based immunotherapy, Kymriah (tisagenlecleucel), to treat a type of leukemia that is the most common childhood cancer in the United States.⁶⁸ Kymriah, which is part of a broader family of cell-based immunotherapies called CAR-T, was developed in part based on NIH-supported research, ranging from pioneering research in the 80’s to more recent improvements of the methodology that make the treatment more effective. Breakthroughs like this allow for more informed and effective health care and will benefit many cancer patients who lack other treatment options.

Combating the Opioid Crisis and Designing More Safe and Effective Opioids

Opioids are powerful drugs that can relieve severe pain through the activation of opioid receptors on nerve cells throughout the body. While opioids generally are safe when used as directed, they have the potential for misuse which can result in addiction and dangerous side effects that include lethal overdoses. The Nation is currently facing an unprecedented crisis in opioid addiction. NIH and its many partners are working to address this crisis on several fronts, including making safer, non-addictive painkillers and understanding how to treat individuals suffering from opioid addiction. NIH-funded researchers found that providing the drug naltrexone, which is used to treat opioid addiction, can reduce the incidence of opioid-related

⁶⁴ Cox DBT, et al. Science. 2017 Oct 25. pii: eaaq0180. doi: 10.1126/science.aaq0180. PMID: 29070703. <https://www.ncbi.nlm.nih.gov/pubmed/29070703>

⁶⁵ Abudayyeh OO, et al. Science. 2016 Aug 5 PMID: 27256883 <https://www.ncbi.nlm.nih.gov/pubmed/27256883>

⁶⁶ Batra R, et al. Cell 2017 Aug 24. PMID: 28803727 <https://www.ncbi.nlm.nih.gov/pubmed/28803727>

⁶⁷ <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm560167.htm>

⁶⁸ <https://directorsblog.nih.gov/2017/08/30/fda-approves-first-car-t-cell-therapy-for-pediatric-acute-lymphoblastic-leukemia/>

emergencies when prescribed to chronic pain patients alongside opioid drugs for their pain.⁶⁹ Another group of researchers found that a similar treatment for opioid addiction, buprenorphine, can safely and effectively treat the withdrawal symptoms of newborn infants exposed to opioids during pregnancy.⁷⁰ NIH is also working to find alternative ways to provide pain relief to those in need. In pre-clinical studies using mouse models, several NIH-funded researchers have found opioid-related compounds which act on more specific subsets of the signaling pathways used by conventional opioids, allowing for effective pain relief without dangerous side effects like addiction, or slowed breathing and heart rate, including two compounds called PZM21⁷¹ and BU08028.⁷² Mice treated with these compounds experience less pain, but do not display drug-seeking behavior or dangerous cardiovascular side effects, suggesting that such compounds may be a safer alternative to current drugs. NIH-funded researchers have also developed new ways to molecularly characterize the mechanism of action for a given opioid drug, allowing them to tease apart the effects on pain relief and effects on breathing to design effective pain therapies that avoid dangerous side effects.⁷³ Such studies have the potential to both treat existing cases of opioid addiction, and provide new therapies for pain relief that can prevent people from getting addicted in the first place.

Informing Prevention of Heart Disease and Stroke

Heart disease and stroke are both among the leading causes of death in Americans, and having high blood pressure is a strong risk factor for both.⁷⁴ A major NIH-funded trial, the Systolic Blood Pressure Intervention Trial (SPRINT), provided key evidence that treating high blood pressure earlier could save lives, and prevent cardiovascular and kidney diseases. The SPRINT trial included more than 9,300 participants recruited from around 100 medical centers and clinical practices around the country, the largest study of its kind to date, examining how maintaining blood pressure at a lower level than previously recommended impacts both cardiovascular and kidney diseases. The study found that aiming for a lower target blood pressure could significantly reduce the rate of death from cardiovascular causes by 43%, and reduce the rate of an initial cardiovascular event, such as a stroke or heart attack, by 25%.⁷⁵ This evidence was cited as a key factor for new guidelines released by the American Heart Association (AHA) and the American College of Cardiology (ACC) in November 2017, which urge doctors to aim for a lower target blood pressure in at-risk patients, using both lifestyle changes, and in some cases, medication.⁷⁶ Successfully implementing these new guidelines will improve the cardiovascular health of the nation, and save lives, reducing the risks for heart disease and stroke.

⁶⁹ Lee JD, et al. *NEJM* 2016 Mar 31;374(13):1232-42. PMID: 27028913

<https://www.ncbi.nlm.nih.gov/pubmed/27028913>

⁷⁰ Kraft WK, et al. *NEJM* 2017 Jun 15;376(24):2341-2348. PMID: 28468518

<https://www.ncbi.nlm.nih.gov/pubmed/28468518>

⁷¹ Manglik A, et al. *Nature* 2016 Sep 8;537(7619):185-190. PMID: 27533032

<https://www.ncbi.nlm.nih.gov/pubmed/27533032>

⁷² Ding H., et al. *PNAS* 2016 Sep 13;113(37):E5511-8. PMID: 27573832

<https://www.ncbi.nlm.nih.gov/pubmed/27573832>

⁷³ Schmid, et al. *Cell*. November 16, 2017.

⁷⁴ <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

⁷⁵ The SPRINT Research Group. *NEJM* 2015 Nov 26. <https://www.ncbi.nlm.nih.gov/pubmed/29262284>

⁷⁶ <https://www.nih.gov/news-events/news-releases/data-landmark-nih-blood-pressure-study-supports-important-part-new-aha-acc-hypertension-guidelines>

All of Us Research Program

Spearheading a precision medicine approach for disease prevention and treatment, which takes into account individual differences in lifestyle, environment, and biology (e.g., genetics), NIH's *All of Us* Research Program is an ambitious effort to gather data on the biological, environmental, and behavioral influences on health and disease over many years from one million or more people living in the US. Already, several key implementation milestones have been reached, including study protocol approval, establishing a state-of-the-art biobank to process and store biological samples from patients, and building a big data IT system to store data for research use. Working together with federal, academic, and industry partners, *All of Us* began participant enrollment for its beta testing phase in May 2017, and, as of mid-January 2018, more than 19,000 participants were enrolled, of whom more than 12,000 have completed the full protocol. This phase will pave the way for a planned full-scale launch at more than 200 sites in the spring of 2018. Already the program is breaking new ground, recently growing the network of medical center partners that will expand the geographic reach of the program and facilitate enrollment of underserved communities. New community partners also are on board to begin building a national network of trusted leaders to motivate a variety of communities to join *All of Us*. As enrollment increases, *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions and enabling individualized prevention and treatment options for patients.

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

For many scientists studying large cohorts of research participants, one of the biggest challenges is collecting data about what happens outside the lab or clinic. The brief period in which a participant provides samples or answers interview questions is just a small slice of a much larger set of both physiological states and lifestyle behaviors. With the advent of wearable technologies that can track a user's heart rate, blood oxygenation, physical activity, sleep, and more, it is now possible to provide study participants with devices that can generate a stream of data—as many as 250,000 measurements per person per day. A recent NIH-funded study evaluated many of these wearable technologies in a real-world setting, and found that they can provide useful, health-relevant information about an individual's physiology, detecting changes related to fatigue, inflammation, Lyme disease, and insulin resistance.⁷⁷ As researchers continue to validate wearable technologies, they will provide promising opportunities for gathering useful, real-world data for clinical research, including integration into larger studies like the *All of Us* research program.

Discovering the Brain's Lymphatic System

The lymphatic system is a key part of the circulatory system, acting as a highway that allows important immune cells to move through the body, and providing a route for waste products to be carried away from the tissues and into the blood. For a long time, the brain was thought to be a notable exception to this system, kept apart from immune cells and the highways they use except in cases of damage or dysfunction. Recent discoveries, however, are challenging this view. First, in 2015, NIH-funded researchers used cutting-edge, high-powered microscopy

⁷⁷ Li, X, et al. PLoS Bio 2017 Jan 12;15(1):e2001402 PMID 28081144
<https://www.ncbi.nlm.nih.gov/pubmed/28081144>

techniques to visualize lymphatic vessels in the layers of protective tissue that surround the mouse brain.⁷⁸ In October 2017, those same researchers collaborated with a group with expertise in non-invasive MRI imaging to demonstrate that these same vessels exist in the human brain.⁷⁹ Since the lymphatic system plays a vital role in immune response, these surprising discoveries open up entirely new areas for research which have potential to shed light on how the brain and immune system interact in disease states. Studying the brain's lymphatic system could lead to new insights for understanding, treating, and preventing brain disorders involving immune-related inflammation, including multiple sclerosis, stroke, Alzheimer's disease, or Parkinson's disease.

Targeted Use of Antibiotics

Antibiotics are ineffective against viruses, but doctors often have no way of quickly determining whether an illness is viral or bacterial, which can lead to inappropriate use of antibiotics in patients who will not benefit from them. In addition to wasting medical resources, this behavior also can accelerate the development of antibiotic-resistant bacterial strains. To meet the need of rapid diagnostics, NIH-funded researchers have developed quicker, more accurate blood tests that can help distinguish between bacterial and viral infections.⁸⁰ Treating infections caused by antibiotic-resistant bacteria can be challenging or even impossible. Another NIH-funded team is working to modify existing antibiotics to be more effective against these types of bacteria. In recent lab tests, one new compound was 10,000 times more effective than current treatments.⁸¹ These advances will help clinicians to use the most effective treatments for patients and avoid unnecessary use of antibiotics.

Developing New Tools for Delivering Anti-Obesity Drugs

Metabolic disorders like obesity and diabetes impact many Americans, and understanding fat cell behavior can provide insight into these disorders and potential methods of treatment. There are two main types of fat cells in the human body: white fat cells, which store calories and are associated with obesity when overabundant, and brown fat cells, which burn calories to generate heat and regulate body temperature. Several clinically-available drugs have been shown to promote a fat cell process known as "browning," which transitions white fat cells into a calorie-burning variety cell called "beige fat." However, when these drugs are taken as pills or injections, they can have unpleasant side effects on parts of the body outside of fatty tissue. NIH-funded researchers are working to get around these side effects on other parts of the body by delivering the drug directly into fatty tissue.^{82,83} Recent efforts have created an on-skin patch

⁷⁸ Absinta M, et al. *Elife*. 2017 Oct 3. <https://www.ncbi.nlm.nih.gov/pubmed/26030524>

⁷⁹ Louveau Et al. *Nature*. 2015 Jul 16 <https://www.ncbi.nlm.nih.gov/pubmed/28971799>

⁸⁰ Sweeney TE, et al. *Sci Transl Med* 2016; 8(346):346ra91. PMID: 27384347

<http://www.ncbi.nlm.nih.gov/pubmed/27384347>

Tsalik EL, et al. *Sci Transl Med* 2016; 8(322):322ra11. PMID: 26791949

<http://www.ncbi.nlm.nih.gov/pubmed/26791949>

⁸¹ Okano A, et al. *Proc Natl Acad Sci USA* 2017; 114(26). PMID: 28559345

<https://www.ncbi.nlm.nih.gov/pubmed/28559345>

⁸² <https://www.nih.gov/news-events/nih-research-matters/nanoparticles-target-transform-fat-tissue>

⁸³ <https://www.nih.gov/news-events/nih-research-matters/microneedle-patch-shrinks-fat-tissue-mice>

which uses microscopic needles to deliver highly localized treatment.⁸⁴ Mice treated with the patch developed beige fat cells and reduced the size of their white fat cells, and treatment had beneficial effects on the metabolisms of obese mice as well. While such patch-based treatments have not yet been attempted in humans, these mouse-model results indicate a promising area for potential future clinical trials.

New Therapies for Cystic Fibrosis

Roughly 30,000 Americans currently suffer from cystic fibrosis (CF), an inherited disease in which malfunctioning secretory glands cause the accumulation of organ-damaging mucus that can lead to respiratory failure. Twenty-five years ago, when NIH-funded researchers discovered the first of several genetic mutations that cause CF⁸⁵, the disease was still considered fatal in childhood. Today, thanks to years of hard work supported by NIH and the Cystic Fibrosis Foundation, the outlook for patients with CF is much brighter. Over time, researchers have uncovered several different mutations that cause CF and have shed light on how those mutations lead to the buildup of mucus. Currently, there are FDA-approved targeted treatments for approximately 40 percent of CF patients, based on their particular mutation. That number may be rising in the near future, as Vertex Pharmaceuticals Inc. recently announced that promising results have been found in Phase 1 and 2 clinical trials of three new triple-drug CF treatments.⁸⁶ Patients were already able to breathe better after 2-4 weeks of treatment, including patients with notoriously difficult-to-treat variants of CF. Assuming Phase 3 clinical trials are successful and the triple-drug formula is approved, doctors may soon be able to treat up to 90 percent of people with CF.⁸⁷

Catalyzing Progress Towards a Universal Flu Vaccine

The flu (influenza) virus is a costly and dangerous pathogen, and seasonal flu places a substantial burden on the US population that encompasses both health and economic losses. While vaccination is the most effective way to reduce both morbidity and mortality caused by the flu, seasonal flu vaccines currently rely on predictions, often made a year in advance, about which individual virus strains will be in circulation. Since these predictions limit the effectiveness of a seasonal vaccine, a single, universal flu vaccine would allow for substantial improvement in the burden of flu, providing safe, effective, long-lasting immunity. On June 28-29, 2017, NIH convened a conference entitled “Pathway to a Universal Influenza Vaccine”, catalyzing the field around a series of unmet needs and knowledge gaps, including understanding the immune response to influenza, developing vaccine platforms, diagnostics for assessing mechanisms of immune protection, and both animal and human models for influenza research. NIH-funded researchers continue to make progress toward this goal by targeting a particular protein on the surface of the flu virus, several versions of which are being evaluated for further clinical study. In addition, Phase 1/2 clinical trials already are underway for an alternative approach involving a

⁸⁴ Zhang, Y. et al. *ACS Nano* 2017; 11(9):9223-9230. PMID: 28914527
<http://pubs.acs.org/doi/10.1021/acsnano.7b04348>

⁸⁵ Rommens JM, et al. *Science*. 1989 Sept 8;245(4922): 1059-1065. PMID: 2772657
<https://www.ncbi.nlm.nih.gov/pubmed/2772657>

⁸⁶ <http://investors.vrtx.com/releasedetail.cfm?ReleaseID=1033559>

⁸⁷ <https://directorsblog.nih.gov/2017/07/20/another-milestone-in-the-cystic-fibrosis-journey/>

DNA-based vaccine and a seasonal booster. Continued investment in this research will enable the fastest possible vaccine development to protect millions of people from infection.

Addressing the Threat of Zika Virus

The recent outbreak of Zika virus, beginning in South America in spring 2015, now has infected more than one million Brazilians, includes documented cases in the continental U.S. and Puerto Rico⁸⁸, and is linked to a steep increase in the number of babies born with microcephaly, a very serious condition characterized by a small head and brain. In response to this emerging threat, NIH has stepped up its efforts to develop innovative approaches against the virus. Three NIH-funded studies^{89,90,91} conducted foundational basic research on the Zika virus, paving the way for future research on Zika prevention and treatment. In August 2016, NIH built on these results and launched the first clinical trial that demonstrated safety and efficacy of one vaccine candidate, leading to a Phase 2/2b trial that began in March 2017 to obtain additional evidence on whether the vaccine is safe and effective against natural Zika infection.^{92,93} NIH research also has found that experimental Zika vaccines administered to female and male mice restricted transmission from mother to fetus as well as prevented infection in the testis, an important discovery given Zika's impact on fetal and infant development and the persistence of Zika virus in the male reproductive system.^{94,95} Furthermore, NIAID-supported researchers developed a novel vaccine approach that may be safe and effective to administer during pregnancy to protect both the mother and the fetus. This new vaccine candidate protected nonhuman primates from infection, and the researchers are pursuing studies in people.^{96,97} To help speed up possible treatments for Zika NIH has been working to identify compounds, including FDA-approved drugs, that potentially can be used to inhibit Zika virus replication and reduce its ability to kill brain cells. Recently NIH identified two such compounds, providing new paths for research into combating the virus.⁹⁸

Human Microbiome Project

In the past, disease-causing germs such as bacteria and microbes have been thought to be invaders, causing negative effects on human health. However, recent research has discovered

⁸⁸ <https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika>

⁸⁹ Sirohi D, et al. *Science* 2016; 352(6284):467-70. PMID: 27033547

<http://www.ncbi.nlm.nih.gov/pubmed/27033547>

⁹⁰ Tang H, et al. *Cell Stem Cell* 2016; 18(5):587-90. PMID: 26952870

<http://www.ncbi.nlm.nih.gov/pubmed/26952870>

⁹¹ Nowakowski TJ, et al. *Cell Stem Cell* 2016; 18(5):591-6. PMID: 27038591

<http://www.ncbi.nlm.nih.gov/pubmed/27038591>

⁹² Gaudinski MR, et al. *Lancet* 2017; S0140-6736(17)33105-7. PMID: 29217376

<https://www.ncbi.nlm.nih.gov/pubmed/29217376>

⁹³ <https://www.nih.gov/news-events/news-releases/gene-based-zika-vaccine-safe-immunogenic-healthy-adults>

⁹⁴ <https://www.nih.gov/news-events/news-releases/experimental-zika-virus-vaccines-restrict-utero-virus-transmission-mice>

⁹⁵ <https://www.niaid.nih.gov/news-events/single-dose-investigational-zika-vaccine-protects-mice-monkeys>

⁹⁶ Magnani, DM, et al. *Sci Transl Med* 2017; 9(410). pii: eaan8184 <https://www.ncbi.nlm.nih.gov/pubmed/28978754>

⁹⁷ <https://www.nih.gov/news-events/news-releases/monoclonal-antibodies-against-zika-show-promise-monkey-study>

⁹⁸ <https://www.nih.gov/news-events/news-releases/nih-collaboration-helps-advance-potential-zika-treatments>

that there is a population of microbes both inside and on the surface of the human body, called the microbiome, that normally work together with the human body. Over the last decade, NIH's Human Microbiome Project (HMP) has expanded our view of the importance of microorganisms, collecting all of the genes of all the microorganisms that live on or in a specific location on the body such as the mouth, a sample known as a metagenome. In a healthy human adult, bacterial cells outnumber human cells, in vast numbers that researchers cannot comprehensively count. In the last 5 years, the HMP has provided new data that includes an additional 1,631 metagenomes taken from 265 volunteers, tripling the discovery of microbes in our bodies.⁹⁹ These studies have led to the surprising discovery that, in perfectly healthy people, the microbes present in the mouth, gut, nose, and several other parts of the body also include fungi, and even several viruses.¹⁰⁰ Thanks to the HMP, NIH-funded researchers have discovered that these large numbers of microbes have helped us adapt to life as we know it. For example, microbes found in the mouth modify chemical processes whose products are linked to blood pressure regulation and prevention of migraines, among other health conditions. The study also was able to begin to delve into the difference between the microbes that live on or in people across different regions of the country, allowing researchers to understand how the environment an individual lives in can affect their microbiome. In the future, research from the HMP could help to further characterize of the human microbiome and the role of these microbes in human health and disease, potentially allowing researchers to target them as a new form of treatment.

Promising New Treatments for Type 1 Diabetes

Type 1 diabetes, usually diagnosed in childhood, is a serious, chronic condition in which the pancreas does not produce sufficient insulin to maintain healthy blood sugar levels. This form of diabetes appears to be an autoimmune disorder, with the immune system attacking the insulin-producing islet cells of the pancreas. Individuals with type 1 diabetes currently manage their disease with multiple daily injections of insulin or a pump that delivers insulin through a catheter placed under the skin. Recent NIH-funded research is providing hope for better treatment options. In one recent trial, islet cell transplantation combined with immunosuppression provided near-normal control of blood sugar levels in 88 percent of participants for the first year, and in 71 percent for the second year.¹⁰¹ A large-scale, long-term study on an artificial pancreas that uses a glucose monitor implant and an adaptive smartphone application to automate insulin pump use and eliminate the need for manual finger sticks is currently underway. This study, along with three others that are slated to start in 2017 and 2018, is potentially the last step before requesting regulatory approval for permanent use of these fully automated devices and ^{102, 103} greatly improving the quality of life for people with this debilitating disease.

⁹⁹ Strains, functions, and dynamics in the expanded Human Microbiome Project. *Nature*. 2017 Sept 20.

¹⁰⁰ Structure, function and diversity of the healthy human microbiome. Human Microbiome Project Consortium. *Nature*. 2012 Jun 13;486(7402):207-14.

¹⁰¹ Hering BJ, et al. *Diabetes Care* 2016; 39(7):1230-40. PMID: 27208344
<http://www.ncbi.nlm.nih.gov/pubmed/27208344>

¹⁰² <http://news.harvard.edu/gazette/story/2016/01/artificial-pancreas-system-aimed-at-type-1-diabetes-mellitus/>

¹⁰³ <https://www.nih.gov/news-events/news-releases/four-pivotal-nih-funded-artificial-pancreas-research-efforts-begin>

Cell-Free Liquid Biopsy

After cells die, fragments of their DNA leak into the bloodstream. Researchers have been trying to detect these free-floating pieces of genetic material to inform clinical care, allowing clinicians and researchers to learn more about an individual's physiology without more invasive procedures. These "liquid biopsy" techniques have been utilized to test maternal blood for DNA from a fetus; test a cancer patient's blood for specific mutations or possible relapse; or test an organ transplant recipient for signs of organ rejection, and could one day test healthy individuals for early signs of future health problems.¹⁰⁴ NIH funded research has even developed a version of the technology that can trace free-floating DNA back to their cellular sources, allowing researchers to quickly pinpoint the location or tissue type of a potential tumor.¹⁰⁵ Using this technology, several NIH-funded researchers have developed blood tests that can detect genetic mutations in DNA released from cancer cells, and use that information to estimate the stage of cancer and the likelihood of cancer returning after surgery.^{106,107,108} Further development and use of the test will transform how those with cancer are treated and monitored.

¹⁰⁴ <https://directorsblog.nih.gov/2016/02/16/a-new-tool-in-the-toolbox-new-method-traces-free-floating-dna-back-to-its-source/>

¹⁰⁵ Snyder MW, et al. *Cell* 2016;164(1-2):57-68. PMID 26771485, <http://www.ncbi.nlm.nih.gov/pubmed/26771485>

¹⁰⁶ <http://www.sciencedirect.com/science/article/pii/S1525157817300107>

¹⁰⁷ https://www.eurekalert.org/pub_releases/2017-08/e-nbt081117.php

¹⁰⁸ Phallen J, et al. *Sci Transl Med*. 2017 Aug 16;9(403). <https://www.ncbi.nlm.nih.gov/pubmed/28814544>

FUNDING HISTORY

Fiscal Year	Amount¹
2015 ²	\$30,311,349,000
2016 ²	\$32,311,349,000
2017 ^{3,4}	\$34,229,139,000
2018 Annualized CR ⁴	\$34,067,456,000
2019 Budget Request ^{4,5}	\$34,766,707,000

¹ Appropriated amounts include discretionary budget authority received from both Labor/HHS appropriations that fund ICs as well as the Interior, Environment & Related Agencies appropriation that supports NIH Superfund Research activities. Also includes mandatory budget authority derived from the Special type 1 Diabetes account (through FY 2018), and NIGMS Program Evaluation financing of \$715 million in FY 2015, \$780 million in FY 2016, \$824 million in FY 2017, \$819 million in FY 2018 and \$741 million in FY 2019.

² Excludes Ebola-related and Zika-related supplemental appropriations or transfers.

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

⁴ Includes funding authorized by the 21st Century Cures Act.

⁵ Includes funding for NIRSQ, NIOSH, and NIDILRR associated with the proposed FY 2019 consolidation as well as PCORTF (NIRSQ) and EEOICPA (NIDILRR) mandatory accounts.

SUMMARY OF REQUEST NARRATIVE

The FY 2019 President's Budget request would provide \$34.8 billion to NIH, which is \$0.7 billion above the FY 2018 Annualized CR level.

The following summary references program level funding, which includes discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriation and in the Department of the Interior, Environment, and Related Agencies appropriation (dedicated to the Superfund Research program), and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act.

This level also includes the consolidation into NIH of the Agency for Healthcare Research and Quality (AHRQ) as the National Institute for Research on Safety and Quality (NIRSQ), the National Institute for Occupational Safety and Health (NIOSH) from the Centers for Disease Control and Prevention (CDC), and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Administration for Community Living (ACL). Both NIRSQ and NIOSH have mandatory funding as well as discretionary.

Many elements of the NIH submission supporting the FY 2019 request were developed prior to announcement of the February 12, 2018 addendum to the President's Budget. Therefore, exhibits reflecting pre-addendum levels were excluded from the NIH budget justification.

The primary budget mechanisms discussed below include mechanism allocations of Program Evaluation Financing, discretionary budget authority of the National Institute for Research on Safety and Quality, and Special type 1 Diabetes funds.

Research Project Grants (RPGs)

The FY 2019 President's Budget would provide \$18.9 billion for RPGs, which is \$0.2 billion less than the FY 2018 Annualized CR level estimate. This amount would fund 9,084 Competing RPGs, or 428 more than estimated for the FY 2018 Annualized CR. It also supports 25,030 Noncompeting RPGs, 438 fewer than the FY Annualized CR level. In addition, the projected Competing RPGs average cost of approximately \$503,245 would be 2.9% below the FY 2018 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2019 President's Budget would provide \$919 million for SBIR/STTR program grants, which is \$8 million below the FY 2018 Annualized CR level. The minimum set-aside requirement is 3.65% in FY 2019.

Research Centers

The FY 2019 President's Budget would provide \$2.5 billion for Research Centers, which is \$1 million less than the FY 2018 Annualized CR level. It would fund 1,363 grants, 141 more than the FY 2018 Annualized CR level.

Other Research

The FY 2019 President's Budget would provide \$2.2 billion for this mechanism, which is \$49 million less than the FY 2018 Annualized CR level. It would fund 7,119 grants, which is 633 more than the FY 2018 Annualized CR level.

Training

The FY 2019 President's Budget would provide \$811 million for training, which is \$29 million below the FY 2018 Annualized CR level. It would fund 15,770 Full-Time Trainee Positions (FTTPs), which is 255 fewer than the FY 2018 Annualized CR level.

Research & Development (R&D) Contracts

The FY 2019 President's Budget would provide \$2.9 billion for R&D contracts, which is \$35 million more than the FY 2018 Annualized CR level. It would fund an estimated 2,003 contracts, which are 15 fewer than the FY 2018 Annualized CR level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2019 President's Budget includes a \$61 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement is 3.65% in FY 2019.

Intramural Research (IR)

The FY 2019 President's Budget would provide \$3.8 billion for IR, which is \$8 million more than the FY 2018 Annualized CR level.

Research Management and Support (RMS)

The FY 2019 President's Budget would provide \$1.8 billion for RMS, which is \$8 million less than the FY 2018 Annualized CR level.

Office of the Director (OD)

The FY 2019 President's Budget would provide \$2.0 billion for OD, which is \$298 million more than the FY 2018 Annualized CR level.

- **Other than Common Fund**
The \$1.2 billion allocated for OD elements other than the Common Fund or the Office of Research Infrastructure Programs is a net increase of \$400 million above the FY 2018 Annualized CR level. This is due, in part, to an increase in funding authorized by the 21st Century Cures Act managed by OD, from \$52 million to \$196 million.
- **Common Fund (CF)**
Approximately \$599 million is allocated for CF-supported programs. This amount is \$80 million below the FY 2018 Annualized CR level.

Buildings & Facilities (B&F)

The FY 2019 President's Budget provides \$220 million for infrastructure sustainment projects associated with the B&F program, which is \$62 million above the FY 2018 Annualized CR

level. This amount includes \$20 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Consolidation

The FY 2019 President's Budget provides \$200 million for NIOSH and \$95.1 million for NIDILRR, in addition to the NIRSQ funding in the mechanisms above.

Superfund Research Program

The FY 2019 President's Budget would provide \$54 million, which is \$23 million less than the FY 2018 Annualized CR level.

Patient-Centered Outcomes Research Trust Fund (PCORTF)

The FY 2019 President's Budget would provide \$124 million in mandatory funding; PCORTF is proposed within NIH to accompany the National Institute for Research on Safety and Quality.

Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

The FY 2019 President's Budget would provide \$55.4 million for EEOICPA.

Program Evaluation Financing

The FY 2019 President's Budget would provide \$741 million for Program Evaluation Financing purposes, which is \$78 million less than the FY 2018 Annualized CR level.

OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
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)	<p>FY 2017: Initiated testing of 45 hypothesized mechanisms of treatment effect of novel interventions; completed testing of 16. Of the 16, 13 progressed to pilot studies of clinical effect.</p> <p>Target: Complete testing of the hypothesized mechanism of treatment of three novel treatment approaches for mental disorders, and advance one promising intervention into further clinical trial testing (pilot study or efficacy trial).</p> <p>(Target Exceeded)</p>	N/A	N/A	N/A
SRO-1.5 By 2020, increase our understanding of cancer trends and outcomes in the context of disparities and population subgroups through expansion of coverage and representation of the US population in the Surveillance, Epidemiology and End Results (SEER) Program registries. (Outcome)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population.</p> <p>(In Progress)</p>	Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population.	Expand SEER to include links with 1-2 outside sources such as biospecimen acquisition, genomics and molecular profile data.	N/A
SRO-1.6 By 2020, determine the effectiveness of an evidence-based, patient-centered multicomponent fall injury prevention strategy in adults 75 years of age and older. (Outcome)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy.</p> <p>(In Progress)</p>	Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy.	Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy and analyze trial data.	N/A
SRO-2.1 By 2023, develop, optimize, and evaluate the effectiveness of nano-enabled	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Optimize properties of 3</p>	Optimize properties of 3 nanoformulations for effective	Further optimize top 2 candidate nanoformulations for co-delivery of	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
immunotherapy (nano-immunotherapy) for one cancer type. (Output)	<p>nanoformulations for effective delivery and antigen-specific response in immune cells.</p> <p>(In Progress)</p>	delivery and antigen-specific response in immune cells.	multiple antigens to enhance anti-tumor response in one animal model.	
SRO-2.2 By 2018, assess the efficacy of one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	<p>FY 2017: Follow-up visits of enrolled subjects and final analysis report were completed.</p> <p>Target: Conduct follow-up visits of enrolled subjects.</p> <p>(Target Met)</p>	Complete study and publish manuscript.	N/A	N/A
SRO-2.3 By 2019, 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)	<p>FY 2017: Enrollment, tracking and follow-up with participants has proven difficult, in part because of greater than expected rates of mobility and migration. Therefore, to ensure that there are sufficient data to meet the primary study objective, the Data and Safety Monitoring Board extended the period of follow-up through June 2018.</p> <p>Target: Complete additional annual follow-up visits of all participants and HIV incidence evaluations.</p> <p>(Target Not Met)</p>	Finish conducting follow-up visits and begin data analysis.	Complete data analyses to evaluate the impact of two community-level combination prevention packages on population-level HIV incidence.	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)	<p>FY 2017: NIH-supported scientists completed a phase I clinical trial of a hearing system to treat hearing loss. Individuals using the Earlens light-driven contact hearing aid demonstrated significant improvement in word recognition.</p> <p>Target: Initiate testing one new potential treatment option for a hearing disorder.</p> <p>(Target Met)</p>	Initiate testing one new potential treatment option for a speech and language disorder.	Initiate testing one new potential treatment option for a hearing disorder.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Develop prototypes for four imaging technologies based on adaptive optics in animal models.</p> <p>(In Progress)</p>	Develop prototypes for four imaging technologies based on adaptive optics in animal models.	Integrate measurements of cell function with anatomical imaging.	N/A
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these changes can be inherited. (Output)	<p>FY 2017: Seven environmental chemicals that altered epigenetic processes in animal models were analyzed.</p> <p>Target: Analyze the impact of how 2-6 distinct/individual environmental exposures alter epigenetic processes in animal models.</p> <p>(Target Exceeded)</p>	Through the use of epigenetic signatures, evaluate if 3 different environmentally induced changes in 3 different tissues or cells obtained noninvasively are similar in major organs or tissues.	Determine and identify, if present, sex differences in three environmentally induced epigenomic signatures in three different mouse tissues.	N/A
SRO-2.7 By 2022, file Phase II Investigational New Drug (IND) application with the FDA for a therapy to treat geographic atrophy in age-related macular degeneration using patient-derived stem cells. (Outcome)	<p>FY 2017: Clinical grade retinal tissue patch derived from AMD patients was safe and effective in rescuing retinal degeneration in rodent and pig models.</p> <p>Target: Complete preclinical work to test safety and efficacy of the clinical product in animal models.</p> <p>(Target Met)</p>	Submit IND application with the FDA to launch phase I clinical trial upon approval.	Recruit 3 AMD patients into Phase I clinical trial.	N/A
SRO-2.8 By 2023, advance the development of three novel drug or biologic therapeutic candidates for Alzheimer's disease (AD) or related dementias toward the point of entry into Phase I human studies. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets.</p> <p>(In Progress)</p>	Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets.	For each of the novel therapeutic targets, select 3-5 candidate therapeutic agents for entry into preclinical optimization studies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	<p>FY 2017: Enrollment of participants continued for both studies.</p> <p>Target: Strategy 1: Continue enrolling participants into two studies to test the safety, tolerability, and effectiveness of VRC01 as an intravenous prevention strategy.</p> <p>(Target Met)</p>	Strategy 2: Analyze primary results of a Phase 2a study examining the long-acting injectable, cabotegravir, for the prevention of HIV.	Strategy 3: Complete final analysis of an open-label extension study that builds on the findings of an earlier trial and aims to assess the continued safety of the dapivirine vaginal ring in a more real-world context and study participants' adherence.	N/A
SRO-2.10 By 2021, develop methods for the regeneration of functional tissues of the human dental, oral, and craniofacial complex to enable initiation of human Phase I clinical trials. (Outcome)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Establish a centralized Resource Center that is fully operational to develop, optimize, and validate tools and strategies for dental, oral, and craniofacial tissue regeneration.</p> <p>(In Progress)</p>	Establish a centralized Resource Center that is fully operational to develop, optimize, and validate tools and strategies for dental, oral, and craniofacial tissue regeneration.	Submit an Investigational New Drug (IND) application for an FDA-approved tissue regeneration combination product.	N/A
SRO-2.12 By 2021, develop, validate, and/or disseminate 3-5 new research tools or technologies that enable better understanding of brain function at the cellular and/or circuit level. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level.</p> <p>(In Progress)</p>	Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level.	Test new and/or existing brain stimulation devices for 2 new therapeutic indications in humans through the BRAIN Public Private Partnership.	N/A
SRO-2.13 By 2023, advance the development of 1-2 new drugs and/or other therapeutic candidates for neurological diseases from lead optimization or device development toward the point of preparedness for	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Initiate lead optimization studies to identify a pre-clinical candidate for 4-7 therapeutic or device candidates.</p>	Initiate lead optimization studies to identify a pre-clinical candidate for 4-7 therapeutic or device candidates.	Identify and characterize 2-4 therapeutic or device candidates in preparation for animal toxicology studies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
first-in-human studies. (Output)	(In Progress)			
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development. (In Progress)	Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development.	Continue to evaluate the impact of adolescent alcohol or other substance use on brain development.	N/A
SRO-3.2 By 2023, establish the feasibility of using one emerging technology to safely and non-invasively obtain real time data on human placenta development and function during pregnancy. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Implement 3 research studies designed to evaluate the potential use of imaging technologies to obtain data on the placenta in humans and/or animal models. (In Progress)	Implement 3 research studies designed to evaluate the potential use of imaging technologies to obtain data on the placenta in humans and/or animal models.	Develop specifications for a curated dataset to serve as a resource for placental research, including identifying research gaps and discovering potential biomarkers and therapeutic targets for drug delivery.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2017: Researchers have designed a compassionate use study to evaluate treatment with Janus Kinase (JAK) inhibitors in juvenile dermatomyositis (JDM). Target: Design a clinical study testing an agent for a disorder of the immune system that affects children. (Target Met)	Initiate an interventional clinical study of a molecularly-targeted therapy in a cohort of patients with a disorder of the immune system that affects children.	Complete an interventional clinical study of a molecularly targeted therapy for a disorder of the immune system that affects children.	N/A
SRO-3.10 By 2017, advance two candidate medications for treatment of substance use disorders to clinical studies in humans. (Outcome)	FY 2017: NIH-supported researchers conducted a human laboratory study to investigate the role of varenicline, a smoking cessation medication, on alcohol craving. Target: Conduct one human	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	laboratory study on a candidate compound. (Target Met)			
SRO-3.11 By 2017, advance the discovery of high need cures through innovations in the therapeutics discovery and development process, by developing 3-D human tissue chips that accurately model the structure and function of human organs. (Outcome)	FY 2017: NIH-funded scientists continued to collaborate to integrate tissue chips into linked systems to mimic complex human organ interactions. Scientists investigated sequential metabolism of drugs through four organ systems (gut, liver, blood-brain barrier, kidney) and investigated off-target side-effects of drugs and metabolites on skeletal muscle. Target: Demonstrate that integrated organ chip systems model the structure and function of human organs. (Target Met)	N/A	N/A	N/A
SRO-4.1 By 2020, enable 1-3 Bridging Interventional Development Gaps (BrIDGs) projects to have sufficient pre-clinical data for therapeutic agents in order to apply for Investigational New Drug (IND) approval from the FDA. (Output)	FY 2017: The BrIDGs program acquired GMP-compliant drug material for one project. However, due to factors outside of BrIDGs' control (deficiency in required drug materials provided by the collaborator), formal GLP toxicology studies could not be conducted. Target: Acquire Good Manufacturing Practice (GMP)-compliant drug material and conduct formal Good Laboratory Practice (GLP) toxicology studies for 1-3 projects. (Target Not Met)	Acquire GMP-compliant drug material for 1-3 projects.	Initiate formal GLP toxicology studies for 1-3 projects.	N/A
SRO-4.2 By 2017, develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in	FY 2017: NIH-supported research examined data related to effective smoking cessation rates in NA communities.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
<p>Native American (NA) populations that are culturally appropriate and promote the adoption of healthy lifestyles. (Outcome)</p>	<p>Target: Continue to develop, adapt, and test the effectiveness of culturally appropriate health promotion and disease prevention interventions in NA populations. Begin analyzing preliminary data from testing interventions in NA communities, and adapt community interventions based on initial finding.</p> <p>(Target Met)</p>			
<p>SRO-4.3 By 2020, advance our characterization and understanding of the cellular and genetic components that make up the diverse composition of most tumors. (Outcome)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Identify the cellular/genetic components of 3 common cancer types.</p> <p>(In Progress)</p>	<p>Identify the cellular/genetic components of 3 common cancer types.</p>	<p>Identify the role various cellular components play in the phenotype of the 3 cancers.</p>	<p>N/A</p>
<p>SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)</p>	<p>FY 2017: The molecular bases of 32 rare diseases were discovered.</p> <p>Target: Discover the molecular bases of an additional 10 rare diseases.</p> <p>(Target Exceeded)</p>	<p>Discover the molecular bases of an additional 10 rare diseases.</p>	<p>Discover the molecular bases of an additional 10 rare diseases.</p>	<p>N/A</p>
<p>SRO-4.8 By 2019, establish a sharable collection of positive Zika virus (ZIKV) biospecimens to increase knowledge of viral infection and associated host immune response to help evaluate potential strategies to ensure the safety of the blood supply. (Output)</p>	<p>FY 2017: The main Brazil transfusion recipient study in Sao Paulo to identify cases of probable transfusion-transmitted arboviral infections was launched in January 2017 and successfully enrolled 946 recipients before enrollment was halted based on a lack of a significant evolving epidemic.</p> <p>Target: Launch the main Brazil transfusion recipient study in Sao Paulo to identify cases of probable transfusion-transmitted ZIKV, chikungunya virus (CHIKV), and dengue virus</p>	<p>Establish a sharable repository of biospecimens from blood donors with ZIKV infection and analyze data from a US natural history of blood donors infected with ZIKV.</p>	<p>Complete the establishment of a shareable repository of Zika bio specimens, analyze data from a US Zika database, establish utility of blood screening for Zika virus, and assess Zika transfusion-transmission risks in animal models.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(DENV). (Target Met)			
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment. (In Progress)	Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment.	Conduct 1 preclinical study and 1 clinical trial to develop non-opioid based medications to treat OUD that may avoid the risks of opioid dependence and overdose.	N/A
SRO-4.10 By 2020, design and develop novel dental composite resins that demonstrate superiority over the currently used restorative materials. (Output)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials. (In Progress)	Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials.	Implement regulatory feedback received by the FDA to demonstrate safety and effectiveness.	N/A
SRO-4.11 By 2020, create a model system that recreates key features of human type 1 diabetes (T1D) autoimmunity for use in therapeutics development and testing. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D. (In Progress)	Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D.	Develop a system for rapid and high fidelity insertion of 2 T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line.	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic outcomes in response to treatment of adolescents with severe obesity. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: By 2018, assess the extent and durability of improvements in diabetes and its comorbid conditions in response to one treatment modality in adolescents with severe obesity and type 2 diabetes.	By 2018, assess the extent and durability of improvements in diabetes and its comorbid conditions in response to one treatment modality in adolescents with	By 2019, evaluate the impact of bariatric surgery for severe obesity during adolescence on weight-related and psychosocial and behavioral outcomes.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(In Progress)	severe obesity and type 2 diabetes.		
SRO-4.13 By 2020, complete analysis from the oral insulin trial for the prevention of type 1 diabetes in relatives at risk for the disease. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Begin final outcomes assessment for the oral insulin trial. (In Progress)	Begin final outcomes assessment for the oral insulin trial.	Complete final outcomes assessment for 450 participants in the oral insulin trial.	N/A
SRO-4.14 By 2020, identify a total of three effective strategies to reduce modifiable health risk factors associated with premature mortality in people with serious mental illness (SMI) and adolescents and youths with serious emotional disturbance (SED). (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI. (In Progress)	Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI.	Conduct testing of 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	N/A
SRO-5.1 By 2020, develop and test the effectiveness of two strategies for translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	FY 2017: Several U54 PACHE Partnerships have developed and/or validated evidence-based interventions and tools to help reduce the burden of cancer disparities in underserved communities across the United States. They are working with various community-based organizations (including faith-based organizations and community-based clinical practices and organizations) to disseminate/translate the interventions and tools in the diverse communities. Target: Develop 2 strategies for translating validated basic knowledge, clinical interventions, or behavioral interventions to diverse communities and clinical practice through establishing the Partnerships to Advance Cancer	Develop and support 2 partnerships to test validated basic cancer knowledge, clinical or behavioral interventions to diverse communities in clinical practice.	Finalize testing and validating the strategies to translate basic cancer knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>Health Equity (PACHE) program between Minority Serving Institutions (MSI) and NCI-designated Cancer Centers (CC).</p> <p>(Target Met)</p>			
<p>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)</p>	<p>FY 2017: Target of completing exome genotyping of 10,171 COPDGENE subjects was not met, due to a shift to whole genome sequencing in response to being awarded the TOPMed X01 announcement. This superior genome sequencing has been completed for 500 cases and 500 controls.</p> <p>Target: Complete exome chip genotyping of 10,171 COPDGENE subjects and identify 1 to 5 new rare and common genetic determinants of COPD.</p> <p>(Target Not Met but Improved)</p>	<p>Identify 1-5 genomic loci that correlate with specific lung patterns of emphysema.</p>	<p>N/A</p>	<p>N/A</p>
<p>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)</p>	<p>FY 2017: NIH met its target of confirming genomic regions of interest in the Discovery and Replication phase data sets and continues to harmonize the Discovery Phase and Replication Phase data sets.</p> <p>Target: Continue confirmation of genomic regions of interest in the Discovery and Replication phase datasets. Continue harmonization of Discovery Phase and Replication Phase datasets.</p> <p>(Target Met)</p>	<p>Continue confirmation of genomic regions of interest in the Discovery using samples from the Replication phase. Continue harmonization of Discovery Phase and Replication Phase datasets. Begin analysis of genomic regions of interest in the genomes of minority cohorts.</p>	<p>Begin analysis of genomic regions of interest in the ADSP Discovery Follow-Up Phase using whole genome sequence data from ethnically diverse cohorts. Continue confirmation of genomic regions of interest in the Discovery Phase using samples from the Follow-Up phase. Continue harmonization of Discovery Phase and Follow-Up Phase datasets.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 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)	<p>FY 2017: Three novel approaches/regimens designed to preserve existing antimicrobials were assessed.</p> <p>Target: Assess two novel approaches/regimens designed to preserve existing antimicrobials.</p> <p>(Target Exceeded)</p>	N/A	N/A	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)	<p>FY 2017: Several point-of-care projects focused on development of technology for use in primary care have continued to progress along the device development pipeline, namely initiating the regulatory process through meetings or discussions with the FDA, or preliminary applications for FDA approval or clearance.</p> <p>Target: Support research on continued development of one or two prototype devices that will begin to initiate the regulatory process.</p> <p>(Target Met)</p>	Support research on refinement of one or two devices for use in primary care that includes end-user feedback.	N/A	N/A
SRO-5.6 By 2017, develop, evaluate, refine, and/or promote strategies for preventing prescription drug abuse and its consequences. (Output)	<p>FY 2017: Basic research explored two different targets related to the endocannabinoid system for the development of treatments for chronic pain that are not associated with development of tolerance or dependence. Three different studies were released with findings that can inform the development of treatment strategies for individuals with co-morbid opioid addiction and chronic pain that can later be tested in clinical research. Translational research exploring the impact of prescription monitoring</p>	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>programs was disseminated in four publications.</p> <p>Target: In basic research: identify new targets or refine existing ones in the endocannabinoid system for the development of treatments of chronic pain without development of tolerance or dependence. In clinical research: develop, evaluate, and/or refine two to four treatment strategies that target co-morbid opioid addiction and chronic pain. In translation research identify the impact of state level prescription monitoring programs (PMP) on prescriber behavior and patient outcomes.</p> <p>(Target Met)</p>			
<p>SRO-5.8 By 2022, obtain pre-clinical and clinical data from newly initiated and current studies to evaluate 1-2 HIV vaccine candidate(s). (Outcome)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population.</p> <p>(In Progress)</p>	<p>Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population.</p>	<p>Evaluate 1-2 alternative HIV vaccine candidates' suitability for human testing.</p>	<p>N/A</p>
<p>SRO-5.9 By 2017, determine the potential contributions of infectious agents to the underlying etiology of urologic chronic pelvic pain syndromes (UCPPS). (Outcome)</p>	<p>FY 2017: The potential contributions of the urinary tract microbial community to the underlying etiology and symptom profiles for urologic chronic pelvic pain syndrome was determined.</p> <p>Target: Determine the potential contributions of infectious agents to the underlying etiology and symptom profiles for urologic chronic pelvic pain syndromes in males and females.</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
SRO-5.10 By 2020, assess the effectiveness of five to seven interventions that focus on eliminating health disparities by utilizing community partnerships to conduct intervention research that will foster sustainable efforts at the community level that will impact disparate conditions. (Output)	<p>FY 2017: Phase II intervention research projects have recruited 60 percent of participants and have begun collection of second year assessment variables.</p> <p>Target: Assess intervention progress and collect second year assessment variables.</p> <p>(Target Met)</p>	Assess intervention progress and collect third year assessment variables.	Assess intervention progress and collect fourth 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)	<p>FY 2017: A smart phone app was developed for lung transplant recipients to facilitate daily self-reporting of clinical signs and symptoms to their clinicians, helping to quickly identify critical changes in health.</p> <p>Target: Assess the efficacy of one strategy that improves health outcomes through symptom self-management.</p> <p>(Target Met)</p>	Test three strategies for symptom management that improve health outcomes across multiple illness trajectories.	N/A	N/A
SRO-5.12 By 2020, develop and/or characterize 3 mouse models for investigation of properties and functions of skin stem cells that can be used to advance research on wound healing, tissue engineering, or skin cancer. (Outcome)	<p>FY 2017: Researchers used mouse models to identify environments that control skin stem cells, demonstrate how other cells affect stem cell behavior, and clarify the function of receptors on stem cell surfaces.</p> <p>Target: Develop and/or characterize a mouse model that can be used to improve understanding of the in vivo conditions required for skin stem cell maintenance.</p> <p>(Target Met)</p>	Develop and/or characterize a mouse model in which skin stem cell life-span is shortened, to determine whether alterations in stem cell life-span modulate wound healing.	Develop and/or characterize a mouse model in which skin stem cell participation in wound repair is impaired.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment. (In Progress)	Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment.	Initiate research to test and refine one new or improved technology that uses acoustic, optical or electromagnetic waves to manipulate cells for treatment of illness.	N/A
SRO-5.14 By 2020, evaluate the effectiveness of one intervention to reduce death and/or neurodisability in pre-term or in full term infants with life-threatening conditions. (Outcome)	FY 2017: Completed follow-up on 168 subjects enrolled in study of newborn infants with brain injury due to low oxygenation. Target: Complete follow-up on 168 subjects enrolled in a study of term or late preterm infants with brain injury due to low oxygenation. (Target Met)	Complete enrollment in study of preterm infants undergoing incubator treatment.	Complete enrollment in transfusion study.	N/A
SRO-5.15 By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations. (Outcome)	FY 2017: NIH promoted and disseminated <i>CollegeAIM</i> and initiated efforts to update <i>CollegeAIM</i> to reflect the latest evidence-based alcohol interventions. Target: Continue to promote the College Alcohol Intervention Matrix (<i>CollegeAIM</i>). (Target Met)	Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native).	N/A	N/A
SRO-5.16 By 2021, conduct research to support pharmaceutical labeling changes for 5 drugs, to reflect safe and appropriate dosing and use specifically in children. (Outcome)	FY 2017: A proposed label change on acyclovir was submitted to the FDA. Target: Submit one proposed label change to FDA. (Target Met)	Complete one Phase I/II clinical trial on a prioritized drug.	Begin one Phase III clinical trial for drug development.	N/A
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-	FY 2018: Result Expected Dec 31, 2018 Target: Initiate development of	Initiate development of new strategies for patient- and	Test at least one novel strategy for improving care for patients with	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
of-life and palliative care. (Outcome)	new strategies for patient- and caregiver-centered decision-making in end-of-life and palliative care. (In Progress)	caregiver-centered decision-making in end-of-life and palliative care.	advanced illness through shared decision-making.	
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2017: Enrollment has been completed for two of the three Restoring Insulin Secretion studies. Target: Complete enrollment for at least one Restore Insulin Secretion protocol. (Target Met)	Complete at least one Restoring Insulin Secretion protocol.	Analyze the baseline data from the three Restoring Insulin Secretion protocols to understand differences between adult and pediatric individuals with pre-diabetes or newly diagnosed type 2 diabetes.	N/A
SRO-6.2 By 2025, advance 1-2 new or repurposed compounds that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Conduct at least 1 study with an animal model to evaluate the effect of a novel or repurposed compound on a neurobiological target involved in alcohol or other substance use disorders. (In Progress)	Conduct at least 1 study with an animal model to evaluate the effect of a novel or repurposed compound on a neurobiological target involved in alcohol or other substance use disorders.	Conduct at least 1 human laboratory study to evaluate the safety and efficacy of candidate compounds for treating alcohol or other substance use disorders.	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 2017: In collaboration with Consumer Reports, NIH-supported investigators produced a web-based calculator that provides personalized estimates of treatment benefits and harms. Target: Integrate the individualized outcome models into an outcomes calculator and assess its use in a web-based environment (Target Met)	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.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
<p>SRO-7.3 By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery or adherence for substance use disorders and related health consequences. (Output)</p>	<p>FY 2017: Research testing the feasibility and efficacy of 3 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including research in 2 different care delivery settings.</p> <p>Target: Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings.</p> <p>(Target Met)</p>	<p>Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities.</p>	<p>Develop and/or evaluate 2 HIT based interventions to prevent or treat substance use disorders or to improve medication adherence.</p>	<p>N/A</p>
<p>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)</p>	<p>FY 2017: Research disseminated through six studies has made significant advances in identifying the structural and functional plasticity of dendritic spines of neurons due to the use of drugs of abuse, withdrawal from chronic use, and relapse. Research shows that exposure to different drugs of abuse can alter dendritic spine morphology, and that drug-induced altered spine morphology occurs in several brain regions and can vary depending on the distance from the cell body. The biological mechanisms that contribute to these changes in dendritic spines are being studied.</p> <p>Target: Identify morphological and functional neuroplastic modifications due to drugs at the level of dendritic spines and electrophysiological indices and their persistence during the development of drug dependence (or during repeated</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	intermittent drug administration). (Target Met)			
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 2017: NIH researchers tested research-to-practice partnerships that were designed to enhance dissemination and implementation evidence-based practices. Three research projects focused on testing the development of organizational structures among research faculty, mental health treatment providers and agency stakeholders in rural primary care. Findings suggest that shared decision-making, written protocols, ongoing collaborative assessments and the implementation of warm hand-offs contributed to increased access to treatment among patients with mental health needs. Target: Establish one research-practice partnerships to improve dissemination, implementation, and continuous improvement of evidence-based mental health care services. (Target Exceeded)	Identify three implementation strategies that improve the sustainability and uptake of evidence-based practices in large public services settings, such as child welfare and mental health agencies.	N/A	N/A
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/intervention programs in minority communities. (Outcome)	FY 2017: The Shake, Rattle and Roll trial demonstrated efficacy of a blood pressure management intervention to reduce racial disparities in blood pressure control, a major contributor to stroke disparities. Target: Complete data analysis for a study that tested culturally tailored interventions to address major contributors to stroke disparities in racial/ethnic minority populations.	Initiate dissemination and implementation (D&I) data analyses to identify scalable components of successful disparities intervention programs.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2017: Award rate to comparison group reached 12%. Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2017: Award rate to comparison group reached 15% and exceeded the target by 5%. Target: N ≥ 10% (Target Exceeded)	N ≥ 10%	N ≥ 10%	N/A
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (Output)	FY 2017: NBS developed the Oracle Managed Cloud Services Performance Work Statement to define the necessary OMCS capacity and capabilities. NBS submitted the PWS to Vendor. Target: (Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud (Target Met)	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System. * Planned - NBS Hosting to Oracle Cloud	(Development [Dev]) Continue development of remediation activities to comply with HHS Accounting Treatment Manual (ATM) and other Treasure Mandates to increase accuracy and functionality of the NIH Business System.	N/A
CBRR-4 By 2021, produce and phenotype 2500 knockout (KO) mouse strains to enhance the capacity of researchers to investigate the in vivo function of mammalian genes and identify new models of human disease. (Outcome)	FY 2017: 413 juvenile lines of genetically modified mice were phenotyped. The mouse production and phenotyping is reported to a central database, and the information is disseminated at www.impc.org . Target: Deliver phenotyping on 300 knockout (KO) juvenile lines of genetically modified mice.	Deliver phenotyping on 500 knockout (KO) juvenile lines.	Deliver phenotyping on 600 knockout (KO) juvenile lines.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CBRR-5 By 2019, enhance the Clinical and Translational Science Awards (CTSA) Program by establishing resources, processes and guidelines to streamline and accelerate the implementation of multisite clinical trials. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and Recruitment Innovation Centers.</p> <p>(In Progress)</p>	Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and Recruitment Innovation Centers.	Launch at least two multi-site clinical trials within the CTSA trial innovation network.	N/A
CBRR-6 By 2019, launch and establish a Biomedical Citizen Science Hub to serve as an online collaboration space for biomedical citizen science research efforts in cancer biology. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Complete development & launch the Biomedical Citizen Science Hub.</p> <p>(In Progress)</p>	Complete development & launch the Biomedical Citizen Science Hub.	Establish 200-300 registered users of the site and 5 subgroups for the Biomedical Citizen Science Hub.	N/A
CBRR-7 By 2017, expand the scope and reach of the National Ophthalmic Diseases Genotyping and Phenotyping Network (eyeGENE®), a national genetics research resource for rare inherited ocular diseases, by adding new patient records to the database, augmenting and refining the phenotypic data collected, and by increasing the number of registered researchers to 900. (Output)	<p>FY 2017: With 6,450 participants (including 3,000 detailed phenotypes), eyeGENE is now an ocular genetics resource with 1,043 registered users in 5 countries and has been cited in 129 research publications.</p> <p>Target: Increase the number of registered eyeGene users to 900.</p> <p>(Target Exceeded)</p>	N/A	N/A	N/A
CBRR-8 By 2017, characterize the three-dimensional atomic structure of 400 proteins of biomedical interest related to infectious agents. (Output)	<p>FY 2017: 205 three-dimensional structures were characterized to enhance the biomedical research community's understanding of these proteins and to assist with the development of structure-based vaccines, diagnostics, and therapeutics.</p>	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>Target: Characterize the three-dimensional structure of an additional 100 protein targets or other molecules of biomedical interest with regard to bacterial, viral, and eukaryotic pathogens.</p> <p>(Target Exceeded)</p>			
<p>CBRR-9 By 2020, enroll a total of 2,352 participants in GenomeConnect, ClinGen’s Patient Registry. (Output)</p>	<p>FY 2017: A cumulative 1,302 participants were enrolled in GenomeConnect.</p> <p>Target: Enroll 1,046 cumulative participants in GenomeConnect.</p> <p>(Target Exceeded)</p>	<p>Enroll 1,652 cumulative participants in GenomeConnect.</p>	<p>Enroll 2,002 cumulative participants in GenomeConnect.</p>	<p>N/A</p>
<p>CBRR-10 By 2020, enroll 180 children into the Pediatric Heart Network (PHN) to support a research resource for investigators conducting research in congenital heart disease across the age spectrum. (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Enroll 50 children with complex congenital heart disease in a clinical research study.</p> <p>(In Progress)</p>	<p>Enroll 50 children with complex congenital heart disease in a clinical research study.</p>	<p>Enroll 50 children with complex congenital heart disease in a clinical research study.</p>	<p>N/A</p>
<p>CBRR-12 By 2017, produce x-ray diffraction data for new protein structures that will enhance an existing x-ray resource for understanding basic biological processes. (Output)</p>	<p>FY 2017: X-ray crystallographic data for 176 new structures of biomedical relevance provided to researchers worldwide.</p> <p>Target: Provide x-ray crystallographic data for 170 new structures of macromolecules of biomedical relevance to researchers worldwide.</p> <p>(Target Met)</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>
<p>CBRR-13 By 2017, archive and annotate new protein structures to support research in human health and disease and drug development. (Output)</p>	<p>FY 2017: In FY 2017, 9,691 structures were archived and annotated at the Protein Data Bank and made available to the community, exceeding the target.</p> <p>Target: Annotate and archive</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	9,200 new protein structures. (Target Exceeded)			
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 2017: A new prevention trial for the NIH StrokeNet – Atrial Cardiomyopathy and Antithrombotic Drugs in Prevention After Cryptogenic Stroke (ARCADIA) – was initiated. Target: To broaden the network’s scope across stroke research, initiate one new trial in stroke prevention or stroke treatment within the stroke network. (Target Met)	Complete enrollment in 1 to 3 trials being conducted within the stroke network.	N/A	N/A
CBRR-17 By 2017, take steps to improve the quality and availability of information to inform decisions about the size of the NIH training programs and the number of people in training to address future needs for the nation's biomedical research workforce. (Output)	FY 2017: NIH has developed and released the xTRACT system, which allows NIH applicants to create data tables for training grant applications electronically and NIH to capture the resulting trainee outcome data. Target: Adopt a system for reporting training grant data and trainee outcomes electronically. (Target Met)	N/A	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	FY 2018: Result Expected Dec 31, 2018 Target: Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample. (In Progress)	Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample.	Review results from the assessment protocol as deployed in the US in 2016-2017 and in other countries in 2017 and 2018. Refine protocol as needed to increase sensitivity and specificity.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
<p>CBRR-19 By 2019, identify and characterize 1900 immune epitopes from infectious pathogens and allergens for deposit into the Immune Epitope Database (www.iedb.org) to accelerate development of more effective vaccines and immune-based therapeutics. (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Identify and characterize 600 T cell and 200 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics.</p> <p>(In Progress)</p>	<p>Identify and characterize 600 T cell and 200 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics.</p>	<p>Identify and characterize 650 T cell and 250 B cell epitopes from infectious pathogens and 100 T cells epitopes from allergens to accelerate development of more effective vaccines and immune-based therapeutics.</p>	<p>N/A</p>
<p>CBRR-20 By 2020, advance the preclinical development of ten candidate products (e.g., vaccines, therapeutics) to combat infectious diseases. (Outcome)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Advance the preclinical development of three vaccine and/or therapeutic candidate products.</p> <p>(In Progress)</p>	<p>Advance the preclinical development of three vaccine and/or therapeutic candidate products.</p>	<p>Advance the preclinical development of three vaccine and/or therapeutic candidate products.</p>	<p>N/A</p>
<p>CBRR-21 By 2020, establish and implement a national collaborative Pilot and Feasibility (P&F) program that utilizes specialized equipment, and expertise in nonmalignant hematology that are available through the Cooperative Centers of Excellence in Hematology (CCEH). (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions.</p> <p>(In Progress)</p>	<p>Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions.</p>	<p>Support 2 P&F projects involving collaboration outside the hematology Centers.</p>	<p>N/A</p>
<p>CBRR-22 By 2020, establish a reference map that will serve as the framework to understand the development of the human urinary tract. (Outcome)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate.</p> <p>(In Progress)</p>	<p>Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate.</p>	<p>Identify and map at least 5 specific cell types or subtypes within the kidney, urinary outflow tract, and/or prostate.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
<p>CBRR-23 By 2019, provide access to laboratory and data analytical services and a data repository that will allow the NIH extramural research community the capability to add or expand the inclusion of environmental exposure analysis in children’s health research. (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Support at least 20-40 studies (or about 20,000 sample analyses) in a project management pipeline from application development and review to laboratory and data analysis.</p> <p>(In Progress)</p>	<p>Support at least 20-40 studies (or about 20,000 sample analyses) in a project management pipeline from application development and review to laboratory and data analysis.</p>	<p>Support analysis for at least 10 additional studies (or about 10,000 sample analyses) and make the results from about 10 studies or 10,000 sample analyses available to the broader scientific community.</p>	<p>N/A</p>
<p>CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5% above baseline.</p> <p>(In Progress)</p>	<p>Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5% above baseline.</p>	<p>Expand by 5% the proportion of NIGMS-supported investigators funded by active R01-equivalent awards who are MIRA recipients.</p>	<p>N/A</p>
<p>CBRR-25 Increase the total number of mentored research career development experiences for trainees from underrepresented backgrounds to promote individual development and to prepare them for a range of research-related careers. (Output)</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: 3505 career experiences across all career stages.</p> <p>(In Progress)</p>	<p>3505 career experiences across all career stages.</p>	<p>3522 career experiences across all career stages.</p>	<p>N/A</p>
<p>CBRR-26 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA Networks of Biomedical Research Excellence (INBRE) program in order to sustain a pipeline of undergraduate students</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Sustain the number of undergraduate mentored research experiences from 2017 level.</p> <p>(In Progress)</p>	<p>Sustain the number of undergraduate mentored research experiences from 2017 level.</p>	<p>Sustain the number of undergraduate mentored research experiences from 2018 level.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
who will pursue health research careers. (Output)				
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Expand the validation of assessment methods for risk of suicide among at least one subgroup (e.g., youth, adults; persons who have experienced trauma) seen in emergency department.</p> <p>(In Progress)</p>	Expand the validation of assessment methods for risk of suicide among at least one subgroup (e.g., youth, adults; persons who have experienced trauma) seen in emergency department.	Validate risk stratification approaches in emergency care settings for youth who are at risk for suicide.	N/A
CBRR-28 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting research on brain and behavior. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Collect brain tissue from 70 new donors and distribute tissue samples or data derived from tissue to 25 researchers studying mental or neurological disorders.</p> <p>(In Progress)</p>	Collect brain tissue from 70 new donors and distribute tissue samples or data derived from tissue to 25 researchers studying mental or neurological disorders.	Collect brain tissue from an additional 70 new donors and distribute tissue samples or data derived from tissue to 30 researchers studying mental or neurological disorders.	N/A
CBRR-29 By 2020, establish an interactive consortium to facilitate efficient data collection and sharing for biomarker studies of vascular contribution to cognitive impairment and dementia (VCID). (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations.</p> <p>(In Progress)</p>	Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations.	Initiate multi-site validation studies for one candidate biomarker.	N/A
CTR-1 By 2018, increase the number of SBIR/STTR outreach events that are targeted to groups that are currently underrepresented in the NIH SBIR/STTR portfolio. (Output)	<p>FY 2017: Three outreach events to women-targeted or minority-targeted organizations were completed.</p> <p>Target: Complete three outreach events with either a minority-targeted organization or program, or a women-targeted organization or program.</p>	Complete four outreach events with either a minority-targeted organization or program, or a women-targeted organization or program.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	(Target Met)			
CTR-2 By 2017, reach 500,000 visits to the website Genome: Unlocking Life’s Code. (Outcome)	<p>FY 2017: As of November 19, 2017, ULC reached 490,456 visits and 1,676,887 page views. The target of 2.5 million pages was not met; however, the 1.68 million pages represents a continuing upward trend from previous years.</p> <p>Target: By 2017, reach 2.5 million total page views.</p> <p>(Target Not Met but Improved)</p>	N/A	N/A	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)	<p>FY 2017: NIH institutes/centers collaborated to develop a new CDE library and to provide centralized access to CDE resources for the clinical research community.</p> <p>Target: Develop collaborative model to enable implementation of the CDE project as a long-term sustainable resource for the clinical research community.</p> <p>(Target Met)</p>	N/A	N/A	N/A
CTR-5 By 2018, increase the number of computer-indexed MEDLINE journals by 469 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	<p>FY 2017: The number of computer-indexed MEDLINE journals was increased by 100 titles, thereby increasing indexing efficiency for MEDLINE.</p> <p>Target: Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 96 titles over the previous year.</p> <p>(Target Exceeded)</p>	Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 60 titles over the previous year.	N/A	N/A
CTR-6 By 2018, improve NIH’s ability to identify outcomes that result from	FY 2017: The Final Research Performance Progress Report is one of three final reports that	By 2018, implement system improvements to	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
<p>NIH funded research projects and reports to the public on research outcomes. (Outcome)</p>	<p>allow NIH to closeout grant awards. The F-RPPR includes a Project Outcomes section that allows recipients to summarize the cumulative outcomes or findings of the project. This section is written in laymen's terms for the general public and will be made public in NIH RePORTER.</p> <p>Target: By 2017, establish an electronic closeout process for NIH research grants which includes a Project Outcomes Report for the general public summarizing the project outcomes or findings that expand fundamental knowledge, enhance health, lengthen life, reduce illness and disability, and otherwise fulfill the programmatic goals of the research activity.</p> <p>(Target Met)</p>	<p>collect inclusion data (i.e., race, gender, etc.) at award closeout in a structured format.</p>		
<p>CTR-7 By 2022, engage a national community in the development, dissemination, and implementation of a comprehensive national strategy to address the burden of Chronic Obstructive Pulmonary Disease (COPD) in the US. (Output)</p>	<p>FY 2017: The COPD National Action Plan was launched on May 22, 2017 at the American Thoracic Society annual meeting in Washington, DC with a press conference and expert panel.</p> <p>Target: Complete development and begin dissemination of a national COPD action plan.</p> <p>(Target Met)</p>	<p>Conduct annual implementation progress webinars/meetings with stakeholders.</p>	<p>Analyze completed webinars and meeting, and brief stakeholders on Action Plan progress.</p>	<p>N/A</p>
<p>CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform agency funding decisions, and promote transparency</p>	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: By 2018, develop a metric that captures the unique number of individuals who apply for and receive NIH funding over a five-year time period.</p>	<p>By 2018, develop a metric that captures the unique number of individuals who apply for and receive NIH funding over a five-year time period.</p>	<p>By 2019, develop a central public report displaying NIH Institute/Center-specific award data on investigator-initiated R01/R37 grants.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
regarding the agency's funding strategies. (Output)	(In Progress)			
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Output)	<p>FY 2017: NIH's leadership development programs incorporated technology to increase engagement and access for remote employees. While students were open to technological tools, participants tend to prefer face-to-face interactions.</p> <p>Target: Assess [AS] results of implementation *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]</p> <p>(Target Met)</p> <p>FY 2017: Recommendations from a prior evaluation were implemented to ensure that the Executive Leadership Program (ExLP) meets participant expectations and organizational requirements.</p> <p>Target: Implement [IM] recommendation from prior year assessments *NIH will implement the recommendations from prior year assessments of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/ AS 2018]</p> <p>(Target Met)</p>	<p>Examine [EX] key area to enhance leadership skills *NIH workforce trends to target junior-level programs to job series with the largest anticipated risk in filling future leadership positions. [IM 2019/ AS 2020]</p> <p>Implement [IM] recommendation from prior year assessments *NIH will implement best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019]</p> <p>Assess [AS] results of implementation *NIH will assess the outcomes of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its</p>	<p>Examine [EX] key area to enhance leadership skills</p> <p>Examine the Management Seminar Series as a method for engaging and encouraging leadership in high-performing NIH employees.</p>	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>FY 2017: The NIH Office of Human Resources found that supervisors need targeted guidance and support on topics specific to supervision and leadership. In addition, hiring managers need to have additional resources to better prepare for onboarding employees.</p> <p>Target: Examine [EX] key area to enhance leadership skills *NIH will examine best practices in supervisory onboarding to determine how to best prepare new NIH supervisors for their roles and ensure that they are engaged and committed to NIH. [IM 2018/ AS 2019]</p> <p>(Target Met)</p>	<p>current content [IM 2017/ AS 2018]</p>		
<p>MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Output)</p>	<p>FY 2017: NIH/OHR successfully increased the use of Global Recruitments as it relates to select positions at the NIH that have Direct Hire Authority as a result of a critical need. As a result, there is a quarterly coordinated and consolidated approach to announcing for Contract Specialist and Medical Officer positions reducing the number of resources across 27 Institutes and Centers and OD Offices for hiring within these positions.</p> <p>Target: Assess [AS] results of implementation *Assess the results of implementation on the Increase use of Global Recruitments. [AS 2017]</p> <p>(Target Met)</p> <p>FY 2017: NIH/OHR managerial</p>	<p>Examine [EX] key area to enhance recruitment *NIH will examine HR CARDS to determine whether it is effective in meeting program goals and streamlining the efficient use of standard HR packages. [IM 2019/AS 2020]</p> <p>Implement [IM] key area to enhance recruitment *Implement the creation of a program that incorporates SMEs during the recruitment process, as</p>	<p>Examine [EX] key area to enhance recruitment</p> <p>Examine recruitment activities to identify the most opportune times throughout the year for NIH to recruit NIH for varying occupations.</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>staff were all interviewed regarding skill gaps and organizational needs. All eligible OHR Interns have been converted into the CSD organization to ensure a pipeline of staff. Also, OHR launched the group working on managing training internally to ensure new staff is trained and functioning quickly.</p> <p>Target: Assess [AS] results of implementation *Assess the results of launching a robust OHR succession planning effort to ensure OHR staff are available to meet the recruitment needs of NIH. [AS 2017]</p> <p>(Target Met)</p> <p>FY 2017: NIH Pathway's Program expanded to include targeted announcements for NIH Student Trainee Bio Science Lab Tech, Health Specialist and Student Trainee Engineering positions. In addition, the NIH continued the Presidential Management Fellow's track of Health Specialist and Public Health Analyst/Advisor.</p> <p>Target: Implement [IM] key area to enhance recruitment *Implement an expansion of the Pathways Program to STEM career path for focused students and supporting of succession planning efforts. [IM 2017] [AS 2018]</p> <p>(Target Met)</p> <p>FY 2017: NIH/OHR created an analysis by reviewing all resumes of two recruitments to study the impact of SME incorporation in the recruitment process.</p>	<p>appropriate. [IM 2018] [AS 2019]</p> <p>Assess [AS] results of implementation *Assess the expansion of the Pathways Program to STEM career path for focused students and in support of succession planning efforts. [IM 2017] [AS 2018]</p>		

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	<p>Target: Examine [EX] key area to enhance recruitment *Examine a way to create a comprehensive program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019]</p> <p>(Target Met)</p>			
<p>MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)</p>	<p>FY 2017: 25% of Principal Investigators were reviewed resulting in 25% of resources recommended to be reallocated.</p> <p>Target: Conduct BSC reviews of 25% of Principal Investigators to assess quality of science in order to prioritize resources.</p> <p>(Target Met)</p>	<p>Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.</p>	<p>Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.</p>	<p>N/A</p>
<p>MPO-5 Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa=85). (Output and Efficiency)</p>	<p>FY 2017: The condition of the facilities portfolio reached a CIwa of 83.08.</p> <p>Target: CIwa = 78.40</p> <p>(Target Exceeded)</p>	<p>CIwa=80.86</p>	<p>CIwa=80.94</p>	<p>N/A</p>
<p>MPO-6 By 2017, maintain the annual condition of buildings and facilities portfolio so that no less than 95% of occupied gross square feet (GSF) will have a CI greater than 65. (Output and Efficiency)</p>	<p>FY 2017: 87.85% of the occupied gross square feet (GSF) reached a CI greater than 65.</p> <p>Target: Target = 85.68%</p> <p>(Target Exceeded)</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>
<p>MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final approved project cost. (Output)</p>	<p>FY 2017: The sixteen (16) active funded projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100% of the final approved project cost.</p>	<p>15 Active Projects</p>	<p>18 Active Projects</p>	<p>N/A</p>

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Target: 16 Active Projects (Target Met)			
MPO-8 Manage design and construction of capital facility projects funded by B&F so that no more than 10% of the projects may incorporate plus or minus 10% adjustments of the approved scope. (Output)	FY 2017: The design and construction for thirteen (13) of the sixteen (16) active funded projects in the portfolio were managed effectively under this target that focused on ensuring that no more than 10% of the portfolio incorporated a plus or minus 10% adjustment of the approved scope. (target Not Met) Target: 16 Active Projects (Target Not Met)	15 Active Projects	18 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (Output)	FY 2017: Obligated 47% of eligible service contracting dollars to PBC. Target: Obligate the FY 2017 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2018 goal of eligible service contracting dollars to PBC.	Obligate the FY 2019 goal of eligible service contracting dollars to PBC.	N/A
MPO-10 Conduct systematic evaluations and pilot studies to identify strategies and future needs for enhancing the quality of peer review and improving efficiency. (Output)	FY 2017: Historical measures of peer review quality and efficiency were identified in 11 studies conducted by CSR. This input was utilized in the planning and implementation of 8 original research and evaluation studies in 2017. Measures to assess peer review quality include those of structure, process, or outcome. Target: Identify historical measures of peer review quality and efficiency. (Target Exceeded)	Design and test measures of peer review quality and efficiency.	Refine and test measures of peer review quality and efficiency.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
MPO-11 Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: 70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.</p> <p>(In Progress)</p>	70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	75% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	N/A
MPO-12 By 2020, enhance the management, oversight, and transparency of NIH-funded clinical trials through reforms to clinical trials grant applications, peer review, and tracking of awards. (Outcome)	<p>FY 2018: Result Expected Dec 31, 2018</p> <p>Target: Improve the quality and strengthen peer review of clinical trial applications by 1) requiring that all clinical trial applications be submitted to clinical trial-specific funding opportunity announcements (FOAs) and 2) introducing new clinical trials-specific review criteria to enhance peer review.</p> <p>(In Progress)</p>	Improve the quality and strengthen peer review of clinical trial applications by 1) requiring that all clinical trial applications be submitted to clinical trial-specific funding opportunity announcements (FOAs) and 2) introducing new clinical trials-specific review criteria to enhance peer review.	Enhance transparency of NIH-funded clinical trials by establishing an NIH policy that expects all NIH-funded clinical trials to register and submit results to ClinicalTrials.gov and by creating a more robust process for assuring compliance with the policy.	N/A

GRANT AWARDS TABLE

	FY 2017 Final³	FY 2018 Annualized CR³	FY 2019 President's Budget^{3,4}
Number of Awards	44,193	43,628	44,431
Average Award (in Whole \$s)	\$538,794	\$545,333	\$530,482
Range of Awards (in Whole \$s) ^{1,2}	\$1,000 to \$47,653,075	\$1,000 to \$34,196,739	\$1,000 to \$33,205,852

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

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

³ Includes 21st Century Cures Act funding.

⁴ Includes NIRSQ and excludes NIOSH, NIDILRR, PCORTF, and EEOICPA.