Appropriations Language

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$5,743,892,000]*$5,051,737,000*, of which up to $30,000,000 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, [$3,488,335,000]*$3,002,696,000*.

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, [$461,781,000]*$397,493,000*.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

For carrying out section 301 and title IV of the PHS Act with respect to diabetes and digestive and kidney disease, [$2,029,823,000]*$1,746,493,000*.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

For carrying out section 301 and title IV of the PHS Act with respect to neurological disorders and stroke, [$2,216,913,000]*$1,956,031,000*.

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, [$5,523,324,000]*$4,754,379,000*.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [$2,872,780,000]*$2,472,838,000*, of which [$1,146,821,000]*$741,000,000* shall be from funds available under section 241 of the PHS Act: Provided, That not less than [$361,573,000]*$311,236,000* is provided for the Institutional Development Awards program.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

For carrying out section 301 and title IV of the PHS Act with respect to child health and human development, [$1,506,458,000]*$1,296,732,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [$796,536,000]*$685,644,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [$774,707,000]*$666,854,000. (Department of Health and Human Services Appropriations Act, 2019.)*

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, $66,581,000.

Note.—A full-year 2019 appropriation for this account was not enacted at the time the budget was prepared; therefore, the budget assumes this account is operating under the Continuing Appropriations Act, 2019 (Division C of P.L. 115–245, as amended). The amounts included for 2019 reflect the annualized level provided by the continuing resolution.

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, [$3,083,410,000]*$2,654,144,000*.

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, [$605,065,000]*$520,829,000*.

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, [$474,404,000]*$408,358,000.*

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [$162,992,000]*$140,301,000.*

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, [$525,591,000]*$452,419,000.*

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [$1,419,844,000]*$1,296,379,000*

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [$1,812,796,000]*$1,560,422,000.*

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [$575,579,000]*$495,448,000.*

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, [$389,464,000]*$335,986,000*.

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, [$146,473,000]*$126,081,000.*

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, [$314,679,000]*$270,870,000.*

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), [$78,109,000]*$67,235,000.*

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [$441,997,000]*$380,463,000: Provided,* That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2020]*2021: Provided further,* That in fiscal year [2019]*2020*, 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, [$806,373,000]*$694,112,000: Provided,* That up to [$80,000,000]*10 percent of the amounts made available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network[: *Provided further,* That at least $559,736,000 is provided to the Clinical and Translational Sciences Awards program].

OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, [$1,909,075,000]*$1,756,544,000: 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 [$165,000,000]*$157,065,000* shall be for the Environmental Influences on Child Health Outcomes study: *Provided further,* That [$606,566,000]*$520,367,000* shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: *Provided further,* That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: *Provided further,* That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act[: *Provided further,* That $50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities][: *Provided further,* That $5,000,000 shall be transferred to and

merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further,* That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further,* That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2019 and 2020 no later than 30 days after the date of enactment of this 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 of, 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]*2024.*

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 2020: 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.

NIH INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

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 NIH in this Act, [$711,000,000]*$492,000,000,* to remain available until expended: *Provided,* That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further,* That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: *Provided further,* That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. (Department of Health and Human Services Appropriations Act, 2019.)

Language Analysis

Language Provision to be Changed	Explanation/Justification
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES *Provided*, That up to [$80,000,000]*10 percent of the amounts made available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network	NIH requests that the provision regarding funding within NCATS for the Cures Acceleration Network (CAN) be structured as a percentage of the NCATS budget level. The unique authorities associated with CAN – use of Other Transactions Authority (OTA) and matching funding – give NCATS flexibility to quickly create or terminate parts of an initiative based on programmatic need and scientific opportunity. Specifying the CAN ceiling as a percentage of the overall NCATS budget ensures that the CAN funding adjusts relative to overall funding levels and enables NCATS to plan CAN activities more strategically.
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES [: *Provided further*, That at least $559,736,000 is provided to the Clinical and Translational Sciences Awards program]	NIH requests that this provision be removed to provide flexibility in the amounts allocated to the Clinical and Translational Sciences Awards program in order to preserve flexibility for NCATS in managing its budget within the President's Budget request level.
OFFICE OF THE DIRECTOR [: *Provided further*, That $50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities]	NIH requests that this provision be removed as the President's Budget does not request continued funding for construction and renovation of extramural research facilities.

Language Provision to be Changed	Explanation/Justification
OFFICE OF THE DIRECTOR [: *Provided further*, That $5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further*, That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2019 and 2020 no later than 30 days after the date of enactment of this Act]	NIH requests these provisions be removed because the President's Budget requests funding for the HHS Office of Inspector General via direct appropriation rather than via transfer from NIH.

Budget Mechanism Table

(Dollars in Thousands)[1,2,3]	FY 2018 Final[4]		FY 2019 Enacted[5]		FY 2020 President's Budget[6]		FY 2020 +/- FY 2019	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	25,858	$13,776,726	27,492	$14,677,360	28,760	$14,536,572	1,268	-$140,788
Administrative Supplements[3]	*(2,743)*	483,035	*(2,695)*	506,430	*(1,858)*	361,166	*(-837)*	-145,264
Competing	11,461	$5,943,802	11,675	$6,311,423	7,894	$3,725,852	-3,781	-$2,585,571
Subtotal, RPGs	37,319	$20,203,562	39,167	$21,495,213	36,654	$18,623,590	-2,513	-$2,871,623
SBIR/STTR	2,035	1,001,946	2,222	1,084,179	1,911	921,133	-311	-163,046
Research Project Grants	39,354	$21,205,508	41,389	$22,579,392	38,565	$19,544,723	-2,824	-$3,034,669
Research Centers:								
Specialized/Comprehensive	1,003	$1,813,976	1,079	$1,908,419	924	$1,547,608	-155	-$360,811
Clinical Research	68	417,709	66	421,640	64	362,000	-2	-59,640
Biotechnology	91	159,963	91	160,916	80	138,518	-11	-22,398
Comparative Medicine	67	129,881	79	133,759	67	115,233	-12	-18,526
Research Centers in Minority Institutions	21	61,478	20	63,407	20	54,594	0	-8,814
Research Centers	1,250	$2,583,007	1,335	$2,688,141	1,155	$2,217,953	-180	-$470,188
Other Research:								
Research Careers	4,040	$747,017	4,161	$780,492	3,792	$708,160	-369	-$72,332
Cancer Education	76	21,182	85	24,857	81	23,614	-4	-1,243
Cooperative Clinical Research	229	409,660	278	497,025	243	411,324	-35	-85,701
Biomedical Research Support	118	85,524	112	73,696	95	62,825	-17	-10,872
Minority Biomedical Research Support	283	101,245	294	104,359	228	81,111	-66	-23,248
Other	2,064	1,081,442	2,066	1,009,259	1,805	922,686	-261	-86,572
Other Research	6,810	$2,446,070	6,996	$2,489,688	6,244	$2,209,720	-752	-$279,968
Total Research Grants	47,414	$26,234,584	49,720	$27,757,221	45,964	$23,972,395	-3,756	-$3,784,825
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,500	$161,753	3,697	$173,134	3,335	$157,779	-362	-$15,355
Institutional Awards	12,697	694,093	12,969	715,821	11,657	644,094	-1,312	-71,727
Total Research Training	16,197	$855,845	16,666	$888,955	14,992	$801,873	-1,674	-$87,082
Research & Develop. Contracts	2,212	$3,072,532	2,177	$3,132,619	1,862	$2,795,430	-315	-$337,189
(SBIR/STTR) (non-add)[3]	*(85)*	*(60,608)*	*(98)*	*(74,336)*	*(79)*	*(64,122)*	*(-19)*	*(-10,214)*
Intramural Research		$3,996,276		$4,129,550		$3,633,805		-$495,745
Res. Management & Support		1,816,210		1,898,356		1,739,376		-158,979
Res. Management & Support (SBIR Admin) (non-add)[3]		*(0)*		*(5,172)*		*(3,559)*		*(-1,613)*
Office of the Director - Appropriation[3,7]		*(1,914,345)*		*(2,112,675)*		*(1,926,144)*		*(-186,531)*
Office of the Director - Other		1,024,420		1,204,300		1,144,168		-60,132
ORIP (non-add)[3,7]		*(289,209)*		*(289,209)*		*(249,009)*		*(-40,200)*
Common Fund (non-add)[3,7]		*(600,716)*		*(619,166)*		*(532,967)*		*(-86,199)*
Buildings and Facilities[8]		146,863		218,000		214,000		-4,000
Appropriation[3]		*(128,863)*		*(200,000)*		*(200,000)*		*(0)*
Type 1 Diabetes[9]		-150,000		-150,000		-150,000		0
Program Evaluation Financing[9]		-922,871		-1,146,821		-741,000		405,821
Subtotal, Labor/HHS Budget Authority		**$36,073,860**		**$37,932,179**		**$33,410,048**		**-$4,522,131**
Interior Appropriation for Superfund Research[10]		77,349		77,349		66,581		-10,768
Total, NIH Discretionary Budget Authority		**$36,151,209**		**$38,009,528**		**$33,476,629**		**-$4,532,899**
Type 1 Diabetes		150,000		150,000		150,000		0
Total, NIH Budget Authority		**$36,301,209**		**$38,159,528**		**$33,626,629**		**-$4,532,899**
Program Evaluation Financing		922,871		1,146,821		741,000		-405,821
Total, Program Level		**$37,224,080**		**$39,306,349**		**$34,367,629**		**-$4,938,720**

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

2 Includes 21st Century Cures Act funding and excludes Ebola-related and supplemental financing.

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

4 Includes $63.3 million of 21st Century Cures, $428.9 million of Opioids, and $123.7 million of Type 1 Diabetes funding not obligated in FY 2018, and carried over into FY 2019. Numbers of grants and dollars for carryover are distributed by mechanism.

5 Reflects transfer of $5.0 million to the HHS OIG.

6 Includes the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ), distributed by mechanism.

7 Number of grants and dollars for the Common Fund and ORIP components of OD are distributed by mechanism and are noted here as non-adds. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.

8 Includes B&F appropriation and monies allocated ($18.0 million in FY 2018, $18.0 million in FY 2019, and $14.0 million in FY 2020) pursuant to appropriations acts provisions that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

9 Number of grants and dollars for mandatory Type 1 Diabetes (T1D) and NIGMS Program Evaluation financing are distributed by mechanism above; therefore, T1D and Program Evaluation financing amounts are deducted to provide subtotals for Labor/HHS Budget Authority.

10 This activity was under a Continuing Resolution at the time the budget estimates were prepared.

Authorizing Legislation

(Dollars in Thousands)	FY 2019 Amount Authorized	FY 2019 Amount Appropriated[1]	FY 2020 Amount Authorized	FY 2020 President's Budget
National Institutes of Health Activity:				
1. Biomedical Research under Section 301 and title IV of the PHS Act:				
General Authorization: Section 402A(a)(1) of the PHS Act	35,585,871	38,360,400	36,472,443	33,390,488
Pediatric Research Initiative: Section 402A(a)(2) of the PHS Act	12,600	12,600	12,600	12,600
2. Superfund Research Program: 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	Indefinite	77,349	Indefinite	66,581
3. 21st Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	186,000	186,000	149,000	149,000
BRAIN Initiative: Section 1001(b)(4)(B)	115,000	115,000	140,000	140,000
Cancer Moonshot: Section 1001(b)(4)(C)	400,000	400,000	195,000	195,000
Regenerative Medicine: Section 1001(b)(4)(D)	10,000	10,000	8,000	8,000
4. Special Diabetes Programs: Section 330B(b) of the PHS Act	150,000	150,000	150,000	150,000
5. Research on Healthcare and Quality: Titles III and Title IX and Section 947(c) of the PHS Act, as amended	SSAN	338,000	SSAN	255,960

[1]The amount appropriated in FY 2019 for the Superfund Research Program reflects the annualized CR level.

SSAN = Such sums as necessary

Appropriations History

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [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
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 [5]
FY 2016	$31,311,349,000 [6]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [7]
FY 2017	$33,136,349,000 [8]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [9]
FY 2018	$26,919,710,000 [10]	$35,184,000,000	$36,084,000,000	$37,311,349,000 [11]
FY 2019	$34,766,707,000 [12,13]	$38,564,000,000	$39,312,349,000	$39,311,349,000 [14]
FY 2020 PB	$34,367,629,000 [15,16]			

[1] Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special type 1 Diabetes Research mandatory funding included. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019 and $492,000,000 in FY 2020.

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

[3] 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.

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

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

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

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

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

[9] Includes Program Evaluation Financing of $824,443,000.

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

[11] Includes Program Evaluation Financing of $922,871,000. Excludes supplemental hurricane funding of $50,000,000 to the Office of the Director for extramural construction.

[12] Includes Program Evaluation Financing of $741,000,000.

[13] Includes funding for National Institute for Research on Safety and Quality (NIRSQ), National Institute for Occupational and Safety Health (NIOSH), and National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) associated with the proposed FY 2019 consolidation as well as Patient-Centered Outcomes Research Trust Fund (PCORTF) and Energy Employee Occupational Illness Compensation Program (EEOICPA) mandatory accounts.

[14] Includes Program Evaluation Financing of $1,146,821,000,000. Reflects Continuing Resolution level for Superfund. Does not reflect $5,000,000 transfer from NIH to the HHS Office of Inspector General.

[15] Includes Program Evaluation Financing of $741,000,000.

[16] Includes funding for NIRSQ associated with the proposed FY 2020 consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH. Figures prior to FY 2020 do not include amounts for AHRQ. For information on AHRQ Funding History, see the NIRSQ chapter of the NIH Congressional Justification.

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2018 Final [1]	FY 2019 Enacted[2]	FY 2020 President's Budget	FY 2020 +/- FY 2019
Program Level[3,4]	$37,224,080	$39,306,349	$34,367,629	-4,938,720
FTE[3,5]	17,536	18,105	18,350	245

[1] Excludes Ebola-related and supplemental financing.

[2] Amount for Superfund program for FY 2019 reflects the Annualized CR level at the time the budget estimates were prepared.

[3] Figures for FY 2020 reflect the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

[4] Includes 21st Century Cures Act funding, Mandatory Type 1 Diabetes, and Superfund in all years; includes NIGMS Program Evaluation funding of $923 million in FY 2018, $1,147 million in FY 2019, and $741 million in FY 2020.

[5] Represents NIH target FTE level, including direct funded and reimbursable funded FTE.

Authorizing Legislation: For existing NIH program, Section 301 and Title IV of the Public Health Act, as amended. For NIRSQ, Title 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.

Allocation Methods: Competitive Grants; Contract; Intramural; Other

Program Description and Accomplishments

NIH Contributions to Improvements in Human Health

Since its establishment more than 100 years ago, NIH has served as the Nation's premier biomedical research agency, supporting and conducting research that has contributed significantly to the extension of healthy lifespans and the reduction of illness and disability. Between 1970 and 2016, the life expectancy of the average American increased by eight years.[19] Further, the yearly death rate for Americans from all causes dropped by 43 percent from 1969 to 2015.[20] At age 65, Americans today can expect to live 19.4 more years, nearly 40 percent longer than in 1950.[21] We can attribute these remarkable improvements in longevity in part to NIH research advances leading to a fundamental understanding of health that has resulted in a host of new ways to prevent, treat, and cure a multitude of diseases and conditions.

Improving Health Across the Lifespan

NIH research has improved health across the lifespan, from the youngest Americans to the oldest. In 1960, 26 of every 1,000 babies born in the U.S. died before their first birthday. By 2016, that rate had fallen to under 6 per 1,000 babies[22] thanks in large part to NIH research to reduce preterm births, neonatal mortality, and other complications. NIH research on preventing and treating HIV/AIDS has resulted in a more than 90 percent decrease since the mid-1990s in the number of children perinatally infected with HIV in the U.S.[23] Because of all these improvements to treatment in the first year of life, infants that survive today will likely live longer, healthier lives than previous generations. In older children and young adults, the leading cause of death is unintentional injuries,[24] yet from 1999 to 2016, deaths from unintentional injuries for those aged 10-19 declined by 24 percent, reaching its lowest point in 2013.[25] Much of this change can be attributed to improvements in clinical care, such as treatment for burns and other traumatic injuries, derived in large part from biomedical research. NIH research advances have also turned the dial for many of the diseases and conditions that can strike throughout the lifespan, including those that cause the greatest disease burden (heart disease and cancer) so that Americans are not only living longer, but are staying healthier. As just one important example in oral health, in the 1960s, almost 50 percent of people had lost all their teeth by age 75. By 2012, that rate was down to 13 percent.[26]

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[19] Kochanek KD, Murphy SL, Xu J, Arias, E. Mortality in the United States, 2016. NCHS Data Brief, no. 293. National Vital Statistics Report. 2017 Dec;(66):1-73.
[20] 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
[21] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[22] Kochanek KD, Murphy SL, Xu J, Tejada-Vera B. Deaths: Final Data for 2014.*National Vital Statistics Reports*. 2016;65(4)
[23] Taylor AW, Nesheim SR, Zhang X et al., Estimated perinatal HIV infection among infants born in the United States, 2002-2013. JAMA Pediatrics. 2017;171(5):435-442.
[24] https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_05.pdf
[25] https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_04.pdf
[26] Dye B, Thornton-Evans G, Li X, Iafolla T.Dental caries and tooth loss in adults in the United States, 2011-2012(link is external). NCHS data brief. 2015(197):197.

Combatting Heart Disease

Though heart disease remains the leading cause of death among Americans, deaths from heart disease decreased by approximately 67 percent between 1969 and 2015, due in large part to NIH research.[27] Begun in 1948, the long-running NIH-funded Framingham Heart Study was the first to identify major cardiovascular disease risk factors, including smoking, high cholesterol, and high blood pressure.[28] By targeting these risk factors, significant progress has been made in preventing heart disease. For example, the first statins (e.g., lovastatin and simvastatin), a class of drugs that help control cholesterol levels, were approved in the late 1990s. These were followed by several second-generation statins, including Crestor in 2003, which was developed and patented by NIH-funded scientists.[29] NIH-supported clinical trials spurred the development of effective pharmacological and behavioral interventions to treat heart disease, including safe and effective surgical and catheter-based procedures to open clogged coronary arteries.[30] These successes have led to increases in U.S. life expectancy from 1970-2000 that have been estimated to add approximately $1.6 trillion per year to national wealth.[31]

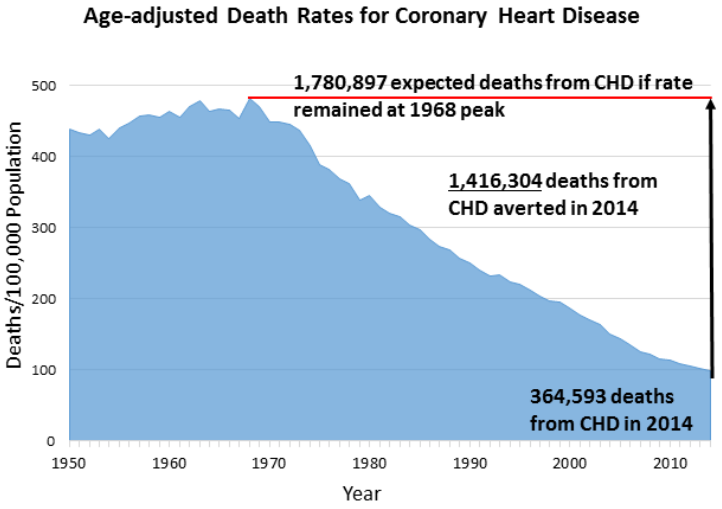

Figure 1. The age-adjusted death rates for coronary heart disease (CHD) have been dropping steadily since 1968. If they had remained at the 1968 peak levels, over one million more heart disease deaths would have occurred. Source: National Vital Statistics Reports, CDC National Center for Health Statistics.

[27] 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

[28] Mahmood SS, Levy D, Vasan RS, Wang TJ. The Framingham Heart Study and the epidemiology of cardiovascular disease: a historical perspective. *Lancet (London, England)*. 2014;383(9921):999-1008. doi:10.1016/S0140-6736(13)61752-3.

[29] Several patents related to Crestor have been granted (6858618; 6316460; 7030152; 7964614; RE37314). Those patents cite NIH support from the following grants: R01CA034944; R01CA040360; R01CA042182; R01HL026490; R01HL034595; R01HL046696.

[30] Ford ES, Ajani U a, Croft JB, et al. Explaining the decrease in U.S. deaths from coronary disease, 1980-2000. *N Engl J Med*. 2007;356(23):2388-2398. doi:10.1097/sa.0b013e31815c1098.

[31] Murphy KM, Topel RH. The Value of Health and Longevity. *J Polit Econ*. 2006;114(5):871-904. doi:10.1086/508033.

Working to Cure Cancer

Thanks to remarkable scientific progress, we can now envision a future in which cancer is curable, or at least a chronic, manageable condition. The death rate for all cancers combined has been declining since the early 1990s for adults, and since the 1970s for children.[32] Overall cancer death rates have dropped by nearly 26 percent in total from 1991-2015 thanks to improvements in cancer treatment, detection, and prevention.[33] Today we can apply a deep understanding of the basic mechanisms by which cancer works towards developing new and highly innovative treatments. Vaccines for human papilloma virus (HPV), made possible by understanding mechanisms of both cancer and immunity, provide nearly 100 percent protection against HPV types 16 and 18, which account for about 70 percent of cervical cancers and an even higher percentage of some other types of HPV-caused cancers.[34] In another example, because scientists were able to isolate the underlying genetic cause of a rare cancer known as chronic myelogenous leukemia (CML), NIH researchers and others developed Gleevec®, approved in 2001. With the availability of this treatment, the 10-year survival rate of CML patients has gone from 30 percent to 83 percent.[35] Gleevec's® effectiveness has paved the way for a new industry of cancer drugs that precisely target similar mechanisms in other cancers, such that by mid-2018, at least 43 new cancer drugs similar to Gleevec® have been approved by the FDA.[36] Cancer immunotherapy, in which a patient's own immune system is harnessed to attack cancer cells, promises to revolutionize cancer treatment. The immunotherapy drug Keytruda was first approved for the treatment of melanoma in 2014 and has now been approved to treat Hodgkin's Lymphoma, non-small cell lung cancer, and squamous cell carcinoma of the head and neck.[37]

Eliminating the Pandemic Threat of HIV/AIDS

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 and there were dire predictions of a potential pandemic that would significantly reduce the world's population. Now, thanks to an unprecedented effort made by NIH and others, there are powerful treatments that can suppress the virus to undetectable levels. Death rates dropped more than 80 percent between 1990 and 2015,[38] and in the United States, a 20-year-old with HIV who is receiving treatment can expect to live into their 70s.[39] The most significant gains have been made with the development of antiretroviral therapy, which can

[32] Jemal A, Ward EM, Johnson CJ, et al. Annual report to the nation on the status of cancer, 1975-2014, featuring survival. JNCI. September 2017. https://doi.org/10.1093/jnci/djx030
[33] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2018. *CA Cancer J Clin*. January 2018;68(1):7-30.
[34] Gillison ML, Chaturvedi AK, Lowy DR. HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women. Cancer. 2008 Nov 15;113(10 Suppl):3036-46. PMID: 18980286
[35] Hochhaus A, Larson RA, Guilhot F, et al. Long-term outcomes of imatinib treatment for chronic myeloid leukemia. N Engl J Med 2017; 376:917-27.
[36] http://www.brimr.org/PKI/PKIs.htm
[37] https://directorsblog.nih.gov/2017/08/30/fda-approves-first-car-t-cell-therapy-for-pediatric-acute-lymphoblastic-leukemia/
[38] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[39] Samji H, et al. *PLoS One* 2013; Dec 18;8(12):e81355 PMID: 24367482
http://www.ncbi.nlm.nih.gov/pubmed/24367482

now effectively suppress the virus to undetectable levels.[40] With further research, it is possible to imagine a world in which the threat of AIDS has been eliminated altogether. Not only has NIH's investment in AIDS resulted in the real potential of an AIDS-free world, but the intensity of the research led to an in-depth understanding of viral biology and the workings of the human immune system that has been applied more broadly. For example, new understanding of how viruses may disrupt immune function has revealed mechanisms underlying certain cancers, autoimmune conditions, and other infectious diseases such as Ebola, Zika, and influenza. Research on HIV pathogenesis also uncovered information about the role of immune activation and inflammation in human disease; for example, increased incidence of heart disease among HIV patients has led to increased understanding of heart disease absent HIV infection as well.[41] Studying the basic immunology of HIV, a lentivirus, led to development of FDA-approved lentiviral gene therapy technology to treat certain cancers such as acute lymphoblastic leukemia. Furthermore, the effort to create a vaccine against HIV has contributed to the creation of other effective vaccines such as one against respiratory syncytial virus, and the knowledge gained in drug development for antivirals has been applied to the development of other medications, including a highly effective treatment for hepatitis C.[42] These are just a few of the advances in diverse fields that resulted from supporting HIV/AIDS research, and ongoing and future investment in HIV research promises to yield similar wide-ranging benefits.

Focusing on Rare Diseases

Not only has NIH research made great strides in alleviating those diseases and conditions that cause the greatest burden, but it has also made significant contributions to understanding and treating rare diseases, offering hope to those patients for whom little or no treatment options are available. Prior to 1995, there were no FDA approved treatments for Gaucher's Disease, a rare genetic disease in which harmful quantities of a fatty substance accumulate throughout the body and brain. The first treatment, approved in 1995 and pioneered by NIH intramural investigators,[43] has now been followed by a newer, orally administered treatment approved in 2014 and based on research performed and patented by NIH-funded researchers.[44] Another rare disorder, lipodystrophy, benefitted from NIH intramural research investment as well. In 2014, the FDA approved a treatment for this disorder in which the body is unable to produce and maintain healthy fat tissues.[45] NIH research also led to breakthrough development of a new class of drugs to treat a family of rare autoinflammatory diseases, each with its own devastating consequences, leading to life-saving and health-preserving treatments.[46] In other research on rare diseases, NIH-supported scientists identified specific disease-related genes which can be

[40] Schwetz TA, Fauci AS. The Extended Impact of Human Immunodeficiency Virus/AIDS Research. J Infect Dis. jiy441, 28 Aug 2018. https://doi.org/10.1093/infdis/jiy441
[41] Schwetz TA, Fauci AS. The Extended Impact of Human Immunodeficiency Virus/AIDS Research. J Infect Dis. jiy441, 28 Aug 2018. https://doi.org/10.1093/infdis/jiy441
[42] Wyles DL. Antiviral resistance and the future landscape of hepatitis C virus infection therapy. J Infect Dis 2013; 207(Suppl 1):S33–9.
[43] https://irp.nih.gov/accomplishments/therapy-for-inherited-enzyme-deficiencies
[44] The FDA approval indicates 3 patents, 1 of which has NIH Funding: 6916802, funded by NIH grants P30CA046592, P50DK039255, and R01DK041487
[45] https://irp.nih.gov/accomplishments/from-hormone-to-pharmaceutical-lipodystrophy
[46] http://directorsblog.nih.gov/2013/04/09/meet-alex-before-and-after-nih-clinical-trial/

targeted with cutting-edge genetic therapies for a rare form of inherited vision loss,[47] other retinal diseases[48] and in 2018, a rare, inherited form of rickets.[49]

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.

Differences in Opioid Drug Receptor Activation

Opioid pain relievers, such as morphine and oxycodone, are generally safe when used for a brief time and as prescribed by a doctor. But some people misuse opioid drugs for their euphoric effects. When misused, these drugs can lead to addiction, overdose, and death. Scientists have previously assumed that all opioids – whether produced by the body (endogenously) or taken as a drug – interact in the same way with opioid receptors. In order to test this assumption, NIH-supported researchers designed a tiny sensor, called a nanobody, which would generate a fluorescent signal when an opioid receptor was activated. Their research found that opioid drugs and the brain's natural opioids differ in how they activate receptors in nerve cells. The different and more rapid ways that opioid drugs, as opposed to endogenous opioids, interact with these receptors may help in explaining their undesired side effects. These findings could have the potential of helping guide the design of pain relievers that would be effective without the negative side effects.

Mouse Immune System Destroys Tumors

All malignant tumors harbor genetic alterations. Some of these alterations lead to the production of modified proteins, known as antigens, which can trigger an immune response. Since tumors are often infiltrated by immune cells that can recognize these antigens, there has been tremendous interest in the burgeoning field of cancer immunotherapy. NIH-supported researchers have taken an approach to stimulating immune cells in the tumor to mount a vigorous response to the cancer cell antigens around them – essentially a cancer vaccination. In studies using mouse models, researchers found a combination of agents that, when injected into a tumor, directs the immune system to destroy not only the injected tumor, but tumors of the same type throughout the body. The results of this experiment also show that the tumor vaccination approach is not dependent on knowing the unique characteristics of the tumor, making it potentially applicable to many different forms of cancer. A clinical trial is now being launched using this vaccination approach in combination with low dose local radiation for individuals with lymphoma.

[47] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm
[48] https://www.nih.gov/news-events/news-releases/nih-funded-study-points-way-forward-retinal-disease-gene-therapy
[49] https://www.niams.nih.gov/newsletters/niams-update/2018/niams-update-june-7-2018

Ultrasound Bacterial Monitoring

Improved understanding of the beneficial roles played by bacteria in the human body has motivated research into the use of microbes for therapeutic applications; for example, probiotics to treat irritable bowel syndrome and bacteria as tumor-targeting drug carriers. Until recently, image-based methods for tracking therapeutically administered bacteria were limited, since light-based detection methods are not effective at penetrating through human tissue. NIH-supported researchers recently developed an ultrasound-based method of imaging bacteria through tissue. The researchers genetically engineered bacterial production of gas-filled internal structures that scatter ultrasound waves in a way that can be detected. This new technique gives researchers the ability to detect bacteria using non-invasive ultrasound, providing a promising potential means of tracking microbes used in therapeutic applications.

New 'Liquid Biopsy' Shows Early Promise in Detecting Cancer

Early detection of cancer increases the chances for more effective treatment. However, many tumors are not caught until they have grown relatively large and spread to other parts of the body. Researchers are developing new and more effective early screening methods. One innovative approach is a "liquid biopsy." A liquid biopsy detects cancer by screening for specific molecules that tumors release into the bloodstream. CancerSEEK, a universal liquid biopsy test funded by NIH, is an advanced biopsy test that analyzes blood samples to detect a significant proportion of eight common cancers. The test detected cancer with 70 percent accuracy and gave very few false positive results. Another advantage of this test compared to other biopsy tests is the machine learning approach that researchers employed to determine the location of a cancer. Researchers were able to trace the tissue of origin to one of two organs in 83 percent of the patients with a positive test result. The next step is to enroll 10,000 participants in a trial to test how well CancerSEEK works in detecting cancer among people with no history of the disease. More data will also be needed to answer questions about whether people with inflammatory or other health conditions that cause detectable tissue damage might also test positive.

Flexible Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is a non-invasive technology that produces three dimensional detailed anatomical images. Soft tissues, such as the brain, spinal cord, muscles, ligaments, and tendons, can be seen much more clearly with MRI than with x-rays. A limitation with modern MRI sensors is that the current model uses low impedance coils that allow current to flow more easily. However, these coils must be precisely arranged to avoid interfering with each other thus corrupting the image. This has resulted in detector designs with limited flexibility that must either sacrifice image sensitivity or restrict a person's movements during the MRI scan. An NIH-supported research project investigated whether high impedance coils could be used to design an MRI that is more versatile, reasoning that the high impedance coils could lower interference and allow imaging while people are moving. As part of the study, high impedance coils were stitched into each finger of a flexible glove so that the fingers could move freely during scans of volunteers playing a piano or grabbing a piece of fruit. The scans with the high impedance coils improved the image sensitivity by more than 80 percent in fingers

compared with the rigid, low impedance coils. The results show promise in using MRI scans to look at moving joints and may help lead to the diagnosis of complex tissue injuries.

Wearable mHealth Device Detects Abnormal Heart Rhythms Earlier

As many as 6 million Americans experience an irregular heartbeat, called atrial fibrillation (AFib), which increases their risk of heart failure and stroke if not detected and treated at an early stage. To detect AFib and start treatment early, NIH supported the mHealth screening to Prevent Strokes (mSToPS) Trial. Notably, the entire study was conducted remotely – the participants and researchers never met face to face. The trial tested a wearable health technology: an FDA-approved wireless electrocardiogram (EKG) patch, called Zio patch, which can monitor a person's heart rate at home. In the mSToPS trial, researchers recruited participants from around the United States who were at increased risk of AFib. More than 2,600 people signed up and were randomly assigned to one of two groups. The first group received a Zio patch by mail within two weeks of enrollment with instructions about how to apply and wear it at home. The second group received a Zio patch in the mail four months later with the same instructions. Researchers diagnosed AFib in 3.9 percent of the participants assigned to the group that received patches within two weeks of enrollment, compared to only 0.9 percent in the group that waited four months before wearing the patch. The researchers also conducted a year-long observational study that followed more than 1,700 participants who underwent EKG monitoring at home in the mSToPS trial and over 3,400 unmonitored matched controls. At the end of the year, about 6 percent who used the Zio patch at home were diagnosed with AFib compared to about 2 percent of controls who didn't use the patch. In most cases, an AFib diagnosis led to early treatment. However, the long-term benefits of the Zio patch in reducing the incidence of strokes, ER visits, and hospitalizations remains unknown. The researchers have recently begun a three-year follow-up study to get those answers.

Advances in Tissue Chips Expand to Recreating Spinal Cord

Tissue chips are designed as accurate models of the structure and function of human organs, and NIH has invested in developing these chips to test therapeutics more quickly and effectively than current methods. Unlike traditional petri dish systems, tissue chips often provide the fluidity and depth necessary to grow both neurons and blood vessels in more life-like environments. An NIH-supported study used organ chips to grow spinal cord sections out of human skin cells. The idea came from a previous study where researchers used stem cells from a participant's skin to recreate interactions between blood vessels and neurons that generally occur when the human fetal spinal cord is forming. For the current study, researchers were able to convert stem cells into a type of cell that lines the walls of brain blood vessels. As the experiment progressed, researchers found that the neurons were firing more often and that the cells were showing similar activity to those found in fetal spinal cord cells. Although more research and analysis is needed, researchers agree that this is a promising start towards developing chips that could potentially mimic the human nervous system.

Molecular Basis for Mental Disorders

NIH-supported researchers are attempting to understand, at the molecular level, the cause of five mental disorders—autism spectrum disorders, schizophrenia, bipolar disorder, depression, and alcoholism—to further explore past evidence showing that these disorders share genetic risk factors. When researchers examined the active genes in the cerebral cortex of deceased patients with the above-mentioned mental health disorders, the researchers found thousands of genes whose activities were either elevated or suppressed. They also found significant overlapping mechanisms between autism spectrum disorder, schizophrenia, and bipolar disorder; and between schizophrenia, bipolar disorder, and depression. Further analysis also supported the idea that there is a substantial genetic component to these mental health disorders. While more research is needed, these findings help provide a framework for understanding the processes that affect the risk for developing mental disorders.

Hope for Infants with Rare Disease Spinal Muscular Atrophy

Spinal muscular atrophy (SMA) is a hereditary neurodegenerative disease that can affect movement, breathing, and swallowing. Individuals with SMA suffer from a specific mutation that is vital for motor function. Although cells have safeguards in place to counteract mutations, these safeguards may not be enough to overcome cell dysfunction. Researchers found that the drug Spinraza is able to overcome the mutation by bypassing certain gene production and increasing essential protein production. Two companies decided to use this innovative approach and launched a clinical study using Spinraza in children with a less severe form of SMA. The trial was successful and led to two subsequent studies in infants suffering from severe SMA. Both studies proved to be successful, with one study dramatically improving the infants' abilities to breathe and eat unassisted, something they could not regularly do on their own. The other study showed that the treatment was safe and effective, with most of the infants gaining control of their heads. Due to these astonishing results, the FDA designated SMA gene therapy as a breakthrough therapy and it has been licensed to a drug company for further development. More infants are being recruited to take part in Phase 3 clinical trials, giving hope to families that new treatments are within reach.

Early Identification of Gestational Diabetes Risk

Gestational diabetes[50] (GD) occurs only in pregnancy and results when the level of blood sugar, or glucose, rises too high. GD increases the mother's chances for high blood pressure disorders of pregnancy and the need for cesarean delivery, as well as the risk for cardiovascular disease and type 2 diabetes later in life. Screening for GD typically occurs between 24 and 28 weeks of pregnancy unless there is a known risk factor, such as obesity. Identifying women at risk for GD earlier in pregnancy could allow for lifestyle changes that may be more effective at reducing their risk. Researchers from NIH evaluated whether the HbA1c test (also called the A1C test[51]), a blood test commonly used to diagnose type 2 diabetes, could identify signs of GD in the first trimester of pregnancy. The HbA1c test indicates the average blood glucose levels over the previous 3 months based on the amount of glucose that has accumulated on the surface of red

[50] https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/gestational/definition-facts
[51] https://www.niddk.nih.gov/health-information/diabetes/overview/tests-diagnosis/a1c-test

blood cells. Using records from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Fetal Growth Study, researchers compared the HbA1c of women who went on to develop GD and those that did not. Women who went on to develop GD had higher HbA1c levels compared to those without GD (an average of 5.3 percent compared to 5.1 percent, respectively). Each 0.1 percent increase in HbA1c above 5.1 percent in early pregnancy was associated with a 22-percent higher risk for GD. The results suggest that the HbA1C test potentially could help identify women at risk for gestational diabetes early in pregnancy.

Role of Stress Gene in Chronic Pain

People respond to pain differently; for most people, acute pain will fade away as an injury heals, but for others, the pain persists beyond the initial healing and becomes chronic. Previous research has shown a connection between chronic pain and blood levels of a particular microRNA. MicroRNAs attach to messenger RNA (mRNA) and block translation of the mRNA into a particular protein. Looking for other clues to explain why some people are more susceptible to chronic pain, researchers recently discovered subtle differences in a gene that controls how the body responds to stress. The stress controlling gene, called *FKBP5*, has at least six different variants. According to recent studies, people who carry one variant of this gene are more likely to develop chronic pain after a trauma. Connecting these results to the earlier finding about microRNA, researchers suggest that the pain-associated *FKBP5* variant does not fold up properly for the microRNA to properly attach, allowing more *FKBP5* proteins to be produced from the *FKBP5* mRNA. Consequently, high levels of *FKBP5* protein leads to release of higher levels of the stress hormone cortisol. Cortisol sensitizes the peripheral nerves, signaling pain. Thus, high levels of cortisol could signal pain even in the absence of nerve damage and lead to chronic pain. More research is needed, but these results could point to a new non-addictive strategy for preventing and controlling chronic pain.

Gene Editing to Treat Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a genetic disease in which the muscles, including skeletal, heart, and diaphragm muscles, weaken to a point where they are not functional. It is ultimately fatal. DMD is caused by errors in the production of dystrophin proteins, which are vital to muscle health. Because it is a genetic disease, gene therapy presents a possible treatment option for DMD. However, a challenge in developing gene therapy for DMD is that the dystrophin gene is especially long and there are thousands of possible mutations that can result in DMD. Researchers funded by NIH endeavored to learn whether the clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (CRISPR/cas9) gene editing system, which uses specific guide RNA to perform precise excision of DNA code in the genome, could excise mutational hot spots in the dystrophin gene, resulting in a shorter but still functional protein. The researchers were able to inject the CRISPR/cas9 cassette using a viral carrier into very young dogs and within 6 weeks the puppies were producing the new dystrophin proteins. The researchers performed a second trial by injecting the cassette intravenously into two young dogs with DMD. In eight weeks, the muscles were producing dystrophins at 3 to 90 percent of normal levels, including production in the heart and diaphragm. Importantly, the dogs did not appear to have an immune response to Cas9, nor was there evidence that the enzyme had cut the DNA in other places, which potentially could cause

other health problems. More studies are needed using larger sample sizes and long-term follow up, but this approach could eventually be tried in children and young adults with DMD.

Funding History

Fiscal Year	Amount[1, 2]
2016	$32,311,349,000
2017 [3]	$34,229,139,000
2018	$37,311,349,000
2019	$39,311,349,000
2020 Budget Request [4]	$34,367,629,000

[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, and NIGMS Program Evaluation financing of $780,000,000 in FY 2016, $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, and $741,000,000 in the FY 2020 Request. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019, and $492,000,000 in FY 2020.

[2] Excludes Ebola-related, Zika-related, and other supplemental appropriations and transfers.

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

[4] Includes the consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ) in the amount of $255,960,000. Figures prior to FY 2020 do not include amounts for AHRQ. For information on AHRQ funding history, see the NIRSQ chapter of the NIH Congressional Justification.

Summary of Request Narrative

The FY 2020 President's Budget request would provide a program level of $34.4 billion to NIH, which is $4.9 billion less than the $39.3 billion received in FY 2019.

The following summary references program level funding, which is the sum of discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriations ($33.4 billion in FY 2020); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research program ($66.6 million in FY 2020); mandatory budget authority provided for Type 1 Diabetes research ($150.0 million in FY 2020); and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act ($741.0 million in FY 2020).

The request includes the consolidation into NIH of Agency for Healthcare Research and Quality (AHRQ) activities as the National Institute for Research on Safety and Quality (NIRSQ). The NIH FY 2020 discretionary budget authority total and the NIH FY 2020 program level include $256.0 million for NIRSQ.

The primary budget mechanisms discussed below include allocations by mechanism of Program Evaluation Financing and Type 1 Diabetes funds. In addition, the mechanism detail for FY 2020 reflects the allocation of discretionary budget authority for NIRSQ.

In FY 2020, NIH will continue providing upfront funding for certain projects, as appropriate, to facilitate efficient management of resources across multiple years. In general, NIH discretionary research project grants are awarded for more than one year and funded incrementally; each year's commitment is obligated from that year's appropriation. Grants are classified as Competing in the first year of award or renewal, and Non-competing in the remaining years of each award. Certain categories of NIH grants are awarded for multiple years with the full funding provided up front. This includes the NIH Director's New Innovator Award (DP2) and the NIH Research Enhancement Award (R15). The latter consists of two programs, the Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions, and the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. In addition, full funding can be provided up front for other NIH grants and cooperative agreements as necessary in special circumstances. This approach requires additional oversight and is used judiciously for select programs and awards. Situations that may require such an approach include appropriations for a new program received late in the fiscal year, rapid increases in funding, or variable outyear funding streams (e.g., under the 21st Century Cures Act). Up-front funding has increased over the last few years (from 2 percent of total research grant dollars to 4 percent in FY 2018), due to the large Congressional increases for Alzheimer's disease research. The use of this approach for Alzheimer's disease research is expected to gradually decrease over time. There is also a one-time increase in up-front funding in FY 2019 due to the HEAL Initiative, because it changed from two-year to one-year money; as a result, more than a year's worth of HEAL appropriations needs to be obligated in FY 2019.

Research Project Grants (RPGs)
The FY 2020 President's Budget would provide $18.6 billion for RPGs, which is $2.9 billion less than the FY 2019 estimate. This amount would fund 7,894 Competing RPGs, or 3,781 less than for the FY 2019 estimate. It would also support 28,760 Noncompeting RPGs, 1,268 more than the FY 2019 estimate. In addition, the projected average cost for Competing RPGs of approximately $472,000 would be 12.7% below the FY 2019 projected average cost of nearly $540,600.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2020 President's Budget would provide $921.1 million for SBIR/STTR program grants, which is $163.0 million below the FY 2019 estimate. The minimum set-aside requirement of 3.65% is achieved in FY 2020.

Research Centers
The FY 2020 President's Budget would provide $2,218.0 million for Research Centers, which is $470.2 million less than the FY 2019 estimate. This amount would fund 1,155 grants, 180 less than the FY 2019 level.

Other Research
The FY 2020 President's Budget would provide $2,209.7 million for this mechanism, which is $280.0 million less than the FY 2019 estimate. This amount would fund 6,244 grants, which is 752 less than the number of awards projected for FY 2019.

Training
The FY 2020 President's Budget would provide $801.9 million for training, which is $87.1 million below the FY 2019 estimate. This amount would fund 14,992 Full-Time Trainee Positions (FTTPs), which is 1,674 fewer than planned for FY 2019.

Research & Development (R&D) Contracts
The FY 2020 President's Budget would provide $2,795.4 million for R&D contracts, which is $337.2 million less than the FY 2019 estimate. The requested amount would fund an estimated 1,862 contracts, or 315 fewer than the FY 2019 level.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR).** The FY 2020 President's Budget includes a $64.1 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts. The minimum set-aside requirement of 3.65% in FY 2020 is attained through a combination of contracts and grant awards.

Intramural Research (IR)
The FY 2020 President's Budget would provide $3,633.8 million for IR, which is $495.7 million less than the FY 2019 level.

Research Management and Support (RMS)
The FY 2020 President's Budget would provide $1,739.4 million for RMS, which is $159.0 million less the FY 2019 level.

Office of the Director (OD)
The FY 2020 President's Budget would provide $1,926.1 million for OD, which is $191.5 million less than the FY 2019 level.

- **Common Fund (CF)**
  Funding of $533.0 million is allocated for CF-supported programs. This amount is $86.2 million below the FY 2019 level.

- **Office of Research Infrastructure Programs (ORIP)**
  Funding of $249.0 million is allocated for ORIP. This amount is $40.2 million below the FY 2019 level.

- **Other**
  The $1,144.2 million allocated for OD elements other than the Common Fund or the Office of Research Infrastructure Programs is a net decrease of $65.1 million from the FY 2019 level. This is due, in part, to a decrease in the portion of funding authorized by the 21st Century Cures Act that is managed by OD, from $196.0 million to $157.0 million. The 21st Century Cures Act resources for FY 2020 include $149.0 million for the *All of Us* Research Program and $8.0 million for Regenerative Medicine research.

Buildings & Facilities (B&F)
The FY 2020 President's Budget provides $214.0 million for infrastructure sustainment projects associated with the B&F program, which is $4.0 million less than the FY 2019 level. This amount includes $14.0 million for facility repair and improvement activities at the National Cancer Institute's Frederick, Maryland, facility.

Superfund Research Program
The FY 2020 President's Budget would provide $66.6 million, which is $10.8 million less than the FY 2019 Annualized CR level.

Program Evaluation Financing
The FY 2020 President's Budget would provide $741.0 million for Program Evaluation Financing purposes, which is $405.8 million less than the FY 2019 level.

Outputs and Outcomes

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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)	FY 2018: As of May 1, 2018, New York, Massachusetts, and Idaho joined the SEER Program as core registries. Target: Expand the SEER Program through inclusion of 1-3 additional core registries to better represent the changing US population. (Target Met)	Expand SEER to include links with 1-2 outside sources such as biospecimen acquisition, genomics and molecular profile data.	Provide trends and rates specific to the clinically relevant cancer subtypes represented by molecular characterization of each tumor.	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)	FY 2018: Recruitment ended after 20 months, with 5,451 patients enrolled in the STRIDE study. Follow-up is ongoing. Target: Complete follow-up of participants enrolled in the trial testing the effectiveness of the evidence-based, patient-centered multicomponent fall injury prevention strategy. (Target Met)	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.	Complete analyses of secondary outcome data. These outcomes include patient concerns about falling, all falls, all fall-related injuries, physical function, disability, anxiety and depression.	N/A
SRO-2.1 By 2023, develop, optimize, and evaluate the effectiveness of nano-enabled immunotherapy (nano-immunotherapy) for one cancer type. (Output)	FY 2018: Researchers developed and/or optimized, in animal models, 3 unique nanodelivery systems for effective anti-cancer immunotherapeutics. Target: Optimize properties of 3 nanoformulations for effective delivery and antigen-specific response in immune cells. (Target Met)	Further optimize top 2 candidate nanoformulations for co-delivery of multiple antigens to enhance anti-tumor response in one animal model.	Further optimize the top candidate nanoformulation for co-delivery of antigens, adjuvants and immuno-modulators and evaluate its efficacy and long-lasting immunity (over 3 months) in preclinical models with established tumors.	N/A
SRO-2.2 By 2018, assess the efficacy of	FY 2018: Patient recruitment, enrollment, and follow-up are	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
one to two anti-inflammatory therapy for cardiovascular disease (CVD) in HIV-infected individuals. (Output)	completed. Primary results paper is under review but has not yet been published. Target: Complete study and publish manuscript. (Target Not Met but Improved)			
SRO-2.3 By 2019, evaluate the impact of a community-level combination prevention package (which includes universal HIV testing and intensified provision of HIV antiretroviral therapy and care) on population-level HIV incidence in the developing world. (Outcome)	FY 2018: All follow-up visits were successfully completed, and primary analysis is in progress. Target: Finish conducting follow-up visits and begin data analysis. (Target Met)	Complete data analyses to evaluate the impact of a community-level combination prevention package on population-level HIV incidence.	N/A	N/A
SRO-2.4 By 2020, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding one new treatment option per year. (Outcome)	FY 2018: Scientist has initiated the testing of a new potential treatment option for aphasia (loss of the ability to understand or express speech) caused by damage or injury to the parts of the brain that control language. Patient enrollment has begun. Target: Initiate testing one new potential treatment option for a speech and language disorder. (Target Met)	Initiate testing one new potential treatment option for a hearing disorder.	Initiate testing one new potential treatment option for a taste disorder.	N/A
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	FY 2018: All five teams in the Audacious Goals Imaging Consortium have developed components of their novel imaging tools and shown proof-of-principle in animal models. Four teams have tested their tools in human volunteers. Target: Develop prototypes for four imaging technologies based	Integrate measurements of cell function with anatomical imaging.	Translate two novel imaging technologies from animal studies into human participants.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	on adaptive optics in animal models. (Target Met)			
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone modifications, and chromatin remodeling to better determine if these changes can be inherited. (Output)	FY 2018: Due to unanticipated technical difficulties, the planned activities are still in progress. Target: 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. (Target Not Met)	Determine and identify, if present, sex differences in three environmentally induced epigenomic signatures in three different mouse tissues.	Determine and identify, if present, sex differences in four additional 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)	FY 2018 IND application submission has been delayed to January 2019, but clinical trial recruitment targets are expected to be met on time. Target: Submit IND application with the FDA to launch phase I clinical trial upon approval. (Target Not Met but Improved)	Recruit 3 AMD patients into Phase I clinical trial.	Recruit 9 more AMD patients.	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)	FY 2018: 20 new drug discovery projects were initiated, 12 of which are seeking to discover new therapeutic agents against 6 novel therapeutic targets. Target: Initiate drug discovery efforts aimed at developing novel candidate therapeutics for AD or AD related dementias against up to 3 novel therapeutic targets. (Target Met)	For each of the novel therapeutic targets, select 3-5 candidate therapeutic agents for entry into preclinical optimization studies.	Complete preclinical proof of concept in animal models of AD for 3-5 new candidate therapeutics.	N/A
SRO-2.9 By 2022, evaluate the safety	FY 2018: Analysis of primary results has been conducted and	Strategy 3: Complete final analysis of an	Strategy 1: Complete follow-up of	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	results are in press. Target: Strategy 2: Analyze primary results of a Phase 2a study examining the long-acting injectable, cabotegravir, for the prevention of HIV. (Target Met)	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.	participants in studies testing the safety, tolerability, and effectiveness of VRC01.	
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)	FY 2018: Two Resource Centers were funded and are operational. 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. (Target Exceeded)	Submit an Investigational New Drug (IND) application for an FDA-approved tissue regeneration combination product.	Initiate a Phase I clinical trial based on tissue engineering and regenerative medicine for a dental, oral, or craniofacial disease or disorder.	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)	FY 2018: Projects funded through the BRAIN Initiative led to novel innovations in four neurotechnologies to enable basic studies of neural activity at the cellular level. Target: Develop four novel neurotechnologies for stimulating/recording in the brain to enable basic studies of neural activity at the cellular level. (Target Met)	Test new and/or existing brain stimulation devices for 2 new therapeutic indications in humans through the BRAIN Public Private Partnership.	Provide broad access to new research approaches and techniques for acquiring fundamental insight about how the nervous system functions in health and disease.	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	FY 2018: 12 preclinical projects developing new treatments for neurological disorders are in lead optimization phases. Target: 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.	Initiate animal toxicology studies for 1-2 therapeutic or device candidates.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
toward the point of preparedness for first-in-human studies. (Output)	(Target Exceeded)			
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2018: Research demonstrated that accelerated gray matter volume declines are associated with alcohol use during adolescence. Target: Initiate or continue 1-3 preclinical or clinical studies to explore how alcohol or other substance use impacts adolescent brain development. (Target Met)	Continue to evaluate the impact of adolescent alcohol or other substance use on brain development.	Examine how individual differences in neurobiology contribute to adolescent substance taking behavior and related health outcomes.	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: Four research studies have assessed technologies that image the placenta in real-time during pregnancy, obtaining data on placental blood flow, oxygen levels, and/or metabolism. 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. (Target Exceeded)	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.	Identify 2 biomarkers that are associated with placental development and/or function.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2018: Researchers have enrolled patients with treatment-resistant juvenile dermatomyositis (JDM) and initiated treatment with a Janus Kinase (JAK) inhibitor. Target: 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. (Target Met)	Continue an interventional clinical study of a molecularly targeted therapy for 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

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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 2018: The BrIDGs program acquired GMP-compliant drug material for one project. Target: Acquire GMP-compliant drug material for 1-3 projects. (Target Met)	Initiate formal GLP toxicology studies for 1-3 projects.	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.	N/A
SRO-4.3 By 2020, advance our characterization and understanding of the cellular and genetic components that make up the diverse composition of most tumors. (Outcome)	FY 2018: The Cancer Systems Biology Consortium has investigated both molecular and cellular complexity of 4 cancer types. Target: Identify the cellular/genetic components of 3 common cancer types. (Target Met)	Identify the role various cellular components play in the phenotype of the 3 cancers.	Based on new understanding of tumor composition, develop 3 computational models to explore new knowledge and treatments.	N/A
SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)	FY 2018: The molecular bases of 29 rare diseases were discovered. Target: Discover the molecular bases of an additional 10 rare diseases (Target Exceeded)	Discover the molecular bases of an additional 10 rare diseases	N/A	N/A
SRO-4.8 By 2019, establish a sharable collection of positive Zika virus (ZIKV) biospecimens to increase knowledge of viral infection and associated host immune response to help evaluate potential strategies to ensure the safety of the blood supply. (Output)	FY 2018: A sharable biorepository, containing biospecimens from ZIKV-infected blood donors who participated in the 2016-2018 US natural history study, was successfully established. Target: 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.	Complete the establishment of a shareable repository of Zika biospecimens, analyze data from a US Zika database, establish utility of blood screening for Zika virus, and assess Zika transfusion-transmission risks in animal models.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2018: A Phase 3 clinical trial to test a non-opioid medication for managing symptoms of opioid withdrawal was completed. Target: Initiate at least one study to improve identification of OUD or evaluate the comparative effectiveness of available pharmacotherapies for OUD treatment. (Target Met)	Conduct 1 pre-clinical study and 1 clinical trial to develop non-opioid based medications to treat OUD that may avoid the risks of opioid dependence and overdose.	Conduct 1 pre-clinical and 1 clinical study of a longer acting formulation of a medication for the treatment of opioid use disorders or opioid 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: Multiple pre-submission interactions with the FDA were completed. Target: Initiate in-person interactions with the FDA to address potential safety and effectiveness concerns of the novel dental materials. (Target Met)	Implement regulatory feedback received by the FDA to demonstrate safety and effectiveness.	One patent application of a novel resin will be completed, reflecting the priorities identified by the FDA.	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: 10 receptors have been isolated and identified from human pancreatic islet-infiltrating lymphocytes and tested for their ability to alter islet function in various types of animal model systems. Target: Isolate and identify 10 receptors used by human autoimmune cells that invade and destroy the human pancreas in T1D. (Target Met)	Develop a system for rapid and high-fidelity insertion of 2 T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line.	Use in vivo model(s) carrying iPSC-derived human beta cells to test the efficacy of 2 approaches aimed at enhancing beta cell viability and/or expansion.	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic	FY 2018: The extent and durability of improvements in diabetes and its comorbid conditions in response to two	By 2019, evaluate the impact of bariatric surgery for severe obesity during	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
outcomes in response to treatment of adolescents with severe obesity. (Outcome)	treatment modalities (surgical and medical) in adolescents with severe obesity and type 2 diabetes were assessed. 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. (Target Met)	adolescence on weight-related and psychosocial and behavioral outcomes.		
SRO-4.13 By 2018, complete analysis from the oral insulin trial for the prevention of type 1 diabetes in relatives at risk for the disease. (Outcome)	FY 2020: Data analysis from the oral insulin trial was completed in FY 2018. Target: Complete data analysis from the oral insulin trial. (Target Met)	N/A	N/A	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). (Outcome)	FY 2018: Five health risk strategies to reduce modifiable health risks associated with premature mortality in adults with SMI were identified. Target: Identify 3 health risk reduction strategies to reduce modifiable health risks associated with premature mortality in adults with SMI. (Target Exceeded)	Conduct testing of 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	Conduct testing of an additional 3 health risk reduction models that have potential to reduce premature mortality in adults with SMI.	N/A
SRO 4.15 By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations. (Output)	(Will begin reporting in December 2019)	Test a screening and brief alcohol intervention in an underage population.	Test a behavioral therapy for intervening with alcohol misuse in an underage population.	N/A
SRO-5.1 By 2020, develop and test the effectiveness of two strategies for	FY 2018: The U54 PACHE Partnerships, through 2 new efforts, developed and/or validated evidence-based	Finalize testing and validating the strategies to translate basic cancer	Finalize testing and validating the strategies to translate basic cancer	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	interventions and tools to help reduce the burden of cancer disparities in underserved communities across the United States. These partnerships continue to work with various community-based organizations (including faith-based organizations and community-based clinical practices and organizations) to disseminate/translate the interventions and tools for use in diverse communities. Target: Develop and support 2 partnerships to test validated basic cancer knowledge, clinical or behavioral interventions to diverse communities in clinical practice. (Target Met)	knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	
SRO-5.2 By 2018, (a) identify genetic factors that enhance or reduce the risk of development and progression of chronic obstructive pulmonary disease (COPD) and (b) validate new genetic and clinical criteria that may be added to COPD classification and contribute to better and/or earlier diagnosis or prognosis of the disease. (Output)	FY 2018: Investigators identified single nucleotide polymorphisms (SNPs) that correlate with emphysema, but not with specific patterns of emphysema. Eight gene variants have been identified that associate with four emphysema patterns. Target: Identify 1-5 genomic loci that correlate with specific lung patterns of emphysema. (Target Not Met but Improved)	N/A	N/A	N/A
SRO-5.3 By 2023, identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-	FY 2018: NIH continued confirmation of genomic regions of interest in the Discovery Phase using samples from the Replication Phase, continued harmonization of Discovery Phase and Replication Phase datasets, and began analysis of	Begin analysis of genomic regions of interest in the ADSP Discovery Follow-Up Phase using whole genome sequence data from ethnically diverse	Continue analysis of ADSP Discovery Follow-Up Phase in ethnically diverse cohorts. Continue confirmation of genomic regions of interest from	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
onset Alzheimer's disease. (Output)	genomes of minority cohorts. Target: Continue confirmation of genomic regions of interest in the Discovery Phase 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. (Target Met)	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.	Discovery Phase and Discovery Follow-Up Phase in ethnically diverse datasets. Compare data on genomic regions of interest by ethnicity.	
SRO-5.5 By 2018, complete pre-commercial development of a point-of-care technology targeted for use in primary care setting. (Output)	FY 2018: Self-collected samples used in a point-of-care device developed for use in a primary care, clinic, or potentially at home, was found to be highly preferably for most patients who participated in the study. The sample collection method was found to be easy and patients were willing to wait 30 minutes to receive the test results. Target: Support research on refinement of one or two devices for use in primary care that includes end-user feedback. (Target Met)	N/A	N/A	N/A
SRO-5.8 By 2022, obtain pre-clinical and clinical data from newly initiated and current studies to evaluate 1-2 HIV vaccine candidate(s). (Outcome)	FY 2018: HVTN 705, a Phase 2b efficacy study, was initiated and is being conducted in women 18-35 years of age in sub-Saharan Africa. Target: Initiate a Phase 2b vaccine efficacy study using an experimental vaccine regimen in a new population. (Target Met)	Evaluate 1-2 alternative HIV vaccine candidates' suitability for human testing.	Further explore identification of correlates of protection in non-human primate animal models.	N/A
SRO-5.10 By 2020, assess the effectiveness of five to seven	FY 2018: Intervention research projects have completed approximately 80 percent of recruitment, and initiated	Assess intervention progress and collect	Complete analyses of five to seven community-based participatory research	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
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)	collection of third year assessment variables to obtain preliminary results and baselines. Target: Assess intervention progress and collect third year assessment variables. (Target Met)	fourth year assessment variables.	interventions to determine effectiveness in impacting health disparity conditions.	
SRO-5.11 By 2018, develop and test three to five strategies for symptom management that reduce the effects of acute and chronic illness. (Output)	FY 2018: Scientists have tested two strategies for managing symptoms such as anxiety, pain, poor sleep quality, and depressive symptoms. Target: Test three strategies for symptom management that improve health outcomes across multiple illness trajectories. (Target Not Met)	N/A	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)	FY 2018: Researchers using mouse models identified factors influencing stem-cell lifespan. Characterization of a mouse model in one study revealed that the vitamin D receptor is required for proper skin wound healing. Another study uncovered a role for mitochondrial DNA in skin aging. Target: 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. (Target Met)	Develop and/or characterize a mouse model in which skin stem cell participation in wound repair is impaired.	Describe the role of stem cells in skin cancer development by creating traceable stem cells that allow researchers to study cancer development from its earliest events.	N/A
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly	FY 2018: Researchers developed a minimally invasive method to deliver drugs across the blood brain barrier and a non-invasive way to track therapeutic effects	Initiate research to test and refine one new or improved technology that uses acoustic, optical or	Initiate research of a prototype technology that uses acoustic, optical, or electromagnetic	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	in the brain using engineered bacteria and ultrasound. Target: Initiate preliminary research on the development of two new or modified technologies to manipulate cells as a method for treatment. (Target Met)	electromagnetic waves to manipulate cells for treatment of illness.	waves as a test case in a specific disease.	
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 2018: Completed enrollment of 364 preterm infants in study of incubator treatment. Study findings have been published. Target: Complete enrollment in study of preterm infants undergoing incubator treatment. (Target Met)	Complete enrollment in transfusion study.	Complete follow-up on subjects enrolled in a comparative-effectiveness study on two surgical procedures to treat intestinal perforation due to necrotizing enterocolitis in infants.	N/A
SRO-5.15 By 2025, 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 2018: Researchers developed and evaluated the effects of combining individual- and community-level interventions to reduce underage drinking by American Indian youth living on rural California reservations. Target: Develop and/or implement additional preventive interventions to address underage alcohol use among specific underserved populations (i.e., American Indian, Alaska Native). (Target Met)	Develop an intervention to prevent or reduce alcohol misuse among college age individuals.	Develop a digital technology-based intervention to prevent or reduce alcohol misuse in underage individuals.	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 2018: The Pediatric Trials Network has completed clinical study reports on caffeine, rifampin, and methadone. Target: Complete one Phase I/II clinical trial on a prioritized drug. (Target Exceeded)	Begin one Phase III clinical trial for drug development.	Obtain preliminary pharmacokinetic results to help assess the safety for mothers and infants of at least 3 common, off-patent drugs when used by breastfeeding women.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	FY 2018: Researchers developed and tested the first measure of decisional fatigue in surrogate decision-makers of the critically ill. Target: Initiate development of new strategies for patient- and caregiver-centered decision-making in end-of-life and palliative care. (Target Met)	Test at least one novel strategy for improving care for patients with advanced illness through shared decision-making.	Develop and test one novel strategy for improving end-of-life/palliative care through better support of family members and informal caregivers.	N/A
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2018: The pediatric protocol for the Restoring Insulin Secretion study was completed. Target: Complete at least one Restoring Insulin Secretion protocol. (Target Met)	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.	Complete final visits and analyze the data from the Restoring Insulin Secretion adult medication study.	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: To advance the development of the ghrelin receptor blocker PF-5190457 as a potential treatment for alcohol use disorder, researchers conducted a preclinical study with rodents to evaluate its safety when administered in combination with alcohol. 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. (Target Met)	Conduct at least 1 human laboratory study to evaluate the safety and efficacy of candidate compounds for treating alcohol or other substance use disorders.	Evaluate 1 compound with potential for treating alcohol and other substance use disorders in a clinical trial.	N/A
SRO-7.2 By 2018, develop an evidence-based, online resource to help	FY 2018: Investigators developed an evidence-based, online resource to help people who have low back pain and their	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
people who have low back pain and their health care providers apply clinical evidence to individual circumstances when weighing treatment options. (Output)	health care providers apply clinical evidence when weighing treatment options. Usability testing in collaboration with Consumer Reports showed that the calculator informed patients about their options, was useful for decision making, and was easy to use. Target: 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. (Target Met)			
SRO-7.3 By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery or adherence for substance use disorders and related health consequences. (Output)	FY 2018: Research testing the feasibility and efficacy of 2 technology-based strategies to improve substance use disorder treatments and adherence was conducted, including (1) reSET-O which is under expedited review by FDA and (2) a web-delivered cognitive behavior therapy for veterans who screen positive for PTSD and SUD. Target: Develop and/or test 1-2 technology-based treatments for substance use disorders and common comorbidities. (Target Met)	Develop and/or evaluate 2 HIT based interventions to prevent or treat substance use disorders or to improve medication adherence.	Develop and test 1-2 FDA-approved digital therapeutic interventions for substance use disorder treatment and/or medication adherence.	N/A
SRO-8.7 By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across	FY 2018: Scientists investigated a range of implementation strategies to determine whether they improved the sustainability and scale-up of evidence-based practices (EBPs) in child welfare, Veterans Affairs and mental health agencies. Findings from four studies suggest that implementation strategies manipulated at the	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
health care systems. (Outcome)	organizational, community and provider levels resulted in improvements in workforce development, staff retention, early adoption, establishment of local expertise in delivering EBPs, increased EBP provider knowledge, expectations and level of confidence in the ongoing utilization, and sustainment and scale-up of EBPs. Target: 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. (Target Exceeded)			
SRO-9.2 By 2018, identify culturally appropriate, effective stroke prevention/ intervention programs in minority communities. (Outcome)	FY 2018: Successful components of the Shake, Rattle, and Roll trial are being disseminated and implemented within community settings. Target: Initiate dissemination and implementation (D&I) data analyses to identify scalable components of successful disparities intervention programs. (Target Met)	N/A	N/A	N/A
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2018: Award rate to comparison group reached 11% Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater	FY 2018: Award rate to comparison group reached 14% and exceeded the target by 4%.	N ≥ 10%	N ≥ 10%	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
retention and long-term success in research careers. (Output)	Target: N ≥ 10% (Target Exceeded)			
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 2018: NBS Cloud Migration is deferred due to priority operational audit findings. 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 Not Met)	(Development [Dev]) Continue development of remediation activities to comply with HHS Accounting Treatment Manual (ATM) and other Treasury Mandates to increase accuracy and functionality of the NIH Business System.	(Deployment [Dep]) Conduct priority deployment activities for the Funds Configuration Initiative to comply with one of the NIH Corrective Action Plan remediation efforts.	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 2018: As of September 2018, over 800 juvenile knockout cell lines have been characterized (phenotyped). Target: Deliver phenotyping on 500 knockout (KO) juvenile lines. (Target Exceeded)	Deliver phenotyping on 600 knockout (KO) juvenile lines.	Deliver phenotyping on 600 knockout (KO) juvenile lines	N/A
CBRR-5 By 2019, enhance the Clinical and Translational Science Awards (CTSA) Program by establishing resources, processes and guidelines to streamline and accelerate the implementation of multisite clinical trials. (Output)	FY 2018: Three CTSA Trial Innovation Centers and one CTSA Recruitment Centers have been established. Innovative resources to support the Network have been developed, such as a Central IRB, Standard Agreements to streamline the contracting process and facilitate the rapid exchange of contracting information, Trial Innovation Dashboards, and a Proposal Management Database. Target: Establish CTSA Program multisite clinical trial innovation resources which will include the Trial Innovation Centers and	Launch at least two multi-site clinical trials within the CTSA trial innovation network.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Recruitment Innovation Centers. (Target Met)			
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)	FY 2018: The Biomedical Citizen Science Hub, called CitSciBio, was successfully developed and launched. Target: Complete development & launch the Biomedical Citizen Science Hub. (Target Met)	Establish 200-300 registered users of the site and 5 subgroups for the Biomedical Citizen Science Hub.	N/A	N/A
CBRR-9 By 2020, enroll a total of 2,352 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	FY 2018: A cumulative 1,826 participants were enrolled in GenomeConnect. Target: Enroll 1,652 cumulative participants in GenomeConnect. (Target Exceeded)	Enroll 2,002 cumulative participants in GenomeConnect.	Enroll a total of 2,352 participants in GenomeConnect, ClinGen's Patient Registry.	N/A
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)	FY 2018: More than 50 children were enrolled in the PHN in 2018. Target: Enroll 50 children with complex congenital heart disease in a clinical research study. (Target Met)	Enroll 50 children with complex congenital heart disease in a clinical research study.	Enroll 50 children with complex congenital heart disease in a clinical research study	N/A
CBRR-14 By 2018, establish and utilize a national clinical network to conduct five stroke clinical trials using shared infrastructure and efficient processes. (Output)	FY 2018: In FY 2018, StrokeNet completed enrollment in four stroke clinical trials that were conducted within the network. Target: Complete enrollment in 1 to 3 trials being conducted within the stroke network. (Target Exceeded)	N/A	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment	FY 2018: A cognitive assessment protocol was applied in the US Health and Retirement Study and in four international comparison	Review results from the assessment protocol as deployed in the US in 2016-	Make data from the Harmonized Cognitive Assessment Protocol	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
for use in large nationally representative samples. (Outcome)	studies. Data have been collected and are being scored. Target: Evaluate data from the initial administration of a harmonized cognitive assessment protocol in a representative US sample. (Target Met)	2017 and in other countries in 2017 and 2018. Refine protocol as needed to increase sensitivity and specificity.	(HCAP) publicly available to the research community and initiate a follow-up study to the HCAP.	
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)	FY 2018: 2,406 T cell and 207 B cell epitopes from infectious disease pathogens and 249 T cell epitopes from allergens were identified and characterized. 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. (Target Exceeded)	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.	N/A	N/A
CBRR-20 By 2020, advance the preclinical development of ten candidate products (e.g., vaccines, therapeutics) to combat infectious diseases. (Outcome)	FY 2018: The development of three vaccine or therapeutic candidate products was advanced in FY 2018. Target: Advance the preclinical development of three vaccine and/or therapeutic candidate products. (Target Met)	Advance the preclinical development of three vaccine and/or therapeutic candidate products.	Advance the preclinical development of four vaccine and/or therapeutic candidate products.	N/A
CBRR-21 By 2020, establish and implement a national collaborative Pilot and Feasibility (P&F) program that utilizes specialized equipment, and expertise in nonmalignant	FY 2018: Five Partner P&F Projects were supported in FY 2018. Target: Support 2 Pilot and Feasibility (P&F) projects involving collaboration between 2 hematology Centers at different institutions.	Support 2 P&F projects involving collaboration outside the hematology Centers.	Support 4 P&F projects involving collaboration outside the hematology Centers.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
hematology that are available through the Cooperative Centers of Excellence in Hematology (CCEH). (Output)	(Target Met)			
CBRR-22 By 2020, establish a reference map that will serve as the framework to understand the development of the human urinary tract. (Outcome)	FY 2018: 20 datasets were released that establish the framework for an atlas of the human prostate. Target: Release 10 datasets that establish the framework for human atlases of the kidney, urinary outflow tract, and/or prostate. (Target Exceeded)	Identify and map at least 5 specific cell types or subtypes within the kidney, urinary outflow tract, and/or prostate.	Generate and release the human/mouse comparative atlases to the general public.	N/A
CBRR-23 By 2019, provide access to laboratory and data analytical services and a data repository that will allow the NIH extramural research community the capability to add or expand the inclusion of environmental exposure analysis in children's health research. (Output)	FY 2018: NIH supported 25 projects (approximately 36,000 sample analyses) at different stages of the project pipeline. 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. (Target Met)	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.	N/A	N/A
CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)	FY 2018: Since inception of the Maximizing Investigators' Research Award (MIRA) program, there have been 944 MIRA-eligible established investigators, 306 of whom submitted applications, and 231 of whom received awards. Target: Building on the results of the initial pilot program, expand the percentage of investigators involved in program-focused awards by 5% above baseline.	Expand by 5% the proportion of NIGMS-supported investigators funded by active R01-equivalent awards who are MIRA recipients.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Exceeded)			
CBRR-25 Increase the total number of mentored research career development experiences for trainees from diverse backgrounds, including groups underrepresented in biomedical research, to promote individual development and to prepare them for a range of research-related careers. (Output)	FY 2018: 3,706 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 were supported across all training related stages, exceeding the target. Target: 3505 career experiences across all career stages. (Target Exceeded)	3,522 career experiences across all career stages.	3,539 career experiences across all career stages	N/A
CBRR-26 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA Networks of Biomedical Research Excellence (INBRE) program in order to sustain a pipeline of undergraduate students who will pursue health research careers. (Output)	FY 2018: Approximately 1,450 undergraduate students participated in mentored research experiences, consistent with 2017 level. Target: Sustain the number of undergraduate mentored research experiences from 2017 level. (Target Met)	Sustain the number of undergraduate mentored research experiences from 2018 level.	Sustain the number of undergraduate mentored research experiences from 2019 level.	N/A
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	FY 2018: Concurrent validation of the 3-item Patient Safety Screener for adults seen in emergency care was conducted. 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.	Validate risk stratification approaches in emergency care settings for youth who are at risk for suicide.	Validate risk stratification approaches in emergency care settings for youth, and test clinical decision-making approaches based on risk stratification.	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
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)	FY 2018: Brain tissue from 90 donors was obtained and tissue was distributed to 23 researchers studying mental or neurological disorders. 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. (Target Met)	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.	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)	FY 2018: The Data Core successfully planned the infrastructure, provisioned the necessary servers, and had test data from multiple sites in the consortium navigate the system from upload to final storage of the metadata. Target: Establish the Data Core's IT infrastructure for receiving real time data entry from multiple remote locations. (Target Met)	Initiate multi-site validation studies for one candidate biomarker.	Initiate multi-site validation studies for two additional biomarker candidates.	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)	FY 2018: Outreach events were conducted with 2 women-targeted organizations and 3 minority-targeted organizations. Target: Complete four outreach events with either a minority-targeted organization or program, or a women-targeted organization or program. (Target Exceeded)	N/A	N/A	N/A
CTR-5 By 2018, increase the number of computer-indexed	FY 2018: The number of computer-indexed MEDLINE journals was increased by 66	N/A	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
MEDLINE journals by 469 titles, thereby increasing indexing efficiency for MEDLINE. (Output)	titles, thereby increasing indexing efficiency for MEDLINE. Target: Increase the number of journals indexed automatically by the Medical Text Indexer First Line (MTIFL) process by 60 titles over the previous year. (Target Exceeded)			
CTR-6 By 2018, improve NIH's ability to identify outcomes that result from NIH funded research projects and reports to the public on research outcomes. (Outcome)	FY 2018: NIH deployed the electronic Human Subjects System (HSS), which allows collection of inclusion data at award closeout in a structured format. Target: By 2018, implement system improvements to collect inclusion data (i.e., race, gender, etc.) at award closeout in a structured format. (Target Met)	N/A	N/A	N/A
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)	FY 2018: Stakeholders were convened to discuss how to move the National Action Plan towards implementation in rural communities. Target: Conduct annual implementation progress webinars/meetings with stakeholders. (Target Met)	Analyze completed webinars and meeting, and brief stakeholders on Action Plan progress.	Analyze completed webinars and meetings, and brief stakeholders on Action Plan progress.	N/A
CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform	FY 2018: NIH developed a metric to capture unique individuals who apply for various extramural grants such as the R21 or R01-equivalents over a five-year period. Target: By 2018, develop a metric that captures the unique number of individuals who apply	By 2019, develop a central public report displaying NIH Institute/Center-specific award data on investigator-initiated R01/R37 grants.	By 2020, develop a central standard report to describe NIH research investments to organizations receiving R01-equivalent and Research Project Grant support	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
agency funding decisions, and promote transparency regarding the agency's funding strategies. (Output)	for and receive NIH funding over a five-year time period. (Target Met)		according to Carnegie Classification and Funding Institute/Center.	
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Output)	FY 2018: Assessments of the revised Executive Leadership Program (ExLP) program indicate that the program changes have been successful to date. Target: Assess [AS] results of implementation *NIH will assess the outcomes of the Executive Leadership Program (ExLP) to determine whether it is effective in meeting its long-term goals, and validate whether the program should continue with its current content [IM 2017/AS 2018] (Target Met) FY 2018: NIH created a pilot best-practices toolkit for implementation. However, NIH experienced limited hiring and new supervisors all transitioned from existing positions within NIH, so usage of the toolkits has been minimal thus far. Target: 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] (Target Met) FY 2018: Upon examining the results, technical rather than leadership skills were deemed most needed at this time.	Examine [EX] key area to enhance leadership skills Examine the Management Seminar Series as a method for engaging and encouraging leadership in high-performing NIH employees.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Interventions were enacted in the budget (560) series, and a model was built that could be used for longer-term leadership development in any targeted job series. Target: 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] (Target Met)			
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2018: Expansion of the NIH Pathways Program enhanced NIH's scientific workforce by 57 student trainees and was 22% of the Pathways population hired. Target: 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] (Target Met) FY 2018: Results of analysis are still being considered as the effort to include SMEs took a significant amount of time. Target: Implement [IM] key area to enhance recruitment *Implement the creation of a program that incorporates SMEs during the recruitment process, as appropriate. [IM 2018] [AS 2019] (Target Not Met) FY 2018: A survey regarding the use of the Human Resources	Examine [EX] key area to enhance recruitment Examine recruitment activities to identify the most opportune times throughout the year for NIH to recruit for varying occupations.	Examine (EX) key area to enhance recruitment. Examine use of the shared recruitment approach, using data gathered in first year of full-time practice, to determine if hiring goals are being met. [IM 2021/AS 2022]	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	Classification and Recruitment Documents System (HR CARDS) was disseminated to HR Specialists and administrative staff across NIH who recently were involved in a recruitment. Overall, 78% of the respondents were satisfied with the system and the content. Target: 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] (Target Met)			
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2018: 25% of Principal Investigators were reviewed resulting in approximately 25% of resources recommended to be reallocated. Target: Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources. (Target Met)	Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.	Conduct BSC reviews annually of 25% of Principal Investigators to assess quality of science and prioritize resources.	N/A
MPO-5 Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa=85). (Ongoing) (Output)	FY 2018: The condition of the facilities portfolio reached a CIwa of 82.42. Target: CIwa=80.86 (Target Exceeded)	CIwa = 79.51	CIwa = 77.78	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100% of the final approved project	FY 2018: Eleven (11) of the fifteen (15) 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.	23 Active Projects	16 Active Projects	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
cost. (Ongoing) (Output)	Target: 15 Active Projects (Target Not Met)			
MPO-8 Manage design and construction of capital facility projects funded by B&F so that no more than 10% of the projects may incorporate plus or minus 10% adjustments of the approved scope. (Ongoing) (Output)	FY 2018: NIH managed the design and construction of eleven (11) of the fifteen (15) funded projects without a plus or minus 10% adjustment to the scope. Target: 15 Active Projects (Target Not Met)	23 Active Projects	16 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2018: Obligated 47% of eligible service contracting dollars to PBC. Target: Obligate the FY 2018 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2019 goal of eligible service contracting dollars to PBC.	Obligate the FY 2020 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 2018: Based on analyses of historical measures and deep institutional knowledge of peer review policies and procedures, NIH has developed a new process to continuously evaluate and maintain the quality and efficiency of peer review at NIH's Center for Scientific Review. The procedures involve both primary and secondary research, evaluations by an external committee of experts from the scientific community and evaluations by an internal committee of NIH leaders. Target: Design and test measures of peer review quality and efficiency.	Refine and test measures of peer review quality and efficiency.	N/A	N/A

Measure [1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	(Target Met)			
MPO-11 Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	FY 2018: Of the 106 active awards, 96 instruments (91%) were installed within 18 months of the Notice of Award date. Target: 70% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award. (Target Exceeded)	75% of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award.	Verify 75% of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 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)	FY 2018: Effective for applications submitted for due dates on or after January 25, 2018, NIH now requires all grant applications with plans to conduct clinical trials to be submitted to a clinical trial FOA. In addition, NIH announced updated review criteria for applications proposing clinical trials and issued updated FOAs in Fall 2017. 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. (Target Met)	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.	Deploy an enterprise-wide system for improved stewardship of NIH-funded clinical trials that will enhance the management and oversight of NIH-funded clinical trials.	N/A

[1] Performance measures do not reflect measures for the Agency for Healthcare Research and Quality (AHRQ), activities of which are proposed to be consolidated into NIH in FY 2020 as the National Institute for Research on Safety and Quality (NIRSQ). For information on AHRQ performance measures, see the NIRSQ chapter of the NIH Congressional Justification.

Grants Awards Table

	FY 2018 Final Allocation[3,4]	FY 2019 Enacted[3]	FY 2020 President's Budget[3,5]
Number of Awards	47,414	49,720	45,964
Average Award (in Whole $s)	$553,309	$558,271	$521,547
Range of Awards (in Whole $s)[1,2]	$1,000 to $38,535,606	$1,000 to $43,696,035	$1,000 to $35,918,115

[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] Figures shown in the FY 2018 column include an estimated 598 awards expected to be made from FY 2018 two-year and no-year appropriations that were carried over into FY 2019.

[5] Figures for FY 2020 include the proposed consolidation of Agency for Healthcare Research and Quality (AHRQ) activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ). Figures for FY 2018 and FY 2019 do not include AHRQ.

Nonrecurring Expenses Fund Narrative

Budget Summary
(Dollars in Thousands)

	FY 2018[2]	FY 2019[3,4,5]	FY 2020[6]
Notification[1]	n/a	$96,000	TBD

Authorizing Legislation:

Authorization…….…….Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method……..……..Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

In recent years, the NEF has provided funds for critical infrastructure needs for NIH buildings, structures, and facilities, as a supplement to the regular NIH Building and Facilities appropriations. The four projects, described below, received NEF funds in FY 2015 and FY 2016.

In FY 2016, the NEF granted NIH $162.1 million for the Renovation of the E-Wing in the NIH Clinical Center (Building 10). The mission of NIH is to uncover new knowledge that leads to better health for everyone. It is a “bench to bed side” research and training mission requiring both hospital and biomedical research laboratory functions. The Clinical Center Complex on the Bethesda Campus is a group of facilities that collectively support this mission. Building 10 is a 59-year-old facility built over 2 years beginning in 1950 that provides clinical services, laboratories and supporting office space. The condition of Building 10 has impaired its ability to fully support its role in this mission-critical complex. Without major renovation of its infrastructure, NIH is at risk of:

- Impacting accreditation by "The Joint Commission" and "College of Anatomical Pathologists" relating to the close proximity of the Anatomical Pathology area located in the adjoining F wing;
- Failing to provide the necessary functional adjacency to the existing Institutes and the Center’s outpatient clinics; and
- Causing the NIH to fail in fulfilling its mission.

In FY 2015, the NEF granted $10.0 million for a new warehouse for the National Institute of Environmental Health Services (NIEHS) in Research Triangle Park, North Carolina. The

government-owned warehouse facility is located on the NIEHS main campus and it replaced an off-site leased facility. This eliminated the need to pay for a continuing lease and provided an increased level of security for the warehouse. The location of the warehouse also routes traffic away from the Institute's research and administrative staff facilities therefore improving the continuity of operations.

In FY 2016, the NEF granted NIH $35.3 million for R22 Refrigerant Chillers. This project involves replacing two existing York 5,000 Ton dual steam turbine/electric driven chillers (CH-21 FY 2016, CH-16 FY 2017) in Building 11 with four new 3,000 ton variable speed electric chillers, two in FY 2017 and two in FY 2018. Due to the efficiency achieved in the current chilled water upgrades accomplished between 2013 and 2015 and the additional efficiency and capacity of the four new chillers, the remaining four R22 chillers will not have to be replaced. The refrigerant removed from the demolished chillers will be used as backup for the four remaining chillers if needed.

In FY 2016, the NEF granted NIH $16.5 million for Emergency Generators. The original Building 10 (B10) with the exception of the F wing is currently serviced from a 60+ year old electrical distribution system of wiring and components. In 2009 under the "Hybrid Vault/Riser" project, ORF commissioned four (4) secondary network distribution vaults to replace the aging vaults 1 thru 5 of B10. In addition, transformers in these legacy vaults contain PCB hazardous material. That project provided complete riser level distribution for the E and F wing renovations to proceed as separate projects in meeting the power requirements of those wings. However, the remaining wings A, B, C, D, G, H, and J of the building are still serviced from the old vaults 1 thru 5 of B10. The distributed electrical closets created to install electrical equipment in 1952 throughout the building are inadequate in size and capacity to house the ever-growing power distribution requirement of the current research and clinical programs and do not meet the current National Electrical Code. Additionally, sub distribution systems including wiring and localized panel boards are as old as the building and do not meet the needs of the current research and clinical programs and do not meet the current National Electrical Code.

FY 2019 Budget Allocations

HHS notified the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018 for $600 million in new projects, including modernization of the NIH Clinical Center Complex. The Nonrecurring Expenses Fund Congressional Justification details the current list of approved projects for FY 2019. Additional projects may be funded from the FY 2019 notification letter upon approval from OMB.

[1] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.
[2] There was no Congressional notification for the planned uses of NEF funds in FY 2018.
[3] Notification #6 submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018.
[4] Amounts notified are approximations of intended use. Amounts displayed here are current best estimates.
[5] Does not include NEF FY 2019 allocation of $1.0 million for the Agency for Healthcare Research and Quality, which is proposed to be consolidated into NIH in FY 2020 as the National Institute for Research on Safety and Quality (NIRSQ). For information on the NEF allocation for AHRQ/NIRSQ, see the NIRSQ chapter of the NIH Congressional Justification.
[6] HHS has not yet notified for FY 2020.