APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$6,245,442,000]*$5,686,173,000*, 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, [$3,624,258,000]*$3,298,004,000*.

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, [$477,429,000]*$434,559,000*.

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, [$2,114,314,000]*$1,924,211,000*.

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, [$2,374,687,000]*$2,195,110,000*.

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, [$5,885,470,000]*$5,445,886,000*.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [$2,937,218,000]*$2,672,074,000*, of which [$1,230,821,000]*$741,000,000* shall be from funds available under section 241 of the PHS Act: *Provided*, That not less than [$386,573,000]*$351,781,000* 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, [$1,556,879,000]*$1,416,366,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [$824,090,000]*$749,003,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [$802,598,000]*$730,147,000*. (Department of Health and Human Services Appropriations Act, 2020.)

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, [$81,000,000]*$73,688,000*. (Department of the Interior, Environment, and Related Agencies Appropriations Act, 2020.)

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, [$3,543,673,000]*$3,225,782,000*.

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, [$624,889,000]*$568,480,000*.

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, [$490,692,000]*$446,397,000*.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [$169,113,000]*$156,804,000*.

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, [$545,373,000]*$497,346,000*.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [$1,462,016,000]*$1,431,770,000*.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [$1,968,374,000]*$1,794,865,000*.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [$606,349,000]*$550,116,000*.

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, [$403,638,000]*$368,111,000*.

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, [$151,740,000]*$138,167,000*.

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, [$335,812,000]*$305,498,000*: *Provided*, That funds may be used to implement a reorganization that is presented to an advisory council in a public meeting and for which the Committees on Appropriations of the House of Representatives and the Senate have been notified 30 days in advance.

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), [$80,760,000]*$73,531,000*.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [$456,911,000]*$415,665,000*: *Provided*, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2021]*2022*: *Provided further*, That in fiscal year [2020]*2021*, 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, [$832,888,000]*$787,703,000*: *Provided*, That up to [$60,000,000]*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 $578,141,000 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, [$2,239,787,000]*$2,086,463,000*: *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 [$180,000,000]*$168,763,500* shall be for the Environmental Influences on Child Health Outcomes study: *Provided further*, That [$626,511,000]*$583,867,000* 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 2020 and 2021 no later than 30 days after the date of enactment of this Act]:*Provided further*, That amounts available under this heading are also available to establish, operate, and support the Research Policy Board authorized by section 2034(f) of the 21st Century Cures 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]*$300,000,000*, to remain available through September 30, [2024]*2025*.

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, $256,660,000: Provided, That section 947(c) of the PHS Act shall not apply in fiscal year 2021: 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, **[**$492,000,000**]***$404,000,000*, 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, 2020.)

LANGUAGE ANALYSIS

Language Provision to be Changed	Explanation/Justification
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES *Provided*, That up to [$60,000,000]*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	The unique authorities associated with the Cures Acceleration Network (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 priority. Specifying the CAN ceiling as a percentage of the overall NCATS budget ensures that 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 $578,141,000 is provided to the Clinical and Translational Sciences Awards program].	This removal would give NCATS flexibility in the amounts allocated to the Clinical and Translational Sciences Awards program in order to preserve flexibility 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]	The FY 2021 President's Budget does not request continued funding for the 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 2020 and 2021 no later than 30 days after the date of enactment of this Act]	The FY 2021 President's Budget does not request funds for NIH to transfer to the Office of Inspector General (OIG). Funding for the OIG is provided directly in the OIG appropriation.

BUDGET MECHANISM TABLE

Budget Mechanism - Total[1,2,3]

(Dollars in Thousands)[1,2,3]	FY 2019 Final[4]		FY 2020 Enacted[5]		FY 2021 President's Budget[6]		FY 2021 +/- FY 2020	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	27,624	$14,564,519	29,508	$16,004,065	30,109	$15,631,587	601	-$372,478
Administrative Supplements[3]	*(2,341)*	437,486	*(2,300)*	501,907	*(1,517)*	277,780	*(-783)*	-224,127
Competing	11,020	$6,313,647	11,379	$6,224,996	9,505	$5,144,843	-1,874	-$1,080,153
Subtotal, RPGs	38,644	$21,315,652	40,887	$22,730,968	39,614	$21,054,209	-1,273	-$1,676,758
SBIR/STTR	2,023	1,052,394	2,140	1,118,874	1,993	1,035,570	-147	-83,304
Research Project Grants	40,667	$22,368,046	43,027	$23,849,842	41,607	$22,089,780	-1,420	-$1,760,062
Research Centers:								
Specialized/Comprehensive	998	$1,927,569	1,021	$1,895,832	926	$1,693,289	-95	-$202,542
Clinical Research	70	420,992	67	427,137	66	397,046	-1	-30,091
Biotechnology	85	142,465	79	134,917	75	122,935	-4	-11,982
Comparative Medicine	50	136,741	49	131,392	47	124,233	-2	-7,159
Research Centers in Minority Institutions	19	63,189	21	74,500	21	68,250	0	-6,250
Research Centers	1,222	$2,690,957	1,237	$2,663,777	1,135	$2,405,752	-102	-$258,024
Other Research:								
Research Careers	4,222	$790,182	4,445	$824,556	4,168	$773,975	-277	-$50,581
Cancer Education	77	20,459	101	26,890	96	25,546	-5	-1,345
Cooperative Clinical Research	257	468,112	277	461,252	232	398,865	-45	-62,387
Biomedical Research Support	131	81,134	128	80,408	119	74,706	-9	-5,702
Minority Biomedical Research Support	286	100,758	280	98,477	240	84,534	-40	-13,943
Other	2,134	1,113,725	2,277	1,171,899	2,159	1,082,833	-118	-89,066
Other Research	7,107	$2,574,370	7,508	$2,663,482	7,014	$2,440,458	-494	-$223,024
Total Research Grants	48,996	$27,633,373	51,772	$29,177,100	49,756	$26,935,990	-2,016	-$2,241,110
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,654	$170,240	3,814	$183,810	3,598	$172,660	-216	-$11,151
Institutional Awards	13,221	695,065	13,833	726,112	12,707	675,043	-1,126	-51,069
Total Research Training	16,875	$865,305	17,647	$909,923	16,305	$847,703	-1,342	-$62,220
Research & Develop. Contracts	2,455	$3,164,921	2,663	$3,349,392	2,409	$3,077,107	-254	-$272,285
(SBIR/STTR) (non-add)[3]	*(129)*	*(91,059)*	*(113)*	*(81,196)*	*(103)*	*(74,359)*	*(-10)*	*(-6,836)*
Intramural Research		$4,143,842		$4,445,880		$4,076,559		-$369,321
Res. Management & Support		1,883,396		2,014,642		1,926,132		-88,510
Res. Management & Support (SBIR Admin) (non-add)[3]		*(8,175)*		*(11,219)*		*(8,426)*		*(-2,793)*
Office of the Director - Appropriation[3,7]		*(2,103,986)*		*(2,404,387)*		*(2,208,063)*		*(-196,324)*
Office of the Director - Other		1,196,712		1,477,063		1,343,000		-134,063
ORIP (non-add)[3,7]		*(288,108)*		*(288,213)*		*(268,596)*		*(-19,617)*
Common Fund (non-add)[3,7]		*(619,166)*		*(639,111)*		*(596,467)*		*(-42,644)*
Buildings and Facilities[8]		217,313		230,000		315,000		85,000
Appropriation[3]		*(199,313)*		*(200,000)*		*(300,000)*		*(100,000)*
Type 1 Diabetes[9,10]		-150,000		-150,000		-150,000		0
Program Evaluation Financing[9]		-1,146,821		-1,230,821		-741,000		489,821
Subtotal, Labor/HHS Budget Authority		**$37,808,041**		**$40,223,179**		**$37,630,491**		**-$2,592,688**
Interior Appropriation for Superfund Research		79,000		81,000		73,688		-7,312
Total, NIH Discretionary Budget Authority		**$37,887,041**		**$40,304,179**		**$37,704,179**		**-$2,600,000**
Type 1 Diabetes[10]		150,000		150,000		150,000		0
Patient-Centered Outcomes Research Trust Fund (PCORTF)		0		0		98,452		98,452
Total, NIH Budget Authority		**$38,037,041**		**$40,454,179**		**$37,952,631**		**-$2,501,548**
Program Evaluation Financing		1,146,821		1,230,821		741,000		-489,821
Total, Program Level		**$39,183,862**		**$41,685,000**		**$38,693,631**		**-$2,991,369**

1 All Subtotal and Total numbers may not add due to rounding.
2 Includes 21st Century Cures Act funding and excludes hurricane-related supplemental financing.
3 All numbers in italics and brackets are non-add.
4 Includes $186.4 million of 21st Century Cures and $76.5 million of Type 1 Diabetes funding appropriated in FY 2019 and carried over into FY 2020. 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 2019, $30.0 million in FY 2020, and $15.0 million in FY 2021) 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 FY 2020 reflects requested extension of Type 1 Diabetes Research from enacted amount of $96.575 million through May 22, 2020 to full-year level of $150.0 million.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2020 Amount Authorized	FY 2020 Amount Appropriated[1]	FY 2021 Amount Authorized	FY 2021 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	36,472,443	40,954,400	TBD	37,698,231
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	81,000	Indefinite	73,688
3. 21st Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	149,000	149,000	109,000	109,000
BRAIN Initiative: Section 1001(b)(4)(B)	140,000	140,000	100,000	100,000
Cancer Moonshot: Section 1001(b)(4)(C)	195,000	195,000	195,000	195,000
Regenerative Medicine: Section 1001(b)(4)(D)	8,000	8,000	0	0
4. Special Diabetes Programs: Section 330B(b) of the PHS Act	96,575	96,575	TBD	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	256,660

[1]The amount appropriated in FY 2020 for the Special Diabetes Programs reflects the extended funding level for Oct 1, 2019 to May 22, 2020.

SSAN = Such sums as necessary

APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2012	$31,979,000,000		$30,630,423,000	$30,852,187,000 [2]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [3]
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 [4]
FY 2016	$31,311,349,000 [5]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [6]
FY 2017	$33,136,349,000 [7]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [8]
FY 2018	$26,919,710,000 [9]	$35,184,000,000	$36,084,000,000	$37,311,349,000 [10]
FY 2019	$34,766,707,000 [11]	$38,564,000,000	$39,312,349,000	$39,313,000,000 [12]
FY 2020	$34,111,669,000 [11]	$41,154,000,000	$42,084,000,000	$41,636,575,000 [13]
FY 2021 PB	$38,693,631,000 [11,14]			

[1] Does not reflect comparability adjustments. Interior appropriation's Superfund Research allocation included for all years. Special Type 1 Diabetes Research mandatory funding included. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019, $492,000,000 in FY 2020, and $404,000,000 in the FY 2021 Request.

[2] 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.

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

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

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

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

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

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

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

[10] 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.

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

[12] Includes Program Evaluation Financing of $1,146,821,000. Does not reflect $5,000,000 transfer from NIH to the HHS Office of the Inspector General or hurricane disaster supplemental of $1,000,000 for National Institute of Environment Health Sciences.

[13] Includes Program Evaluation Financing of $1,230,821,000. Does not reflect $5,000,000 transfer from NIH to HHS Office of the Inspector General.

[14] Includes funding of $355,112,000 for the National Institute for Research on Safety and Quality (NIRSQ) associated with the proposed FY 2021 consolidation into NIH. Figures prior to FY 2021 do not include amounts for the Agency for Healthcare Research and Quality (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 2019 Final [1]	FY 2020 Enacted [2]	FY 2021 President's Budget	FY 2021 +/- FY 2020
Program Level [3,4]	$39,183,862	$41,685,000	$38,693,631	-2,991,369
FTE [3,5]	17,231	18,105	18,350	245

[1] Excludes hurricane-related supplemental financing.

[2] Amount for FY 2020 reflects directive transfer of $5.0 million to the HHS Office of Inspector General and requested extension of Type 1 Diabetes Research from enacted amount of $96.575 million through May 22, 2020 to full-year level of $150.0 million.

[3] Figures for FY 2021 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 2019 and FY 2020 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 $1,146.8 million in FY 2019, $1,230.8 million in FY 2020, and $741.0 million in FY 2021.

[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 DESCRIPTIONS AND ACCOMPLISHMENTS

NIH Contributions and Scientific Advances Towards Improving Human Health

NIH is the largest public funder of biomedical research in the world, investing taxpayer dollars wisely to achieve its mission to enhance health, lengthen life, and reduce illness and disability. In pursuing this mission, NIH improves health by promoting treatment and prevention, contributes to society by driving economic growth and productivity, and expands the biomedical knowledge base by funding cutting-edge research and cultivating the biomedical workforce of today and tomorrow.

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 recent NIH-funded research accomplishments are listed below.

AI Approach Outperformed Human Experts in Identifying Cervical Precancer

A research team led by investigators from NIH and Global Good developed a computer algorithm that can analyze digital images of a woman's cervix and accurately identify precancerous changes that require medical attention.[11] This artificial intelligence (AI) approach, called automated visual evaluation, has the potential to revolutionize cervical cancer screening, particularly in low-resource settings.

Researchers used comprehensive datasets to "train" a learning algorithm to recognize patterns in complex visual inputs, such as medical images.[12] To create the algorithm, the research team used more than 60,000 cervical images from a National Cancer Institute (NCI) archive of photos collected during a cervical cancer screening study that was carried out in Costa Rica in the 1990s. More than 9,400 women participated in that population study, with follow-up that lasted up to 18 years. Because of the prospective nature of the study, the researchers gained nearly complete information on which cervical changes became precancers and which did not. The findings were then subsequently confirmed independently by experts at the National Library of Medicine (NLM).

The researchers plan to further train the algorithm on a sample of representative images of cervical precancers and normal cervical tissue from women in communities around the world, using a variety of cameras and other imaging options. The ultimate goal of the project is to create the best possible algorithm for common, open use.

Curing Sickle Cell Disease

In large part due to the advances made through NIH-supported research, many patients with Sickle Cell Disease (SCD) now can expect to live between 55-65 years of age.[13] As recently as

[11] www.nih.gov/news-events/news-releases/ai-approach-outperformed-human-experts-identifying-cervical-precancer
[12] Hu L. et al. *J Natl Cancer Inst*. 2019 Sep;111(9):923-932. doi: 10.1093/jnci/djy225. PMID:30629194
[13] magazine.medlineplus.gov/article/is-a-widely-available-cure-for-sickle-cell-disease-on-the-horizon

the 1970s, the average person with SCD died in childhood, mainly from infection. Children suffering from SCD were also especially vulnerable to suffering fatal or debilitating strokes. NIH-supported research discovered that a daily dose of penicillin could prevent life-threatening infections in infants with SCD, thus establishing a new standard of care and providing an impetus for now universal newborn screening in the United States.[14] Research has also found ways to identify children with SCD who are at high risk for stroke. As a result, the risk of childhood stroke has been reduced by 90 percent.

The future for those with SCD has never been more promising, as there are a variety of new and innovative strategies being explored to cure this devastating disease. One particularly promising avenue of research involves using gene editing techniques. Shortly after birth, babies usually stop producing fetal hemoglobin and switch over to the adult form. However, rare individuals continue to produce high levels of fetal hemoglobin throughout their lives. Studies have shown that individuals with SCD who continue producing fetal hemoglobin have an extremely mild version of the disease—essentially the presence of significant quantities of fetal hemoglobin provides protection against SCD. Researchers are now exploring ways to boost the fetal hemoglobin levels in everyone with SCD, and gene editing may provide an effective, long-lasting way to do this.[15]

Based on this and other approaches currently being tested, it appears that we are within sight of curing sickle cell disease. Even more exciting, if a cure for SCD is finally realized, a similar strategy could be applied to other genetic conditions that currently lack any effective treatment.

Scientists Translate Brain Signals into Speech Sounds

Scientists used brain signals recorded from epilepsy patients to program a computer to mimic natural speech — an advancement that could one day have a profound effect on the ability of certain patients to communicate. Speech scientists and neurologists from the University of California, San Francisco recreated many vocal sounds with varying accuracy using brain signals recorded from epilepsy patients with normal speaking abilities.[16] The patients were asked to speak full sentences, and the data obtained from brain scans was then used to drive computer-generated speech. Furthermore, simply miming the act of speaking provided sufficient information to the computer for it to recreate several of the same sounds.

The loss of the ability to speak can have devastating effects on patients whose facial, tongue, and larynx muscles have been paralyzed due to stroke or other neurological conditions. Technology has helped these patients to communicate through devices that translate head or eye movements into speech. Because these systems involve the selection of individual letters or whole words to build sentences, the speed at which they can operate is very limited. Instead of recreating sounds based on individual letters or words, the goal of this project was to synthesize the specific sounds used in natural speech.

[14] archives.nih.gov/asites/report/09-09-2019/report.nih.gov/nihfactsheets/ViewFactSheet2ad4.html?csid=116
[15] directorsblog.nih.gov/tag/fetal-hemoglobin/
[16] Anumanchipalli, G.K. *Nature*. 2019 Apr; 568(7753):493-498. doi: 10.1038/s41586-019-1119-1. PMID: 31019317.

Scientists first recorded signals from patients' brains while they were asked to speak or mime sentences and then built maps of how the brain directs the vocal tract, including the lips, tongue, jaw, and vocal cords, to make different sounds. The researchers then applied those maps to a computer program that produced synthetic speech. Volunteers were asked to listen to the synthesized sentences and to transcribe what they heard. More than half the time, the listeners were able to determine the sentences being spoken by the computer correctly.

The researchers' next plan is to design a clinical trial involving paralyzed, speech-impaired patients to determine how best to gather brain signal data that can then be applied to the previously trained computer algorithm.

Study Funded by NIH Supports Optimal Threshold for Diagnosing COPD

An NIH-funded study provides evidence to support a simple measurement for diagnosing clinically significant airflow obstruction, the key characteristic of chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the United States.[17] The study found that a 70 percent ratio of two indicators of lung function proved as accurate as or more accurate than other thresholds for predicting COPD-related hospitalizations and deaths.

The research, which draws on a wide range of multi-ethnic studies, validates current guidelines from major respiratory societies and contributes to identify a fixed threshold of disease severity. This approach has led to great strides in early detection and treatment of other conditions such as hypertension and diabetes.

The researchers aimed to determine how accurate various thresholds were in predicting COPD-related hospitalizations and mortality. For that, the NHLBI Pooled Cohorts Study analyzed data from four U.S. population-based studies that collected spirometry results and followed up participants for COPD-related clinical events. The study included 24,207 adult participants, of whom 54 percent were women, 69 percent white, and 24 percent black.

Establishing a diagnostic threshold may result in earlier detection and treatment options for patients.

Brain Biomarkers Could Help Identify Those at Risk for PTSD

A study has shed light on the neurocomputational contributions to the development of post-traumatic stress disorder (PTSD) in combat veterans.[18] The findings revealed distinct patterns for how the brain and body respond to learning danger and safety, depending on the severity of PTSD symptoms. These findings could help explain why symptoms of PTSD can be severe for some people but not others.

One theory explaining why some symptoms of PTSD develop suggests that during a traumatic event, a person may learn to view the people, locations, and objects that are present as being

[17] Bhatt, S.P. et al. *JAMA*. 2019 Jun; 321(24): 2438–2447. doi: 10.1001/jama.2019.7233 PMCID: PMC6593636
[18] Homan, Philipp, et al. *Nat Neurosci*. 2019 Mar; 22(3): 470–476. P. doi: 10.1038/s41593-018-0315-x PMCID: PMC6829910

dangerous if they become associated with the threatening situation. While some of these things may be dangerous, some are safe. PTSD symptoms result when these safe stimuli continue to trigger fearful and defensive responses long after the trauma has occurred. Despite the prominence of this theory, the way in which this learning occurs is not well understood.

Researchers at Yale University and Mount Sinai examined how the mental adjustments performed during learning and the way in which the brain tracks these adjustments relate to PTSD symptom severity. Although all participants, regardless of PTSD symptomology, were able to perform a reversal learning exercise, when the researchers took a closer look at the data, they found highly symptomatic veterans responded with greater corrections in their physiological arousal and several brain regions to cues that did not predict what they had expected.

These results show that PTSD symptom severity is reflected in how combat veterans respond to negative surprises in the environment—when outcomes predicted by cues are not as expected—and the way in which the brain is attuned to these stimuli is different. These findings will allow for a more fine-grained understanding of how learning processes may go awry in the aftermath of combat trauma and provide more specific targets for treatment.

Data Sharing Uncovers Five New Risk Genes for Alzheimer's Disease

An international study involving the analysis of genetic data from more than 94,000 individuals revealed 5 new risk genes for Alzheimer's disease and confirmed 20 known others.[19] The researchers also reported for the first time that mutations in genes specific to tau, a hallmark protein of Alzheimer's disease, may play an earlier role in the development of the disease than originally thought. These new findings support developing evidence that groups of genes associated with specific biological processes, such as cell trafficking, lipid transport, inflammation, and the immune response, are "genetic hubs" that are an important part of the disease process.

In addition to confirming the known association of 20 genes with risk of Alzheimer's and identifying 5 additional Alzheimer's-associated genes, these genes were analyzed to see what cellular pathways might be implicated in the disease process. The pathway analysis implicated the immune system, lipid metabolism, and amyloid precursor protein (APP) metabolism. Mutations in the APP gene have been shown to be directly related to early onset Alzheimer's. The present study, done in late onset Alzheimer's subjects, suggests that variants affecting APP and amyloid beta protein processing are associated with both early-onset autosomal dominant Alzheimer's and with late onset Alzheimer's**.** In addition, for the first time, the study implicated a genetic link to tau binding proteins. Taken together, data suggest that therapies developed by studying subjects with early-onset disease could also be applied to the late-onset form of Alzheimer's.

Once the functions of the 5 genes newly associated with Alzheimer's are understood and examined in conjunction with the functions of the 20 known genes, researchers will be in a better position to identify where the genetic hubs of Alzheimer's are clustering. Armed with these

[19] Kunkle BW et al. *Nature Genetics*. 2019 Feb; 51:414-430. doi: 10.1038/s41588-019-0358-2

findings, researchers can look more deeply into these genetic hubs to reveal disease mechanisms and potential drug targets.

Scientists Find New Approach That Shows Promise for Treating Cystic Fibrosis

Researchers have discovered that a widely used antifungal drug may hold promise for treating people with cystic fibrosis, a life-threatening genetic disorder that causes serious damage to the lungs.[20] In studies using human cells and animal models, the researchers found that the drug, called amphotericin, helps lung cells function in a way that could make it easier for patients to fight chronic bacterial lung infections that are a hallmark of the disease.

If subsequent human studies validate the findings, the use of the drug could be good news to the more than 30,000 people in the United States and 70,000 worldwide who live with cystic fibrosis, a disease with no cure and few treatment options. It holds special promise for a subset of patients, about 10 percent of the people with cystic fibrosis, who do not respond to any treatment.

In their studies, the researchers used lung tissue from patients with cystic fibrosis, as well as pig models of cystic fibrosis, and found that amphotericin spurred a host of changes associated with improved lung function — restoration of pH levels, improved viscosity, and increased antibacterial activity, among others.

The researchers noted that amphotericin can be delivered directly to the lungs to avoid common side effects. More experimental studies are needed before the drug is safe to treat cystic fibrosis in people, but experts are hopeful.

Gene Therapy Restores Immunity in Infants with Rare Immunodeficiency Disease

A small clinical trial has shown that gene therapy can safely correct the immune systems of infants newly diagnosed with a rare, life-threatening inherited disorder in which infection-fighting immune cells do not develop or function normally. Eight infants with the disorder, called X-linked severe combined immunodeficiency (X-SCID), received an experimental gene therapy co-developed by NIH scientists.[21] They experienced substantial improvements in immune system function and were growing normally up to two years after treatment. The new approach appears safer and more effective than previously tested gene-therapy strategies for X-SCID.

Infants with X-SCID, caused by a gene mutation, are highly susceptible to severe infections. If untreated, the disease is fatal, usually within the first year or two of life.[22] Infants with X-SCID typically are treated with transplants of blood-forming stem cells, ideally from a genetically matched sibling. However, less than 20 percent of infants with the disease have such a donor.

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[20] Muraglia, KA et al. *Nature*. 2019 Mar; 567(7748): 405–408. doi: 10.1038/s41586-019-1018-5 PMCID: PMC6492938

[21] Mamcarz, E et al. *N Engl J Med.* 2019 Apr; 380(16): 1525-1534. doi: 10.1056/NEJMoa1815408 PMCID: PMC6636624

[22] www.nih.gov/news-events/news-releases/gene-therapy-restores-immunity-infants-rare-immunodeficiency-disease

Those without a matched sibling typically receive transplants from a parent or other donor, which are lifesaving, but often only partially restore immunity. These patients require lifelong treatment and may continue to experience complex medical problems, including chronic infections.

To restore immune function to those with X-SCID, scientists developed an experimental gene therapy that involves inserting a normal copy of the mutated gene into the patient's own blood-forming stem cells. Compared with previously tested gene-therapy strategies for X-SCID, which used other vectors and chemotherapy regimens, the current approach appears safer and more effective. Researchers are continuing to monitor the infants who received the lentiviral gene therapy to evaluate the durability of immune reconstitution and assess any potential long-term side effects of the treatment.

Emergency Treatment Guidelines Improve Survival of People with Severe Head Injury

A large study of more than 21,000 people finds that training emergency medical services (EMS) agencies to implement prehospital guidelines for traumatic brain injury (TBI) may help improve survival in patients with severe head trauma.[23]

Based on observational studies, guidelines for prehospital management of TBI that were developed in 2000, and updated in 2007, focused on preventing low oxygen, low blood pressure, and hyperventilation in people with head injury. Collectively, the studies suggested that controlling those factors before patients arrived at the hospital could improve survival, but actual adherence to the guidelines had not been examined.

Researchers compared patient outcomes before and after the guideline implementation. All patients in the study experienced head injury with loss of consciousness. The results revealed that the guidelines helped double the survival rate of people with severe TBI and triple the survival rate in severe TBI patients who had to have a breathing tube inserted by EMS personnel. The guidelines were also associated with an overall increase in survival to hospital admission.

Although the guidelines provide specific recommendations for oxygen levels and blood pressure, researchers will examine whether those ranges should be revised. More research is needed to determine the best strategies for airway management and breathing support to optimize ventilation. Additional studies will investigate the best methods for national and global adoption of the TBI guidelines.

Human Antibody Reveals Hidden Vulnerability in Influenza Virus

Scientists have discovered that the "head" of an influenza virus protein has an unexpected Achilles heel. The team discovered and characterized the structure of a naturally occurring human antibody that recognizes and disrupts a portion of the hemagglutinin (HA) protein that the virus uses to enter and infect cells. The investigators determined that the antibody, FluA-20,

[23] Spaite DW.. et al., *Acad Emerg Med.* 2014 Jul;21(7):818-30. doi: 10.1111/acem.12411. PMCID: PMC4134700

binds tightly to an area on the globular head of the HA protein that is only very briefly accessible to antibody attack.[24] The site was not expected to be vulnerable to such a strike.

The researchers isolated the FluA-20 antibody from a person who had received many influenza immunizations. In a series of experiments, they showed that FluA-20 can "reach into" an otherwise inaccessible part of the HA molecule and cause it to fall apart, thus preventing the spread of the virus from cell to cell. This discovery came as a surprise because this region of HA was thought to be stable and inaccessible to antibodies.

In mouse studies, FluA-20 prevented infection or illness when the animals were exposed to four different influenza A viral subtypes that cause disease in humans. Two viruses used in the experiments are Group 1 influenza subtypes, while the two others are members of Group 2. Current influenza vaccines must contain viral components from both subtypes to elicit matching antibodies. A single vaccine able to generate potent antibodies against members of both groups could provide broad multi-year protection against influenza.

Blood Test Shows Promise for Early Detection of Severe Lung-Transplant Rejection

Researchers have developed a simple blood test that can detect when a newly transplanted lung is being rejected by a patient, even when no outward signs of the rejection are evident.[25] The test could make it possible for doctors to intervene faster to prevent or slow down so-called chronic rejection—which is severe, irreversible, and often deadly—in those first critical months after lung transplantation. Researchers believe this same test might also be useful for monitoring rejection in other types of organ transplants.

The test relies on DNA sequencing, and as such, represents a great example of personalized medicine, as it will allow doctors to tailor transplant treatments to those individuals who are at highest risk for rejection. Lung transplant recipients have the shortest survival rates among patients who get solid organ transplantation of any kind—only about half live past five years. Lung transplant recipients face a high incidence of chronic rejection, which occurs when the body's immune system attacks the transplanted organ. Existing tools for detecting signs of rejection, such as biopsy, either require the removal of small amounts of lung tissue or are not sensitive enough to discern the severity of the rejection. The new test appears to overcome those challenges.

If validated, this blood test could become a routine tool used to monitor transplant patients at very early stages of rejection, the researchers said.

New Protocol Could Ease Diagnosis of Bacterial Infections in Infants

A new protocol could help emergency room physicians to rule out life-threatening bacterial infections among infants up to two months of age who have fevers, potentially eliminating the

[24] Bangaru S. et al. *Cell*. 2019 May ;177(5):1136-1152. doi: 10.1016/j.cell.2019.04.011 PMCID:PMC6629437
[25] Agbor-Enoh, S. et al. *EBioMedicine*. 2019 Feb; 40: 541–553. doi: 10.1016/j.ebiom.2018.12.029 PMCID: PMC6412014

need for spinal taps, unnecessary antibiotic treatments or expensive hospital stays[26]. Researchers from the Pediatric Emergency Care Applied Research Network (PECARN) developed the protocol from a study of more than 1,800 infants seen at 26 emergency departments around the country.

Previous studies suggest that 8 to 13 percent of infants up to 2 months of age who have a fever may have a serious bacterial infection. These include urinary tract infections, bacteremia, and bacterial meningitis. Often, a physician will need to confirm a diagnosis with a spinal tap, in which a small amount of fluid is extracted from the spinal canal. Although complications of the procedure are rare, they include inflammation of the spinal canal, bleeding and headache. In addition, an infant may be given antibiotics when a bacterial infection is suspected and may be admitted to a hospital for observation.

The new protocol measures the levels of bacteria in urine, of procalcitonin (a substance produced in response to bacterial infection) in serum, and of neutrophils (an infection-fighting white blood cell). The researchers ruled out a serious bacterial infection (SBI) if tests showed low levels of bacteria and procalcitonin and a normal neutrophil count. They were able to rule out accurately all but 3 of the 170 cases of SBI ultimately detected, including all cases of meningitis.

NIH Establishes Network to Improve Opioid Addiction Treatment in Criminal Justice Settings

NIH awarded 15 grants to form the Justice Community Opioid Innovation Network (JCOIN) to support research on quality addiction treatment for opioid use disorder (OUD) in criminal justice settings nationwide.[27] The awards total an estimated $141.3 million from the National Institute on Drug Abuse (NIDA).

JCOIN will establish a national network of investigators collaborating with justice and behavioral health stakeholders to research promising interventions and other approaches to improve the capacity of the justice system to respond to the opioid crisis.[28] JCOIN is part of the NIH Helping to End Addiction Long-term (HEAL) Initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. The NIH HEAL Initiative is focused on improving prevention and treatment strategies for opioid misuse and addiction and enhancing pain management.

Awarded research centers will study evidence-based medications, behavioral interventions, digital therapeutics, and comprehensive patient-centered treatments in 15 states and Puerto Rico. Each grantee will work with five or more communities, where they will engage with organizations in justice settings and service providers in the community. JCOIN will address gaps in OUD treatment and related services in a wide range of criminal justice settings, including jails, drug courts, problem-solving courts, policing and diversion, re-entry, and probation and parole.

[26] Kuppermann, N. *JAMA pediatrics*. 2019 Feb, 173(4): 342. DOI: 10.1001/jamapediatrics.2018.5501
[27] heal.nih.gov/research/research-to-practice/jcoin
[28] www.nih.gov/news-events/news-releases/nih-establishes-network-improve-opioid-addiction-treatment-criminal-justice-settings

Drug Delays Type 1 Diabetes in People at High Risk

Researchers showed that a treatment affecting the immune system has effectively slowed the progression to clinical type 1 diabetes in high-risk individuals.[29] The study is the first to show that clinical type 1 diabetes can be delayed by two or more years among people who are at high risk.

The international study involved treatment with an anti-CD3 monoclonal antibody (teplizumab) aimed at discovering ways to delay or prevent type 1 diabetes. Researchers enrolled 76 participants ages 8-49 who were relatives of people with type 1 diabetes and had at least 2 types of diabetes-related autoantibodies and abnormal sugar tolerance. Participants were randomly assigned to either the treatment group, which received a 14-day course of teplizumab, or the control group, which received a placebo. All participants received glucose tolerance tests regularly until the study was completed, or until they developed clinical type 1 diabetes – whichever came first.

During the trial, 72 percent of people in the control group developed clinical diabetes, compared to only 43 percent of the teplizumab group. The median time for people in the control group to develop clinical diabetes was just over 24 months, while those who developed clinical diabetes in the treatment group had a median time of 48 months before progressing to diagnosis.

The effects of the drug were greatest in the first year after it was given, when 41 percent of participants developed clinical diabetes, mainly in the placebo group. Many factors, including age, could have contributed to the ability of teplizumab to delay clinical disease, since at-risk children and adolescents are known to progress to type 1 diabetes faster than adults. Faster progression of type 1 diabetes is associated with a highly active immune system, which may explain the impact of immune system-modulating drugs like teplizumab.

NIH Funds Clinical Trials Using Genomics to Treat Chronic Diseases

NIH will fund clinical trials to assess the benefits, applicability, and efficacy of applying genomic medicine interventions to improve management of diseases such as high blood pressure, depression, and chronic pain.[30] The trials are part of the second phase of the Implementing Genomics in Practice (IGNITE) Network.[31] The trials are scheduled to begin in 2020.
The first trial will examine whether early access to patients' genomic data can help with treatment of high blood pressure, hypertension, and chronic kidney disease. Both hypertension and high blood pressure exacerbate end-stage kidney diseases, and all three conditions are more common among people of African ancestry than European and Asian descent. Researchers will compare whether medical intervention provided to those tested for a specific gene variant immediately after recruitment versus those tested three months later will have subsequent benefits.

[29] www.nih.gov/news-events/news-releases/drug-delays-type-1-diabetes-people-high-risk
[30] www.nih.gov/news-events/news-releases/nih-funds-clinical-trials-using-genomics-treat-chronic-diseases
[31] www.genome.gov/Funded-Programs-Projects/Implementing-Genomics-in-Practice-IGNITE-2-Pragmatic-Clinical-Trials-Network

The second trial will focus on pain and depression – two conditions where finding safe and effective drug treatments has been difficult. Because there are few clinically useful predictors for whether a depression treatment will be successful, patients often struggle to find effective therapies. To combat these issues, the study seeks to test whether patients with acute post-surgical pain, chronic pain, and depression have better clinical outcomes if pharmacogenomics guide opioid and antidepressant prescriptions.

These projects build upon the first phase of research from the IGNITE Network, which the National Human Genome Research Institute (NHGRI) funded in spring 2013 and focused on challenges and possible solutions to incorporating genomic information into electronic health records.

Study Helps Solve Mystery of How Sleep Protects Against Heart Disease

Researchers say they are closer to solving the mystery of how a good night's sleep protects against heart disease. In studies using mice, they discovered a previously unknown mechanism between the brain, bone marrow, and blood vessels that appears to protect against the development of atherosclerosis or hardening of the arteries — but only when sleep is healthy and sound.[32]

The discovery of this pathway underscores the importance of getting enough, quality sleep to maintain cardiovascular health and could provide new targets for fighting heart disease, the leading cause of death among women and men in the United States, the researchers said.

To learn more about the impact of sleep deficiency on cardiovascular disease, the researchers focused on a group of mice that were genetically engineered to develop atherosclerosis. They disrupted the sleep patterns of half the mice and allowed the other half to sleep normally. Over time, the mice with disrupted sleep developed progressively larger arterial lesions compared to the other mice. Specifically, the sleep-disrupted mice developed arterial plaques, or fatty deposits, that were up to one-third larger than the mice with normal sleep patterns. The sleep-disrupted mice also produced twice the level of certain inflammatory cells in their circulatory system than the control mice — and lower amounts of hypocretin, a hormone made by the brain that is thought to play a key role in regulating sleep and wake states.

The researchers also showed that sleep-deficient, atherosclerotic mice that received hypocretin supplementation tended to produce fewer inflammatory cells and develop smaller atherosclerotic lesions when compared to mice that did not get the supplementation. These results, they said, demonstrate that hypocretin loss during disrupted sleep contributes to inflammation and atherosclerosis. But they cautioned that more studies are needed, particularly in humans, to validate these findings and especially before experimenting with hypocretin therapeutically.

[32] McAlpine, S. et al. *Nature.* 2019 Feb; 566(7744): 383–387. doi: 10.1038/s41586-019-0948-2 PMCID: PMC6442744

Still, health experts say, targeting the newly discovered biological mechanism — a so-called neuro-immune axis — could be a breakthrough that one day leads to new treatments for heart disease, sleep, and other disorders.

FUNDING HISTORY

Fiscal Year	Amount[1, 2]
2017 [3]	$34,229,139,000
2018	$37,311,349,000
2019	$39,313,000,000
2020	$41,636,575,000
2021 Budget Request [4]	$38,693,631,000

[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. Includes NIGMS Program Evaluation financing of $824,443,000 in FY 2017, $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, and $1,230,820,000 in FY 2020, and $741,000,000 in FY 2021. Includes CURES amounts of $352,000,000 in FY 2017, $496,000,000 in FY 2018, $711,000,000 in FY 2019, $492,000,000 in FY 2020, and $404,000,000 in the FY 2021 request.

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

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

[4] Includes the consolidation of the 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 $355,112,000, including $98,452,000 for the Patient-Centered Outcomes Research Trust Fund. Figures prior to FY 2021 do not include amounts for the Agency for Healthcare Research and Quality (AHRQ). For information on AHRQ funding history, see the NIRSQ chapter of the NIH Congressional Justification.

SUMMARY OF REQUEST NARRATIVE

The FY 2021 President's Budget request provides a program level of $38.7 billion for NIH, which is $3.0 billion less than the FY 2020 Enacted level of $41.7 billion.

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 ($37.6 billion in FY 2021); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research program ($73.7 million in FY 2021); mandatory budget authority provided for Type 1 Diabetes research ($150.0 million in FY 2021); 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 2021).

The request includes the consolidation into NIH of Agency for Healthcare Research and Quality (AHRQ) activities as a new National Institute for Research on Safety and Quality (NIRSQ). The NIH FY 2021 discretionary budget authority request includes $256.7 million for NIRSQ and the NIH FY 2021 program level includes an additional $98.5 million for the related Patient-Centered Outcomes Research Trust Fund (PCORTF).

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 2021 reflects the allocation of discretionary budget authority for NIRSQ. The Superfund Research program and PCORTF are as lump-sum amounts within the NIH mechanism tables.

In FY 2021, 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 appropriate in special circumstances. Situations that may benefit from such an approach can include, but are not limited to, appropriations for new programs, rapid increases in funding, or variable outyear funding streams (e.g., under the 21st Century Cures Act). The use of upfront funding for new programs makes some base funding available for competing awards in the following year. Up-front funding has increased over the last few years (from two percent of total research grant dollars to nearly six percent in FY 2019), due in part to the large Congressional increases for Alzheimer's disease research. FY 2019 also included a one-time increase in up-front funding 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 were obligated in FY 2019.

Research Project Grants (RPGs)
The FY 2021 President's Budget provides $22.1 billion for RPGs, which is $1.8 billion less than the FY 2020 level. This amount would fund 9,505 Competing RPGs, or 1,874 less than for the FY 2020 level. It would also support 30,109 Noncompeting RPGs, 601 more than the FY 2020 level. In addition, the projected average cost for Competing RPGs of approximately $541,000 would be 1.1% below the FY 2020 projected average cost of nearly $547,000.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) RPGs.** The FY 2021 President's Budget provides $1,035.6 million for SBIR/STTR program grants, which is $83.3 million below the FY 2020 level. The statutory minimum set-aside requirement of 3.65% for NIH-wide SBIR/STTR support is achieved in FY 2021.

Research Centers
The FY 2021 President's Budget provides $2,405.8 million for Research Centers, which is $258.0 million less than the FY 2020 level. This amount would fund 1,135 grants, 102 less than the FY 2020 level.

Other Research
The FY 2021 President's Budget provides $2,440.5 million for this mechanism, which is $223.0 million less than the FY 2020 level. This amount would fund 7,014 grants, which is 494 less than the number of awards projected for FY 2020.

Training
The FY 2021 President's Budget provides $847.7 million for research training, which is $62.2 million below the FY 2020 level. This amount would fund 16,305 Full-Time Trainee Positions (FTTPs), which is 1,342 fewer than planned for FY 2020.

Research & Development (R&D) Contracts
The FY 2021 President's Budget provides $3,077.1 million for R&D contracts, which is $272.3 million less than the FY 2020 level. The requested amount would fund an estimated 2,409 contracts, or 254 fewer than the FY 2020 level.

- **SBIR/STTR R&D Contracts.** The FY 2021 President's Budget includes a $74.4 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts.

Intramural Research (IR)
The FY 2021 President's Budget provides $4,076.6 million for IR, which is $369.3 million less than the FY 2020 level.

Research Management and Support (RMS)
The FY 2021 President's Budget provides $1,926.1 million for RMS, which is $88.5 million less the FY 2020 level.

Office of the Director (OD)
The FY 2021 President's Budget provides $2,208.1 million for OD, which is $196.3 million less than the FY 2020 level.

- **Common Fund (CF)**
  Funding of $596.5 million is allocated for CF-supported programs. This amount is $42.6 million below the FY 2020 level.

- **Office of Research Infrastructure Programs (ORIP)**
  Funding of $268.6 million is allocated for ORIP. This amount is $19.6 million below the FY 2020 level.

- **Other**
  The $1,343.0 million allocated for OD components other than the Common Fund or the Office of Research Infrastructure Programs is a net decrease of $134.1 million from the FY 2020 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 $157.0 million to $109.0 million. The 21st Century Cures Act resources for FY 2021 in OD consists of $109.0 million for the *All of Us* Research Program. The request does not include funding for Regenerative Medicine, for which the final year of 21st Century Cures Act funding was FY 2020.

Buildings & Facilities (B&F)
The FY 2021 President's Budget provides $315.0 million for infrastructure sustainment projects associated with the B&F program, which is $85.0 million more than the FY 2020 level. This amount includes $300.0 million for NIH's Buildings and Facilities appropriation, an increase of $100.0 million from the FY 2020 level, and $15.0 million within the appropriation for the National Cancer Institute (NCI) for facility repair and improvement activities at NCI's Frederick, Maryland, facility. The FY 2021 amount of $15.0 million is an estimate and may increase up to the $30.0 million allowable by law as needs are evaluated.

Superfund Research Program
The FY 2021 President's Budget provides $73.7 million, which is $7.3 million less than the FY 2020 level.

Program Evaluation Financing
The FY 2021 President's Budget provides $741.0 million for Program Evaluation Financing purposes in NIGMS, which is $489.8 million less than the FY 2020 level.

OUTPUTS AND OUTCOMES

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 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 2019: The SEER Program has successfully created linkages with Genomic Health, Inc. (GHI) for the collection of genomic data and with pharmacy vendors for the collection of pharmacy data. Target: Expand SEER to include links with 1-2 outside sources such as biospecimen acquisition, genomics and molecular profile data. (Target Met)	Provide trends and rates specific to the clinically relevant cancer subtypes represented by molecular characterization of each tumor.	N/A	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 2019: The follow-up of all the participants enrolled in this clinical trial has been completed. Target: 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. (Target Met)	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	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 2019: Two unique nanodelivery systems for effective anti-cancer immunotherapeutics were further optimized in different animal models and showed promising results for consideration in clinical trials. Target: Further optimize top two candidate	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	Further optimize the top candidate nanoformulation for co-delivery of antigens, adjuvants and immuno-modulators and evaluate its efficacy towards near and distance metastatic lesions in preclinical	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	nanoformulations for co-delivery of multiple antigens to enhance anti-tumor response in one animal model. (Target Met)	with established tumors.	models with established tumors.	
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 2019: Researchers completed data analyses for evaluating the impact of a community-level combination prevention package on population-level HIV incidence. Target: Complete data analyses to evaluate the impact of a community-level combination prevention package on population-level HIV incidence. (Target Met)	N/A	N/A	N/A
SRO-2.4 By 2025, 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 2019: An NIH-funded study has initiated testing one new potential treatment option for congenital cytomegalovrius (CMV)-induced hearing loss that develops in the first year of life. This study is enrolling infants born infected with CMV yet who have no clinical symptoms (asymptomatic) to treat them with antiviral drugs. Target: Initiate testing one new potential treatment option for a hearing disorder. (Target Met)	Initiate testing one new potential treatment option for a taste disorder.	Initiate testing one new potential treatment option for a disorder affecting voice, speech, or language.	N/A
SRO-2.5 By 2021, develop three non-	FY 2019: All five teams in the Audacious Goals	Translate two novel imaging technologies	Complete development of three	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
invasive imaging technologies that can image retinal cell function and circuitry. (Output)	Functional Imaging Consortium have integrated measurements of cell function with anatomical imaging. Target: Integrate measurements of cell function with anatomical imaging. (Target Met)	from animal studies into human participants.	non-invasive imaging technologies which image retinal cell function and circuitry.	
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 2019: Researchers identified sex differences in three environmentally induced epigenomic signatures in three different mouse tissues. Target: Determine and identify, if present, sex differences in three environmentally induced epigenomic signatures in three different mouse tissues. (Target Met)	Determine and identify, if present, sex differences in four additional environmentally induced epigenomic signatures in three different mouse tissues.	N/A	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 (AMD) using patient-derived stem cells. (Outcome)	FY 2019: The IND application was submitted in 2019, but FDA has not yet given approval to enroll patients into Phase I clinical trial. Target: Recruit three AMD patients into Phase I clinical trial. (Target Not Met but Improved)	Recruit 3 AMD patients into Phase I clinical trial.	Complete Phase I trial enrollment to treat a total of 12 AMD patients.	N/A
SRO-2.8 By 2023, advance the development of three novel drug or biologic therapeutic candidates	FY 2019: For the target mechanisms of inflammation and synaptic plasticity, 12 candidate therapeutic agents were	Complete preclinical proof of concept in animal models of AD for 3-5 new	Initiate Investigational New Drug-enabling studies for 2-3 new	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
for Alzheimer's disease (AD) or related dementias toward the point of entry into Phase I human studies. (Output)	selected to undergo preclinical optimization studies. Target: For each of the novel therapeutic targets, select 3-5 candidate therapeutic agents for entry into preclinical optimization studies. (Target Exceeded)	candidate therapeutics.	candidate therapeutics.	
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	FY 2019: NIH-funded investigators completed final analysis of an open-label extension study that built on the findings of an earlier trial and aimed to assess the continued safety of the dapivirine vaginal ring and study participants' adherence to its use. Target: Strategy 3: Complete final analysis of an open-label extension study that builds on the findings of an earlier trial and aims to assess the continued safety of the dapivirine vaginal ring in a more real-world context and study participants' adherence. (Target Met)	Strategy 1: Complete follow-up of participants in at least one of the studies testing the safety, tolerability, and effectiveness of VRC01.	Strategy 1: Analyze data of two studies testing the safety, tolerability, and effectiveness of VRC01 broadly neutralizing antibody (bnAb).	N/A
SRO-2.10 By 2024, 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 2019: Seven interdisciplinary translational projects have advanced in the FDA review process. Target: Submit an Investigational New Drug (IND) application for an FDA-approved tissue regeneration combination	Initiate pre-clinical animal studies that will lead to the development of regenerative medicine therapies of human dental, oral, and craniofacial diseases and conditions.	The Resource Centers will facilitate the development of five Investigational New Drug (IND)/Investigational Device Exemption (IDE) applications from the current pool of Interdisciplinary	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	product. (Target Met)		Translational Projects.	
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 2019: The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative Public-Private Partnership Program initiated testing of brain stimulation devices for six new therapeutic indications in humans and continued to enable current and potential BRAIN investigators to gain access to medical device tools and technologies from some of the top medical device manufacturers. Target: Test new and/or existing brain stimulation devices for two new therapeutic indications in humans through the BRAIN Public Private Partnership. (Target Exceeded)	Provide broad access to new research approaches and techniques for acquiring fundamental insight about how the nervous system functions in health and disease.	Expand our understanding of brain function at the cellular or circuit level using 3-5 new tools and technologies.	N/A
SRO-2.13 By 2023, advance the development of 1-2 new drugs and/or other therapeutic candidates for neurological diseases from lead optimization or device development toward the point of preparedness for first-in-human studies. (Output)	FY 2019: A total of seven therapeutic and device candidates have been identified and advanced for animal toxicology studies. Target: Identify and characterize 2-4 therapeutic or device candidates in preparation for animal toxicology studies. (Target Exceeded)	Initiate animal toxicology studies for 1-2 therapeutic or device candidates.	Determine the margin of safety for 1-2 therapeutic or device candidates.	N/A
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use	FY 2019: Research in animal models has demonstrated that adolescent alcohol exposure results in a persistent loss of	Examine how individual differences in neurobiology contribute to	Conduct preclinical studies to identify persistent neurobiological adaptations that	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
or other childhood experiences. (Outcome)	cholinergic cells in the basal forebrain, an adaptation associated with cognitive dysfunction. Target: Continue to evaluate the impact of adolescent alcohol or other substance use on brain development. (Target Met)	adolescent substance taking behavior and related health outcomes.	occur as a result of exposure to alcohol during adolescence.	
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 2019: NIH developed the Placental Atlas Tool to provide a collaborative research and discovery platform for the placental research community. Target: 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. (Target Met)	Identify two biomarkers that are associated with placental development and/or function.	Utilize one innovative technology to characterize longitudinal changes in normal vs. abnormal placenta during pregnancy.	N/A
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2019: Researchers have treated four patients with treatment-resistant juvenile dermatomyositis (JDM) with a Janus Kinase (JAK) inhibitor for over one year. Patients have shown clinical and laboratory evidence of a beneficial and sustained response. Target: 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	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	(Target Met)			
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 2019: The BrIDGs program completed necessary studies for a project to file an IND application with FDA. Target: Initiate formal GLP toxicology studies for 1-3 projects. (Target Met)	Enable 1-3 BrIDGs projects to have sufficient pre-clinical data for therapeutic agents in order to apply for IND approval from the FDA.	N/A	N/A
SRO-4.3 By 2020, advance our characterization and understanding of the cellular and genetic components that make up the diverse composition of most tumors. (Outcome)	FY 2019: Researchers have identified cells and associated molecules in numerous cancer types that show promise in understanding and managing cancer. Examples include specific immune cells in breast cancer, neuroblastoma, head and neck, and pancreatic cancer Target: Identify the role various cellular components play in the phenotype of the 3 cancers. (Target Met)	Based on new understanding of tumor composition, develop three computational models to explore new knowledge and treatments.	N/A	N/A
SRO-4.4 By 2019, discover the molecular basis for 60 rare diseases. (Output)	FY 2019: The molecular bases of 28 rare diseases were discovered. Target: Discover the molecular bases of an additional 10 rare diseases (Target Exceeded)	N/A	N/A	N/A
SRO-4.8 By 2019, establish a sharable collection of positive Zika virus (ZIKV) biospecimens to increase	FY 2019: A sharable biorepository, containing biospecimens from ZIKV-infected blood donors who participated in the 2016-	N/A	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
knowledge of viral infection and associated host immune response to help evaluate potential strategies to ensure the safety of the blood supply. (Output)	2018 US Natural History Study, was successfully established and completed. Target: 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. (Target Met)			
SRO-4.9 By 2020, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2019: A pre-clinical study of a novel opiate withdrawal therapy was conducted, and a clinical trial of a therapy for both opioid withdrawal and associated insomnia was also conducted. Target: Conduct one pre-clinical study and one clinical trial to develop non-opioid based medications to treat OUD that may avoid the risks of opioid dependence and overdose. (Target Met)	Conduct one pre-clinical and one clinical study of a longer acting formulation of a medication for the treatment of opioid use disorders or opioid overdose.	N/A	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 2019: Discussions with the FDA facilitated articulation and achievement of milestones for commercial viability. Target: 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	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	(Target Met)			
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 2019: A system was developed for rapid and high-fidelity insertion of two T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line. Target: Develop a system for rapid and high-fidelity insertion of two T1D-associated risk alleles into a human induced pluripotent stem cell (iPSC) line. (Target Met)	Use in vivo model(s) carrying iPSC-derived human beta cells to test the efficacy of two approaches aimed at enhancing beta cell viability and/or expansion.	N/A	N/A
SRO-4.12 By 2019, evaluate weight-related, psychosocial, and metabolic outcomes in response to treatment of adolescents with severe obesity. (Outcome)	FY 2019: The impact of the impact of bariatric surgery for severe obesity during adolescence on weight-related and psychosocial and behavioral outcomes was evaluated. Target: By 2019, evaluate the impact of bariatric surgery for severe obesity during adolescence on weight-related and psychosocial and behavioral outcomes. (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 2019: Researchers tested three health risk reduction models with the potential to reduce premature mortality in adults with SMI. Target: Conduct testing of three health risk reduction models that have potential to reduce premature mortality in adults with	Conduct testing of an additional three health risk reduction models that have potential to reduce premature mortality in adults with SMI.	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	SMI. (Target Met)			
SRO-4.15 By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations. (Output)	FY 2019: Researchers tested the *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide's* two-question screening tool to determine its predictive ability in identifying future risk for alcohol-related problems in an underage population. Target: Test a screening and brief alcohol intervention in an underage population. (Target Met)	Test a behavioral therapy for intervening with alcohol misuse in an underage population.	Test another 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 translating cancer knowledge, clinical interventions, or behavioral interventions to underserved communities in community-based clinical settings. (Outcome)	FY 2019: Two U54 Partnerships to Advance Cancer Health Equity finalized testing and validating evidence-based interventions and tools to help translate basic cancer knowledge and clinical or behavioral interventions to underserved communities across the United States. They continue to work with various community-based organizations to disseminate these interventions and tools. Target: Finalize testing and validating the strategies to translate basic cancer knowledge, clinical or behavioral interventions to underserved communities and into clinical practice. (Target Met)	Finalize testing and validating the strategies to translate basic cancer knowledge, clinical or behavioral interventions to underserved communities and into clinical practice.	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
SRO-5.2 By 2025, develop or evaluate the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD). (Outcome)	Note: SRO-5.2 will begin reporting in December 2020.	Conduct 3-5 pilot studies to test the efficacy of promising prevention interventions for SUD.	Complete 1-2 pilot studies to test the efficacy of a prevention intervention for SUD.	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-onset Alzheimer's disease. (Output)	FY 2019: The Alzheimer's Disease Sequencing Project (ADSP) Follow-Up Phase has begun its analysis of genomic regions of interest using whole genome sequence data from ethnically diverse cohorts. The ADSP has continued its confirmation of genomic regions identified in the Discovery Phase of the Project. Genetic data for all phases of the ADSP have been harmonized. Target: Begin analysis of genomic regions of interest in the ADSP Discovery Follow-Up Phase using whole genome sequence data from ethnically diverse cohorts. Continue confirmation of genomic regions of interest in the Discovery Phase using samples from the Follow-Up Phase. Continue harmonization of Discovery Phase and Follow-Up Phase datasets. (Target Met)	Continue analysis of ADSP Discovery Follow-Up Phase in ethnically diverse cohorts. Continue confirmation of genomic regions of interest from Discovery Phase and Discovery Follow-Up Phase in ethnically diverse datasets. Compare data on genomic regions of interest by ethnicity.	Continue analysis of ADSP Discovery Follow-Up Study in ethnically diverse cohorts. Continue confirmation of genomic regions of interest from Discovery Phase and Discovery Follow-Up Phase in ethnically diverse datasets. Begin harmonization of phenotypic data with ADSP genetic data across multiple types of study approaches from large epidemiology and clinical cohorts that are outside of the ADSP.	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 2019: Evaluated two alternative HIV vaccine candidates' suitability for human testing. Target: Evaluate 1-2 alternative HIV vaccine	Further explore identification of correlates of protection in non-human primate animal models.	Enroll half (1,900) of the 3,800 participants needed for a Phase 3 vaccine study.	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	candidates' suitability for human testing. (Target Met)			
SRO-5.10 By 2020, assess the effectiveness of five to seven interventions that focus on eliminating health disparities by utilizing community partnerships to conduct intervention research that will foster sustainable efforts at the community level that will impact disparate conditions. (Output)	FY 2019: The intervention projects have completed approximately 90 percent of enrollment. Projects have initiated assessments of the interventions' outcomes and are developing plans for data sharing and dissemination of results. Target: Assess intervention progress and collect fourth year assessment variables. (Target Met)	Complete analyses of five to seven community-based participatory research interventions to determine effectiveness in impacting health disparity conditions.	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 2019: Researchers characterized mouse models in which stem cell participation in wound healing is impaired or could be enhanced. One study showed that a population of fat precursor cells needed to repair skin wounds is decreased in aged mice. Two other studies in mice uncovered different mechanisms by which wound healing by stem cells in the skin might be improved. Target: Develop and/or characterize a mouse model in which skin stem cell participation in wound repair is impaired. (Target Met)	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	N/A
SRO-5.13 By 2022, complete research to the pre-clinical stage of	FY 2019: Researchers developed methods to non-invasively deliver	Initiate research of a prototype technology that uses acoustic,	Conduct research on continued development and	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	therapeutics across the blood-brain barrier and track the exact dose and location the drugs reach to treat brain disease. Target: Initiate research to test and refine one new or improved technology that uses acoustic, optical or electromagnetic waves to manipulate cells for treatment of illness. (Target Met)	optical, or electromagnetic waves as a test case in a specific disease.	preliminary testing of one prototype technology that uses acoustic, optical, or electromagnetic waves to manipulate cells for treatment of a specific disease and begin to develop a plan for initiating the regulatory process.	
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 2019: The Transfusion of Prematures (TOP) Trial completed enrollment of 1,824 participants. Target: Complete enrollment in transfusion study. (Target Met)	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	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 2019: Researchers demonstrated the efficacy of interventions involving brief motivational interviewing and a supplemental activity for reducing alcohol misuse among college age individuals. Target: Develop an intervention to prevent or reduce alcohol misuse among college age individuals. (Target Met)	Develop a digital technology-based intervention to prevent or reduce alcohol misuse in underage individuals.	Disseminate information to the public about evidence-based interventions for underage populations.	N/A
SRO-5.16 By 2021, conduct research to support pharmaceutical labeling changes for five drugs, to reflect safe and	FY 2019: The multi-center digoxin study, which aims to study pharmacokinetics and safety of digoxin in children less than six	Obtain preliminary pharmacokinetic results to help assess the safety for mothers and infants	Assess pharmacokinetics, pharmacodynamics, and safety of 5 drugs	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
appropriate dosing and use specifically in children. (Outcome)	months old, launched in August 2019. The study is currently enrolling participants. Target: Begin one Phase III clinical trial for drug development. (Target Met)	of at least three common, off-patent drugs when used by breastfeeding women.	in pediatric populations.	
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	FY 2019: Studies found that a family-centered advance planning intervention improved end-of-life care communication between individuals living with HIV and their family surrogate decision-makers. Target: Test at least one novel strategy for improving care for patients with advanced illness through shared decision-making. (Target Met)	Develop and test one novel strategy for improving end-of-life/palliative care through better support of family members and informal caregivers.	Develop and test at least one effective intervention for improving quality of life for patients at the end of life through enhanced shared decision-making and support of 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 2019: The baseline data from the three Restoring Insulin Secretion protocols (pediatric medication, adult medication, and adult surgery) were analyzed. Target: 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. (Target Met)	Complete final visits and analyze the data from the Restoring Insulin Secretion adult medication study.	Complete all final participant visits in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study, according to the study protocol.	N/A
SRO-6.2 By 2025, advance 1-2 new or repurposed compounds	FY 2019: Researchers conducted a human laboratory study to evaluate	Evaluate one compound with potential for treating	Conduct a preclinical evaluation of a novel or repurposed	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	the safety of the ghrelin receptor blocker PF-5190457 as a potential treatment for alcohol use disorder when administered in combination with alcohol. Target: Conduct at least one human laboratory study to evaluate the safety and efficacy of candidate compounds for treating alcohol or other substance use disorders. (Target Met)	alcohol and other substance use disorders in a clinical trial.	compound that acts on neurobiological targets implicated in alcohol use disorder.	
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 2019: Development of five promising interventions to prevent or treat substance use disorders or to improve medication adherence have been initiated. Target: Develop and/or evaluate two HIT-based interventions to prevent or treat substance use disorders or to improve medication adherence. (Target Exceeded)	Develop and test 1-2 FDA-approved digital therapeutic interventions for substance use disorder treatment and/or medication adherence.	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 2019: Award rate to comparison group reached 11 percent. Target: N ≥ 10% (Target Met)	N ≥ 10%	N ≥ 10%	N/A
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2019: Award rate to comparison group reached 15 percent and exceeded target by five percent. Target: N ≥ 10%	N ≥ 10%	N ≥ 10%	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	(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 2019: NBS implemented Fund Configuration Initiative as planned. Target: (Development [Dev]) Continue development of remediation activities to comply with HHS Accounting Treatment Manual and other Treasury Mandates to increase accuracy and functionality of the NBS. (Target Met)	(Deployment [Dep]) Conduct priority deployment activities for the Funds Configuration Initiative to comply with one of the NIH Corrective Action Plan remediation efforts.	(Development [Dev]) Continue to conduct priority deployment activities for the NIH Corrective Action Plan remediation efforts.	N/A
CBRR-4 By 2021, produce and phenotype 2,500 knockout 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 2019: Over 600 knockout juvenile lines were characterized (phenotyped). Target: Deliver phenotyping on 600 knockout juvenile lines. (Target Exceeded)	Deliver phenotyping on 600 knockout juvenile lines.	Provide a cumulative total of 2,500 knockout mouse juvenile lines and associated resources to support research into gene function and human diseases.	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 2019: Nine active multi-site clinical trials are active in the Trial Innovation Network of the CTSA program. Target: Launch at least two multi-site clinical trials within the CTSA trial innovation network. (Target Met)	N/A	N/A	N/A
CBRR-6 By 2019, launch and establish a Biomedical Citizen Science Hub to serve as an online collaboration space for biomedical	FY 2019: There are more than 300 registered users of the site and more than five subgroups for the Biomedical Citizen Science Hub.	N/A	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
citizen science research efforts in cancer biology. (Output)	Target: Establish 200-300 registered users of the site and 5 subgroups for the Biomedical Citizen Science Hub. (Target Met)			
CBRR-9 By 2020, enroll a total of 3,010 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	FY 2019: A cumulative 2,584 participants were enrolled in GenomeConnect. Target: Enroll 2,002 cumulative participants in GenomeConnect. (Target Exceeded)	Enroll a total of 3,010 participants in GenomeConnect, ClinGen's Patient Registry.	N/A	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 2019: More than 50 children were enrolled in the PHN in 2019. 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.	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	FY 2019: Data collection is complete in US, Mexico, and England. Results from these efforts were reviewed and used to refine assessment protocols to increase sensitivity and specificity. Target: Review results from the assessment protocol as deployed in the US in 2016-2017 and in other countries in 2017 and 2018. Refine protocol as needed to increase sensitivity and specificity.	Make data from the Harmonized Cognitive Assessment Protocol (HCAP) publicly available to the research community and initiate a follow-up study to the HCAP.	Complete follow-up assessment in the Health and Retirement Study using the refined HCAP.	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	(Target Met)			
CBRR-19 By 2019, identify and characterize 1,900 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 2019: 199 T cell and 275 B cell epitopes from infectious disease pathogens and 312 T cell epitopes from allergens were identified and characterized. Target: 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. (Target Not Met)	N/A	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 2019: More than 10 vaccine and therapeutic candidate products were advanced in FY 2019. Target: Advance the preclinical development of three vaccine and/or therapeutic candidate products. (Target Exceeded)	Advance the preclinical development of four vaccine and/or therapeutic candidate products.	N/A	N/A
CBRR-21 By 2020, establish and implement a national collaborative Pilot and Feasibility (P&F) program that utilizes specialized equipment, and expertise in nonmalignant hematology that are available through the Cooperative Centers of Excellence in Hematology (CCEH). (Output)	FY 2019: Eight P&F projects involving collaborations outside of the hematology Centers were supported in FY 2019. Target: Support two P&F projects involving collaboration outside the hematology Centers. (Target Met)	Support four P&F projects involving collaboration outside the hematology Centers.	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
CBRR-22 By 2020, establish a reference map that will serve as the framework to understand the development of the human urinary tract. (Outcome)	FY 2019: Five types of epithelial cells in the human prostate were identified and mapped. Target: Identify and map at least five specific cell types or subtypes within the kidney, urinary outflow tract, and/or prostate. (Target Met)	Generate and release the human/mouse comparative atlases to the general public.	N/A	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 2019: NIH supported approximately 15,000 sample analyses involving 7 new studies. The results from 2,322 sample analyses or two studies are available to the broader scientific community; the results from an additional 14,741 sample analyses or 10 studies are currently under embargo pending initial client publication. Target: 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. (Target Met)	N/A	N/A	N/A
CBRR-24 By 2019, pilot test and assess alternative funding mechanisms such as program-focused awards. (Output)	FY 2019: The proportion of NIGMS grantees who are Maximizing Investigators' Research Award (MIRA) recipients increased by five percentage points from FY 2017 to FY 2018. Target: Expand by five percent the proportion of	N/A	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
	NIGMS-supported investigators funded by active R01-equivalent awards who are MIRA recipients. (Target Met)			
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 2019: Trainees from diverse backgrounds received a total of 3,797 career experiences across all career stages. Target: 3,522 career experiences across all career stages. (Target Exceeded)	3,539 career experiences across all career stages	3,540 career experiences across all career stages	N/A
CBRR-26 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA (Institutional Development Award) Networks of Biomedical Research Excellence (INBRE) program in order to sustain a pipeline of undergraduate students who will pursue health research careers. (Output)	FY 2019: Approximately 1,450 undergraduate students participated in mentored research experiences, consistent with 2018 level. Target: Sustain the number of undergraduate mentored research experiences from 2018 level. (Target Met)	Sustain the number of undergraduate mentored research experiences from 2019 level.	Sustain the number of undergraduate mentored research experiences from 2020 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 2019: Researchers validated the Computerized Adaptive Screening in a study of adolescent patients in emergency care settings. Target: 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	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 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 2019: Brain tissue from 75 donors was obtained and tissue or data were distributed to 35 researchers. Target: 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. (Target Exceeded)	Collect brain tissue from an additional 50 new donors and distribute tissue samples or data derived from tissue to 20 researchers studying mental or neurological disorders.	Collect brain tissue from an additional 50 new donors and distribute tissue samples or data derived from tissue to 20 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 2019: Cerebrovascular Reactivity (CVR) biomarker kit protocol was finalized, staff at all four participating validation sites were trained, and sites began enrolling subjects and acquiring data. Target: Initiate multi-site validation studies for one candidate biomarker. (Target Met)	Initiate multi-site validation studies for two additional biomarker candidates.	N/A	N/A
CBRR-30 By 2024, expand the use of program-focused versus target-focused award mechanisms by NIGMS investigators. (Output)	Note: CBRR-30 will begin reporting in December 2021.	N/A	Expand NIGMS investigator participation in the Maximizing Investigators' Research Award (MIRA) program by 2 percentage points.	N/A
CTR-7 By 2022, engage a national community in the development, dissemination, and implementation of a comprehensive national	FY 2019: Stakeholders convened to share updates and discuss progress made towards implementation of the goals and objectives in the National Action Plan.	Analyze completed webinars and meetings, and brief stakeholders on Action Plan progress.	Analyze completed webinars and meetings, and brief stakeholders on Action Plan progress.	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
strategy to address the burden of chronic obstructive pulmonary disease in the US. (Output)	Target: Analyze completed webinars and meeting, and brief stakeholders on Action Plan progress. (Target Met)			
CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform agency funding decisions, and promote transparency regarding the agency's funding strategies. (Output)	FY 2019: NIH developed a publicly available, trans-NIH report that displays Institute/Center-specific funding priorities and statistics on R01-equivalent grants. Target: By 2019, develop a central public report displaying NIH Institute/Center-specific award data on investigator-initiated R01/R37 grants. (Target Met)	By 2020, develop a central standard report to describe NIH research investments to organizations receiving R01-equivalent and Research Project Grant support according to Carnegie Classification and Funding Institute/Center.	N/A	N/A
MPO-2 Provide opportunities for enhanced leadership skills to meet the challenges of workforce management and/or individual advancements. (Output)	FY 2019: NIH examined the Management Seminar Series by conducting pre- and post-session surveys. As a result of this examination, the agenda topics covered were adjusted. The feedback generated from the series indicated that participants applied discussed concepts immediately. Target: 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. (Target Met)	N/A	N/A	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2019: NIH pulled and analyzed various data sets to investigate if there was an efficient method to forecast and plan recruitment cycles based on recruitment trend data across the NIH. Target: 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. (Target Met)	Examine (EX) key area to enhance recruitment - Examine use of the shared recruitment approach, using data gathered in the first year of full-time practice, to determine if hiring goals are being met. [IM 2021/AS 2022]	Assess [AS] results of implementation - Assess process in place to identify the most opportune times throughout the year for NIH to recruit for varying occupations. [EX 2019/IM 2020]	N/A
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2019: 25 percent of Principal Investigators were reviewed resulting in approximately 25 percent of resources recommended to be reallocated. Target: Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources. (Target Met)	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	N/A
MPO-5 Improve facility conditions in order to reach and maintain a Condition Index (CI) weighted average of 85 or above (CIwa=85). (Ongoing) (Output and Efficiency)	FY 2019: The condition of the facilities portfolio reached a CIwa of 81.91. Target: CIwa = 79.51 (Target Exceeded)	CIwa = 77.78	CIwa=77.63	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100 percent of the final	FY 2019: 29 of the 34 active funded projects at the Facility Project Approval Agreement level threshold were effectively managed to ensure completion within	25 Active Projects	21 Active Projects	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
approved project cost. (Ongoing) (Output)	100 percent of the final approved cost. Target: 23 Active Projects (Target Exceeded)			
MPO-8 Manage design and construction of capital facility projects funded by Building and Facilities (B&F) so that no more than 10 percent of the projects may incorporate plus or minus 10-percent adjustments of the approved scope. (Ongoing) (Output)	FY 2019: NIH managed the design and construction of 29 of the 34 funded projects without a plus or minus 10-percent adjustment to the scope. Target: 23 Active Projects (Target Exceeded)	25 Active Projects	21 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2019: Obligated 47 percent of eligible service contracting dollars to PBC. Target: Obligate the FY 2019 goal of eligible service contracting dollars to PBC. (Target Met)	Obligate the FY 2020 goal of eligible service contracting dollars to PBC.	Obligate the FY 2021 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 2019: Four clusters of study sections were evaluated, with approximately 10 study sections in each cluster. Some new measures were developed during this process and added to the data considered. Target: Refine and test measures of peer review quality and efficiency. (Target Met)	N/A	N/A	N/A
MPO-11 Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-	FY 2019: Of the 109 active awards, 89 instruments (82 percent) were installed within 18 months of the	Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-	Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-	N/A

Measure[1]	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
supported research institutions across the nation. (Output)	Notice of Award date. Target: 75 percent of the awarded state-of-the-art instruments are acquired and installed at NIH-supported research institutions 18 months after award. (Target Exceeded)	supported research institutions across the nation 18 months after award.	supported research institutions across the nation 18 months after award.	
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 2019: NIH has implemented a policy that expects all NIH-funded clinical trials to register and submit results to ClinicalTrials.gov for all applications for grant funding, other transactions, and contracts submitted after January 18, 2017. Target: 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. (Target Met)	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	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 2021 as the National Institutes for Research on Safety and Quality (NIRSQ). For information on AHRQ performance measures, see the NIRSQ chapter of the NIH Congressional Justification.

GRANT AWARDS TABLE

	FY 2019 Final Allocation[3]	FY 2020 Enacted[3]	FY 2021 President's Budget[3,4]
Number of Awards	48,996	51,772	49,756
Average Award (in Whole $s)	$563,992	$563,569	$541,362
Range of Awards (in Whole $s)[1,2]	$1,000 to $29,408,845	$1,000 to $34,673,751	$1,000 to $34,343,806

[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] The number of awards 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).

NEF NARRATIVE

Budget Summary
(Dollars in Thousands)

	FY 2019[33]	FY 2020[34]	FY 2021[35]
Notification[36]	$96,000		TBD
Congressional Allocation		$225,000	

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 (B&F) appropriations. The projects described below received NEF funds in FY 2016, FY 2017, and FY 2019.

In FY 2016, NIH received $162.1 million from the NEF for the Renovation of the E-Wing in the NIH Clinical Center Complex (CCC) - Building 10 (B10). The mission of NIH is to uncover new knowledge that leads to better health for everyone. It is a "bench to bedside" research and training mission requiring both hospital and biomedical research laboratory functions. The CCC on the Bethesda Campus is a group of facilities that collectively support this mission. B10 is a 66-year-old facility built over two years beginning in 1950 that provides clinical services, laboratories, and supporting office space. With failing infrastructure, the condition of B10 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:

[33] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018. Amount shown is notified amount, including $12,959 thousand not released to NIH.
[34] HHS has not yet notified for FY 2020. Amount shown is amount allocated to NIH from the NEF per Section 237 of Division A of the Further Consolidated Appropriations Act, 2020.
[35] HHS has not yet notified for FY 2021.
[36] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

- Impacting accreditation by The Joint Commission and College of Anatomical Pathologists relating to the 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
- Failing to fulfill its mission.

The renovation of the E-Wing in B10 provides major new research laboratory space replacing laboratories from aged distal wings in the complex and provides replacement of critical Clinical programs, including the Department of Transfusion Medicine. It also provides critical new state-of-the-art current Good Manufacturing Practice (cGMP) facilities to further develop Cellular Engineering initiatives for all Institutes requiring Cell Processing.

In FY 2017, NIH received $35.3 million from the NEF for R22 Refrigerant Chiller replacement. This project involves replacing one of the six existing R22 chillers, a York 5,000-ton dual steam turbine/electric driven chiller (CH-16) in Building 11, with two new 3,000-ton variable speed electric chillers and associated cooling towers. Three additional chillers (CH-17,18 and 19) will be replaced between FY 2021 and FY 2024 using B&F funds. Due to the efficiency achieved in the chilled water upgrades accomplished between 2013 and 2015, and the additional efficiency and capacity of the two new chillers, the remaining R22 chillers (CH-20 and 21) 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.

Also in FY 2017, NIH received $16.5 million from the NEF for Emergency Generators to support the Centralized Utility Plant (CUP). The original scope of this project was to install three 2,500-kilowatt (KW) emergency generators and associated electrical gear adjacent and within the Building 11 Central Utility Plant (CUP) to feed enough power to run three steam-driven Chillers (21, 22 and 23). The Cogeneration (COGEN) Plant at NIH, which runs on natural gas, is unique in that it is believed to be the most efficient source of electrical power and steam from a stand-alone system in the world. The plant has the capability of delivering 22 megawatts (MW) of power to various substations on the Bethesda Campus, which in turn feeds the CUP. The new scope of work for this project is to direct the new emergency power generator or generators (2000 KW total) toward the startup of the COGEN plant should a loss of power occur from the local electrical utility service. In order to protect the critical mission of the NIH from disruption if the electric utility service for any reason suffers a severe voltage reduction or loss of the electrical system, the COGEN system and campus electric distribution system would automatically shut down and restart by energizing the COGEN plant through the new emergency generation system. This system will guarantee uninterrupted cooling and steam service to the most critical facilities on campus.

In FY 2019, NIH received $63.5 million from the NEF for a new CCC Utility Vault and Parking Garage. This project is for the completion of a new, 330,000 gross square foot (GSF) Utility Vault and Multi-Level Parking Garage to serve the CCC. The new Utility Vault and Parking Garage will ensure the reliability and long-term sustainability of the electrical power feeds to the 4.5 million square foot hospital and biomedical research complex and will mitigate the security risk, personal safety risk, and liability risk associated with the existing underground parking garage.

Also in FY 2019, NIH received $19.5 million from the NEF for Electrical Power Reliability at the CCC. The CCC is composed of three major structures, including the original B10, the Ambulatory Care Research Facility (ACRF), and the CRC, built in 1952, 1980, and 2005, respectively. This project consists of two major initiatives in order to achieve electrical power reliability in the CCC, including electrical vault decommissioning and upgrades to existing electrical vaults. NIH will decommission the existing vaults and fully remove existing equipment in vaults 6 and 10, including environmental requirements for removal of transformers contaminated with Polychlorinated biphenyls (PCB). NIH will replace and upgrade electrical vaults 7, 8 and 9, one vault at a time, while maintaining full functional service to the CCC in subsequent years using B&F funds.

In the FY 2020 Enacted Appropriations bill, NIH was allocated $225 million from NEF for building and facilities related investments pursuant to Section 237 of Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), provided:

> Of the unobligated balances available in the ‘‘Nonrecurring Expenses Fund’’ established in section 223 of division G of Public Law 110–161, $225,000,000, in addition to any funds otherwise made available for such purpose in this or subsequent fiscal years, shall be available for buildings and facilities at the National Institutes of Health.