APPROPRIATIONS LANGUAGE

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$6,364,852,000]*$6,539,302,000*, 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, [$3,664,811,000]*$3,845,681,000*.

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, [$484,867,000]*$516,197,000*.

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, [$2,131,975,000]*$2,219,298,000*.

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, [$2,463,393,000]*$2,707,300,000*.

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, [$6,069,619,000]*$6,245,926,000*.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, [$2,991,417,000]*$3,096,103,000*, of which $1,271,505,000 shall be from funds available under section 241 of the PHS Act: *Provided*, That not less than [$396,573,000]*$410,453,000* 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, [$1,590,337,000]*$1,942,117,000*.

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, [$835,714,000]*$858,535,000*.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, [$814,675,000]*$937,107,000*. (Department of Health and Human Services Appropriations Act, 2021.)

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, [$81,500,000]*$83,540,000*. (Department of the Interior, Environment, and Related Agencies Appropriations Act, 2021.)

NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, [$3,899,227,000]*$4,035,591,000*.

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, [$634,292,000]*$680,186,000*.

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, [$498,076,000]*$511,792,000*.

NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research, [$174,957,000]*$199,755,000*.

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, [$554,923,000]*$570,165,000*.

NATIONAL INSTITUTE ON DRUG ABUSE

For carrying out section 301 and title IV of the PHS Act with respect to drug abuse, [$1,479,660,000]*$1,852,503,000*.

NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, [$2,053,708,000]*$2,137,574,000*.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, [$615,780,000]*$632,973,000*.

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, [$410,728,000]*$422,039,000*.

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, [$154,162,000]*$184,323,000*.

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, [$390,865,000: *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] *$652,244,000*.

JOHN E. FOGARTY INTERNATIONAL CENTER

For carrying out the activities of the John E. Fogarty International Center (described in subpart 2 of part E of title IV of the PHS Act), [$84,044,000]*$96,322,000*.

NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, [$463,787,000]*$474,864,000*: *Provided*, That of the amounts available for improvement of information systems, $4,000,000 shall be available until September 30, [2022]*2023*: *Provided further*, That in fiscal year [2021]*2022*, 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, [$855,421,000]*$878,957,000*: *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 $586,841,000 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, [$2,411,110,000]*$2,237,259,000*: *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 shall be for the

Environmental Influences on Child Health Outcomes study: *Provided further*, That] [$635,939,000]*$645,939,000* 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] *up to $30,000,000* shall be used to carry out section 404I of the PHS Act (42 U.S.C. [283K), relating to biomedical and behavioral research facilities]*283k) with respect to the National Primate Research Centers and Caribbean Primate Research Center*: *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] *notification to* 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 [2021 and]2022 *and 2023* 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*, of which $3,000,000 shall be derived from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code*. (Department of Health and Human Services Appropriations Act, 2021.)

[(INCLUDING TRANSFER OF FUNDS)]

[For an additional amount for "Office of the Director", $1,250,000,000, to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally: *Provided*, That of the amount appropriated under this heading in this Act, $1,150,000,000 shall be provided for research and clinical trials related to long-term studies of COVID-19: *Provided further*, That of the amount appropriated under this heading in this Act, no less than $100,000,000 shall be for the Rapid Acceleration of Diagnostics: *Provided further*, That funds appropriated under this heading in this Act may be transferred to the accounts of Institutes and Centers of the National Institutes of Health (NIH): *Provided further*, That this transfer authority is in addition to any other transfer authority available to the NIH: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.] (Coronavirus Response and Relief Supplemental Appropriations Act, 2021.)

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]*$250,000,000*, to remain available through September 30, [2025]*2026*. (Department of Health and Human Services Appropriations Act, 2021.)

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, [$404,000,000]*$496,000,000*, 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, 2021.)

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to advanced research projects for health, $6,500,000,000, to remain available through September 30, 2024.

GENERAL PROVISIONS

SEC. 216. Not to exceed [$45,000,000] *1 percent* of funds appropriated by this Act to the *offices,* institutes and centers of the National Institutes of Health may be [used for alteration, repair, or improvement of facilities, as necessary for the proper and efficient conduct of the activities authorized herein, at not to exceed $3,500,000 per project] *transferred to and merged with funds appropriated under the heading "National Institutes of Health-Buildings and Facilities": Provided, That the use of such transferred funds shall be subject to a centralized prioritization and governance process: Provided further, That the Director of the National Institutes of Health shall notify the Committees on Appropriations of the House of Representatives and the Senate at least 15 days in advance of any such transfer: Provided further, That this transfer authority is in addition to any other transfer authority provided by law*. (Department of Health and Human Services Appropriations Act, 2021.)

LANGUAGE ANALYSIS

Language Provision to be Changed	Explanation/Justification
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES [: *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].	This provision may be removed, since the reorganization of NIMHD is expected to be completed by the end of FY 2021.
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 $586,841,000 is provided to the Clinical and Translational Sciences Awards program].	The removal of this provision would give NCATS flexibility in the amounts allocated to the Clinical and Translational Sciences Awards (CTSA) program in order to preserve flexibility in managing its budget within the President's Budget request level.
OFFICE OF THE DIRECTOR [$180,000,000 shall be for the Environmental Influences on Child Health Outcomes study: *Provided further*, That]	The removal of this provision permits a planned transfer of the ECHO program from OD to NICHD.
OFFICE OF THE DIRECTOR That [$50,000,000] *up to $30,000,000* shall be used to carry out section 404I of the PHS Act (42 U.S.C. [283K), relating to biomedical and behavioral research facilities]*283k) with respect to the National Primate Research*	The FY 2022 President's Budget does not request continued funding for the construction and renovation of extramural research facilities. It proposes refocusing funding on non-human primate infrastructure.

Language Provision to be Changed	Explanation/Justification
Centers and Caribbean Primate Research Center	
OFFICE OF THE DIRECTOR *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] *notification to* the Committees on Appropriations of the House of Representatives and the Senate	Revised text clarifies that the requirement in this provision is for Congressional notification of transfers between activities.
OFFICE OF THE DIRECTOR *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.*	This provision authorizes the use of funds for the establishment, operation, and support of the Research Policy Board.
OFFICE OF THE DIRECTOR [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*, of which $3,000,000 shall be derived from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code.*	The 10-Year Pediatric Research Initiative Fund is expected to have insufficient balances in FY 2022 to make the $12.6 million appropriation. The provision specifies that the Pediatric Fund will provide the first $3.0 million of the appropriation and the general fund of the Treasury will support the remaining amount.
ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH *For carrying out section 301 and title IV of the PHS Act with respect to advanced research projects for health, $6,500,000,000, to remain available through September 30, 2024.*	This provision provides appropriations for the Advanced Research Projects Agency for Health (ARPA-H).

BUDGET MECHANISM TABLE

Budget Mechanism - Total[1,2,3]

(Dollars in Thousands)[1,2,3]	FY 2020 Final[7,8]		FY 2021 Enacted[7,8]		FY 2022 President's Budget[7,9]		FY 2022 +/- FY 2021	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	28,415	$15,903,452	29,040	$16,402,139	29,718	$17,350,182	678	$948,043
Administrative Supplements[3]	*(2,723)*	555,090	*(2,573)*	509,636	*(2,388)*	456,192	*(-185)*	-53,443
Competing	11,395	$6,395,871	11,189	$6,492,703	12,664	$7,191,779	1,475	$699,075
Subtotal, RPGs	39,810	$22,854,413	40,229	$23,404,478	42,382	$24,998,153	2,153	$1,593,675
SBIR/STTR	1,833	1,127,734	1,854	1,154,534	1,961	1,229,604	107	75,069
Research Project Grants	41,643	$23,982,147	42,083	$24,559,013	44,343	$26,227,757	2,260	$1,668,744
Research Centers:								
Specialized/Comprehensive	999	$1,937,294	1,063	$2,036,557	1,104	$2,132,854	41	$96,297
Clinical Research	70	432,804	67	419,359	66	418,554	-1	-805
Biotechnology	73	125,526	64	102,802	59	93,653	-5	-9,149
Comparative Medicine	48	138,385	51	141,435	52	141,514	1	79
Research Centers in Minority Institutions	21	74,111	22	78,386	25	86,000	3	7,614
Research Centers	1,211	$2,708,120	1,267	$2,778,539	1,306	$2,872,575	39	$94,036
Other Research:								
Research Careers	4,461	$835,776	4,558	$862,683	4,761	$896,618	203	$33,935
Cancer Education	59	14,878	83	20,939	85	21,439	2	500
Cooperative Clinical Research	272	498,295	265	501,540	268	508,255	3	6,715
Biomedical Research Support	125	89,486	131	91,397	130	90,994	-1	-403
Minority Biomedical Research Support	286	98,392	257	88,594	190	66,696	-67	-21,898
Other	2,127	1,273,872	2,265	1,431,756	2,454	1,512,570	189	80,814
Other Research	7,330	$2,810,700	7,559	$2,996,908	7,888	$3,096,571	329	$99,663
Total Research Grants	50,184	$29,500,967	50,909	$30,334,460	53,537	$32,196,903	2,628	$1,862,443
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3,919	$186,323	4,005	$196,857	4,106	$209,440	101	$12,584
Institutional Awards	13,089	720,929	13,550	755,007	13,843	809,755	293	54,748
Total Research Training	17,008	$907,252	17,555	$951,864	17,949	$1,019,196	394	$67,332
Research & Develop. Contracts	2,304	$3,295,504	2,355	$3,362,683	2,521	$3,561,276	166	$198,593
(SBIR/STTR) (non-add)[3]	*(109)*	*(71,684)*	*(116)*	*(76,634)*	*(121)*	*(82,267)*	*(5)*	*(5,632)*
Intramural Research		$4,460,682		$4,548,996		$4,695,985		$146,989
Res. Management & Support		1,979,165		2,090,554		2,184,166		93,612
Res. Management & Support (SBIR Admin) (non-add)[3]		*(7,762)*		*(10,128)*		*(10,116)*		*(-11)*
Office of the Director - Appropriation[3,4]		*(2,163,516)*		*(2,283,867)*		*(2,394,859)*		*(110,992)*
Office of the Director - Other		1,230,430		1,335,443		1,431,636		96,194
ORIP (non-add)[3,4]		*(293,976)*		*(299,885)*		*(304,684)*		*(4,798)*
Common Fund (non-add)[3,4]		*(639,111)*		*(648,539)*		*(658,539)*		*(10,000)*
ARPA-H		0		0		6,500,000		6,500,000
Buildings and Facilities[5]		230,000		230,000		280,000		50,000
Appropriation[3]		*(200,000)*		*(200,000)*		*(250,000)*		*(50,000)*
Type 1 Diabetes[6]		-150,000		-150,000		-141,450		8,550
Program Evaluation Financing[6]		-1,230,821		-1,271,505		-1,271,505		0
Subtotal, Labor/HHS Budget Authority		**$40,223,179**		**$41,432,495**		**$50,456,208**		**$9,023,713**
Interior Appropriation for Superfund Research		81,000		81,500		83,540		2,040
Total, NIH Discretionary Budget Authority		**$40,304,179**		**$41,513,995**		**$50,539,748**		**$9,025,753**
Type 1 Diabetes		150,000		150,000		141,450		-8,550
Total, NIH Budget Authority		**$40,454,179**		**$41,663,995**		**$50,681,198**		**$9,017,203**
Program Evaluation Financing		1,230,821		1,271,505		1,271,505		0
Total, Program Level		**$41,685,000**		**$42,935,500**		**$51,952,703**		**$9,017,203**

1 All Subtotal and Total numbers may not add due to rounding.
2 Includes 21st Century Cures Act funding and excludes supplemental financing.
3 All numbers in italics and brackets are non-add.
4 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.
5 Includes B&F appropriation and monies allocated pursuant to appropriations acts provisions such that funding may be used for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
6 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.
7 Reflects transfer of $5.0 million to the HHS OIG.
8 Amounts are adjusted for comparability with the proposed transfer of ECHO and INCLUDE from OD to NICHD in FY 2022.
9 Reflects Type 1 Diabetes Research sequestration of $8.55 million.

AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2021 Amount Authorized	FY 2021 Amount Appropriated	FY 2022 Amount Authorized	FY 2022 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[1]	TBD	42,292,400	TBD	51,224,113
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	81,500	Indefinite	83,540
3. 21st Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	109,000	109,000	150,000	150,000
BRAIN Initiative: Section 1001(b)(4)(B)	100,000	100,000	152,000	152,000
Cancer Moonshot: Section 1001(b)(4)(C)	195,000	195,000	194,000	194,000
4. Special Diabetes Programs: Section 330B(b) of the PHS Act[2]	150,000	150,000	150,000	141,450

[1]The authorization of appropriations expired as of September 30, 2020.

[2]The amount for the Special Diabetes Programs in the FY 2022 President's Budget reflects the reduction due to sequestration.

APPROPRIATIONS HISTORY

Fiscal Year	Budget Request to Congress	House Allowance	Senate Allowance	Appropriation [1]
FY 2013				
Base	$30,852,187,000		$30,810,387,000	$30,929,977,000 [2]
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 [3]
FY 2016	$31,311,349,000 [4]	$31,411,349,000	$32,311,349,000	$32,311,349,000 [5]
FY 2017	$33,136,349,000 [6]	$33,463,438,000	$34,311,349,000	$34,229,139,000 [7]
FY 2018	$26,919,710,000 [8]	$35,184,000,000	$36,084,000,000	$37,311,349,000 [9]
FY 2019	$34,766,707,000 [10]	$38,564,000,000	$39,312,349,000	$39,313,000,000 [11]
FY 2020	$34,367,629,000 [10]	$41,154,000,000	$42,084,000,000	$41,690,000,000 [12]
FY 2021	$39,133,215,000 [10]	$42,071,000,000	$43,536,500,000	$42,940,500,000 [13]
FY 2022 PB	$51,957,703,000 [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, $404,000,000 in FY 2021, and $496,000,000 in the FY 2022 Request.

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

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

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

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

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

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

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

[9] 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.

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

[11] 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.

[12] 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. Also does not reflect three COVID-19 supplementals totaling $3,587,400,000: the amounts are $836,000,000 in P.L. 116-123, $945,400,000 in P.L. 116-136, and $1,806,000,000 in P.L. 116-139 that was provided to NIH through directive transfer from the PHSSEF.

[13] Includes Program Evaluation Financing of $1,271,505,000. Does not reflect $5,000,000 transfer from NIH to HHS Office of the Inspector General. Also does not reflect COVID-19 supplemental of $1,250,000,000 in P.L. 116-260 for the Office of the Director.

[14] Includes Program Evaluation Financing of $1,271,505,000 and reflects the sequestration of the mandatory funding for the Special Type 1 Diabetes Research account. Does not reflect $5,000,000 transfer from NIH to HHS Office of the Inspector General.

APPROPRIATIONS NOT AUTHORIZED BY LAW

	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2021
NIH Labor/HHS Budget Authority[1]	FY 2020	$36,472,442,775	$40,954,400,000	$42,292,400,000

[1]Appropriations under general authorization of appropriations in Section 402A(a)(1) of the PHS Act. Excludes appropriations related to the Cures Act and the Gabriella Miller Pediatric Research Initiative.

NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Thousands)	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Program Level[1,2,3,4]	$41,685,000	$42,935,500	$51,952,703	$9,017,203
FTE[5]	17,623	18,785	19,303	518

[1] All years reflect directive transfer of $5.0 million to the HHS Office of Inspector General.

[2] Includes 21st Century Cures Act funding, Mandatory Type 1 Diabetes, and Superfund in all years; includes Program Evaluation financing of $1,230.8 million in FY 2020 and $1,271.5 million in FY 2021 and FY 2022.

[3] Excludes supplemental appropriations.

[4] Reflects sequestration of $8.55 million for Mandatory Type 1 Diabetes in FY 2022.

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

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

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 over $40 billion in taxpayer dollars each year 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 stimulating economic growth and productivity, and expands the biomedical knowledge base by supporting cutting-edge research and investing in the biomedical workforce of the future.

NIH-funded scientists are making ground-breaking contributions across the full arc of biomedical science — from basic and translational research to clinical research studies. Since the beginning of 2020, NIH has focused intensively on research related to SARS-CoV-2 and COVID-19, including standing up an unprecedented set of efforts to understand this new disease and develop diagnostics, therapeutics, and vaccines to combat the pandemic. The pandemic has posed challenges to conducting research in other areas, but that research continues with necessary precautions. NIH efforts related to SARS-CoV-2 and COVID-19 are described below, followed by examples of selected other recent NIH-funded research accomplishments.

Speeding Towards Treatments, Vaccines and Diagnostics for COVID-19

NIH is part of the trans-governmental effort being led by the Department of Health and Human Services and part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. In April 2020, NIH received up to $483 million in support for Moderna's then-candidate vaccine for COVID-19 (co-developed with NIH and described further below), which received a fast-track designation from the Food and Drug Administration (FDA) and was authorized for use in December 2020. Additionally, the Department continues to support NIH clinical trials under the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership (ACTIV-2 and ACTIV-3), described further below, to develop monoclonal antibody treatments for COVID-19. The Department will also ensure harmonization among efforts at NIH and those at other agencies including the Biomedical Advanced Research and Development Authority (BARDA), the FDA, the Centers for Disease Control and Prevention (CDC) and the Department of Defense.

NIH-Wide Strategic Plan for COVID-19 Research

To address the unprecedented challenge that the COVID-19 pandemic poses to public health and economy, NIH has mounted a vigorous research response against COVID-19 in coordination with Congress, HHS, the Department of Defense, and partners in the private and public sector. The NIH-Wide Strategic Plan for COVID-19 Research[43] provides a framework for improving, advancing, and optimizing COVID-19-related research in five key areas: fundamental knowledge, detection and diagnosis, treatment, prevention, and health disparities in an effort to improve basic understanding of SARS-CoV-2 and COVID-19 and develop the necessary tools and approaches to better diagnose, prevent, and treat this disease. The Plan includes efforts to expand the capacity for and accuracy of testing and an unprecedented public-private partnership to accelerate development of therapeutics and vaccines. NIH research also will tackle the disturbing disparities seen in the COVID-19 response, with the aim of developing effective,

[43] www.nih.gov/research-training/medical-research-initiatives/nih-wide-strategic-plan-covid-19-research

evidence-based methods to ensure that diagnostics, treatments, and vaccines reach all populations, particularly those disproportionately affected by this devastating disease. Implementation of components of the strategic plan has already begun as NIH develops and tests diagnostics through the Rapid Acceleration of Diagnostics (RADx) effort,[44] develops therapeutics via the ACTIV public-private partnership (PPP)[45] and the COVID-19 Prevention Network,[46] and ramps up testing of a number of candidate vaccines through clinical trials.[47,48] In December 2020, NIH released a Request for Information (NOT-OD-21-018)[49] inviting public comment on the Strategic Plan and anticipates the release of an updated NIH-Wide Strategic Plan for COVID-19 Research, incorporating both public input and evolutions in the COVID-19 pandemic response and research, in mid-2021.

Breakthroughs and Partnerships to Development Therapies and Vaccines for COVID-19
Announced in April 2020, NIH has assembled a distinguished team of senior scientists from government, industry, and academia to lead the ACTIV partnership. This exciting new PPP has four fast-track focus areas, each led by a working group of experts that is developing a collaborative, streamlined forum to identify preclinical treatments, accelerate clinical testing of the most promising vaccines and treatments, improve clinical trial capacity and effectiveness, and speed the evaluation of vaccine candidates to enable rapid authorization or approval. Together, this group has already put into place a framework for advancing COVID-19 therapeutics, vaccines and clinical trials in a matter of months that would normally take years to develop.

Six clinical trial initiatives (ACTIV-1 through ACTIV-6) are currently being developed and launched through this effort. These trials test a wide range of medical countermeasures in both inpatient and outpatient settings, including immune modulators, monoclonal antibodies for prevention and therapy, antithrombotics, and a host of repurposed drugs that have been tested for other indications. As part of this overarching effort, in early August 2020, NIH announced the launch of two ACTIV clinical trials. ACTIV-2 is a phase 2 clinical trial to evaluate monoclonal antibodies (mAbs), including LY-CoV555, in patients who have mild to moderate disease not requiring hospitalization.[50] In November 2020, the FDA issued an Emergency Use Authorization (EUA) for LY-CoV555 for this indication as a result of clinical data from this study. More recent clinical studies have shown that addition of another monoclonal antibody, called etesevimab, to LY-CoV555 provides enhanced clinical benefit and this combination will be pursued together as a new therapy. In April 2021, FDA revoked the EUA for the use of LY-CoV555 alone for treating mild-to-moderate COVID-19 in adults and certain pediatric patients due to issues caused by SARS-CoV-2 variants. Another clinical trial, ACTIV-3, a global Phase 3 randomized, controlled trial testing multiple mAb treatments for COVID-19 (including LY-

[44] www.nih.gov/research-training/medical-research-initiatives/radx
[45] www.nih.gov/research-training/medical-research-initiatives/activ
[46] www.niaid.nih.gov/news-events/niaid-clinical-trials-monoclonal-antibodies-prevent-covid-19-now-enrolling
[47] www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins
[48] www.niaid.nih.gov/news-events/nih-launches-clinical-trials-network-test-covid-19-vaccines-and-other-prevention-tools
[49] grants.nih.gov/grants/guide/notice-files/NOT-OD-21-018.html
[50] www.nih.gov/news-events/news-releases/nih-clinical-trial-test-antibodies-other-experimental-therapeutics-mild-moderate-covid-19

CoV555)[51] using an adaptive two-phase study design that can be modified to test additional experimental therapeutics as they emerge. ACTIV-3 also supports concurrent testing in COVID-19 patients hospitalized with differing levels of disease severity and leverages the clinical trial resources and infrastructure of the National Institute of Allergy and Infectious Diseases (NIAID) and the National Heart, Lung, and Blood Institute (NHLBI). Initial results from ACTIV-3 indicated that LY-CoV555 did not provide any benefit to hospitalized patients with COVID-19.

In addition to these activities supported through ACTIV, NIH has also launched other clinical trials to test additional therapies for COVID-19, including existing antiviral agents known to be effective against related coronaviruses which cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome. In February 2020, the Adaptive COVID-19 Treatment Trial (ACTT) was launched and demonstrated the safety and efficacy of remdesivir in shortening time to recovery. ACTT has since improved on those results, showing additive benefit of baricitinib in hospitalized patients. ACTT provided high quality, interpretable data that contributed to the FDA's licensure of remdesivir and the EUA of baricitinib.

Building upon existing research on related coronaviruses at the NIAID Vaccine Research Center and a research collaboration with Moderna, NIAID scientists were able to initiate development of an mRNA vaccine candidate for COVID-19 as soon as viral sequences were posted on international databases. Sixty-five days later, a Phase 1 clinical trial was launched to evaluate this promising vaccine candidate, and within one year, the vaccine received an EUA by the FDA. By capitalizing on established clinical research infrastructure, NIH facilitated the rapid testing of additional vaccine candidates. These efforts provided the critical data for the FDA issuance of EUAs for two additional vaccine candidates to alleviate the public health crisis caused by COVID-19. Additionally, as variants of SARS-CoV-2 emerge, the need to update these vaccines is imperative. As such, NIH initiated a Phase 1 clinical trial of the Moderna vaccine candidate against the B.1.351 variant to evaluate its safety and immunogenicity.

Lastly, a cancer drug called acalabrutinib, a Bruton tyrosine kinase inhibitor, is known to suppress an overactive immune response found in certain cancers such as lymphoma. In a joint study supported by the National Cancer Institute (NCI) and NIAID published in June 2020, this drug was shown to reduce the need for supplemental oxygen in patients with COVID-19,[52] and is also thought to be part of the disease process in response to SARS-CoV-2 infection. This finding is now being used to design a randomized, controlled clinical trial to further assess the efficacy of this drug in treating severe COVID-19.

Since May 2020, using emergency supplemental appropriations, NCI evaluated more than 100 commercial assays at the COVID-19 Serology Lab in Frederick, Maryland, to assist FDA regulatory decisions. In December 2020, the NCI lab produced the U.S. Serology Standard, a tool that scientists conducting serology studies can use to calibrate their research, to harmonize assays that measure SARS-CoV-2 antibodies, and to make comparisons across studies including different candidate vaccines.

[51] www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-test-antibody-treatment-hospitalized-covid-19-patients

[52] www.nih.gov/news-events/nih-research-matters/cancer-drug-may-reduce-symptoms-severe-covid-19

The NCI Serology Lab is part of an array of programs NCI launched with the emergency appropriation from Congress. Other examples include –

- SeroNet, a large, highly coordinated effort to understand immune response to SARS-CoV-2, the virus responsible for the pandemic. SeroNet involves 25 academic institutions along with the NIAID, other NIH Institutes, and others working to answer fundamental questions about the virus and support vaccine development.
- SeroHub, an NCI effort launched in collaboration with NIAID and the CDC. SeroHub is a central repository for studies of SARS-CoV-2 seroprevalence. Seroprevalence shows how the virus is spreading within the population and allows scientists to better understand populations most at risk for the disease. SeroHub's interactive dashboard allows scientists, clinicians, and policymakers to compare seroprevalence by geography, testing date, and other factors.
- Digital Health Solutions funds businesses and universities to develop user-friendly tools, smartphone apps, and wearable devices to support pandemic response, such as efficiently identifying and tracing contacts with infected individuals. In partnership with the National Institute of Biomedical Imaging and Bioengineering, this NCI initiative is supporting new technologies to meet pandemic-related needs.

Rapid Acceleration of Diagnostics (RADx) for COVID-19

In complement to the efforts focused on therapies and vaccines for COVID-19, the NIH RADx program is a $1.5 billion effort designed to address the COVID-19 pandemic by speeding innovation, commercialization, and implementation of SARS-CoV-2 diagnostic testing.[53] This four-part effort will fund innovative technologies and novel approaches to enhance the speed and accessibility of SARS-CoV-2 tests while seeking opportunities to evaluate effective and equitable strategies for testing and implementation. Across all four RADx initiatives, NIH is working closely with other agencies, including the FDA, CDC and BARDA, to advance these goals and increase the availability of accurate, innovative diagnostic testing.

The four parts of RADx are outlined below, and each component has published calls for applications and ideas, with awards and contracts being awarded starting in late July through 2021.

RADx Tech, which aims to advance innovative technologies, is supporting scientists and inventors through a nationwide competition to expand access to new technologies for SARS-CoV-2 diagnostics and laboratory-based testing. RADx-Advanced Technology Platforms (ATP) reduces barriers for scaling up advanced technologies to increase the capacity for rapid, high-throughput testing infrastructure. These initiatives use a phased review process to identify and advance the most promising candidates. Thirty successful candidates have begun the Phase 2 of the competition.[54] The Phase 2 point-of-care awards include a hand-held device to test for SARS-CoV-2 genetic material with results in 30 minutes, a test kit for nursing homes to detect viral proteins and provide results in 15 minutes, and a compact device which uses isothermal amplification of genetic material and optical detection to provide results in 30 minutes. The promising lab-based approaches include a scale-up of next generation sequencing, a combination of automated testing and bulk shipping of test kits, a microfluidics platform utilizing saliva

[53] www.nih.gov/research-training/medical-research-initiatives/radx
[54] www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-dashboard

samples, and finally a CRISPR gene-editing system to detect pieces of SARS-CoV-2 genetic material. Together, RADx Tech and RADx-ATP have increased national testing capacity by 6.1 million diagnostic tests per day and supported 17 FDA authorized tests including one over-the-counter test for at-home use as of February 2021.

RADx-Radical (RADx-rad) advances nontraditional approaches and repurposing of existing approaches for SARS-CoV-2 testing such as community-level wastewater surveillance, chemosensory technologies for SARS-CoV-2 detection, and methods to detect COVID-19 severity in children.[55] Other RADx-rad components will support the development of electronic nose technology aiming to detect compounds in breath, saliva, or skin associated with both symptomatic and asymptomatic COVID-19. If successful, this program will lead to a safe, effective, and noninvasive method for detecting SARS-CoV-2 infected individuals in everyday settings. With longer development timelines, RADx-rad projects will address gaps in SARS-CoV-2 testing that may be used in future outbreaks of COVID-19 and other as yet unknown infectious diseases.

RADx-Underserved Populations (RADx-UP) leverages existing partnerships to develop and implement strategies to enable and enhance SARS-CoV-2 testing of underserved, under-resourced, rural, and/or vulnerable populations across the United States. Sites within RADx-UP use large consortiums, multi-site trials, centers and other current networks that have adequate capacity, infrastructure, and established community relationships to support and expand testing efforts. A key feature of RADx-UP is the development of testing strategies to utilize the advances made by the other RADx initiatives in real-world settings. This initiative is also specifically examining the range of social, ethical, and behavioral issues associated with testing/diagnostic technologies and information/data (including stigma associated with a positive test result) in research, clinical, or other settings. Comprised of two phases, the first phase of RADx-UP focused on communities with well-established research infrastructure and partnerships to better understand SARS-CoV-2 testing patterns and approaches. The second phase will advance the scientific mission described above while being responsive to the changing diagnostic landscape, continued need for behavioral mitigation strategies, and the effects of the implementation and scale-up of COVID-19 vaccine distribution efforts. Research will be focused on understanding COVID-19-related disparities and implementing testing interventions to mitigate these disparities in the context of vaccine implementation and uptake among underserved and vulnerable populations.

This includes developing and implementing testing interventions for school settings to enable evidenced-based approaches for safely returning students and staff to in-person school. Further, establishing partnerships with other COVID-19 programs will continue to ensure the needs of vulnerable and disproportionately affected communities are addressed.

The entire RADx program is supported by the Data Management for Testing for Safe Release Project, which is working to build an infrastructure and coordination of the various data management needs for the many COVID-19 efforts. This Project is developing a platform to integrate individual and population level data from a variety of sources, including serology and

[55] www.nih.gov/research-training/medical-research-initiatives/radx/funding#radx-rad

genetic test results, self-reported symptoms, and demographic data, to provide a source of indexed, searchable data and analytical tools for additional research including longitudinal studies.

Addressing Health Disparities through Research

Multiple lines of evidence have highlighted disparities in health outcomes among racial and ethnic minorities, social disadvantaged groups, rural residents, and other populations. In response to this need, NIH is supporting multidisciplinary research on health disparities across a range of populations, diseases, and disorders. Recent developments in this area include a study supported by both NHLBI and the National Institute on Minority Health and Health Disparities (NIMHD), which announced its findings in April 2020. The study found that African American men and women who had severe sleep apnea or other disrupted sleep patterns had higher blood sugar levels than those who slept normally. African American men and women are up to two times more likely to develop diabetes over their lifetimes than white Americans. These findings suggest that screening and treatment of sleep apnea and supporting better sleep habits may be another strategy to reduce the risk of diabetes in African Americans.[56]

Recent studies have also found that racial and ethnic minorities are disproportionately affected by COVID-19. Specifically, African Americans, Latinos, American Indians, and Pacific Islanders are more likely to acquire SARS-CoV-2 infection and African Americans especially are more likely to become seriously ill with COVID-19 and have greater mortality from the disease. In addition to the RADx-UP effort described above, NIH has launched trans-agency COVID-19 science initiatives, with a special focus on racial/ethnic minorities, such as the Social, Behavioral, and Economic Health Impacts of COVID-19 (SBE). Co-led by NIMHD, the National Institute of Mental Health (NIMH), the National Institute on Aging (NIA), the Office of Behavioral and Social Sciences Research (OBSSR) and the Office of Extramural Research (OER), and engaging with 24 Institutes and Centers (ICs) and offices, this effort is both leveraging existing opportunities at NIH and also actively soliciting applications to address secondary impacts of the pandemic in health disparity and other vulnerable populations. In FY 2020, 52 projects spanning research on alcohol, substance abuse, and mental health outcomes, public health mitigation impacts and adherence, and chronic health conditions were supported.[57] An important aspect of FY 2020 support was to supplement longitudinal studies to capture initial and longer-term effects of the pandemic on population health and health disparities. For example, the Understanding America Study tracks a nationally representative sample of adults across the pandemic, providing rapid access to data to support SBE research that has yielded early results on topics including adherence to pandemic mitigation interventions, childcare and parental mental health and use of protective behaviors.[58] In order to better understand how

[56] www.nih.gov/news-events/nih-research-matters/poor-sleep-linked-higher-blood-sugar-levels-african-americans
[57] grants.nih.gov/grants/guide/notice-files/NOT-OD-20-118.html
[58] Understanding America Study data and publications can be found on their website (uasdata.usc.edu/index.php). Example papers: Gema Zamarro and María J. Prados , "Gender differences in couples' division of childcare, work and mental health during COVID-19. " Review of Economics of the Household Vol. 19, pp 11-40 (2021); Robert F. Schoeni, Emily E. Wiemers, Judith A. Seltzer and Kenneth M. Langa, "Association Between Risk Factors for Complications From COVID-19, Perceived Chances of Infection and Complications, and Protective Behavior in the US" JAMA Netw. Open 4(3) (2021); Matthew Crane, Kenneth Shermock and Saad Omer, "Change in Reported Adherence to Nonpharmaceutical Interventions During the COVID-19 Pandemic, April-November 2020" JAMA January 22 (2021).

pandemic associated economic change (e.g., income insecurity caused by unemployment) influenced health, SBE supplemented research by the National Bureau of Economic Research which has already produced findings referenced in academic journals and the popular press.[59] Additionally in FY 2021, the workgroup is funding new research on community and digital healthcare interventions to leverage and extend the limited healthcare workforce to address social, behavioral, and economic impacts of the pandemic as well as initiatives to access, extract, integrate, share, and analyze existing data from various sources with broad population coverage including underserved and vulnerable populations to understand short and long-term impacts of the pandemic on healthcare use and health.

Maternal Mortality

U.S. rates of maternal deaths (approximately 700 each year) and complications are higher than in any other developed country and continue to rise, with black women and other women of color facing higher risks than white women. NIH increased efforts in FY 2020 to address maternal morbidity and mortality (MMM) in disproportionately affected populations (i.e., African American, American Indian/Alaska Native, women with advanced maternal age, people with disabilities, low socioeconomic status, or rural locales) by supporting initiatives targeted at geographical, racial, and ethnic disparities, including an initiative focused on determining mechanisms underlying racial and ethnic disparities in MMM. Led by the NIH Maternal Mortality Task Force, the new Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative, which provided supplemental research awards in FY 2020, focuses on biological, behavioral, sociocultural, and structural factors that affect pregnancy-related or -associated morbidity and mortality (PRAMM) and addresses leading causes of death and disability, including cardiovascular disease, infection and immunity, and significant morbidity associated with mental health for disproportionately affected populations. Awards include topics ranging from expanding telehealth obstetrics programs in rural Midwestern hospitals to studying the contribution of lifetime trauma in Black women to increased maternal morbidity risks.

Additional research in FY 2020 lent insight into PRAMM related to infection and immunity, cardiovascular disease, and severe maternal morbidity. One NIH-funded study found that among women readmitted to hospitals for sepsis, 61 percent of readmissions occurred after six weeks—the time point at which women generally have their postpartum visit.[60] For cardiovascular disease, the NuMoM2b Heart Health Study[61] showed an association of adverse pregnancy outcomes in a first pregnancy with maternal hypertension two to seven years postpartum, suggesting that preventive care for women should include a detailed history of pregnancy when determining hypertension risk. Researchers also sought insight into severe maternal morbidity by analyzing maternal birth outcomes from nearly 6.5 million health records of women. They found that women who have stillbirths are at substantially higher risk of severe maternal

[59] Examples include Cutler, David and Lawrence Summers. 2020. "The COVID-19 Pandemic and the $16 Trillion Virus." JAMA, doi:10.1001/jama.2020.19759; https://www.washingtonpost.com/business/2021/01/25/lockdowns-job-losses/;

[60] pubmed.ncbi.nlm.nih.gov/31529451/

[61] pubmed.ncbi.nlm.nih.gov/31564189/

morbidity than women with live births.[62] All of these studies revealed factors that play into the risk of complications and long-term health impacts associated with or related to pregnancy.

To align and support these and other collaborative maternal health initiatives, NIH remains actively engaged in coordinated efforts across HHS, including the HHS Task Force on Research Specific to Pregnant Women and Lactating Women,[63] the Surgeon General's Call to Action to Address Maternal Mortality and Morbidity, and the Healthy Women, Healthy Pregnancies, Healthy Futures: The U.S. Department of Health and Human Services' Action Plan to Improve Maternal Health in America.

Scientific Breakthroughs Across NIH

As the largest funder of public health research in the U.S., the mission of NIH includes a broad range of biomedical and public health research and services. To accomplish that mission, the ICs of the NIH each support research in specific areas of health, the human body, and disease, and each take varied approaches to funding biomedical research and the scientific workforce. While each IC is unique, all have supported critical scientific breakthroughs over the last year, and a few examples are provided below to illustrate their breadth and scope:

The National Institute of Dental and Craniofacial Research (NIDCR) recently announced a new bone-regenerating system in mice which uses nanoparticles released from a biodegradable scaffold near damaged areas to deliver a bone growing drug to nearby stem cells.[64] These stem cells, once triggered by the drug, regenerate new bone leading to an observed decrease in the size of damage averaging 50 percent after 6 weeks. This work has the potential to regenerate bone on-site, eliminating the need for bone grafts, the current standard of care, which increase risk of infection and nerve damage.

In response to research on the increase in mortality and morbidity for older adults transitioning to a care facility, scientists supported by the National Institute of Nursing Research (NINR) developed a novel sensor technology to monitor daily movement patterns, such as restlessness in bed, of new facility residents.[65] These sensors generate a report for nurses and physicians to monitor for clinically relevant changes in behavior and to predict approaching or worsening illnesses 10-14 days before symptoms begin, leading to earlier detection and treatment and potentially saving lives.

A team of scientists supported jointly by the National Center for Complementary and Integrative Health (NCCIH) and the National Institute of Neurological Disorders and Stroke (NINDS) announced the discovery of a new technique to manipulate two genes (NGN2 and BRN3A) in developing stem cells, triggering them to grow into sensory neurons which can detect cold temperatures and touch.[66] Individuals with a rare genetic disorder called PIEZO2 deficiency lack both a sense of touch and body position. The team found that cells from these

[62] pubmed.ncbi.nlm.nih.gov/31306335/
[63] www.nichd.nih.gov/about/advisory/PRGLAC
[64] www.nidcr.nih.gov/news-events/news/2020/scientists-take-crack-bone-regeneration
[65] www.ninr.nih.gov/all-stories-of-discovery
[66] www.nccih.nih.gov/research/research-results/stem-cell-technology-helps-scientists-generate-a-previously-unknown-type-of-sensory-neuron

individuals could be genetically corrected with this new technique and CRISPR Cas-9 to restore the senses in individuals with PIEZO2 deficiency. This discovery shows how stem cells can be a vital tool in advancing the field of sensory biology.

Researchers supported by NCCIH recently released findings that acupuncture can relieve inflammation through several independent mechanisms. Using mice as a model, the team investigated how distinct types of stimulation from acupuncture relieved systemic inflammation with what is known as a somatotropic organization, meaning stimulating a specific area produced an effect in a specific, corresponding tissue.[67] Varying intensities of stimulation also altered the effect. Comparing manual to electroacupuncture, the investigation showed electroacupuncture to be more effective as it is easier to control. These findings should lead to improved acupuncture practices and the potential for more optimized treatment.

Finally, researchers supported by the National Institute on Deafness and Communication Disorders (NIDCD) discovered a potential new drug for slowing hearing loss caused by nerve damage.[68,69] Previously considered irreversible with no approved medications, this type of hearing loss, known as sensorineural hearing loss, is the most common cause of age-related hearing loss. A new study found that a drug for preventing bone density loss given to mice dramatically reduced nerve damage and restored cochlear function 24 hours after exposure to loud, damaging noises. This discovery has the potential to lead to clinical trials to determine if this same drug type could prevent hearing loss in people.

NIH will continue to serve in its critical role of advancing basic and clinical biomedical research to advance knowledge of human disease and enhance public health. Through careful stewardship of taxpayer dollars and broad investment in cutting-edge ideas and the scientific workforce, NIH will build on these and other breakthroughs to further champion human health.

Harnessing Computational Biology/Data Science and Artificial Intelligence to Advance Biomedical Research

NIH is leveraging advanced computational and data science techniques, including artificial intelligence (AI) and machine learning (ML), to accelerate and expand biomedical and clinical research and improve clinical care. Researchers are using computational biology and data science to unravel the inner workings of intricate biological processes, including those that impact mental health, aging, and infectious diseases. For example, NIH is supporting research analyzing neural networks to help with early diagnosis of Alzheimer's disease and to discover and optimize treatments for mental illnesses, emotional disturbance, and abnormal behavior.[70,71] In clinical care, NIH-supported research is incorporating AI and ML techniques to facilitate interpretation of imaging results for radiological diagnosis of diseases (e.g., cancer[72] and COVID-19[73]), remote telehealth monitoring using wearable devices, and clinical decision

[67] www.nccih.nih.gov/research/research-results/new-findings-suggest-acupuncture-stimulation-reduces-systemic-inflammation
[68] hms.harvard.edu/news/dramatic-effect
[69] www.nidcd.nih.gov/research
[70] www.nibib.nih.gov/science-education/science-topics/artificial-intelligence-ai
[71] grants.nih.gov/grants/guide/pa-files/PAR-19-344.html
[72] directorsblog.nih.gov/2020/01/14/artificial-intelligence-speeds-brain-tumor-diagnosis/
[73] www.nih.gov/news-events/news-releases/nih-harnesses-ai-covid-19-diagnosis-treatment-monitoring

support systems that use health observations and case knowledge to assist with treatment decisions.[74] Telehealth and clinical decision support systems could be particularly useful in rural and other under-resourced areas where patients have limited access to health care and specialized health care providers. For example, an ongoing study is testing a ML approach on maternal delivery hospitalization data from Maryland state databases to develop a predictive risk assessment tool for severe maternal morbidity (SMM). Such a tool could help clinicians without specialized training identify women at high-risk of SMM to help avoid or minimize adverse outcomes.[75]

Data science can also be used to address emerging public health needs. A major challenge for clinicians is the rapid and accurate assessment of SARS-CoV-2-infected hearts and lungs on medical images to predict COVID-19 disease severity and treatment response. Across NIH, several institutes are supporting the Medical Imaging and Data Resource Center (MIDRC)[76] for Rapid Response to COVID-19 Pandemic. MIDRC aims to develop and implement new diagnostics, including ML algorithms, that will allow rapid and accurate assessment of disease status and help physicians optimize patient treatment. NIH also has joined with the AI community, the White House, and key industry and university leaders to develop text mining tools to help analyze the thousands of scholarly articles for insights on coronavirus through the COVID-19 Research Data Set (CORD-19).[77] A complementary effort by NIH's Office of Portfolio Analysis created a sortable, machine readable comprehensive listing of COVID-19 publications and preprints to assist researchers.[78] The tool can drill down through a variety of data facets and includes visualizations to group articles into clusters based on key terms.

To unleash the full potential that data science has to offer in aiding scientific discovery and clinical care, NIH must take steps to ensure that appropriate infrastructure, resources, and expertise are available to drive advances. To this end, the NIH Office of Data Science Strategy (ODSS) continues to implement the NIH Strategic Plan for Data Science.[79] These trans-NIH collaborative approaches are building resources, unifying efforts, training staff, recruiting new talent, and enabling broad use of data science and computational approaches in biomedical research. NIH is also engaging stakeholders to identify priorities and opportunities specifically for AI and ML. Plans are in progress to implement many of the recommendations derived through workshops and working groups, including the NIH Advisory Committee to the Director AI Working Group.[80]

All of Us Genomic Program and Expansion of the Workbench

The *All of Us* Research Program is preparing to launch one of the largest genomic sequencing activities in the world and continues its progress to build one of the largest and most diverse datasets to advance health research, in partnership with its more than 381,000 and counting participants as of April 2021. *All of Us* began genotyping and sequencing participant biosamples

[74] www.nibib.nih.gov/science-education/science-topics/artificial-intelligence-ai
[75] projectreporter.nih.gov/project_info_details.cfm?aid=9767258&icde=0
[76] www.nih.gov/news-events/news-releases/nih-harnesses-ai-covid-19-diagnosis-treatment-monitoring
[77] www.kaggle.com/allen-institute-for-ai/CORD-19-research-challenge
[78] nexus.od.nih.gov/all/2020/04/15/new-nih-resource-to-analyze-covid-19-literature-the-covid-19-portfolio-tool/
[79] datascience.nih.gov/strategicplan
[80] acd.od.nih.gov/working-groups/ai.html

in August 2020, and initial genomic data, including robust sets of whole genome sequences and arrays, are anticipated to be available to approved researchers in late 2021 or early 2022 The scale of this program – both participants and data collected – will set it apart from other studies. In the future, the program will expand the data available within, functionality of, and access to its Researcher Workbench, the platform researchers use to access *All of Us* data. *All of Us* began beta testing the Researcher Workbench in May 2020, allowing researchers to start using the program's initial dataset and tools in studies and comment on what is working and what the program can improve. This early version of its Researcher Workbench includes data generously shared with the program from more than 315,000 of its first participants, 80 percent of whom are from communities that are historically underrepresented in research, and more than 50 percent of diverse races and ethnicities. The platform will grow more robust over time with additional data and tools, including genomics, wearable device data, and linkages to other datasets. The program plans regular releases of new data and will continue to explore expanding access to the platform beyond the current beta audience, including citizen and community scientists and researchers in the private sector. The Researcher Workbench's expansion aims to enable research that will increase wellness and resilience, and promote healthy living; reduce health disparities and improve health equity; develop improved risk assessment and prevention strategies to preempt disease; provide earlier and more accurate diagnosis to decrease illness burden; and improve health outcomes and reduce disease burden through improved treatment and development of precision interventions.

The *All of Us* Research Program also has risen to the challenge of addressing the COVID-19 pandemic.[81] *All of Us* tested blood samples from over 24,000 participants for the presence of SARS-CoV-2 antibodies, indicating prior infection. Researchers tested samples collected in March 2020 and worked backwards until positive samples were no longer found to help determine the prevalence, rates of infection, and timing of SARS-CoV-2 infection in regions across the country. Additionally, *All of Us* is collecting relevant information from the electronic health records of more than 240,000 participants, some of whom have been diagnosed with COVID-19 or sought healthcare for related symptoms to help researchers look for patterns and learn more about COVID-19 symptoms and the effects of different medicines and treatment. Another effort focuses on understanding the mental and physical impacts of the COVID-19 pandemic on participants and includes questions on symptoms, stress, social distancing, and economic impacts. As data become available from all of these efforts, researchers will look for new leads that may bring greater precision to the diagnosis, treatment, and prevention of COVID-19, including those communities that have been hit the hardest.

Accelerating Precision Nutrition Research

The National Institutes of Health Nutrition Research Task Force (NRTF) was established in 2016 to coordinate and accelerate progress in nutrition research across the NIH, and to guide the development and implementation of the first NIH-wide strategic plan for nutrition research for the next 10 years.[82] In May 2020, the task force released the 2020-2030 Strategic Plan for NIH Nutrition Research, reflecting the wide range of nutrition research supported across NIH and

[81] directorsblog.nih.gov/2020/06/16/nihs-all-of-us-program-joins-fight-against-pandemic/

[82] National Institute of Diabetes and Digestive Kidney Disease. *NIH Nutrition Research Task Force*. www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/nih-nutrition-research-task-force

accounting for over $1.9 billion in FY 2019.[83] The strategic plan emphasizes cross-cutting, innovative opportunities to advance nutrition research across a wide range of areas, from basic science to experimental design to research training.[84] These opportunities complement and enhance ongoing research efforts across NIH to improve health and to prevent or combat diseases and conditions affected by nutrition.

Several areas in nutrition research that are ripe for further development include rapidly advancing technologies, such as high throughput "omics" (genomics, epigenomics, proteomics, metabolomics, etc.) and artificial intelligence, combined with the growing emphasis on personalized medicine approaches. To support the goals of NRTF and the strategic plan on nutrition research, the *All of Us* Research Program is developing the Nutrition for Precision Health program. This initiative will aim to understand individual responses to diet, enabling tailored dietary recommendations to be provided by physicians, as well as development of tools to allow individuals to make more informed decisions about healthy food choices.

Eliminating HIV/AIDS

Decades of research sponsored by the NIH, led by NIAID, has provided the critical treatment and prevention toolkits to theoretically end the HIV epidemic in the United States. With effective antiretroviral therapy (ART), a person with HIV now can expect a near-normal lifespan. The *Ending the HIV Epidemic (EHE) in the U.S.*[85] initiative aims to implement major scientific strategies and interventions to reduce new HIV transmissions by 75 percent over the next 5 years and by 90 percent by 2030. The strategy focuses on implementing evidence-based HIV treatment and prevention tools in geographic and demographic "hot spots" in this country where more than 50 percent of new HIV infections are concentrated.

NIH-sponsored clinical trials have demonstrated that individuals who receive ART and have achieved and maintained an undetectable viral load cannot sexually transmit the virus to others – the evidence-base for the concept, Undetectable=Untransmittable, or U=U. NIH-sponsored studies have demonstrated that ART used daily as pre-exposure prophylaxis (PrEP) can also protect those who are at risk of HIV acquisition. NIAID is supporting research on the optimal implementation of these strategies and on novel approaches to improve diagnosis, linkage to care, and treatment of people with HIV and to protect those at risk of acquiring HIV.

NIAID, the NIH Office of AIDS Research, and NIMH provided supplemental funding to institutions participating in the NIH-funded Centers for AIDS Research (CFAR)[86] and AIDS Research Center (ARC)[87] programs to conduct pilot and exploratory studies that will enhance the knowledge base needed for future implementation of science-based interventions to support the

[83] National Institutes of Health. (2020, May 27). NIH releases strategic plan to accelerate nutrition research over next 10 years [Press release]. www.nih.gov/news-events/news-releases/nih-releases-strategic-plan-accelerate-nutrition-research-over-next-10-years

[84] National Institute of Diabetes and Digestive Kidney Disease. *2020-2030 Strategic Plan for NIH Nutrition Research*. www.niddk.nih.gov/about-niddk/strategic-plans-reports/strategic-plan-nih-nutrition-research

[85] www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

[86] www.niaid.nih.gov/research/centers-aids-research

[87] www.nimh.nih.gov/about/organization/dar/aids-research-centers-program/aids-research-centers-program.shtml

EHE Initiative. In FY 2020, this partnership has extended and expanded these programs and added important new topics for reducing HIV incidence in at-risk populations. Notably, clinical trials funded by NIAID, the National Child Health and Human Development (NICHD), and NIMH showed that use of the dapivirine vaginal ring decreased women's risk of acquiring HIV.[88] This ring has recently been given a positive opinion by the European Medicines Agency for use in low- and middle-income countries. Further studies are examining the safety of the dapivirine ring during adolescence and pregnancy, when the risk of HIV acquisition is heightened. NIAID is continuing to develop new and improved HIV treatment and prevention tools, as well as the translation of basic and clinical biomedical research findings into strategies and modalities that are user- friendly and can be effectively and efficiently taken up in real-world settings by diverse communities. Several approaches aimed at achieving these treatment goals include: eradication of HIV from the body (i.e., achieving a "cure"), long-acting anti-retroviral therapry (ART) that could be taken intermittently, and broadly neutralizing antibodies (bNAbs). Novel prevention strategies being pursued include: long-acting pre-exposure prophylaxis (PrEP), bNAbs, and vaccine candidates.

Developing A Universal Flu Vaccine

FY 2021 appropriations included $220 million to bolster the ongoing efforts of NIAID to develop a "universal" influenza vaccine that will provide robust, long-lasting protection against multiple strains of influenza virus, including emerging strains that could spread globally. This includes developing state-of-the-art vaccine platforms, such as DNA, mRNA, virus-like particles, viral vectors, and nanoparticles, that are easier to produce and adapt. Scientists at the NIAID Vaccine Research Center (VRC) built on previous studies suggesting that vaccines targeting the "stem" region of the influenza hemagglutinin (HA) protein on the surface of the virus offer broader protection than existing strain-specific influenza vaccines that typically target the HA "head" region, which varies from year to year. NIAID VRC is testing experimental vaccine candidates using nanoparticle platform technology to target the HA stem, and in FY 2020, one nanoparticle vaccine candidate was proven to be safe and immunogenic in a Phase 1 clinical trial. A second vaccine candidate will be tested in a similar trial in FY 2021. In addition, a "mosaic nanoparticle"–based vaccine candidate that displays multiple influenza HAs is currently being manufactured by the VRC for testing in a Phase 1 clinical trial. In collaboration with industry partners, NIAID scientists in the Division of Intramural Research recently completed a Phase 2 clinical trial assessing a novel peptide-based candidate vaccine in a human influenza challenge model. The experimental vaccine, called FLU-v, targets several proteins conserved across influenza strains and yielded promising efficacy results. Advances in the areas of influenza virology, structural biology, protein engineering, immunology, and vaccinology result from many NIAID-supported research programs, including the Collaborative Influenza Vaccine Innovation Centers (CIVICS), the Infectious Diseases Clinical Research Consortium (IDCRC) network, and the Adjuvant Discovery and Development Programs. NIAID will continue targeted investments to generate critical information for the development of safe and effective universal vaccine candidates against both seasonal and pandemic influenza.

[88] www.nih.gov/news-events/news-releases/vaginal-ring-hiv-prevention-receives-positive-opinion-european-regulator

Gene Therapy Cures for Sickle Cell Disease and HIV

In an effort to develop affordable, gene-based cures for sickle cell disease (SCD) and HIV, the NIH launched a new collaboration with the Bill & Melinda Gates Foundation (Gates Foundation) to fund research that develops curative strategies using gene-based treatments. Together, the NIH and the Gates Foundation will invest at least $200 million to advance safe, effective, and durable gene-based cures to clinical trials in the United States and relevant countries in sub-Saharan Africa within the next 7 to 10 years.[89] To accomplish these goals, the partnership will focus on two areas of coordination – identifying potential candidates for curing SCD and HIV for pre-clinical and clinical evaluation and defining long-term opportunities to work together on advancing promising candidates to late-phase clinical trials.[90]

To meet the goal of a scalable HIV cure, a number of approaches are being considered[91] and will improve coordination with ongoing research efforts, thereby accelerating studies into early phase clinical trials to safely test promising tools and interventions. An approach of interest is to identify the location of the reservoir of infected cells that still harbor integrated HIV genomes after treatment and target those DNA sequences with gene editing technology.

Recently, NIH studies targeting SCD demonstrated the effectiveness of correcting defective genes outside the body and infusing them into the body of SCD patients to reverse the disease.[92] Although a substantial breakthrough, the process is time intensive and involves many complex manufacturing and clinical steps. Under the collaboration with the Gates Foundation, the goal for SCD is to develop an easy-to-administer, gene-based intervention to correct the SCD gene mutations or promote fetal hemoglobin gene expression to achieve normal hemoglobin function. The path to a cure will rely in part on the development of gene-based delivery systems capable of selectively targeting hematopoietic stem cells, which will result in the precise correction of gene mutations or the addition of a gene to promote sufficient levels of normal hemoglobin expression and function.[93]

Another NIH initiative targeting SCD is the Cure Sickle Cell Initiative (CureSCi) launched in 2018 by NHLBI to move the most promising gene-based therapies safely into clinical trials within five to ten years.[94] Accomplishments include development of a data consortium to collect and harmonize existing SCD datasets, support for research and platforms toward the launch of clinical trials (e.g., an SCD stem cell biobank, manufacture of Good Manufacturing Practice

[89] NIH Director's Blog. (2019, October 28). Joining Forces Against Sickle Cell Disease and HIV Infection. directorsblog.nih.gov/2019/10/28/joining-forces-against-sickle-cell-disease-and-hiv-infection/

[90] National Institutes of Health. Backgrounder: NIH Collaboration on Gene-Based Cures for SCD and HIV. www.nih.gov/news-events/news-releases/backgrounder-nih-collaboration-gene-based-cures-scd-hiv

[91] National Institutes of Health. (2019, October 23). NIH launches new collaboration to develop gene-based cures for sickle cell disease and HIV on global scale. www.nih.gov/news-events/news-releases/nih-launches-new-collaboration-develop-gene-based-cures-sickle-cell-disease-hiv-global-scale

[92] National Institutes of Health. Backgrounder: NIH Collaboration on Gene-Based Cures for SCD and HIV. www.nih.gov/news-events/news-releases/backgrounder-nih-collaboration-gene-based-cures-scd-hiv

[93] National Institutes of Health. (2019, October 23). NIH launches new collaboration to develop gene-based cures for sickle cell disease and HIV on global scale. www.nih.gov/news-events/news-releases/nih-launches-new-collaboration-develop-gene-based-cures-sickle-cell-disease-hiv-global-scale

[94] National Heart, Lung, and Blood Institute. Data Consortium. curesci.azurewebsites.net

(GMP) vectors, new clinical outcome measures and biomarkers), in addition to patient, caregiver, and provider engagement.

These initiatives are some examples of many gene therapy efforts, including the NIH Common Fund's Somatic Cell Genome Editing (SCGE) program, that will help to reduce the burden of common and rare diseases caused by genetic changes, and potentially develop curative treatments.[95]

Identifying and Addressing Structural Racism

NIH is committed to bringing diverse perspectives, backgrounds, and skillsets to enhance scientific productivity and solve complex biomedical and health research problems. To identify new ways of supporting diversity, equity, and inclusion and dismantle policies and practices that may harm our workforce and our ability to advance critical scientific discoveries and improve lives, NIH launched the UNITE initiative in February 2021.

The goal of the UNITE initiative is to identify and address structural racism within the NIH community and the greater biomedical research community. UNITE is comprised of five core activities with coordinated objectives to address racism and discrimination in science and develop methods to promote diversity and inclusion in biomedical research:

- **U**nderstanding stakeholder experiences through listening and learning
- **N**ew research on health disparities, minority health, and health equity
- **I**mproving the NIH culture and structure for equity, inclusion and excellence
- **T**ransparency, communication, and accountability with internal and external stakeholders
- **E**xtramural research ecosystem: changing policy, culture and structure to promote workforce diversity

The UNITE initiative will work to address challenging issues stemming from structural racism such as attracting and retaining scientists from underrepresented groups; addressing disparities in success rates for grants supporting Black/African American scientists; improving transparency of race-based demographic data; increasing funding of research for minority health, health disparities, and health equity; and addressing racism in the NIH workplace. Led by the NIH Office of the Director, the 5 core areas of the UNITE initiative bring together nearly 80 appointed members representing all of the 27 ICs of the NIH. As these critical efforts begin, the UNITE initiative will engage these members as well as the scientific community and the public to bolster the NIH's effort to increase diversity within the scientific workforce, achieve racial equity on the NIH campus, and enhance opportunity and achievement within the scientific community.

Protecting U.S. Biomedical Intellectual Innovation

NIH recognizes the importance of scientific collaborations to advance its mission, and NIH and the biomedical research enterprise have a long history of international collaborations with rules of engagement that allow science to advance while protecting intellectual capital and proprietary

[95] National Institutes of Health. (2019, October 23). Somatic Cell Genome Editing (SCGE). commonfund.nih.gov/editing

information. However, in August 2018, the NIH Director issued a statement about incidents that violate core principles and threaten the integrity and academic competitiveness of U.S. biomedical research and innovation.[96] Such incidents include failure by some researchers at NIH-funded institutions to disclose contributions of resources from other organizations, diversion of intellectual property produced by NIH-supported biomedical research, and sharing of confidential information by peer reviewers or otherwise attempting to influence funding decisions.

NIH has taken a number of steps to address these risks, including convening a working group of the Advisory Committee to the Director (ACD) to advise on how best to address it.[97] NIH has also communicated these concerns to over 10,000 recipient institutions within the research community and has contacted over 90 institutions regarding specific concerns about scientists who may have failed to disclose foreign affiliations, financial conflicts of interest, and/or research support from foreign governments. The agency has also extensively communicated the responsibilities of all participants in the NIH peer review process and the consequences of a breach of review integrity. NIH continues to address this issue by implementing ACD working group recommendations, outreach and communication within NIH and with the broader research community, as well as active partnerships with other Federal departments and agencies, scientific professional societies, and recipient institutions to establish best practices to protect the integrity of NIH-supported science. NIH appreciates the proactive efforts many institutions are taking to address these serious issues, such as updating institutional disclosure policies and providing outreach to faculty and staff regarding reporting requirements to ensure that U.S. institutions and the American public benefit from their investment in biomedical research.

[96] www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research

[97] acd.od.nih.gov/working-groups/foreign-influences.html

FUNDING HISTORY (FIVE-YEAR FUNDING TABLE)

Fiscal Year	Amount[1, 2]
2018	$37,311,349,000
2019	$39,313,000,000
2020	$41,690,000,000
2021	$42,940,500,000
2022 Budget Request[3]	$51,957,703,000

[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 $922,871,000 in FY 2018, $1,146,821,000 in FY 2019, $1,230,821,000 in FY 2020, $1,271,505,000 in FY 2021 and $1,271,505,000 in the FY 2022 request. Includes CURES amounts of $496,000,000 in FY 2018, $711,000,000 in FY 2019, $492,000,000 in FY 2020, $404,000,000 in FY 2021 and $496,000,000 in the FY 2022 request.

[2] Excludes supplemental appropriations and permissive and directive transfers.

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

SUMMARY OF REQUEST NARRATIVE

The FY 2022 President's Budget request provides a program level of $52.0 billion for NIH, which is $9.0 billion more than the FY 2021 Enacted level of $42.9 billion. This request includes $6.5 billion to establish a new Advanced Research Projects Agency for Health (ARPA-H) within NIH.

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 ($50.5 billion in FY 2022); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research Program ($83.5 million in FY 2022); mandatory budget authority provided for Type 1 Diabetes research ($141.4 million in FY 2022[98]); and Program Evaluation Financing for the National Institute of General Medical Sciences under Section 241 of the Public Health Service Act ($1,271.5 million in FY 2022).

The primary budget mechanisms discussed below include allocations by mechanism of Program Evaluation Financing and Type 1 Diabetes funds. The Superfund Research program is a lump-sum amount within the NIH mechanism tables.

In FY 2022, NIH will continue providing upfront funding for certain research 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, due in part to the large Congressional increases for Alzheimer's disease research.

Research Project Grants (RPGs)

The FY 2022 President's Budget provides $26.2 billion for RPGs, which is $1.7 billion more than the FY 2021 level. This amount would fund 12,664 Competing RPGs, or 1,475 more than for the FY 2021 level. It would also support 29,718 Noncompeting RPGs, 678 more than the FY 2021 level. In addition, the projected average cost for Competing RPGs of approximately $568,000 would be 2.1% below the FY 2021 projected average cost of $580,000.

[98] Reflects a mandatory appropriation of $150.0 million, reduced by $8.6 million for sequestration pursuant to the Budget Control Act.

- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) RPGs.** The FY 2022 President's Budget provides $1,229.6 million for SBIR/STTR program grants, which is $75.1 million above the FY 2021 level. The statutory minimum set-aside requirement of 3.65% for NIH-wide SBIR/STTR support is achieved in FY 2022.

Research Centers
The FY 2022 President's Budget provides $2,872.6 million for Research Centers, which is $94.0 million more than the FY 2021 level. This amount would fund 1,306 grants, 39 more than the FY 2021 level.

Other Research
The FY 2022 President's Budget provides $3,096.6 million for this mechanism, which is $99.7 million more than the FY 2021 level. This amount would fund 7,888 grants, which is 329 more than the number of awards projected for FY 2021.

Training
The FY 2022 President's Budget provides $1,019.2 million for research training, which is $67.3 million above the FY 2021 level. This amount would fund 17,949 Full-Time Trainee Positions (FTTPs), which is 394 more than planned for FY 2021, and would fund a new child care subsidy allowance for individual and institutional trainees that was phased in starting in FY 2021.

Research & Development (R&D) Contracts
The FY 2022 President's Budget provides $3,561.3 million for R&D contracts, which is $198.6 million more than the FY 2021 level. The requested amount would fund an estimated 2,521 contracts, or 166 more than the FY 2021 level.

- **SBIR/STTR R&D Contracts.** The FY 2022 President's Budget includes a $82.3 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts.

Intramural Research (IR)
The FY 2022 President's Budget provides $4,696.0 million for IR, which is $147.0 million more than the FY 2021 level.

Research Management and Support (RMS)
The FY 2022 President's Budget provides $2,184.2 million for RMS, which is $93.6 million more the FY 2021 level.

Office of the Director (OD)
The FY 2022 President's Budget provides $2,394.9 million for OD, which is $111.0 million more than the FY 2021 level.

- **Common Fund (CF)**
  Funding of $658.5 million is allocated for CF-supported programs. This amount is $10.0 million more than the FY 2021 level.

- **Office of Research Infrastructure Programs (ORIP)**
  Funding of $304.7 million is allocated for ORIP. This amount is $4.8 million above the FY 2021 level.

- **Other**
  The $1,431.6 million allocated for OD components other than the Common Fund or ORIP is a net increase of $96.2 million from the FY 2021 level. This is due, in part, to an increase in the portion of funding authorized by the 21st Century Cures Act that is managed by OD, from $109.0 million to $150.0 million for the *All of Us* Research Program.

Advanced Research Projects Agency for Health (ARPA-H)
The FY 2022 President's Budget provides $6.5 billion to establish ARPA-H as a new research entity within NIH. ARPA-H will complement the research portfolio of NIH's existing Institutes and Centers, investing in breakthrough health technologies and strategies to accelerate the development of evidence-based, real-world-driven cures for and transformative advances in a range of biomedical and health research areas and diseases.

Buildings & Facilities (B&F)
The FY 2022 President's Budget provides $280.0 million for infrastructure sustainment projects associated with the B&F program, which is $50.0 million more than the FY 2021 level. This amount includes $250.0 million for NIH's Buildings and Facilities appropriation, an increase of $50.0 million from the FY 2021 level, and $30.0 million within the appropriation for the National Cancer Institute (NCI) for facility repair and improvement activities at NCI's Frederick, Maryland, facility.

Superfund Research Program
The FY 2022 President's Budget provides $83.5 million for the Superfund Research Program, which is $2.0 million more than the FY 2021 level.

Program Evaluation Financing
The FY 2022 President's Budget provides $1,271.5 million for Program Evaluation Financing purposes in NIGMS, which is the same as the FY 2021 level.

OUTPUTS AND OUTCOMES

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 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 2020: With the recent expansion, SEER is able to provide trends and rates specific to the clinically relevant cancer subtypes represented by molecular characterization of each tumor. This expansion was implemented by adding U.S. cancer registries that include more underserved and ethnic and racial minority populations. Target: Provide trends and rates specific to the clinically relevant cancer subtypes represented by molecular characterization of each tumor. (Target Met)	N/A	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 2020: Analyses of secondary outcome data were completed. Target: 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. (Target Met)	N/A	N/A	N/A
SRO-2.1 By 2021, develop, optimize, and evaluate the effectiveness of nano-enabled immunotherapy (nano-immunotherapy) for one cancer type. (Output)	FY 2020: Two nanodelivery systems, which were identified as top candidates, were further optimized and are currently being tested in cancer patients who have advanced stages of cancer. Target: Further optimize	Further optimize the top candidate nanoformulation for co-delivery of antigens, adjuvants and immuno-modulators and evaluate its efficacy towards near and distance metastatic	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	the top candidate nanoformulation for co-delivery of antigens, adjuvants and immuno-modulators and evaluate its efficacy and long-lasting immunity (over 3 months) in preclinical models with established tumors. (Target Met)	lesions in preclinical models with established tumors.		
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 2020: This study is not currently enrolling participants due to COVID-19 restrictions. Target: Initiate testing one new potential treatment option for a taste disorder. (Target Not Met)	Initiate testing one new potential treatment option for a disorder affecting voice, speech, or language.	To be determined[99]	N/A
SRO-2.5 By 2021, develop three non-invasive imaging technologies that can image retinal cell function and circuitry. (Output)	FY 2020: Four novel imaging technologies have been translated from animal studies into human participants. Some of the teams have completed their work ahead of schedule. Target: Translate two novel imaging technologies from animal studies into human participants. (Target Exceeded)	Complete development of three non-invasive imaging technologies which image retinal cell function and circuitry.	N/A	N/A
SRO-2.6 By 2020, investigate the pathways and mechanisms of how seven environmental agents can alter epigenetic processes such as DNA methylation, recruitment of specific histone	FY 2020: Researchers identified sex differences in six additional environmentally induced epigenomic signatures in five different mouse tissues. Target: Determine and	N/A	N/A	N/A

[99] The longer-term impact of COVID-19 on patient recruitment is unknown at this time.

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
modifications, and chromatin remodeling to better determine if these changes can be inherited. (Output)	identify, if present, sex differences in four additional environmentally induced epigenomic signatures in three different mouse tissues. (Target Exceeded)			
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 2020: FDA approved the IND application in December 2019. Three initial patients were enrolled and were preparing to receive the transplant, but the COVID-19 pandemic prevented implementation of treatment. Target: Recruit three AMD patients into Phase I clinical trial. (Target Not Met)	Complete Phase I trial enrollment to treat a total of 12 AMD patients.	To be determined[100]	N/A
SRO-2.8 By 2023, advance the development of three novel drug or biologic therapeutic candidates for Alzheimer's disease (AD) or related dementias toward the point of entry into Phase I human studies. (Output)	FY 2020: Proof-of-concept animal model studies were completed for eight new candidate therapeutics. Target: Complete preclinical proof of concept in animal models of AD for 3-5 new candidate therapeutics. (Target Exceeded)	Initiate Investigational New Drug (IND)-enabling studies for 2-3 new candidate therapeutics.	Complete IND-enabling studies for 2-3 new candidate therapeutics.	N/A
SRO-2.9 By 2022, evaluate the safety and effectiveness of 1-3 long-acting strategies for the prevention of HIV. (Outcome)	FY 2020: NIH-funded investigators completed follow-up of participants in two 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	Initiate an open label extension of two studies, HPTN 083 and HPTN 084, investigating the safety and efficacy of the long-acting	N/A

[100] The longer-term impact of COVID-19 on patient recruitment and treatment implementation is unknown at this time.

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	Target: Strategy 1: Complete follow-up of participants in at least one of the studies testing the safety, tolerability, and effectiveness of VRC01. (Target Met)	neutralizing antibody (bnAb).	injectable antiretroviral drug cabotegravir (CAB).	
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 2020: Pre-clinical testing has been completed for a bone adhesive biomaterial. Target: Initiate pre-clinical animal studies that will lead to the development of regenerative medicine therapies of human dental, oral, and craniofacial diseases and conditions. (Target Met)	The Resource Centers will facilitate the development of five Investigational New Drug (IND)/ Investigational Device Exemption (IDE) applications from the current pool of Interdisciplinary Translational Projects.	One FDA application for a tissue regeneration combination product will be approved and one Phase 1 clinical trial protocol will be developed.	N/A
SRO-2.12 By 2021, develop, validate, and/or disseminate 3-5 new research tools or technologies that enable better understanding of brain function at the cellular and/or circuit level. (Output)	FY 2020: The Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative supported the development of novel technologies for brain stimulation and recording and efforts to disseminate resources and integrate them into neuroscience research practice. Target: Provide broad access to new research approaches and techniques for acquiring fundamental insight about how the nervous system functions in health and disease. (Target Met)	Expand our understanding of brain function at the cellular or circuit level using 3-5 new tools and technologies.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
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 2020: Animal toxicology studies have been initiated and/or completed for a total of seven neurotherapeutic/ device candidates. Target: Initiate animal toxicology studies for 1-2 therapeutic or device candidates. (Target Exceeded)	Determine the margin of safety for 1-2 therapeutic or device candidates.	Demonstrate efficacy of trial-ready formulation of 1-2 therapeutic or device candidates in preclinical disease models.	N/A
SRO-3.1 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2020: Researchers investigated the relationships among childhood trauma, functional brain connectivity, executive dysfunction, and the development of binge drinking during adolescence. Target: Examine how individual differences in neurobiology contribute to adolescent substance taking behavior and related health outcomes. (Target Met)	Conduct preclinical studies to identify persistent neurobiological adaptations that occur as a result of exposure to alcohol during adolescence.	Continue preclinical research to identify brain-based predictors of alcohol use initiation and misuse among adolescents.	N/A
SRO-3.2 By 2023, establish the feasibility of using one emerging technology to safely and non-invasively obtain real time data on human placenta development and function during pregnancy. (Outcome)	FY 2020: NIH-funded research that identified two biomarkers associated with placental function and pregnancy complications. Target: 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.	To be determined[101]	N/A

[101] Research activities were temporarily halted due to COVID-19. The longer-term impact of COVID-19 on these research activities is unknown at this time.

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	(Target Met)			
SRO-3.9 By 2020, identify two molecular-targeted therapies for disorders of the immune system that affect children. (Outcome)	FY 2020: Researchers completed an interventional clinical study and published results from four patients with treatment-resistant juvenile dermatomyositis (JDM) who responded to treatment with a Janus Kinase (JAK) inhibitor. Patients improved clinically by standard research laboratory measures and have exhibited a sustained response. Target: Complete an interventional clinical study of a molecularly targeted therapy for a disorder of the immune system that affects children. (Target Met)	N/A	N/A	N/A
SRO-4.1 By 2020, enable 1-3 Bridging Interventional Development Gaps (BrIDGs) projects to have sufficient pre-clinical data for therapeutic agents in order to apply for Investigational New Drug (IND) approval from the FDA. (Output)	FY 2020: BrIDGs researchers and their collaborators filed an Investigational New Drug (IND) application with the FDA and initiated clinical evaluation in late FY 2019. Target: Enable 1-3 BrIDGs projects to have sufficient pre-clinical data for therapeutic agents in order to apply for IND approval from the FDA. (Target Met)	N/A	N/A	N/A
SRO-4.3 By 2020, advance our characterization and understanding of the cellular and genetic	FY 2020: Studies of tumor composition by the Cancer Systems Biology Consortium and the Physical Sciences	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
components that make up the diverse composition of most tumors. (Outcome)	Oncology Network led to the development of six computational models that enhance understanding of dynamic tumor biology and enable predictions of cancer patient outcomes. Target: Based on new understanding of tumor composition, develop three computational models to explore new knowledge and treatments. (Target Exceeded)			
SRO-4.9 By 2023, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2020: NIH conducted a pre-clinical development study of a novel long-acting formulation of nalmefene for treating OUD, and a clinical study of a novel long-acting implant that delivers naltrexone, an effective treatment for OUD. Target: 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. (Target Met)	Conduct a Phase I clinical trial of an anti-opioid vaccine and a new medication to treat OUD.	Conduct a clinical trial of a medication for relapse prevention of OUD or overdose.	N/A
SRO-4.10 By 2020, design and develop novel dental composite resins that demonstrate superiority over the currently used restorative materials. (Output)	FY 2020: A filling has been developed that is stronger and longer lasting than current fillings, resulting in two patents. Target: One patent application of a novel resin will be completed, reflecting the priorities identified by the FDA.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 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 2020: Mouse models carrying induced pluripotent stem cell (iPSC)-derived human beta cells were used to test the efficacy of two approaches aimed at enhancing beta cell viability. Target: 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. (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 2020: Researchers tested three additional health risk reduction models that have the potential to reduce premature mortality in people with SMI. Target: Conduct testing of an additional three health risk reduction models that have potential to reduce premature mortality in adults with SMI. (Target Met)	N/A	N/A	N/A
SRO-4.15 By 2021, evaluate three interventions for facilitating treatment of alcohol misuse in underage populations. (Output)	FY 2020: Researchers tested the effectiveness of multiple behavioral interventions for reducing alcohol use and other harmful behaviors in underaged incarcerated and homeless youth. Target: Test a behavioral	Test another behavioral therapy for intervening with alcohol misuse in an underage population.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	therapy for intervening with alcohol misuse in an underage population. (Target Met)			
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 2020: Building on earlier efforts, two U54 Partnerships to Advance Cancer Health Equity (PACHE) validated strategies to help translate basic cancer knowledge and clinical or behavioral interventions to underserved communities across the United States and U.S. territories. These partnerships continue to work with various community-based organizations to disseminate these interventions and to assess their effectiveness in promoting health equity. 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)	N/A	N/A	N/A
SRO-5.2 By 2025, develop or evaluate the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD). (Outcome)	FY 2020: Nine prevention pilot studies were conducted as part of the Helping to End Addiction Long-term (HEAL℠) Initiative. Target: Conduct 3-5 pilot studies to test the efficacy of promising prevention interventions for SUD.	Launch 1-2 clinical trials, based on pilot study results, to test the effects of a prevention intervention for opioid use disorder.	Conduct 1-2 studies to test the effectiveness of prevention interventions focused on electronic nicotine delivery systems (including vaping).	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	(Target Exceeded)			
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 2020: Data analysis for the Alzheimer's Disease Sequencing Project (ADSP) Discovery follow-up Phase continued. Ongoing data analysis includes analysis from genomic regions of interest in ethnically diverse cohorts with increased sample size and data comparison on genomic regions of interest by ethnicity. Target: 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. (Target Met)	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.	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. Continue 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. Begin analysis of ADSP genetic data using artificial intelligence approaches.	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 2020: Findings from three NIH-funded studies have helped advance understanding of correlates of protection in non-human primates. Target: Further explore identification of correlates of protection in non-human primate animal models. (Target Met)	Enroll 25 percent - 50 percent of the 3,800 participants needed for a Phase III vaccine study.	Collect clinical data from a Phase IIb vaccine efficacy study.	N/A
SRO-5.10 By 2020, assess the effectiveness of five to seven	FY 2020: Five projects finalized their interventions and initiated dissemination	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
interventions that focus on eliminating health disparities by utilizing community partnerships to conduct intervention research that will foster sustainable efforts at the community level that will impact disparate conditions. (Output)	of results through scientific publications. Target: Complete analyses of five to seven community-based participatory research interventions to determine effectiveness in impacting health disparity conditions. (Target Met)			
SRO-5.12 By 2020, develop and/or characterize three 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 2020: Researchers made a mouse melanoma model that mimics the initial radial growth phase of human melanoma. Another mouse model uncovered a mechanism in which skin stem cells with a cancer-driving mutation multiply more but balance this by reducing their renewal rate. Target: 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. (Target Met)	N/A	N/A	N/A
SRO-5.13 By 2022, complete research to the pre-clinical stage of development of a new or significantly improved targeted, minimally invasive biomodulation technology for therapy. (Outcome)	FY 2020: Researchers created a technology using acoustic waves to direct small objects like kidney stones out of the body without the need for surgery. Target: Initiate research of a prototype technology that	Conduct research on continued development and preliminary testing of one prototype technology that uses acoustic, optical, or electromagnetic waves to manipulate cells for treatment of a specific	To be determined[102]	N/A

[102] Research activities were temporarily halted due to COVID-19. The longer-term impact of COVID-19 on these research activities is unknown at this time.

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	uses acoustic, optical, or electromagnetic waves as a test case in a specific disease. (Target Met)	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 2020: Completed follow-up on 310 subjects enrolled in a study of Laparotomy vs. Drainage for Infants with Necrotizing Enterocolitis (NEST). Target: 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. (Target Met)	N/A	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 2020: Researchers developed and tested three technology-based interventions to prevent and reduce underage drinking. Target: Develop a digital technology-based intervention to prevent or reduce alcohol misuse in underage individuals. (Target Met)	Disseminate information to the public about evidence-based interventions for underage populations.	Develop and/or evaluate preventive interventions to address underage alcohol use among specific underserved populations.	N/A
SRO-5.16 By 2021, conduct research to support pharmaceutical labeling changes for five drugs, to reflect safe and appropriate dosing and use specifically in children. (Outcome)	FY 2020: The Pediatric Trials Network has completed study enrollment for nine off-patent drugs and is enrolling patients to gather data on an additional 23 drugs. Due to the COVID-19 pandemic, there have been delays in patient enrollment.	Assess pharmacokinetics, pharmacodynamics, and safety of five drugs in pediatric populations.	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	Target: Obtain preliminary pharmacokinetic results to help assess the safety for mothers and infants of at least three common, off-patent drugs when used by breastfeeding women. (Target Not Met)			
SRO-5.17 By 2022, develop and test the effectiveness of three strategies to enhance end-of-life and palliative care. (Outcome)	FY 2020: Research developed culturally tailored interventions to improve advanced care planning for diverse populations. Target: Develop and test one novel strategy for improving end-of-life/palliative care through better support of family members and informal caregivers. (Target Met)	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.	Develop and test at least three effective interventions to enhance end-of-life and palliative care by: improving quality of life for patients; providing support for family members and informal caregivers; and/or facilitating shared decision-making.	N/A
SRO-5.18 By 2026, enhance understanding of how five health information technologies can be applied effectively to improve minority health or to reduce health disparities. (Output)	Note: SRO-5.18 will begin reporting in December 2021.	Develop an adaptive smoking cessation intervention targeting adolescents of health disparity populations using the quitStart mobile application.	Determine if a mobile phone app is effective in promoting physical activity or reducing weight among racial and ethnic minority populations.	N/A
SRO-6.1 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2020: The final visits were completed and the data analyzed from the Restoring Insulin Secretion (RISE) adult medication study. Target: 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 (GRADE) Study, according to the study protocol.	Analyze the primary outcome results from Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Study.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	(Target Met)			
SRO-6.2 By 2025, advance 1-2 new or repurposed compounds that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	FY 2020: Researchers examined the effects of ghrelin and ghrelin receptor blockade, a potential pharmacotherapy for alcohol use disorder, on inflammation in individuals with chronic heavy alcohol use. Target: Evaluate one compound with potential for treating alcohol and other substance use disorders in a clinical trial. (Target Met)	Conduct a preclinical evaluation of a novel or repurposed compound that acts on neurobiological targets implicated in alcohol use disorder.	Evaluate the efficacy of a candidate compound used in combination with a behavioral therapy for the treatment of alcohol use disorder.	N/A
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 2020: NIH completed testing for two FDA approved digital therapeutic interventions for substance use disorder treatment. These projects focused on developing or testing health IT-based interventions to prevent or treat substance use disorders or to improve medication adherence. Target: Develop and test 1-2 FDA-approved digital therapeutic interventions for substance use disorder treatment and/or medication adherence. (Target Met)	N/A	N/A	N/A
CBRR-1.1 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in	FY 2020: Award rate to comparison group reached 11 percent. Target: N ≥ 10%	N ≥ 10%	N ≥ 10%	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
research careers. (Output)	(Target Met)			
CBRR-1.2 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2020: Award rate to comparison group reached 16 percent and exceeded target by 6 percent. Target: N ≥ 10% (Target Exceeded)	N ≥ 10%	N ≥ 10%	N/A
CBRR-2 Promote data sharing and provide information in real time through the NIH Business System (NBS) by developing, integrating, deploying and maintaining business modules. (Output)	FY 2020: NBS implemented priority deployment activities for the Fund Configuration Initiative as planned. Target: (Deployment [Dep]) Conduct priority deployment activities for the Funds Configuration Initiative to comply with one of the NIH Corrective Action Plan remediation efforts. (Target Met)	(Development [Dev]) Continue to conduct priority deployment activities for the NIH Corrective Action Plan remediation efforts.	(Development [Dev]) Initiate development of planned business modules to build capacity and functionality of the NIH Business System.	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 2020: Over 600 knockout juvenile lines were characterized (phenotyped). Target: Deliver phenotyping on 600 knockout juvenile lines (Target Exceeded)	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	N/A
CBRR-9 By 2020, enroll a total of 3,010 participants in GenomeConnect, ClinGen's Patient Registry. (Output)	FY 2020: A cumulative 3,106 participants were enrolled in GenomeConnect. Target: Enroll a total of 3,010 participants in GenomeConnect, ClinGen's Patient Registry.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	(Target Exceeded)			
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 2020: More than 50 children were enrolled in the PHN in 2020. Target: Enroll 50 children with complex congenital heart disease in a clinical research study (Target Met)	N/A	N/A	N/A
CBRR-18 By 2021, develop and validate a new protocol for dementia assessment for use in large nationally representative samples. (Outcome)	FY 2020: Baseline Harmonized Cognitive Assessment Protocol (HCAP) data collection is complete in the US, Mexico, England, China and India. Data and documentation have been publicly released. Follow-up studies were planned but not initiated due to the COVID-19 pandemic. Target: Make data from the HCAP publicly available to the research community and initiate a follow-up study to the HCAP. (Target Not Met but Improved)	Complete follow-up assessment in the Health and Retirement Study using the refined HCAP.	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 2020: Four vaccine and therapeutic products were advanced in FY 2020. Target: Advance the preclinical development of four vaccine and/or therapeutic candidate products. (Target Met)	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
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 2020: Eight pilot and feasibility projects involving collaborations outside the hematology Centers were supported in FY 2020. Target: Support four P&F projects involving collaboration outside the hematology Centers. (Target Met)	N/A	N/A	N/A
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 2020: Comparative atlases of the human and mouse prostate and kidney were generated and released to the general public. Target: Generate and release the human/mouse comparative atlases to the general public. (Target Met)	N/A	N/A	N/A
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 2020: Trainees from diverse backgrounds received a total of 3,779 career development experiences across all career stages. Target: 3,539 career experiences across all career stages (Target Exceeded)	3,540 career experiences across all career stages	3,545 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	FY 2020: Due to the COVID-19 pandemic, the INBRE program was not able to provide summer research programs during FY 2020.	Sustain the number of undergraduate mentored research experiences from 2020 level.	Sustain the number of undergraduate mentored research experiences from FY 2021 level.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
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)	Target: Sustain the number of undergraduate mentored research experiences from 2019 level. (Target Not Met)			
CBRR-27 By 2020, develop a suicide risk validated assessment tool that can easily be implemented in emergency care settings. (Output)	FY 2020: Researchers validated the Computerized Adaptive Screen for Suicidal Youth (CASSY). Target: Validate risk stratification approaches in emergency care settings for youth, and test clinical decision-making approaches based on risk stratification. (Target Not Met but Improved)	N/A	N/A	N/A
CBRR-28 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting research on brain and behavior. (Output)	FY 2020: Brain tissue from 30 new donors was obtained and tissue or data were distributed to 35 researchers. Target: 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. (Target Not Met but Improved)	Collect brain tissue from an additional 30 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 25 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	FY 2020: Multi-site validation studies have been initiated for 10 additional biomarker candidates, bringing the total to 11 biomarker	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
vascular contribution to cognitive impairment and dementia (VCID). (Output)	candidates undergoing instrumental and clinical multi-site validation within the Consortium. Target: Initiate multi-site validation studies for two additional biomarker candidates. (Target Exceeded)			
CBRR-30 By 2024, expand the use of program-focused versus target-focused award mechanisms by National Institute of General Medical Sciences (NIGMS) investigators. (Output)	Note: CBRR-30 will begin reporting in December 2021.	Expand NIGMS investigator participation in the Maximizing Investigators' Research Award (MIRA) program by 2 percentage points.	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 strategy to address the burden of Chronic Obstructive Pulmonary Disease (COPD) in the US. (Output)	FY 2020: NIH analyzed information from completed webinars and meetings and briefed stakeholders on National Action Plan progress. Target: Analyze completed webinars and meetings, and brief stakeholders on Action Plan progress. (Target Met)	Launch COPD National Action Plan Community Action Tool for stakeholders to capture Action Plan progress and conduct webinar and other promotional activities to encourage its use.	Analyze Action Plan implementation activities reported by stakeholders.	N/A
CTR-8 By 2020, improve the breadth of available metrics used to assess the number of scientists seeking research awards from NIH, and report on these expanded measures to both inform agency funding decisions, and promote transparency regarding the agency's funding strategies. (Output)	FY 2020: NIH developed summary reports to characterize grantee organizations that receive funding using multiple classification schemes, including the Department of Education Carnegie Classification. The framework provides a landscape of higher education granting postsecondary organizations.	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	Target: 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. (Target Met)			
MPO-3 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2020: NIH examined the use of the shared recruitment approach to determine if hiring goals were being met. The success of shared recruitments identified in the evaluation process led NIH to implement an even more proactive solution involving an entire schedule of shared recruitments that launched in the fall of 2020. Target: Examine (EX) key area to enhance recruitment. Examine use of the shared recruitment approach, using data gathered in first year of full-time practice, to determine if hiring goals are being met. [IM 2021/AS 2022] (Target Met)	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]	Assess [AS] results of implementation. Assess the shared recruitment approach, using data gathered in first year of full-time practice, to determine if hiring goals are being met. [EX 2020/IM 2021]	N/A
MPO-4 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors. (Output)	FY 2020: 25 percent of Principal Investigators were reviewed resulting in approximately 25 percent of resources recommended to be reallocated.	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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	Target: Conduct Board of Scientific Counselors (BSC) reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources. (Target Met)			
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 2020: The condition of the facilities portfolio reached a CIwa of 80.16. Target: CIwa = 77.78 (Target Exceeded)	CIwa = 77.63	CIwa = 76.95	N/A
MPO-7 Manage all Buildings and Facilities (B&F) line item projects so it is completed within 100 percent of the final approved project cost. (Ongoing) (Output)	FY 2020: 37 of the 45 active projects at the Facility Project Approval Agreement (FPAA) level threshold were effectively managed to ensure completion within 100 percent of the final approved cost. Target: 25 Active Projects (Target Exceeded)	21 Active Projects	28 Active Projects	N/A
MPO-8 Manage design and construction of capital facility projects funded by 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 2020: NIH managed the design and construction of 37 of the 45 funded projects without a plus or minus 10 percent adjustment to the scope. Target: 25 Active Projects (Target Exceeded)	21 Active Projects	28 Active Projects	N/A
MPO-9 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2020: Obligated 47 percent of eligible service contracting dollars to PBC. Target: Obligate the FY 2020 goal of eligible	Obligate the FY 2021 goal of eligible service contracting dollars to PBC.	Obligate the FY 2022 goal of eligible service contracting dollars to PBC.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2021 Target	FY 2022 Target	FY 2022 Target +/-FY 2021 Target
	service contracting dollars to PBC. (Target Met)			
MPO-11 Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation. (Output)	FY 2020: Of the 120 grant awards, 90 instruments (75 percent) were installed within 18 months of the Notice of Award date. Target: Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 18 months after award. (Target Met)	Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 18 months after award.	Verify 75 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 18 months after award.	N/A
MPO-12 By 2020, enhance the management, oversight, and transparency of NIH-funded clinical trials through reforms to clinical trials grant applications, peer review, and tracking of awards. (Outcome)	FY 2020: NIH has deployed an enterprise-wide system for improved stewardship of NIH-funded clinical trials. The system has the ability to identify NIH-funded clinical trials and to receive and manage Clinical Trial data for grants, contracts and intramural projects and integrate with ClinicalTrials.gov to enhance availability of data and compliance. Target: 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. (Target Met)	N/A	N/A	N/A

Grant Awards Table

	FY 2020 Final Allocation*,3	FY 2021 Enacted*,3	FY 2022 President's Budget a,3
Number of Awards	50,184	50,909	53,537
Average Award (in Whole $s)	$587,856	$595,857	$601,395
Range of Awards (in Whole $s)[1,2]	$1,000 to $32,595,654	$1,000 to $38,339,743	$1,000 to $37,780,409

[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.

[*] To make the figures for FY 2020 and FY 2021 comparable to FY 2022, grant awards for the ECHO & INCLUDE programs have been added to the NICHD mechanism tables for those years, adding 103 and 89 awards to the NIH total figures, respectively.

[a] Figures do not include any awards related to the proposed ARPA-H program.

NEF NARRATIVE

Budget Summary
(Dollars in Thousands)

	FY 2020	FY 2021	FY 2022[103]
Notification[104]	--	--	TBD
Congressional Direction	$225,000	$225,000	TBD

Authorizing Legislation:

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

Program Description and Accomplishments

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

In recent years, the NEF has provided funds for critical infrastructure needs for NIH buildings, structures, and facilities, as a supplement to the regular NIH Building and Facilities (B&F) appropriations. The projects described below received NEF funds in FY 2016, FY 2017, FY 2019, FY 2020, and FY 2021.

FY 2016

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 CCC on the Bethesda Campus is a group of facilities that collectively support the NIH biomedical research mission by serving research hospital and laboratory functions. 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:

- 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

[103] HHS has not notified Congress in FY 2022.
[104] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

- 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.

FY 2017

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 Central 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 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.

FY 2019

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 project will also include several enabling tasks for the proposed Surgery, Radiology, and Laboratory Medicine (SRLM) building, to be built as an addition to the Clinical Research Center (CRC). The enabling tasks include a new 2MW generator and switchgear for the SRLM building and the Clinical Data Center, as well as replacement of the electrical duct bank currently serving the CRC, which is in the footprint of

the new SRLM building. Also, repairs include a new CO2 storage tank, a new electrical feeder from Building 63 to the utility vault and parking garage, and utility vault housing for the future Building 59 & 59A (emergency generators and switchgear) replacement.

In FY 2019, NIH also 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. 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.

FY 2020

In FY 2020, NIH received $225 million from the NEF through Congressional direction, and allocated $12.6 million to upgrade and replace the obsolete Building Automation System of the CCC (inclusive of the original B10, ACRF, and CRC) with a new state-of-the-art, cost-effective, contiguous, simple, and secure system. The upgrade includes replacement of primary network controllers, controllers serving air-moving equipment and associated sensors, controllers serving hydronic systems and associated sensors, and replacement of pneumatic actuators with electronic actuators (except for speed-critical and high-torque devices). In order to minimize disruption to operations, terminal unit (VAV box) controllers and interfaces to Phoenix airflow control systems will remain and integrate into the new system. To a large extent, existing network and end device wiring will remain and be reused. This project was originally included in the FY 2019 NEF notification to Congress, and it continues to be one of the most pressing facility needs for NIH.

In FY 2020, NIH also allocated $212.4 million for its highest priority construction project, the SRLM building. This project will construct a new addition and repurpose two floors of the West Laboratory Wing of the CRC. The project will include the CCC Departments of Perioperative Medicine and Interventional Radiology, Radiology and Imaging Sciences, and Laboratory Medicine, now located in the ACRF's Wings S&T, and the National Cancer Institute's (NCI) research labs located on floors 1W and 3W of the CRC West Laboratory Wing. The total project will consist of 629,440 GSF, including new construction of 547,290 GSF and 82,150 GSF of renovation. The new wing will be an 8-story above-grade structure (with interstitial floors), plus one floor below grade and a mechanical penthouse. A below-grade Cardiovascular Intervention Program suite is also planned. The addition will be located on the west end of the CRC-West Laboratory Wing. Once the new addition is completed, four floors of the West Lab wing will be renovated after the existing NCI Research Labs are moved to the new addition.

The most recent Building Condition Index conducted by NIH has the ACRF, built in 1982, in the POOR category. Some of the major deficiencies include the following: 1) functional space

inadequacies/ inefficiencies; 2) inefficient routes of circulation; 3) numerous limitations restricting the facility's reliability of operations/flexibility/adaptability to address growth and change; 4) deficient and unreliable infrastructure systems (major areas of concern include normal and emergency power, communication systems, heating, cooling, and ventilation); and 5) structural problems (light steel structure), resulting in unacceptable vibration levels in some areas of the building.

Of the $212.4 million of FY 2020 NEF funds devoted to the SRLM, NIH plans to use $12.0 million to further the development of the SRLM bridging documents and conduct an independent cost estimate. This work will also include developing plans to get final approval from the National Capital Planning Commission and the Maryland Department of the Environment concept plans approved, construction logistics plan, air entrainment studies, traffic studies, analysis of potential crane usage/safety, materials staging, worker access, utilities shutdowns, and more.

FY 2021

While the SRLM project was shovel-ready in FY 2020, NIH did not have sufficient funds from its B&F appropriation and the NEF to award the $492.0 million construction contract. NIH carried over $200.4 million of the FY 2020 NEF funds, which are available until expended, to make the construction award in late FY 2021 or early FY 2022 using both FY 2020 and FY 2021 resources. In FY 2021, NIH intends to devote an additional $225.0 million in NEF funds, in addition to $62.6 million of FY 2020 and $4.0 million of FY 2021 B&F appropriations, to SRLM to award the construction contract using the remaining FY 2020 and new FY 2021 funds. The current target for issuing the solicitation for a Design-Build Contract is May 2021, with the target date for awarding the contract in the first quarter of FY 2022.