#### APPROPRIATIONS LANGUAGE

#### NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, \$7,839,141,000, of which \$716,000,000 shall remain available until expended, and of which up to \$50,000,000 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, \$3,997,086,000.

#### 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, \$521,695,000.

#### 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, \$2,309,991,000.

#### 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, \$2,788,327,000.

#### NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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For carrying out section 301 and title IV of the PHS Act with respect to allergy and infectious diseases, \$6,581,291,000.

#### NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to general medical sciences, \$3,249,375,000, of which \$2,018,482,000 shall be from funds available under section 241 of the PHS Act: Provided, That not less than \$427,231,000 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, \$1,766,415,000.

#### NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, \$898,818,000.

#### NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, \$916,791,000.

#### NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

For necessary expenses for the National Institute of Environmental Health Sciences in carrying out activities set forth in section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9660(a)) and section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, \$83,035,000.

#### NATIONAL INSTITUTE ON AGING

For carrying out section 301 and title IV of the PHS Act with respect to aging, \$4,425,295,000.

## 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, \$689,697,000.

## 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, \$535,929,000.

#### NATIONAL INSTITUTE OF NURSING RESEARCH

For carrying out section 301 and title IV of the PHS Act with respect to nursing research,

\$198,263,000.

## NATIONAL INSTITUTE ON ALCOHOL EFFECTS AND ALCOHOL-ASSOCIATED DISORDERS

For carrying out section 301 and title IV of the PHS Act with respect to alcohol misuse, alcohol use disorder, and other alcohol-associated disorders, \$598,903,000.

#### NATIONAL INSTITUTE ON DRUGS AND ADDICTION

For carrying out section 301 and title IV of the PHS Act with respect to drugs and addiction, \$1,668,343,000.

#### NATIONAL INSTITUTE OF MENTAL HEALTH

For carrying out section 301 and title IV of the PHS Act with respect to mental health, \$2,503,162,000.

#### NATIONAL HUMAN GENOME RESEARCH INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to human genome research, \$663,660,000.

#### 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, \$441,944,000.

#### 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, \$170,894,000.

#### NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

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For carrying out section 301 and title IV of the PHS Act with respect to minority health and health disparities research, \$526,710,000.

#### 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), \$95,415,000.

#### NATIONAL LIBRARY OF MEDICINE

For carrying out section 301 and title IV of the PHS Act with respect to health information communications, \$526,796,000: Provided, That of the amounts available for improvement of information systems, \$4,000,000 shall be available until September 30, 2026: Provided further, That in fiscal year 2025, 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, \$926,086,000: Provided, That up to \$70,000,000 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network: Provided further, That at least \$631,444,000 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, \$3,000,855,000:

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 \$722,401,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: Provided further, That \$153,909,000 shall be available for the Office of Research on Women's Health established under section 486 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 up to \$10,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 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 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 2025 and 2026 no later than 30 days after the date of* 

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enactment of this Act: Provided further, That amounts made available under this heading are also available to establish, operate, and support the Research Policy Board authorized by section 2034(f) of the 21<sup>st</sup> Century Cures Act.

In addition to other funds appropriated for the Office of the Director, \$12,600,000 is appropriated from the 10-year Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986 (26 U.S.C. 9008), for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act.

#### **BUILDINGS AND FACILITIES**

For the study of, construction of, demolition of, renovation of, and acquisition of equipment for, facilities of or used by NIH, including the acquisition of real property, \$350,000,000, to remain available through September 30, 2029.

#### 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, \$127,000,000, 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.

#### **GENERAL PROVISIONS**

SEC. 214. Not to exceed \$100,000,000 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 \$5,000,000 per project.

#### LANGUAGE ANALYSIS

Language Provision to be Changed <sup>112</sup>	Explanation/Justification
<b>OFFICE OF THE DIRECTOR</b> <i>Provided further, That \$153,909,000 shall be available for the Office of Research on Women's Health established under section 486 of the PHS Act</i>	This revision specifically enumerates the funding for the Office of Research on Women's Health within the Office of the Director (OD).
<b>OFFICE OF THE DIRECTOR</b> In addition to other funds appropriated for the Office of the Director, \$12,600,000 is appropriated from the 10-year Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986 (26 U.S.C. 9008), 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.	This proposed revision removes references to the Common Fund within the Gabriella Miller section of the OD appropriations language since as of FY 2025 the Gabriella Miller Kids First Pediatric Research program will be funded within the OD Division of Program Coordination, Planning, and Strategic Initiatives rather than in the Common Fund.

<sup>&</sup>lt;sup>112</sup> Language changes are relative to appropriations language proposed in the FY 2024 President's Budget. 49

#### BUDGET MECHANISM TABLE

	FY 2023		FY 2024		FY 2025		FY 2025	
$(\mathbf{D}_{-}\mathbf{H}_{-})^{1,2,3}$	1	Final <sup>9</sup>		CR <sup>9</sup>	Preside	nt's Budget <sup>9</sup>	+/- FY 2023 Final	
(Donais in Thousands)	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	30,177	\$17.975.116	31.389	\$19.039.410	31,481	\$19.444.480	1.304	\$1.469.365
Administrative Supplements <sup>3</sup>	(3,793)	535,090	(3,048)	368,151	(2,999)	351,610	(-794)	-183,480
Competing	11,106	\$6,783,224	9,739	\$5,643,337	10,273	\$6,069,919	-833	-\$713,305
Subtotal, RPGs	41,283	\$25,293,430	41,128	\$25,050,898	41,754	\$25,866,009	471	\$572,580
SBIR/STTR	1,893	1,287,467	1,845	1,256,967	1,882	1,275,239	-11	-12,227
Research Project Grants	43,176	\$26,580,896	42,973	\$26,307,866	43,636	\$27,141,249	460	\$560,352
Research Centers:								
Specialized/Comprehensive	1,045	\$2,271,984	1,065	\$2,317,655	1,119	\$2,480,487	74	\$208,504
Clinical Research	57	328,369	36	258,996	24	198,750	-33	-129,619
Biotechnology	40	64,909	40	65,869	30	42,739	-10	-22,171
Comparative Medicine	49	137,280	47	131,225	47	130,065	-2	-7,214
Research Centers in Minority Institutions	23	78,613	23	79,164	23	79,164	0	551
Research Centers	1,214	\$2,881,155	1,211	\$2,852,909	1,243	\$2,931,206	29	\$50,051
Other Research								
Research Careers	5.043	\$928,335	5.030	\$935,151	5.048	\$945,157	5	\$16.822
Cancer Education	83	23,219	82	22,837	82	22,837	-1	-382
Cooperative Clinical Research	269	485,641	245	485,100	436	1,008,525	167	522,884
Biomedical Research Support	126	111,657	120	103,257	47	54,321	-79	-57,336
Minority Biomedical Research Support	154	55,759	86	37,745	30	25,523	-124	-30,236
Other	2,536	1,732,101	2,457	1,605,568	2,764	1,861,395	228	129,294
Other Research	8,211	\$3,336,712	8,020	\$3,189,658	8,407	\$3,917,757	196	\$581,046
Total Research Grants	52,601	\$32,798,763	52,204	\$32,350,433	53,286	\$33,990,212	685	\$1,191,449
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	3.968	\$191.272	4.113	\$200.800	4.122	\$203.304	154	\$12.032
Institutional Awards	13,469	793,060	13,812	820,640	13,800	830,904	331	37,844
Total Research Training	17,437	\$984,331	17,925	\$1,021,440	17,922	\$1,034,208	485	\$49,876
Research & Development Contracts	2,745	\$4,032,891	2,623	\$3,857,225	2,933	\$4,582,467	188	\$549,576
(SBIR/STTR) (non-add) <sup>3</sup>	(101)	(75,193)	(79)	(61,364)	(166)	(130,942)	(65)	(55,750)
Intramural Research		\$5,046,199		\$5,133,445		\$5,274,376		\$228,177
Research Management & Support		2,331,451		2,442,336		2,689,558		358,107
SBIR Admin (non-add) <sup>3</sup>		(10,098)		(10,881)		(11,287)		(1,188)
occ. c.d. D:		(3.066.208)		(2 885 514)		(3.044.455)		(21753)
Office of the Director - Appropriation		2 021 814		(2,885,514)		2 062 661		(-21,755)
$OPIP(non, add)^{3,4}$		(309 393)		(309 393)		(259 393)		(-50,000)
$Common Fund (non-add)^{3,4}$		(735.001)		(735.001)		(722.401)		(-12.600)
common r una (non-uau)		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(,, , , , , , , , , , , , , , , , , ,		(, ,
ARPA-H		1,500,000		1,500,000		1,500,000		0
Buildings and Facilities <sup>5</sup>		380,000		380,000		400,000		20,000
Appropriation <sup>3</sup>		(350,000)		(350,000)		(350,000)		(0)
Type 1 Diabetes <sup>6,7</sup>		-141,450		-250,000		-260,000		-118,550
Mandatory Cancer Moonshot <sup>6</sup>		0		0		-1,448,000		-1,448,000
Program Evaluation Financing <sup>6</sup>		-1,412,482		-1,412,482		-2,018,482		-606,000
		¢ 48 5 41 5 40		\$4C 0/2 540		¢ 45 005 000		\$265 400
Subtotal, Labor/HHS Budget Authority		\$47,541,518		\$46,863,518		\$47,807,000		\$265,482
Total NIH Discontionary Rubert Authority		\$3,035		\$46.046.553		\$3,035		0 \$265.492
Type 1 Dishetes <sup>7</sup>		1/11/150		φ <b>40,940,553</b> 250,000		260.000		\$205,482 118 550
Type 1 Diabetes Mandatory Cancer Moonshot		141,430		230,000		1 448 000		1 448 000
Total. NIH Budget Authority		\$47,766.003		\$47,196,553		\$49,598.035		\$1,832,032
Program Evaluation Financing		1.412.482		1.412 482		2.018 482		606 000
Total, Program Level		\$49,178,485		\$48,609.035		\$51,616.517		\$2,438.032
Pandemic Preparedness Mandatory via PHSSEF (non-add) <sup>8</sup>		(0)		(0)		(2,690,000)		(2,690,000)

See footnotes on following page.

#### **OVERALL APPROPRIATIONS**

#### Budget Mechanism Table Footnotes.

- <sup>1</sup> Subtotal and Total numbers may not add due to rounding.
- <sup>2</sup> Includes 21st Century Cures Act funding and excludes supplemental financing.
- <sup>3</sup> Numbers in italics and brackets are non-add.
- <sup>4</sup> 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.
- <sup>5</sup> 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.
- <sup>6</sup> Number of grants and dollars for mandatory Type 1 Diabetes (T1D), mandatory Cancer Moonshot, and 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.
- <sup>7</sup> Amount in FY 2023 reflect a reduction of \$8.550 million for Budget Control Act sequestration. FY2024 reflects annualized CR level of \$150.0 million plus \$100.0 million reauthorization proposal.
- <sup>8</sup> The FY 2025 budget also provides \$20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, NIH will receive \$2,690 million.
- <sup>9</sup> Reduced by a transfer of \$5.0 million from OD to the HHS Office of Inspector General.

#### AUTHORIZING LEGISLATION

(Dollars in Thousands)	FY 2024 Amount Authorized	FY 2024 Amount Appropriated <sup>1</sup>	FY 2025 Amount Authorized	FY 2025 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 <sup>2</sup>	TBD	46,361,400	TBD	48,190,882
Advanced Research Projects Agency-Health: Section 499A(s) of the PHS Act	500,000	1,500,000	500,000	1,500,000
Pediatric Research Initiative: Section $402A(a)(2)$ of the PHS Act <sup>3</sup>	TBD	12,600	TBD	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	83,035	Indefinite	83,035
3. 21 <sup>st</sup> Century Cures Act:				
Precision Medicine: Section 1001(b)(4)(A)	235,000	235,000	36,000	36,000
BRAIN Initiative: Section 1001(b)(4)(B)	172,000	172,000	91,000	91,000
Cancer Moonshot: Section 1001(b)(4)(C)	0	0	0	0
4. Special Diabetes Programs: Section 330B(b) of the PHS Act <sup>4</sup>	65,753	65,753	TBD	260,000

<sup>1</sup>Reflects annualized amounts under the FY 2024 Continuing Resolution.

<sup>2</sup>The authorization of appropriations expired as of September 30, 2020.

<sup>3</sup>The authorization of appropriations expired as of September 30, 2023.

<sup>4</sup>The amount for the Special Diabetes Programs in the FY 2024 Amount Appropriated column reflects the funding level enacted on January 19, 2024 in Public Law 118-35.

#### APPROPRIATIONS NOT AUTHORIZED BY LAW

	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2024 <sup>1</sup>
NIH Labor/HHS Budget Authority <sup>2</sup>	FY 2020	\$36,472,442,775	\$40,954,400,000	\$46,361,400,000

<sup>1</sup>Reflects annualized levels under the FY 2024 Continuing Resolution.

<sup>2</sup>Appropriations under general authorization of appropriations in Section 402A(a)(1) of the PHS Act. Excludes appropriations related to the Cures Act, the Gabriella Miller Pediatric Research Initiative, and the Advanced Research Projects Agency for Health.

#### NARRATIVE BY ACTIVITY TABLE/HEADER TABLE

(Dollars in Millions)	FY 2023 Final <sup>3</sup>	FY 2024 CR <sup>3</sup>	FY 2025 President's Budget <sup>3</sup>	FY 2025 +/- FY 2023
Program Level <sup>1,2</sup>	\$49,178.5	\$48,609.0	\$51,616.5	\$2,438.0
Program Level, excluding ARPA-H <sup>1,2</sup>	\$47,678.5	\$47,109.0	\$50,116.5	\$2,438.0
FTE	19,180	20,942	21,256	2,076

<sup>1</sup> All columns exclude supplemental funds.

<sup>2</sup> Includes 21st Century Cures Act funding, mandatory funding for Cancer Moonshot and Type 1 Diabetes, and Superfund; includes NIGMS Program Evaluation funding of (in thousands) \$1,412,482 in FY 2023, \$1,412,482 in FY 2024, and \$2,018,482 in FY 2025.

<sup>3</sup> Reduced by transfer to the HHS Office of Inspector General (\$5.0 million).

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 seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to improve the health of the Nation. To achieve these goals, NIH supports research on the causes, prevention, and treatments of human diseases and disorders; processes in healthy development and aging; and methods for collecting and disseminating data and health information. NIH invests over \$45 billion annually in research programs to achieve its mission.

In FY 2023, NIH-funded scientists have continued to make paradigm-shifting contributions across the full spectrum of biomedical, behavioral, and social sciences research from groundbreaking basic science through pivotal clinical trials and implementation research. As the coronavirus disease 2019 (COVID-19) pandemic has shifted, NIH has continued adopting new approaches, learned during the pandemic, to enhance mission-critical scientific research and funding. The lessons learned continue to both inform other research areas and ensure preparedness for future public health emergencies. Examples of these critical efforts and scientific research areas are described below.

#### Looking beyond the COVID-19 Pandemic

With the COVID-19 Public Health Emergency ending, NIH has prioritized the overarching review of its response to the COVID-19 pandemic, including the assessment of NIH's management, operations, procedures, policies and resource allocations. In FY 2023, together with partner organizations, NIH leadership outlined NIH's COVID-19 research response and critical lessons learned, highlighting recent biomedical efforts and developments that will inform the public health research response to future pandemics. By building on decades of basic and applied research and engaging in highly collaborative public-private partnerships, NIH and the broader biomedical community were able to quickly develop safe and effective vaccines, therapeutics, and diagnostics in response to the fast-evolving COVID-19 pandemic. Lessons learned from the COVID-19 pandemic will be translated into actionable initiatives, policy changes, and other recommendations that will ensure NIH is prepared for the next pandemic and public health crisis. Efforts to prepare for the next emerging and re-emerging disease are already underway with NIH-funded research teams working to develop universal vaccines against diseases with pandemic potential and to support global surveillance of pathogens and advance response readiness.

A paramount focus of NIH's COVID-19 response was community engagement. In collaboration with the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), NIH launched the Home Test to Treat program.<sup>113</sup> This virtual community health intervention provided free COVID-19 health services, including athome rapid COVID-19 tests, telehealth sessions, and athome treatments to communities across the country. As part of the RADx-Tech effort, NIH was also instrumental in working with biomedical device manufacturers to quickly develop home-based COVID-19 tests.<sup>114</sup> Building

 <sup>&</sup>lt;sup>113</sup> www.nih.gov/news-events/news-releases/nih-launches-home-test-treat-pilot-covid-19-telehealth-program
<sup>114</sup> www.nibib.nih.gov/covid-19/radx-tech-program/listening-session/agenda

on the important work and infrastructure developed to respond to the COVID-19 pandemic, NIH is more prepared than ever to respond to emerging and re-emerging pathogens and diseases.

While many people recover fully within a few days or weeks of being infected by SARS-CoV-2, the virus that causes COVID-19, others suffer from long-lasting symptoms. To better understand, treat, and prevent this condition, termed Long COVID, the NIH launched the NIHwide Researching COVID to Enhance Recovery (RECOVER) initiative<sup>115</sup> in 2021. Led by the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Neurological Disorders and Stroke (NINDS), in coordination with the Office of the Director (OD) the RECOVER initiative addresses the widespread and diverse manifestations of Long COVID through a national research network that includes observational cohort studies, *in silico* studies of electronic health records, clinical trials, and studies on the underlying pathobiology. RECOVER's comprehensive research framework has provided the critical foundation for understanding and treating Long COVID and is already providing valuable insights into the condition. In FY 2023, NIH also launched and opened enrollment for Phase 2 clinical trials that will evaluate potential treatments for Long COVID, including drugs, biologics, medical devices, and other therapies. The trials are designed to evaluate multiple treatments simultaneously to identify more swiftly those that are safe and effective. The RECOVER-VITAL clinical protocol is looking at whether viral persistence is a cause of some Long COVID symptoms, and RECOVER-NEURO is examining interventions for cognitive dysfunction related to Long COVID, including brain fog, memory problems, and difficulty with attention, thinking clearly, and problem solving. Additional protocols are expected to launch in the coming months.

# Addressing Health Disparities and Inequities in Biomedical Research and Supporting a Diverse Health Disparities and Biomedical Research Workforce

Health disparities, preventable differences in health status and outcomes that adversely impact certain populations,<sup>116</sup> are a key focus of NIH's mission to improve health in the United States. NIH is dedicated to improving minority health, reducing health disparities, and removing barriers to health disparities research. Only by researching the influence of environment, social determinants, and other underlying mechanisms which lead to differential health outcomes can disparities in health be prevented. Efforts across NIH are underway to study mechanisms and reduce disparities in all areas of health, with each IC supporting health disparities research and efforts to support a diverse biomedical research workforce as part of their overall portfolios.

At NIH, the National Institute on Minority Health and Health Disparities (NIMHD) leads the way on research to improve minority health and reduce health disparities, collaborating across NIH and the federal government to advance promising studies. NIMHD supports all aspects of this research ranging from genetic, molecular, and biologic science to clinical, behavioral, and translational research, as well as research on health systems, workforce development, and environmental justice. NIMHD recently awarded \$60 million in grants through the John Lewis NIMHD Research Endowment Program.<sup>117</sup> These grants will create institutional endowments for the development and expansion of research capacity and infrastructure in recipient

<sup>&</sup>lt;sup>115</sup> recovercovid.org/

<sup>&</sup>lt;sup>116</sup> www.nih.gov/ending-structural-racism/minority-health-health-disparities-research

<sup>117</sup> www.nimhd.nih.gov/programs/extramural/research-endowment.html

institutions. This program also supports research education opportunities for students from diverse backgrounds and those from underrepresented groups.

In recognition of the fundamental importance of addressing health disparities in all aspects of the research enterprise, all of the NIH Institutes, Centers, and Offices (ICOs) lead efforts to advance health disparities research and address inequities within their scientific and medical areas of interest. For example, the NIH Common Fund addresses emerging scientific opportunities in biomedical research that no single NIH Institute or Center (IC) can address on its own. The programs within the Common Fund are considered high priority for NIH. One such program is the Community Partnerships to Advance Science for Society (ComPASS).<sup>118</sup> The ComPASS program aims to 1) develop, share, and evaluate community-led health equity structural interventions that leverage partnerships across multiple sectors to reduce health disparities, and 2) develop a new health equity research model for use across NIH and other federal agencies.<sup>119</sup> This first-of-its-kind community-led research program aims to redefine the culture at NIH-funded extramural institutions by implementing a cohort faculty recruitment model and building a community of scientists committed to diversity and inclusivity.

Diversity in the workforce is a key component of innovation and achievement in all areas of research, including health disparities research. The NIH UNITE Initiative was launched in 2021 as an NIH-wide effort committed to ending racial inequities across the biomedical research enterprise. It is composed of five committees, each with a specific, targeted focus: (U)nderstanding stakeholder experiences through listening and learning; (N)ew research on health disparities/minority health/health inequity; (I)mproving the NIH culture and structure for equity, inclusion, and excellence; (T)ransparency, communication, and accountability with NIH's internal and external stakeholders; and (E)xtramural research ecosystem and changing policy, culture, and structure to promote workforce diversity. To support research on health inequities the UNITE Initiative reviews NIH's research portfolio to identify and make recommendations for addressing research gaps, reviews systems for measuring and tracking health disparity research, and supports research on behavioral, biological, and social determinants of health, structural racism, and discrimination. The NIH UNITE Initiative has received considerable community input through a Request for Information (RFI) on how NIH might advance diversity within the biomedical and behavioral research workforce and expand research to eliminate or lessen health disparities and inequities with over 1,100 written responses and an audience of over 1,300 participants across 14 listening sessions. Community input received through the RFI is leading the way for future UNITE Initiative developments. Accountability and communication are a commitment for the UNITE Initiative which is tracking facts and figures regarding aggregated diversity, equity, and inclusion-related data and analyses related to funding, the internal NIH staff, and the external scientific workforce through a public Data Dashboard.<sup>120</sup>

The Chief Officer for Scientific Workforce Diversity (COSWD) Office in the NIH OD leads NIH's efforts in diversifying the national scientific workforce. In 2023, the COSWD Office announced a new initiative, the Diversity, Equity, Inclusion and Accessibility (DEIA) Prize

<sup>&</sup>lt;sup>118</sup> commonfund.nih.gov/compass

<sup>&</sup>lt;sup>119</sup> commonfund.nih.gov/first

 $<sup>^{120}\</sup> www.nih.gov/sites/default/files/research-training/initiatives/ending-structural-racism/UNITE-progress-report-2022.pdf$ 

competition.<sup>121</sup> This competition was developed to recognize and reward institutions whose biomedical, social, and behavioral science departments, centers, programs or divisions have identified gaps/barriers towards addressing DEIA; as well as those institutions that, design, implement, and evaluate interventions to address gaps to successfully achieve sustained improvement in DEIA within their faculty, postdoctoral scholars, and student bodies.

In March 2023, NIH released the NIH-Wide Strategic plan for Diversity, Equity, Inclusion and Accessibility.<sup>122</sup> The five-year strategic plan articulates NIH's commitment to strengthen DEIA across the agency to enhance its operations, research, and the workforce. The DEIA Strategic Plan also includes approaches to advance DEIA within the broader biomedical, behavioral, and social sciences research enterprise, including within NIH's workforce and through the research it supports.

In September 2023, NIH designated people with disabilities as a population with health disparities for research support by NIH. People with disabilities often experience a broad and varying range of health conditions leading to poorer health and shorter lifespan. In addition, discrimination, inequality and exclusionary structural practices, programs and policies inhibit access to timely and comprehensive health care, which further results in poorer health outcomes.<sup>123</sup> This decision was made in consultation with the Agency for Healthcare Research and Quality and after careful consideration of a report<sup>124</sup> developed by an NIMHD advisory council, input from the disability community, and a review of the science and evidence. A report<sup>125</sup> issued in December 2022 by the Advisory Committee to the (NIH) Director (ACD), informed by the work of the Subgroup on Individuals with Disabilities, explored similar issues faced by people with disabilities. NIH has also issued a notice of funding announcement<sup>126</sup> calling for research applications focused on novel and innovative approaches and interventions that address the intersecting impact of disability, race and ethnicity, and socioeconomic status on healthcare access and health outcomes. These actions are among the important steps NIH is taking to address health disparities faced by people with disabilities and ensure their representation in NIH research.

NIH will continue to increase coordinated support for research on health disparities and approaches to reducing them and enhance opportunities for scientists and trainees from diverse backgrounds and life experiences. By supporting these goals, NIH will foster scientific innovation, improve the quality of research, and advance opportunities for populations facing health disparities to participate in and benefit from biomedical, behavioral, and social sciences research.

#### **Reignite the Biden Cancer Moonshot**

The Cancer Moonshot launched in 2016 with goals of accelerating scientific discovery in cancer, fostering greater collaboration, and improving the sharing of cancer research data. Since its

<sup>&</sup>lt;sup>121</sup> www.nihdeiaprize.org/about

<sup>&</sup>lt;sup>122</sup> NIH-Wide Strategic Plan for DEIA

 $<sup>^{123} \</sup>text{ nih.gov/news-events/news-releases/nih-designates-people-disabilities-population-health-disparities} \\ ^{124} \text{ nimhd.nih.gov/docs/advisory-}$ 

 $council/nacmhd\_workGrpOnHealthDisparitiesAndPeopleWithDisabilities\_report\_2023 sept.pdf$ 

<sup>&</sup>lt;sup>125</sup> acd.od.nih.gov/documents/presentations/12092022\_WGD\_Disabilities\_Subgroup\_Report.pdf

<sup>&</sup>lt;sup>126</sup> grants.nih.gov/grants/guide/pa-files/PAR-23-309.html

launch, the Cancer Moonshot has made significant progress, launched over 70 research programs and consortia, and supported more than 250 research projects, leading to more than 2,000 research publications and 49 clinical trials. Research advances resulting from the Cancer Moonshot have led to more precise cancer diagnostic tools, novel cancer treatment options, and new data sharing networks and collaborations. In 2022, the Biden Cancer Moonshot was announced with a new ambitious goal to reduce the cancer death rate by half in the next 25 years. To reach this goal, NIH is substantially increasing the number and diversity of people who participate in clinical trials, ensuring access to current and new standards of cancer care, enhancing diversity in the cancer research workforce, and increasing the pipeline of new cancer drugs.<sup>127</sup>

As an example of Cancer Moonshot activities, the Human Tumor Atlas Network supports research to construct three-dimensional atlases of the cellular, morphological, and molecular features of human cancers as they evolve from precancerous lesions to advanced disease.<sup>128</sup> Understanding the molecular features of a cancer cell or tumor can significantly inform diagnostic and treatment decisions by adding clarity to which treatment options a tumor may be most responsive to. A recently released colorectal cancer atlas gives researchers a new and highly detailed view of colorectal cancer tumors, leading to the discovery of previously unnoticed structural and molecular tumor features. The researchers leading the colorectal cancer atlas previously released a melanoma cancer atlas and will soon develop atlases for breast and brain cancer. In addition to their laboratory-based research, scientists are expanding their research methods and bringing their colorectal cancer atlas into the clinic to deliver improved cancer diagnostic and treatment tools to clinicians and patients.<sup>129</sup>

As examples of National Cancer Institute (NCI)-funded research which directly led to development of new therapeutics to make a real difference to patients, the Experimental Therapeutics Clinical Trials Network leverages NCI's relationships with academic institutions. pharmaceutical companies, and individual investigators to support a coordinated, collaborative, and inclusive team-based approach to early phase experimental therapeutic clinical trials. In December 2022, the first of these clinical trials resulted in an U.S. Food and Drug Administration (FDA) approval of an immunotherapy treatment for advanced alveolar soft part sarcoma (ASPS).<sup>130</sup> ASPS is a rare cancer that affects mostly adolescents and young adults. The approval of the ASPS immunotherapy drug, atezolizumab (Tecentriq) was the result of the largest study ever conducted on ASPS, which enabled sarcoma specialists at academic medical centers across North America to enroll patients in the trial. Nearly all of the patients in the clinical trial experienced stable disease and one-third of patients experienced tumor shrinkage as a result of the treatment.<sup>131</sup> In another recent NIH-funded study, patients with pancreatic ductal adenocarcinoma (PDAC), the most common type of pancreatic cancer and one of the deadliest cancer types, were treated with the same immunotherapy drug approved for ASPS in preparation for receiving a customized mRNA vaccine that was developed to specifically target each patient's tumors. Patients who exhibited a strong immune response to their customized mRNA vaccine had an excellent prognosis with no sign of cancer cells returning for a year and a half

<sup>127</sup> www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/progress

<sup>&</sup>lt;sup>128</sup> humantumoratlas.org/

<sup>&</sup>lt;sup>129</sup> directorsblog.nih.gov/2023/01/

 $<sup>^{130}\</sup> www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-approval-atezolizumab-alveolar-soft-part-sarcoma$ 

<sup>&</sup>lt;sup>131</sup> www.cancer.gov/news-events/press-releases/2022/nci-trial-atezolizumab-approval-alveolar-soft-part-sarcoma

after treatment.132

As another example of research addressing urgent needs, NIH launched in 2023 the Persistent Poverty Initiative to address the structural and institutional factors of persistent poverty in the context of cancer.<sup>133</sup> Specifically, those who live in areas where 20 percent or more of the population has lived below the federal poverty line for at least 30 years have a higher incidence of cancer, experience delays in cancer diagnosis and treatment, and are more likely to die from cancer than people living in other areas. Despite the known impact that poverty has on cancer diagnoses, care, and prognoses, there has been limited research on how to improve cancer outcomes in persistent poverty areas. This initiative will support five new Centers for Cancer Control Research in Persistent Poverty Areas, lowering barriers to entry and leading to an expansion in the number of people who participate in clinical trials, ensuring that new approaches to preventing and treating cancer work for everyone. The Biden Cancer Moonshot builds on the exceptional research progress since the launch of the Cancer Moonshot and focuses on areas of cancer research and prevention that are most likely to benefit the American people.

# Increasing Participation and Representation in Artificial Intelligence and Machine Learning Research Through the AIM-AHEAD Program

Another example of how NIH-funded research is pushing the boundaries of research to benefit everyone is the launch of the Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity, or AIM-AHEAD, program in 2021.<sup>134</sup> The artificial intelligence and machine learning (AI/ML) research field lacks diversity in its researchers as well as in the data sets that it uses. These gaps pose a risk of creating and continuing harmful biases in how AI/ML is used, how algorithms are developed and trained, and how findings are interpreted. Critically, these gaps can lead to continued health disparities and inequities for underrepresented communities.

To close these gaps, the AIM-AHEAD program aims to increase the participation and representation of the researchers and communities that are currently underrepresented in AI/ML modeling and applications by creating mutually beneficial partnerships. Efforts are focused on four key areas: partnerships, research, infrastructure, and data science training. By creating a "network of networks" through regional, multi-disciplinary partnerships, AIM-AHEAD is working to integrate AI/ML-focused, data science research networks with community engagement and clinical research networks to form mutually beneficial collaborations and to engage underrepresented scientists across the career pipeline. These multi-disciplinary partners will use existing real-world data, such as electronic health records, image data, and social determinants of health research data to develop and enhance AI/ML algorithms and apply AI/ML approaches to address health inequities and disparities. AIM-AHEAD is also expanding capacity and infrastructure to support AI/ML research in minority-serving institutions (MSIs), through the AIM-AHEAD Program for AI Readiness (PAIR) program and Data and Infrastructure Capacity Building (DICB) program.<sup>135,136</sup>

<sup>132</sup> www.nih.gov/news-events/nih-research-matters/mrna-vaccine-treat-pancreatic-cancer

<sup>&</sup>lt;sup>133</sup> www.cancer.gov/news-events/press-releases/2023/nci-launches-persistent-poverty-initiative

<sup>134</sup> datascience.nih.gov/artificial-intelligence/aim-ahead

 $<sup>^{135}\</sup> www.aim-ahead.net/call-for-proposals-year-2/hub-specific-pilot-grant-program/$ 

<sup>&</sup>lt;sup>136</sup> www.aim-ahead.net/call-for-proposals-year-2/consortium-development-projects/

Looking into the future, AIM-AHEAD is training a new generation of diverse researchers and leaders in AI/ML by supporting early-career researchers from underrepresented populations. The AIM-AHEAD Research Fellows program trains researchers in biomedical research to use novel and innovative data science to solve data-focused research problems.<sup>137</sup> A complementary program, the AIM-AHEAD Fellowship Program in Leadership, engages a diverse group of participants to acquire the skills and competencies necessary to become leaders who can advocate for the use of AI/ML as a tool to address health disparities in their communities.<sup>138</sup> AIM-AHEAD also supports training of AI/ML through efforts like the AIM-AHEAD Data Science Training Core Training Practicum (PRIME), which provides AI/ML training for graduate and undergraduate students, and the AIM-AHEAD Connect platform, which serves as a virtual hub to enhance collaboration and connect early-career researchers with mentors.<sup>139,140</sup> These efforts are part of a broader set of investments in training and career development programs across NIH to improve our future.

#### **Research** Across the Lifespan

NIH supports research across the human lifespan from screening newborns for fatal disease to better understanding the fundamental reasons why humans age and how healthy lifespan can be improved and even extended. For humans to live a long and healthy life, it is critical to identify disease early and to identify and understand any possible mitigating factors for disease onset and progression.

A study led by researchers at NIAID recently demonstrated just how important early disease detection can be. The NIH-funded Primary Immune Deficiency Treatment Consortium (PIDTC) led a study to measure how effective population-wide newborn screening for a disease called severe combined immunodeficiency (SCID) is at preventing health complications and death. Infants with SCID appear healthy at birth, but are highly susceptible to severe infections and death unless they receive immune-restoring treatment. Analyzing data from the PIDTC, researchers found that early detection using newborn screening and subsequent intervention of SCID led to a 5-year survival rate of 92.5 percent among children with no family history of the disease.<sup>141</sup>

Early intervention and prevention of disease onset is also essential for asthma, which affects over 4 million children in the United States and causes about 150 child deaths per year.<sup>142</sup> Research on mitigating asthma has largely been focused on urban environments and industrial regions where poor air quality contributes to asthma but little work has been done to investigate the impact of air pollutants on asthma in rural agricultural areas. The National Institute of Environmental Health Sciences (NIEHS) supported a study that worked with families and community partners to develop a small sensor that could measure the presence of known asthma irritants in homes and to overcome barriers related to rural agricultural communities' reluctance to participate in clinical studies. Researchers found that pairing the installation of HEPA

<sup>&</sup>lt;sup>137</sup> www.aim-ahead.net/research-fellowship/

<sup>&</sup>lt;sup>138</sup> www.aim-ahead.net/leadership-fellowship/

<sup>&</sup>lt;sup>139</sup> www.aim-ahead.net/data-science-training-core/data-science-training-core-pilot-programs/aim-ahead-training-practicum-prime/

<sup>&</sup>lt;sup>140</sup> connect.aim-ahead.net

<sup>141</sup> www.nih.gov/news-events/news-releases/screening-newborns-deadly-immune-disease-saves-lives

 $<sup>^{142}</sup> www.cdc.gov/asthma/most_recent\_national\_asthma\_data.htm$ 

filtration systems in homes with community outreach and education greatly reduced exposure to agricultural irritants and reduced symptoms and biomarkers of asthma in children.<sup>143</sup>

Researchers are working to better understand the fundamental biological processes for why humans age, what factors contribute to aging, and how we might be able to slow down or mitigate risks that contribute to aging and age-related disease. A recent study supported by the National Human Genome Research Institute (NHGRI) contributed to our fundamental understanding of the biological process of senescence, a hallmark of human aging, where cells are in an arrested state, no longer growing or dividing. While studying tissue regeneration in *Hydractinia symbiolongicarpus*, a small, tube-like shaped animal that is related to both jellyfish and coral, researchers found senescent cells. This discovery that senescent cells are involved in regeneration in *Hydractinia* changes how researchers think of senescence, its role in aging, and how the function of senescence may have evolved over time.<sup>144</sup> In another surprising discovery, researchers who have long studied a role for hunger and fasting in aging and longevity found that genetically altering fruit flies to activate their brain's hunger response could increase lifespan, suggesting that activating the biological processes involved in hunger is sufficient to increase lifespan, even when animals are not actually fasting.<sup>145</sup>

NIH supports basic science and health research that promises to benefit all ages, from testing that saves the lives of newborns to research that provides insights on how to live longer, healthier lives.

#### Down Syndrome Research and the INCLUDE Project

The INCLUDE Project is a NIH-wide initiative, engaging 17 institutes across NIH, that aims to better understand critical health and quality-of-life needs for individuals with Down syndrome (DS). Now entering its fifth year, the INCLUDE Project continues to expand its research portfolio by releasing innovative funding opportunities and building the field of investigators by enhancing career pathways for trainees, early-stage investigators, and established investigators with expertise related to conditions commonly experienced by individuals with DS. Since its launch in FY 2018, the INCLUDE Project has funded approximately 200 research studies spanning all 3 components of the initiative: basic science studies on chromosome 21, large cohort development for individuals with DS, and the inclusion of individuals with DS in clinical trials.

The INCLUDE project touches the full spectrum of basic, translational, and clinical research to address the specific needs of the DS community. The studies supported by the INCLUDE Project are building on countless basic scientific discoveries to make promising contributions to the field and develop an understanding of both the biological and genetic underpinnings of DS and the conditions commonly experienced by individuals with DS. The goal of this NIH-wide program is to prevent these conditions from reducing the capacity of people with DS to lead healthy and optimal lives. To support basic science and foundational investigations on DS, the INCLUDE Project has already driven advances in data sharing and storage infrastructure to increase collaboration, rigor, and transparency in DS-related research. The INCLUDE Data

 $<sup>^{143}\</sup> www.nih.gov/sites/default/files/about-nih/impact/asthma-case-study.pdf$ 

<sup>&</sup>lt;sup>144</sup> www.nih.gov/news-events/news-releases/scientists-discover-clues-aging-healing-squishy-sea-creature

<sup>&</sup>lt;sup>145</sup> www.nia.nih.gov/news/study-fruit-flies-finds-hunger-causes-brain-changes-slow-aging

Coordinating Center<sup>146</sup> offers free, accessible tools, including the INCLUDE Data Hub,<sup>147</sup> to bring together and share information and resources for researchers to study DS, a relatively rare condition difficult to study in large populations, more quickly. Basic science research and data tools will increase the potential for DS research to enhance the quality of life for individuals with DS and their families.

The INCLUDE Project also aims to establish needed knowledge and infrastructure for advancing treatments and other clinical therapies inclusive of people with DS. In FY 2021, the INCLUDE Project supported seven clinical studies investigating potential treatments for critical and co-occurring conditions associated with DS. These studies aim to assess treatments for sleep apnea and ADHD, and to evaluate the impact of hypoglossal nerve stimulation on cognition and language.<sup>148</sup> Early results show promise for each potential therapy, despite setbacks caused by the COVID-19 pandemic. NIH anticipates increasing its support for clinical trials in the coming years, including support for a trial to examine the effect of anti-amyloid drugs in individuals with DS. As the INCLUDE Project continues to support the highest quality, targeted research designed to address critical health and quality-of-life needs for individuals with DS and their families, the applications of such research will lead to even greater improvements to care.

The INCLUDE Project is also expanding the diversity of participants in study cohorts and clinical trials through dedicated outreach to underrepresented communities. The INCLUDE Project recently developed a Strategic Communication and Outreach plan. This plan outlines unique opportunities the INCLUDE Project will pursue to amplify communications, ensure representation and diversity in DS research by reaching new communities, and engage new and early-stage investigators through websites, workshops, and resources for scientists and clinicians. In Fall 2022, the INCLUDE Project held a virtual workshop<sup>149</sup> on diverse cohort recruitment for investigators, clinicians, self-advocates, and family members to identify barriers for research participants as well as researchers. INCLUDE has used the input from this workshop and listening sessions, as well as the strategies presented, to advance INCLUDE Project goals to improve diverse recruitment and support researchers.

In 2022, NICHD and the INCLUDE Project jointly published the next iteration of the NIH INCLUDE DS Research Plan,<sup>150</sup> detailing a vision for the goals and objectives for NIH-funded DS research until 2028. Importantly, the plan incorporates input from key partners including the public, collected through two RFIs. Approaches to address the need for greater diversity among DS research participants; a better understanding of health disparities among individuals with DS; and expanding the pipeline of new and early-stage investigators with a diversity of expertise and perspectives will be integrated throughout the plan. The DS Research Plan offers a broad overview of NIH-funded projects and summaries of some of the key DS research findings, identified from the projects' nearly 600 publications over the last 7 years while touching on 5 broad themes: basic research, cohort development and epidemiology, clinical research and co-occurring conditions, living and aging with DS services research, and research infrastructure and

<sup>&</sup>lt;sup>146</sup> includedcc.org/

<sup>&</sup>lt;sup>147</sup> portal.includedcc.org/

<sup>148</sup> www.nih.gov/include-project/include-project-down-syndrome-ds-research-plan

<sup>149</sup> videocast.nih.gov/watch=46235

<sup>&</sup>lt;sup>150</sup> www.nih.gov/sites/default/files/research-

training/initiatives/include/NIH\_INCLUDE\_DS\_Research\_Plan\_Final2022.pdf

tools. The plan offers a roadmap for DS-related research, highlighting the continued importance of partnerships among researchers, clinicians, family members, other stakeholders, and most importantly, individuals with DS.

To continue robust support for research on DS, the INCLUDE Project is now both renewing previously successful funding opportunities for researchers and moving into new areas, expanding on what the project has learned and heard from the community to take the INCLUDE Project into the future.

#### All of Us

Launched in 2018, the *All of Us* Research Program is an ambitious effort to gather health data from one million or more people living in the United States to accelerate research that may improve health. As a longitudinal cohort study, *All of Us* aims to accelerate health and medical breakthroughs to enable individualized prevention, treatment, and care for all. *All of Us* is committed to recruiting a diverse participant pool that includes members of groups that have been left out of research in the past. Currently, more than 50 percent of *All of Us* participants who have completed initial steps of the program identify with a racial or ethnic minority group, and about 80 percent of participants are from populations underrepresented in biomedical research, including people over age 65, LGBTQ+ people, those who live in rural areas, people with low income or limited education, and people with disabilities.

With over half a million participants already enrolled, *All of Us* is building one of the largest, most diverse health databases of its kind, capable of informing thousands of studies on a variety of health conditions. Genomic data from *All of Us* can be used to identify genetic variants, which are genes that are slightly different across the population. Although most genetic variants are harmless, some have been linked to health problems and disease. Demonstrating the power of this resource, researchers have recently used *All of Us* data to identify genetic variants in a gene called *G6PD*, which can cause G6PD deficiency, sometimes leading to anemia, fatigue, trouble breathing, and dizziness. Researchers were able to identify 118 *G6PD* gene variants and distinguish which variants led to G6PD deficiency with or without anemia.<sup>151</sup> Discoveries like this are possible because of the diversity of *All of Us* participants and the amount of health data they share.

Along with identifying genetic variants, *All of Us* data can answer many other questions about human health. For example, researchers recently used *All of Us* data to explore how the COVID-19 pandemic affected the mental health of people who were blind or had low vision. Previous work has identified that half of people with blindness or low vision have anxiety or depression at rates twice as high as people with normal vision. During the pandemic, people with blindness or low vision were at a higher risk of developing new or worsening feelings of anxiety or depression than people with normal vision.<sup>152</sup> Data from *All of Us* allow researchers to explore the links between disability, mental health, and disease, giving insight into the experiences, health, and well-being of a specific population at a unique point in time.

 $<sup>^{151}</sup> allofus.nih.gov/news-events/research-highlights/discovering-more-genetic-variants-thanks-to-all-of-us-data$ 

<sup>&</sup>lt;sup>152</sup> allofus.nih.gov/news-events/research-highlights/what-all-us-data-says-blindness-mental-health-covid-19

#### Maternal Health and Growth of the IMPROVE Initiative

The United States has a higher maternal mortality rate than any other developed nation and maternal health outcomes have only worsened in recent years. In 2021, the U.S. maternal mortality rate increased to 32.9 deaths per 100,000 live births from a rate of 23.8 in 2020 and 20.1 in 2019. Outcomes are significantly worse for certain groups, with non-Hispanic Black women experiencing the highest maternal mortality rate at 69.9 deaths per 100,000 live births.<sup>153</sup> NIH generates ground-breaking research that seeks to better understand the dynamics of maternal health in the United States.

Launched in 2019, the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE)<sup>154</sup> initiative supports research to reduce preventable causes of maternal deaths and to improve health for women before, during, and after delivery. IMPROVE places a special emphasis on health disparities and populations that are disproportionately affected by severe pregnancy complications and maternal death. In FY 2023, as part of this initiative, NIH distributed \$8 million in awards to the winners of the Rapid Acceleration of Diagnostics Technology (RADx® Tech) for Maternal Health Challenge,<sup>155</sup> a prize competition aimed to accelerate the development of technologies to improve maternal health outcomes in "maternity care deserts." IMPROVE also sponsored the Connecting the Community for Maternal Health Challenge<sup>156</sup> to encourage and reward non-profit community-based or advocacy organizations to develop research capabilities and infrastructure to pursue research projects in the area of maternal health, inclusive of maternal morbidity and mortality. In FY 2023, NIH also supported the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b) follow-up nuMoM2b Heart Health Study. Researchers supported by this study found that certain pregnancy complications are associated with increased risks for heart disease, such as developing high blood pressure, years after pregnancy.<sup>157</sup> Additionally, NIH awarded \$24 million in first-year funding to establish Maternal Health Research Centers of Excellence in FY 2023, which are designed to develop and implement research projects to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. They will focus on populations that experience health disparities, including racial and ethnic minorities, socioeconomically disadvantaged populations, those living in underserved rural areas, sexual and gender minority populations and people with disabilities. Research centers will partner with community collaborators, such as state and local public health agencies, community health centers and faith-based organizations. Additionally, the research centers will support training and professional development of maternal health researchers, including those from backgrounds underrepresented in the biomedical research workforce.

In FY 2023, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) sponsored the NIH Technology Accelerator Challenge (NTAC) for Maternal Health,<sup>158</sup> a prize competition that awarded innovative diagnostic technologies for identifying maternal health conditions. This challenge aimed to spur the development of low-cost, point-of-care molecular, cellular, and/or metabolic sensing and diagnostic technologies integrated with a digital platform

<sup>&</sup>lt;sup>153</sup> www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.pdf

<sup>&</sup>lt;sup>154</sup> www.nichd.nih.gov/research/supported/IMPROVE

<sup>&</sup>lt;sup>155</sup> www.nichd.nih.gov/newsroom/news/040323-RadxTech-Deep-Dive

<sup>&</sup>lt;sup>156</sup> www.challenge.gov/?challenge=community-maternal-health

 $<sup>^{157}</sup> www.nhlbi.nih.gov/news/2023/moms-helping-moms-through-research$ 

<sup>&</sup>lt;sup>158</sup> www.nibib.nih.gov/research-program/NIH-Technology-Accelerator-Challenge

to guide rapid clinical decision-making, improve patient outcomes, and ultimately prevent maternal morbidity and mortality.

NIH-supported maternal health research has provided much-needed insight into causes of death or morbidity during pregnancy and postpartum. NIH's continued efforts to better understand social, structural, and genetic risk factors that increase maternal mortality rates will lead to more innovative technologies, earlier intervention, and better disease detection that will improve maternal health outcomes in the United States.

To align and support these and other collaborative maternal health initiatives, NIH remains actively engaged in coordinated efforts across the federal government, including the HHS Task Force on Research Specific to Pregnant Women and Lactating Women, the White House Blueprint for Addressing the Maternal Health Crisis and Maternal Health Interagency Policy Committee, and the establishment of HHS agency priority goals for maternal health.

#### Innovations in Mental Health Research and Treatment

Research shows that mental illnesses are common in the United States, affecting tens of millions of people each year, but estimates suggest that only half of people with mental illnesses receive treatment.<sup>159</sup> These acute needs were further brought to light during the rise of mental health condition incidence during the COVID-19 pandemic. Scientific and clinical advances are paving the way for improvement of mental health conditions. NIMH supports innovative research to transform the understanding and treatment of mental illness and to pave the way for prevention, recovery, and cure. Recent basic science advances include a new study showing that the G protein-coupled receptor GPR158 is capable of altering activity in an area of the brain important for understanding and treatments for mental disorders.<sup>160</sup> This discovery presents a potential new target for developing improved treatments for mental disorders like anxiety and depression.

Building on findings from the Recovery After an Initial Schizophrenia Episode (RAISE) initiative,<sup>161</sup> the Early Psychosis Intervention Network (EPINET)<sup>162</sup> is a broad clinical research initiative that aims to determine the best way to treat people experiencing symptoms of early psychosis. Psychosis refers to a collection of symptoms that affect the mind, where there has been some loss of contact with reality. During an episode of psychosis, a person's thoughts and perceptions are disrupted, and they may have difficulty recognizing what is real and what is not. Left untreated, psychotic symptoms can disrupt school and work activities, strain family relationships, lead to separation from friends, and make a person's mental health problems worse. Research from RAISE demonstrated that coordinated specialty care (CSC) was more effective for treating psychosis than typical care. CSC is a recovery-oriented, team approach to treating early psychosis that promotes easy access to care and shared decision-making among specialists, the person experiencing psychosis, and family members.<sup>163</sup> It involves individual or

<sup>&</sup>lt;sup>159</sup> www.nimh.nih.gov/health/statistics

<sup>160</sup> doi.org/10.1126/science.add7150

<sup>&</sup>lt;sup>161</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/recovery-after-an-initial-schizophrenia-episode-raise

<sup>&</sup>lt;sup>162</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/early-psychosis-intervention-network-epinet

<sup>&</sup>lt;sup>163</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/recovery-after-an-initial-schizophrenia-episode-raise

group psychotherapy, family support and education programs, medication management, supported employment and education services, and case management. EPINET funded awards to establish regional scientific hubs connected to multiple CSC programs that provide early psychosis treatment and a national data coordinating center. The initiative has expanded to 8 regional hubs in 17 states with more than 100 clinics that provide coordinated specialty care.<sup>164</sup>

Mental health disorders are highly prevalent among youth and the rates of youth with moderate and severe depression have increased over the last 20 years. The increased prevalence of severe mental health disorders in youth has led to a devastating increase in suicide rates across all youth age groups (10-14 years; 15-19 years; 20-24 years) since 2001.<sup>165</sup> These rates are even more devastating when the data is disaggregated by race, revealing a disparity in suicide rates in Black and American Indian/Alaska Native youth compared to youth who identify with other races.<sup>166</sup> To respond to the need to increase the effectiveness of mental health interventions and to address disparities in the delivery and quality of mental health services for youth populations, NIMH launched the Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness (ALACRITY) Research Center program.<sup>167</sup> ALACRITY supports 14 mental health research centers across the country whose goals are to rapidly transform treatments for youth mental illness by providing a space to develop and test new mental health research and interventions in a clinical setting. NIH continues to support funding for ALACRITY and to renew resources for research in mental health disorders, test new mental health interventions, and support clinical trials at ALACRITY Research Centers; thereby, reducing barriers to access for cutting edge mental health treatment for youth across the country.

Additionally, NIH is investing in understanding the impacts of social media on the mental health of children and youth. The Adolescent Brain Cognitive Development (ABCD) Study<sup>168</sup> is the largest long-term study of brain development and child health in the United States. Approximately 12,000 children ages 9-10 years have joined the study and will be surveyed into young adulthood about digital media and technology use. Data can be correlated with other assessments, such as measures of mental health, cognition, and sleep. Current research explores the relation between technology and digital media use and children's executive functioning, language development, attention, and other health outcomes, as well as ways to promote healthy screen time usage. NIMH recently published a request for applications to study the Bidirectional Influences Between Adolescent Social Media Use and Mental Health, responding to the U.S. Surgeon General's Advisory on Youth Mental Health.<sup>169,170</sup>

 $<sup>^{164}\</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/early-psychosis-intervention-network-epinet$ 

<sup>&</sup>lt;sup>165</sup> www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases

<sup>&</sup>lt;sup>166</sup> www.nimh.nih.gov/health/statistics

<sup>&</sup>lt;sup>167</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/advanced-laboratories-for-accelerating-the-reach-and-impact-of-treatments-for-youth-and-adults-with-mental-illness-alacrity

 $<sup>^{168}\</sup> www.nimh.nih.gov/research/research-funded-by-nimh/research-initiatives/adolescent-brain-cognitive-developmentsm-study-abcd-studyr$ 

<sup>&</sup>lt;sup>169</sup> grants.nih.gov/grants/guide/rfa-files/RFA-MH-23-115.html

<sup>170</sup> www.hhs.gov/sites/default/files/surgeon-general-youth-mental-health-advisory.pdf

**OVERALL APPROPRIATIONS** 

#### Understanding the BRAIN

The NIH *Brain Research Through Advancing Innovative Neurotechnologies*<sup>®</sup> (BRAIN) Initiative is an ambitious program to develop and apply new technologies to answer fundamental questions about the brain and ultimately to inspire new treatments for brain diseases.<sup>171</sup> The NIH BRAIN Initiative is managed by 10 ICs whose missions and current research portfolios complement the goals of the BRAIN Initiative, with primary funding provided by NINDS and NIMH.<sup>172</sup> The BRAIN Initiative is highly collaborative within NIH, across Federal agencies, and with private organizations and the international scientific community.

Within NIH, the BRAIN Initiative collaborates with the NIH Helping to End Addiction Longterm (HEAL) Initiative (see below). In a major scientific advance from this effort, researchers have recorded pain-related data from inside the brain of individuals with chronic pain disorders caused by stroke or phantom limb pain from amputation. A long sought-after goal has been to understand how pain is represented by brain activity and how to modulate that activity to relieve suffering from chronic pain. By collecting data from patients at home over the span of months and analyzing them using machine learning tools, researchers identified an area of the brain associated with chronic pain and objective biomarkers of chronic pain in individual patients. This study represents an initial step towards uncovering the patterns of brain activity that underlie our perception of pain. Identifying such a pain signature will enable the development of new therapies that can alter brain activity to relieve suffering due to chronic pain.<sup>173</sup> Additional research co-funded by BRAIN and HEAL showed that psychedelic drugs being tested as therapies for treatment-resistant depression activate receptors within brain cells that promote new brain cell connections.<sup>174</sup> A better understanding of these mechanisms could lead to related drugs that encourage new brain cell connections while avoiding hallucinogenic effects.

BRAIN Initiative advances bolstered by collaborations between NIH and other governmental agencies include the Machine Intelligence from Cortical Networks (MICrONS) program, supported by the Intelligence Advanced Research Projects Activity (IARPA), part of the Office of the Director of National Intelligence. The MICrONS program aims to better understand the brain's internal wiring and allows scientists to sift through reams of data from high-resolution electron microscopy imaging to masterfully reconstruct individual neurons and their connections. With this increased knowledge, researchers will develop more sophisticated machine learning algorithms for AI applications, which will in turn advance fundamental basic science discoveries and the practice of life-saving medicine.<sup>175</sup> For instance, these applications may help in the future to detect and evaluate a broad range of neural conditions, including those that affect the primary motor cortex.

The BRAIN Initiative is also improving understanding of brain structure, which allows for comprehensive knowledge of the cellular basis of brain function and dysfunction and helps pave the way for a new generation of precision therapeutics for people with mental disorders and other disorders of the brain. The BRAIN Initiative Cell Census Network (BICCN), a cooperative network to promote collaboration and coordination among the projects within the BRAIN

<sup>&</sup>lt;sup>171</sup> officeofbudget.od.nih.gov/pdfs/FY23/br/Overview of FY 2023 Cross-cutting Initiatives.pdf

<sup>172</sup> braininitiative.nih.gov/about/overview

<sup>&</sup>lt;sup>173</sup> www.ninds.nih.gov/news-events/press-releases/brain-signatures-chronic-pain-identified-small-group-individuals

<sup>174</sup> pubmed.ncbi.nlm.nih.gov/36795823/

<sup>&</sup>lt;sup>175</sup> directorsblog.nih.gov/2022/12/

Initiative, aims to develop a comprehensive inventory of the cells in the brain, including where they are, how they develop, how they work together, and how they regulate their activity. In 2023, an international team of scientists supported by the BRAIN Initiative created the first-ever complete cell atlas of a whole mammalian brain,<sup>176</sup> describing the type, location, and molecular and functional information of more than 32 million mouse brain cells. Researchers also mapped the genetic, cellular, and structural makeup of both the human brain and the nonhuman primate brain with great detail.<sup>177</sup> Investigators collected cell census data and developed comprehensive 3D common reference brain cell atlases that integrate molecular, anatomical, and functional data for describing specific cell types. Research funded by the BRAIN Initiative continues to improve the scientific community's understanding of how brain disorders develop and progress and lays the foundation for the development of a new generation of precision therapeutics for people with mental and neurological disorders of the brain.

#### **Opioid Use Disorder (OUD) and Pain Research**

The HEAL Initiative is an NIH-wide effort to improve prevention and treatment strategies for opioid misuse and addiction and to enhance pain management. In 2018, NIH launched the HEAL Initiative®, to find scientific solutions for the opioid public health emergency. The lack of safe and effective treatments for pain continues to be a main driver of the national opioid and overdose crisis. HEAL has two main goals: improving the understanding, management, and treatment of pain, and improving the prevention and treatment of opioid misuse and addiction. HEAL research in pain and opioid misuse and addiction addresses urgent unmet needs across the lifespan – from infants exposed to opioids during pregnancy to teens treated with opioids after a routine medical procedure and adults living with chronic pain. HEAL research covers many areas of scientific promise and concrete strategies capable of providing rapid and lasting solutions to the opioid crisis.

The HEAL Initiative continues to respond to an evolving overdose crisis on several fronts. Today we are seeing the return on this investment with major new findings that will change clinical care.<sup>178</sup> HEAL researchers through the Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)<sup>179</sup> research program found that using the Eat, Sleep, Console (ESC) care approach cut hospital stays by nearly seven days for babies experiencing extreme discomfort and withdrawal symptoms. The ESC care approach also reduced by 63 percent the infants' need for opioid medications to recover from withdrawal symptoms. ESC prioritizes non-opioid care as a first line of treatment – including involving mothers as therapy with skin-to-skin contact, holding, swaddling, and rocking in a low light and quiet environment. ACT NOW is a partnership between the IDeA States Pediatric Clinical Trials Network<sup>180</sup> (itself a part of the NIH Environmental influences on Child Health Outcomes program, or ECHO)<sup>181</sup> and the Neonatal Research Network,<sup>182</sup> funded by NICHD. The Eat, Sleep, Console clinical trial was conducted across 18 states and included 1,305 infants and their primary caregivers at more than

<sup>&</sup>lt;sup>176</sup> www.nih.gov/news-events/news-releases/scientists-unveil-complete-cell-map-whole-mammalian-brain

<sup>&</sup>lt;sup>177</sup> www.nih.gov/news-events/news-releases/scientists-unveil-detailed-cell-maps-human-brain-nonhuman-primate-brain

<sup>&</sup>lt;sup>178</sup> www.nejm.org/doi/full/10.1056/NEJMoa2214470

<sup>179</sup> heal.nih.gov/research/infants-and-children/act-now

<sup>&</sup>lt;sup>180</sup> www.nih.gov/echo/idea-states-pediatric-clinical-trials-network-clinical-sites-foa

<sup>&</sup>lt;sup>181</sup> www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program

<sup>&</sup>lt;sup>182</sup> neonatal.rti.org/

2 dozen hospitals in urban and rural environments. This diversity enabled the research team to address the needs of communities that have been impacted especially hard by the opioid crisis. The research results are also more likely to be generalizable across the country. Conducted mostly during the height of the COVID-19 pandemic, the Eat, Sleep, Console research team faced many challenges; however, the team is significantly invested in improving care for this young population. The team trained about 5,000 nurses in the ESC care approach.<sup>183</sup>

Chronic pain and its companion crisis of opioid misuse have taken a terrible toll on Americans. The impact has been even greater on U.S. service members and veterans, who often deal with the compounded factors of service-related injuries and traumatic stress.<sup>184</sup> This disproportionate burden of chronic pain among veterans and service members led NIH's National Center for Complementary and Integrative Health (NCCIH) to forge a collaboration in 2017 across NIH, the U.S. Department of Defense (DoD), and the U.S. Department of Veteran's Affairs (VA) to establish the Pain Management Collaboratory (PMC).<sup>185,186</sup> The PMC's research focusing on the implementation and evaluation of non-drug approaches for the management of pain is urgently needed in the military and across our entire country. Non-drug approaches require a shift in thinking: rather than focusing solely on blocking pain temporarily using analgesics, non-drug approaches work with the mind and body to promote the resolution of chronic pain and the longterm restoration of health. This resolution comes through techniques and practices such as manual therapy, yoga, and mindfulness-based interventions. Addressing chronic pain in ways that do not only rely on drugs means addressing underlying issues, such as joints and connective tissue that lack adequate movement or training our brains to "turn down the volume" on pain signals. Using mind and body practices to reduce pain can help promote health in other ways. Possible additional benefits include better sleep, more energy for physical activity, a better mindset for making good nutritional choices, and/or improved mood. The PMC supports a shared resource center and 11 large-scale pragmatic clinical trials. Within this real-world health care setting, the clinical trials have enrolled more than 8,200 participants across 42 veteran and military health systems. These studies offer both significant numbers of participants and insights into what happens when learnings from controlled clinical trials collide with the realities of health care delivery and the complexities of daily life.

NIH research through the HEAL initiative seeks to bring tangible solutions to people with addiction and at risk for overdose. Recent studies led by the National Institute on Drugs and Addiction (NIDA)<sup>187</sup> aimed to improve access to and success of the medication buprenorphine, a lifesaving tool for the treatment of opioid use disorder. Although medications can prevent overdose and death and aid individuals on their path to long-term recovery, most individuals with an opioid use disorder are not prescribed medication. Recent NIH-supported findings<sup>188</sup> have demonstrated that providing patients with buprenorphine in the emergency room following

<sup>&</sup>lt;sup>183</sup> heal.nih.gov/director/power-of-connection

 $<sup>^{184}\</sup> directors blog.nih.gov/2023/03/28/a-whole-person-approach-to-lifting-the-burden-of-chronic-pain-among-service-members-and-veterans/$ 

 $<sup>^{185}\</sup> www.nccih.nih.gov/news/press-releases/federal-agencies-partner-for-military-and-veteran-pain-management-research$ 

<sup>&</sup>lt;sup>186</sup> painmanagementcollaboratory.org/

<sup>&</sup>lt;sup>187</sup> The FY 2025 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.

<sup>&</sup>lt;sup>188</sup> nida.nih.gov/news-events/news-releases/2023/03/Buprenorphine-initiation-in-ER-found-safe-and-effective-for-individuals-with-OUD-using-fentanyl

an overdose was safe and effective for individuals using fentanyl, a powerful synthetic opioid responsible for 75 percent of overdose deaths. Additional studies<sup>189</sup> found that higher doses of buprenorphine were associated with improved long-term retention in treatment for opioid use disorder. Together this research gives hospitals and clinicians vital tools to help people with addiction and prevent opioid overdose death.

In a continued commitment to elevating health in every community, NIH held Tribal Consultations in 2018 and 2022 to seek input on research needs for addressing opioid misuse and improving pain management in Native communities.<sup>190,191</sup> Many themes emerged, including the importance of Indigenous Knowledge and local expertise and the need to invest in research and data led by Tribes and Native American Serving Organizations (T/NASOs). In direct response to priorities identified in Tribal Consultations, the HEAL Initiative developed and launched the Native Collective Research Effort to Enhance Wellness (N CREW) Program, a highly collaborative partnership between NIH, T/NASOs, and ally organizations established to directly respond to the opioid/drug public health emergency.

The N CREW Program<sup>192</sup> will support T/NASOs to conduct locally prioritized research to address overdose, substance use, and pain, including related factors such as mental health and wellness. Research led by Native communities is essential for enhancing culturally grounded, strengths-based, effective, and sustainable intervention strategies, ultimately promoting healthy equity. The N CREW Program has three main goals including: 1) supporting T/NASOs to lead community-prioritized research projects, including research elevating and integrating Indigenous Knowledge and culture; 2) enhancing capacity within T/NASOs to conduct locally prioritized research by developing and providing novel, accessible, culturally grounded technical assistance and training, resources, and tools; and 3) improving access to and the quality of data on substance use, pain, and related health and wellbeing factors to maximize their potential for use in local decision-making. These and other efforts across NIH work together to steward NIH's investments in the best science to improve health and life in every community.

### Scientific Breakthroughs Ushered by NIH

The NIH ICOs support basic, translational, and clinical research in specific areas of health, the human body, and disease to fulfill both their own unique missions and the broader NIH mission of enhancing public health and advancing scientific breakthroughs. The distinctive approaches to research taken by each ICO have led to critical scientific discoveries and work together to accomplish the NIH mission. Among the many examples of accomplishments supported by the ICOs this past year include:

• Building on ten years of major scientific breakthroughs at the NIAID Vaccine Research Center (VRC), FDA approval was granted to the first Respiratory Syncytial Virus (RSV) vaccine for adults 60 years and older. RSV can cause severe illness or death in elderly

 $<sup>^{189}\</sup> nida.nih.gov/news-events/news-releases/2023/09/higher-buprenorphine-doses-associated-with-improved-retention-in-treatment-for-opioid-use-disorder$ 

<sup>&</sup>lt;sup>190</sup> dpcpsi.nih.gov/thro/nih-tribal-consultation-opioid-crisis-indian-country

<sup>&</sup>lt;sup>191</sup> dpcpsi.nih.gov/sites/default/files/HEAL-ConsultationReport2022.pdf

 $<sup>^{192}\</sup> heal.nih.gov/research/research-to-practice/native-collective-research-effort-enhance-wellness-overdose-substance-mental-health-pain$ 

populations, young children, and those with existing heart, lung, or immune conditions. The vaccine, Arexvy, targets the prefusion F protein that was developed at NIAID and is more than 80 percent effective at preventing symptomatic RSV infection in those 60 years and older.<sup>193</sup> The decade-long dedication of NIAID researchers and clinical trial volunteers, along with collaborations with academic partners and the pharmaceutical industry, will prevent thousands of hospitalizations and deaths from RSV infections in older adults each year.

- The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) funded research through the Human Placenta Project that developed a sameday test to identify abnormal fetal chromosomes.<sup>194</sup> Using samples collected during prenatal testing, the Short-read Transpore Rapid Karyotyping (STORK) test, detects extra or missing chromosomes. STORK has shown an accuracy rate of 98 to 100 percent, which is comparable to standard clinical tests, and is faster, costs less, and does not require transporting samples to a clinical laboratory. This innovation may be particularly useful in identifying genetic causes of miscarriage and streamlining the in vitro fertilization (IVF) process.<sup>195</sup>
- The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supported a clinical trial that showed an artificial pancreas improved blood glucose control in children ages 2 to 5 years with Type 1 Diabetes (T1D). During the trial, children with the artificial pancreas spent 12 percent more time within their target blood glucose range compared to children using traditional blood glucose management and a continuous glucose monitor. These findings are especially promising because, compared to adults and older children with T1D who are better able to understand and communicate their needs, young children with T1D tend to have blood glucose levels that are higher, or lower, than they should be.<sup>196</sup> In addition, much of this study was conducted virtually, suggesting the potential to integrate the technology into remote and underserved areas.
- Research studies funded by the National Institute of Mental Health (NIMH), National Institute on Aging (NIA), and NCI showed that blocking an enzyme involved in forming HIV particles stopped the virus from becoming infectious and points to a possible new target for treating HIV infection. The researchers investigated whether a newly developed compound was effective in blocking a cellular enzyme called nSMase2, which is vital to forming HIV particles. Researchers found that blocking nSMase2 disrupted the formation of the virus and prevented the processing of a protein required for the virus to mature and become infectious.<sup>197</sup> These research studies have introduced the potential of improved medications to treat HIV long-term or possibly lead to a cure for HIV infection.

These and other discoveries by NIH-funded investigators deliver new treatments, cures, and innovative prevention strategies to communities and patients around the world. In FY 2024, NIH

<sup>&</sup>lt;sup>193</sup> www.niaid.nih.gov/news-events/nih-celebrates-fda-approval-rsv-vaccine-people-60-years-age-and-older

<sup>194</sup> www.nichd.nih.gov/research/supported/human-placenta-project/default

<sup>&</sup>lt;sup>195</sup> www.nichd.nih.gov/newsroom/news/081722-STORK

<sup>&</sup>lt;sup>196</sup> www.niddk.nih.gov/about-niddk/meet-director/directors-update/2023-summer/research-updates

<sup>&</sup>lt;sup>197</sup> www.nimh.nih.gov/news/science-news/2023/blocking-hiv-enzyme-reduces-infectivity-and-slows-viral-rebound

continues to make bold investments in novel ideas and enable the scientific workforce with cutting-edge resources and opportunities.

#### FUNDING HISTORY (FIVE-YEAR FUNDING TABLE)

Fiscal Year	Amount <sup>1, 2</sup>
2021	
2022 <sup>3,4</sup>	\$46,182,990,000
2023 <sup>3,5</sup>	\$49,183,485,000
2024 <sup>6</sup>	\$48,514,035,000
2025 Budget Request <sup>7</sup>	\$51,621,517,000

<sup>1</sup> Appropriated amounts include discretionary budget authority received from both Labor/HHS appropriations as well as the Interior, Environment & Related Agencies appropriation that supports NIH Superfund Research activities. Also includes mandatory budget authority derived from the Special Type 1 Diabetes account and \$1,448,000,000 in the FY 2025 request for Cancer Moonshot. Includes NIGMS Program Evaluation financing of \$1,271,505,000 in FY 2021, \$1,309,313,000 in FY 2022, \$1,412,482,000 in FY 2023, \$1,412,482,000 under the FY 2024 Continuing Resolution (CR), and \$2,018,482,000 in the FY 2025 request. Includes CURES Act amounts of \$404,000,000 in FY 2021, \$496,000,000 in FY 2022, \$1,085,000,000 in FY 2023, \$407,000,000 under the FY 2024 CR and \$127,000,000 in the FY 2025 request.

<sup>2</sup> Excludes supplemental appropriations and permissive and directive transfers unless otherwise noted.

<sup>3</sup> Reflects mandatory sequestration of \$8,550,000 for the Special Type 1 Diabetes Research account.

<sup>4</sup> Reflects \$1,000,000,000 for the Advanced Research Projects Agency for Health (ARPA-H) provided to NIH through transfer from HHS Office of the Secretary (OS).

<sup>5</sup> Reflects \$1,500,000,000 for the ARPA-H provided to NIH through transfer from HHS OS.

<sup>6</sup> Reflects annualized levels under the FY 2024 CR, including \$1,500,000,000 for ARPA-H.

<sup>7</sup> Reflects \$1,500,000,000 for ARPA-H.

SUMMARY OF REQUEST NARRATIVE

The FY 2025 President's Budget (PB) request provides a program level of \$50.1 billion for NIH, excluding the Advanced Research Projects Agency for Health (ARPA-H). This request is an increase of \$2.4 billion, or 5.1 percent, over the FY 2023 Final level of \$47.7 billion.

The following summary references program level funding, which is the sum of discretionary budget authority in the Department of Labor, Health and Human Services, and Education, and Related Agencies appropriations (\$46.4 billion in FY 2025); discretionary budget authority in the Department of the Interior, Environment, and Related Agencies appropriations dedicated to the Superfund Research Program (\$83.0 million in FY 2025); mandatory budget authority provided for Type 1 Diabetes research (\$260.0 million in FY 2025) and Cancer Moonshot (\$1.448 billion in FY 2025); and Program Evaluation Financing for the National Institute of General Medical Sciences (NIGMS) under Section 241 of the Public Health Service Act (\$2.018 billion in FY 2025).

The FY 2025 Budget provides \$20.0 billion in mandatory funding across HHS for pandemic preparedness, provided through the Public Health and Social Services Emergency Fund. Of this total, \$2.69 billion is allocated to NIH. This allocation is not included in the program level total above.

The primary budget mechanisms discussed below include allocations by mechanism of Program Evaluation Financing, Type 1 Diabetes, and Cancer Moonshot funds. The Superfund Research Program and ARPA-H are a lump-sum amount within the NIH mechanism tables.

In FY 2025, 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.

#### **Research Project Grants (RPGs)**

The FY 2025 President's Budget provides \$27.1 billion for RPGs, which is \$0.6 billion more than the FY 2023 Final level. This amount would fund 10,273 Competing RPGs, or 833 fewer than the FY 2023 Final level. It would also support 31,481 Noncompeting RPGs, 1,304 more than the FY 2023 Final level. In addition, the projected average cost for Competing RPGs of

approximately \$591,000 would be 3.3 percent below the FY 2023 Final level projected average cost of \$611,000.

• Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) RPGs. The FY 2025 President's Budget provides \$1,275.2 million for SBIR/STTR program grants, which is \$12.2 million below the FY 2023 Final level. The statutory minimum set-aside requirement of 3.65 percent for NIH-wide SBIR/STTR support is achieved in FY 2025.

#### **Research Centers**

The FY 2025 President's Budget provides \$2,931.2 million for Research Centers, which is \$50.1 million more than the FY 2023 Final level. This amount would fund 1,243 grants, 29 more than the FY 2023 Final level. Resources for specialized/comprehensive research centers reflect allocations of a portion of the mandatory funding for the Cancer Moonshot into this submechanism line.

#### **Other Research**

The FY 2025 President's Budget provides \$3,917.8 million for this mechanism, which is \$581.0 million more than the FY 2023 Final level. This amount would fund 8,407 grants, which is 196 more than the number of awards projected in the FY 2023 Final level. Resources for cooperative clinical research and the "other research other" line reflect allocations of a portion of the mandatory funding for the Cancer Moonshot into these submechanism lines, and resources for biomedical research support reflect a proposed reduction of \$50.0 million in grants for instrumentation that are located in this submechanism line.

#### Training

The FY 2025 President's Budget provides \$1,034.2 million for research training, which is \$49.9 million above the FY 2023 Final level. This amount would fund 17,922 Full-Time Trainee Positions (FTTPs), which is 485 more than in the FY 2023 Final level, and would reflect assumed stipend increases of 2.0 percent for FY 2024 and FY 2025.

#### **Research & Development (R&D) Contracts**

The FY 2025 President's Budget provides \$4,582.5 million for R&D contracts, which is \$549.6 million more than the FY 2023 Final level. Resources for R&D contracts reflect allocations of a portion of the mandatory funding for the Cancer Moonshot into this mechanism line. The requested amount would fund an estimated 2,933 contracts, or 188 more than the FY 2023 Final level.

• SBIR/STTR R&D Contracts. The FY 2025 President's Budget includes a \$130.9 million set-aside within the R&D Contracts mechanism for support of qualified SBIR/STTR contracts.

#### **Intramural Research (IR)**

The FY 2025 President's Budget provides \$5,274.4 million for IR, which is \$228.2 million more than the FY 2023 Final level. This level would account for required pay cost increases for NIH employees in FY 2024 and FY 2025, including actual and proposed pay raises for civilian and military personnel and the estimated cost increase in the agency share for health insurance

premiums. It also incorporates an allocation of a portion of the mandatory Cancer Moonshot increase to the IR program within the National Cancer Institute (NCI).

#### **Research Management and Support (RMS)**

The FY 2025 President's Budget provides \$2,689.6 million for RMS, which is \$358.1 million more than the FY 2023 Final level. As with intramural research, the amount covers anticipated pay cost increases for military personnel as well as growth in health insurance premiums for civilian employees.

#### **Office of the Director (OD)**

The FY 2025 President's Budget provides \$3,044.5 million for OD, which is \$21.8 million less than the FY 2023 Final level.

#### • Common Fund (CF)

Funding of \$722.4 million is allocated for CF-supported programs, which is \$12.6 million less than the FY 2023 Final level. The reduction is due to the shift of the Gabriella Miller Kids First Pediatric Research Program out of the Common Fund and into OD Other.

#### • Office of Research Infrastructure Programs (ORIP)

Funding of \$259.4 million is allocated for ORIP, which is \$50.0 million less than the FY 2023 Final level. The reduction is due to proposed cuts in ORIP's instrumentation grant program.

#### • Other

The \$2,062.7 million allocated for OD components other than the Common Fund or ORIP is a net increase of \$40.8 million from the FY 2023 Final level. The request for OD Other includes initiative increases of \$76.4 million for the Office of Research on Women's Health and \$12.5 million for firearms research, along with an increase of \$12.6 million due to the shift of the Gabriella Miller Kids First Pediatric Research Program from the Common Fund. These increases are partially offset by a \$70.0 million reduction in funding for grants for extramural facilities. This reduction reduces an existing \$80.0 million appropriations set-aside for this purpose to \$10.0 million, with the remaining funding repurposed to support facilities needs for non-human primate research centers.

#### **Buildings & Facilities (B&F)**

The FY 2025 President's Budget provides \$400.0 million for infrastructure sustainment projects associated with the B&F program, which is \$20.0 million above the FY 2023 Final level. This amount includes \$350.0 million for NIH's Buildings and Facilities appropriation, unchanged from FY 2023, and \$50.0 million within the appropriation for the National Cancer Institute (NCI) for facility repair and improvement activities at NCI's Frederick, Maryland, facility, an increase of \$20.0 million.

#### **Superfund Research Program**

The FY 2025 President's Budget provides \$83.0 million for the Superfund Research Program, which is equal to the FY 2023 Final level.

#### **Program Evaluation Financing**

The FY 2025 President's Budget provides \$2,018.5 million for Program Evaluation Financing purposes in NIGMS, which is a \$606.0 million increase over the FY 2023 Final level.

#### OUTPUTS AND OUTCOMES

Measure	Year and Most Recent	FY 2024	FY 2025	FY 2025
	Result /	Target	Target	Target
	Target for Recent Result / (Summary of Result)	0	0	+/-FY 2024 Target
SR-NCI-001 By 2027, address critical knowledge gaps and lack of representation in clinical data by enrolling 2,400 participants in the Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network, including 40 percent from underrepresented and underserved populations, and increase the number of tumors sequenced from tumor types and populations that lack clinical data by sequencing 1,400 tumors from the enrolled patients. (Output)	FY 2023: The PE-CGS Network enrolled 890 participants (around 30 percent from underserved communities and about 70 percent with rare cancers) and sequenced 100 tumors (more than 90 percent from underserved communities and less than 10 percent from rare cancers). Target: Enroll 500 participants and sequence 50 tumors lacking clinical data, including rare cancers/subtypes, highly lethal cancers, cancers with an early age of onset, cancers with high disparities in incidence and/or mortality, or cancers in understudied populations. (Target Exceeded)	Enroll an additional 500 participants and sequence an additional 200 tumors lacking clinical data, including rare cancers/subtypes, highly lethal cancers, cancers with an early age of onset, cancers with high disparities in incidence and/or mortality, or cancers in understudied populations.	Enroll an additional 800 participants and sequence an additional 400 tumors lacking clinical data, including rare cancers/subtypes, highly lethal cancers, cancers with an early age of onset, cancers with high disparities in incidence and/or mortality, or cancers in understudied populations.	N/A
SR-NIA-001 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 2023: The Alzheimer's Disease Sequencing Project consortium identified risk and protective alleles suggesting two molecular pathways as candidates for drug target intervention against late-onset Alzheimer's disease. Two candidate drugs are currently in phase two and three clinical trials, respectively. One drug is targeting a molecular pathway (TREM2) in brain immune cells and another is targeting a fat metabolism molecular pathway (Apo-E) previously implicated in Alzheimer's disease.	N/A	N/A	N/A

### NIH-Wide Strategic Plan Objective: Advancing Biomedical and Behavioral Sciences

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)	Turget	Turget	+/-FY 2024 Target
	Target: Identify risk and protective alleles that lead to one novel therapeutic approach, drug target, or pathway to prevention for late-onset Alzheimer's disease. (Target Exceeded)			
SR-NIA-002 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 one human studies. (Output)	FY 2023: Eleven new drug candidates for Alzheimer's disease (AD) or related dementias have been developed and have advanced into phase one human trials. These drug candidates are diverse in type of drug (e.g., vaccine, gene therapy, antibody, small molecule) and variety of biological target (e.g., inflammation, growth factors and hormones, brain receptors, brain proteins Tau and Amyloid beta previously implicated in AD). Target: Advance the development of three novel drug or biologic therapeutic candidates for AD or related dementias toward the point of entry into phase one human studies. (Target Exceeded)	N/A	N/A	N/A
SR-NIAAA-001 By 2025, develop, refine, and evaluate the effectiveness of evidence- based intervention strategies for facilitating treatment of alcohol misuse in underage populations. (Output)	FY 2023: Researchers conducted a study to evaluate the efficacy of a novel behavioral economic and wellness-based intervention for non-student emerging adults to reduce alcohol use. Target: Evaluate the effectiveness of an alcohol intervention in reducing alcohol misuse among emerging adults outside of	Continue a clinical trial to evaluate the effectiveness of screening and brief intervention in primary care for reducing alcohol misuse among underage populations.	Conduct research to develop and evaluate the effectiveness of mobile and telehealth interventions to address alcohol misuse in underage populations.	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result /			+/-FY 2024 Target
	(Summary of Result)			
	(Target Met)			
SR-NIAAA-002 By 2025, identify neurobehavioral precursors or consequences of adolescent substance use or other childhood experiences. (Outcome)	FY 2023: In a clinical study, researchers examined whether risk factors (e.g., childhood trauma) during adolescence increased the risk for alcohol use among high school students. In a preclinical study using an animal model of adolescent alcohol consumption, researchers explored whether alcohol use during adolescence contributed to increased pain during adulthood. Target: Conduct preclinical and clinical studies to better understand the predictors and consequences associated with adolescent alcohol misuse. (Target Met)	Examine the neurobiological mechanisms that underlie the relationship between childhood trauma and increased risk of alcohol misuse during adolescence and adulthood.	Conduct research to identify or characterize neurobiological mechanisms underlying the relationship between sleep and adolescent alcohol misuse.	N/A
SR-NIAAA-003 By 2025, advance one to two new or repurposed compounds that act on neurobiological targets that may have the potential for treating alcohol or other substance use disorders. (Outcome)	FY 2023: NIH supported preclinical and clinical studies to evaluate the potential of repurposed, FDA-approved drugs in reducing alcohol consumption in individuals with alcohol use disorder (AUD). One study found that a high blood pressure medication reduced alcohol consumption in an animal model, and another study found that a psoriasis medication reduced drinks consumed per day in individuals with AUD. Target: Evaluate a candidate compound for the treatment of alcohol use disorder in a preclinical and/or clinical	Conduct a clinical study to evaluate a candidate compound for the treatment of alcohol use disorder in individuals with a co-occurring mental health condition.	Evaluate a repurposed candidate compound that acts on a neurobiological target for the treatment of alcohol use disorder in a preclinical and/or clinical study.	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result /			+/-FY 2024 Target
	(Summary of Result)			
	study.			
	(Target Met)			
SR-NIAAA-004 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 2023: Researchers tested a family-based intervention to decrease violence in families, promote wellness, and reduce/postpone alcohol and other drug use among Native Americans. Target: Evaluate a culturally appropriate family-based intervention to prevent and reduce underage drinking among an underserved population. (Target Met)	Develop and/or evaluate a preventive intervention to address alcohol use in underage populations.	Develop and/or evaluate an intervention to address alcohol misuse among college age individuals and disseminate these or other evidence-based intervention strategies for preventing substance misuse and its consequences in underage populations.	N/A
SR-NIAID-001 By 2026, advance the preclinical or clinical development of 10 antivirals for current or future infectious disease threats. (Outcome)	FY 2023: Researchers advanced the preclinical development of three antiviral therapeutic candidates and supported two phase three clinical studies that are evaluating antiviral therapeutics. Target: Advance preclinical or clinical development of two antiviral therapeutics. (Target Exceeded)	Advance preclinical or clinical development of two antiviral therapeutics.	Advance preclinical or clinical development of two antiviral therapeutics.	N/A
SR-NIBIB-001 By 2026, establish a formalized funding pathway for the development, validation, and regulatory review of diagnostic technologies to enhance surveillance and pandemic preparedness. (Outcome and Efficiency)	FY 2023: NIH supported the development of six at-home COVID-19 tests, one of which addresses the accessibility needs of people with disabilities, one point- of-care (POC) COVID-19 test, and two POC multiplex tests for COVID-19 and flu. All nine tests received an FDA emergency use authorization for marketability. Target: Receive FDA	Receive FDA authorization or approval (including updated authorization or approval) for at least two home, point-of- care, or lab-based diagnostics, at least one of which is more accessible to people with disabilities.	Submit for FDA authorization or approval two home, point-of-care, or lab- based diagnostics, at least one of which detects multiple pathogens.	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2024 Target
	authorization or approvals for two home, point-of-care, or lab-based diagnostics, at least one of which addresses accessibility needs of people with disabilities. (Target Exceeded)			
SR-NIDA-001 By 2026, evaluate the efficacy of new or refined interventions to treat opioid use disorders (OUD). (Output)	FY 2023: Completion of a phase two clinical trial of a long-acting formulation of an opioid antagonist is delayed due to lingering effects of the COVID-19 pandemic and unanticipated delays in receiving FDA regulatory approval. The trial is expected to launch in FY 2024 and proceed as planned. Target: Complete a phase two trial of a long-acting formulation of an opioid antagonist. (Target Not Met)	Conduct phase one clinical trials of at least two anti-opioid vaccines.	File one New Drug Application with FDA for a new treatment for OUD.	N/A
SR-NIDA-002 By 2025, develop or evaluate the efficacy or effectiveness of new or adapted prevention interventions for substance use disorders (SUD). (Outcome)	FY 2023: Researchers conducted two clinical trials testing approaches to prevent opioid and other substance misuse by intervening on social determinants of health. Target: Launch one to two clinical trials testing approaches to prevent opioid and other substance misuse by intervening on social determinants of health. (Target Met)	Launch preliminary epidemiological research studies to inform pilot studies that will develop novel strategies to prevent substance use among youth and young adults.	Continue preliminary epidemiological research studies to inform pilot studies that will develop novel strategies to prevent substance use among youth and young adults.	N/A
SR-NIDA-003 By 2027, develop evidence on the effectiveness and implementation of new and existing harm reduction services and identify strategies to	FY 2023: Researchers launched nine clinical research studies to examine the effectiveness and/or implementation of new and existing harm reduction strategies, and began	Initiate steps of the dissemination and publication plan to ensure that findings from the clinical research studies will	Begin data analysis for clinical research studies and begin sharing data collected as part of these studies via the Helping to End	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2024 Target
address barriers to implementing these services, through research studies and community engagement. (Outcome)	community engagement by convening the Community Engagement Council and Community Advisory Boards. Target: Launch nine clinical research studies to examine the effectiveness and/or implementation of new and existing harm reduction strategies, and begin community engagement by convening the Community Engagement Council and the Community Advisory Boards. (Target Met)	reach a broad audience.	Addiction Long-term (HEAL) Initiative® Data Ecosystem, a cloud-based platform for sharing and analyzing data collected through the HEAL Initiative®.	
SR-NIDA-004 By 2027, strengthen community- informed research on the effectiveness of recovery support services for persons taking medications for opioid use disorder (MOUD). (Outcome)	FY 2023: Researchers launched two pilot trials to assess the feasibility, acceptability, and preliminary effectiveness of interventions to retain individuals on MOUD but, due to unexpected delays, one survey to assess MOUD capacity in recovery homes was not completed. Target: Launch two pilot trials to assess the feasibility, acceptability, and preliminary effectiveness of interventions to retain individuals on MOUD, and one survey to assess MOUD capacity in recovery homes. (Target Not Met but Improved)	Launch a third pilot trial to test the feasibility, acceptability, and preliminary effectiveness of an intervention to link individuals taking MOUDs to recovery community centers.	Publicly report early results of the pilot studies and disseminate recovery research tools to other researchers via the Helping to End Addiction Long-term (HEAL) Initiative® data ecosystem.	N/A
SR-NIDCD-001 By 2025, increase the number of potential treatment options for communication disorders that are being tested in clinical trials by adding	FY 2023: NIH initiated a clinical trial testing one new treatment for a disorder affecting hearing. Target: Initiate testing one new treatment for a disorder	Initiate testing one new treatment for a disorder affecting balance.	Initiate testing one new treatment for a disorder affecting speech.	N/A

Measure	Year and Most Recent Result / Target for Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024
	(Summary of Result)			Target
one new treatment option per year. (Outcome)	affecting hearing. (Target Met)			
SR-NIDDK-001 By 2023, perform comparative effectiveness studies to test five therapies for prevention or treatment of type 2 diabetes. (Outcome)	FY 2023: The Alliance of Randomized Trials of Medicine vs. Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) study found that bariatric surgery results in a more sustained remission of type 2 diabetes compared to intensive medical/lifestyle management alone. Target: Determine the long- term durability of diabetes remission following bariatric surgery compared with medical/lifestyle intervention. (Target Met)	N/A	N/A	N/A
SR-NIGMS-001 By 2025, expand the use of program-focused versus target-focused award mechanisms by National Institute of General Medical Sciences (NIGMS) investigators. (Output)	FY 2023: Out of 4,389 investigators supported by R01 or MIRA/R35 grants, 2,414 were MIRA/R35 investigators (55 percent). This is an increase of 8 percentage points from 47 percent in FY 2022. Target: Expand NIGMS investigator participation in the Maximizing Investigators' Research Award (MIRA) program by two percentage points. (Target Exceeded)	Expand NIGMS investigator participation in the MIRA program by two percentage points.	Expand NIGMS investigator participation in the MIRA program by two percentage points.	N/A
SR-NIMHD-001 By 2026, enhance understanding of how five health information technologies can be applied effectively to improve minority health	FY 2023: Investigators leveraged natural language processing and informatics to build and pilot test the Rosie the Chatbot mobile app. The investigators assessed the application's ability to provide information that	Identify barriers and enhancers to adoption of health information technologies, such as clinical decision aids, from the perspective of	Identify barriers and enhancers to adoption of chronic disease self-management support enhanced by health IT, from the perspective of racial or ethnic minority,	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
or to reduce health disparities. (Output)	meets the maternal health and infant care needs of racial and ethnic minority mothers who experience health disparities. Target: Assess the feasibility of using data mining, natural language processing and/or other technological advances to improve health or healthcare for individuals who experience health disparities. (Target Met)	physicians who care for populations who experience health disparities.	rural, sexual and gender minority, or socioeconomically disadvantaged patients.	
SR-NINDS-001 By 2023, advance the development of one to two 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 2023: Thirteen therapeutic or device candidates for the treatment of neurological diseases have advanced to the point of preparedness for first-in- human studies. Target: Advance the development of one to two 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. (Target Exceeded)	N/A	N/A	N/A

# NIH-Wide Strategic Plan Objective: Developing, Maintaining, and Renewing Scientific Research Capacity

Measure	Year and Most Recent	FY 2024 Target	FY 2025 Target	FY 2025 Target	
		Target	Target	larget	
	Target for Recent Result /			+/-FY 2024 Target	
	(Summary of Result)				
RC-NIGMS-001 Maintain the yearly number of undergraduate students with mentored research experiences through the IDeA (Institutional Development Award) Networks of Biomedical Research Excellence (INBRE) program in	FY 2023: More than 1,450 undergraduate students participated in mentored research experiences, consistent with FY 2022 level. Target: Sustain the number of undergraduate mentored research experiences from FX 2022 level	Sustain the number of undergraduate mentored research experiences from FY 2023 level.	Sustain the number of undergraduate mentored research experiences from FY 2024 level.	N/A	
order to sustain a pipeline of undergraduate students who will pursue health research careers. (Output)	(Target Met)				
RC-NIGMS-002 Increase the total number of National Research Service Award (NRSA) slots for high-quality research training awarded to Historically Black Colleges and Universities (HBCUs), Tribal Colleges and Universities (TCUs), Tribal Organizations (TOs), and institutional Development Award (IDeA) states, to develop a diverse pool of well- trained scientists with the skills necessary to conduct rigorous, reproducible research and transition into careers in the biomedical research workforce. (Output)	FY 2023: Approximately 483 NRSAs were supported at HBCUs, TCUs, TOs, or institutions in IDeA states. Target: Support 424 NIGMS NRSAs at HBCUs, TCUs, TOs, or institutions in IDeA states. (Target Exceeded)	Support 498 NIGMS NRSAs at HBCUs, TCUs, TOs, or institutions in IDeA states.	Support 503 NIGMS NRSAs at HBCUs, TCUs, TOs, or institutions in IDeA states.	N/A	
RC-NIMH-001 Collect and distribute human tissue samples and molecular and genetic data from human tissues to the scientific community with the purpose of supporting	FY 2023: Brain tissue from 40 new donors was obtained. Samples were distributed to 36 researchers. Target: Collect brain tissue from an additional 30 new donors and distribute tissue	Collect brain tissue from an additional 30 new donors and distribute tissue samples or data derived from tissue to 20 researchers	Collect brain tissue from an additional 30 new donors and distribute tissue samples or data derived from tissue to 25 researchers studying mental or	N/A	

Measure	Year and Most Recent Result / Target for Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
research on brain and behavior. (Output)	(Summary of Result) samples or data derived from tissue to 20 researchers studying mental or neurological disorders. (Target Exceeded)	studying mental or neurological disorders.	neurological disorders.	
RC-OER-001 Provide research training for predoctoral trainees and fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2023: Award rate to comparison group reached 15 percent. Target: N ≥ 10 percent (Target Exceeded)	N ≥ 10 percent	N ≥ 10 percent	N/A
RC-OER-002 Provide research training for postdoctoral fellows that promotes greater retention and long-term success in research careers. (Output)	FY 2023: Award rate to comparison group reached 18 percent. Target: N ≥ 10 percent (Target Exceeded)	N ≥ 10 percent	N ≥ 10 percent	N/A
Correction(Target Exceeded)RC-ORIP-001 Verify 75FY 2023: The NIH'sbercent of awarded state- of-the-art instruments are installed at NIH- supported research nation. (Output)FY 2023: The NIH's Shared Instrumentation Grant (S10) Program awarded 128 grants in FY 2021. Of the 126 grant awards, 109 instruments (85 percent) were installed within 24 months of the Notice of Award date.Target: Verify 60 percent of awarded state-of-the-art instruments are installed at NIH-supported research institutions across the nation 24 months after award.		Verify 70 percent of awarded state-of-the- art instruments are installed at NIH- supported research institutions across the nation 24 months after award.	Verify 75 percent of awarded state-of-the- art instruments are installed at NIH- supported research institutions across the nation 24 months after award.	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2024 Target
RC-OSC-001 By 2030, foster cultures of inclusive excellence (cultivating and benefiting from a full range of talent) in the biomedical research community by supporting diverse early-career faculty cohorts and institutional culture change, through the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program. (Outcome)	[Measure will begin reporting in FY 2024.]	Complete hiring and development of individual development plans (IDPs) for first set of faculty cohorts; implement tailored activities, interventions, and policies/practices to promote cultures of inclusive excellence at each awardee site.	Complete hiring and development of individual development plans (IDPs) for second set of faculty cohorts; implement tailored activities, interventions, and policies/practices to promote cultures of inclusive excellence at each awardee site.	N/A

#### NIH-Wide Strategic Plan Objective: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2024 Target
OS-NBS-001 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 2023: NBS successfully implemented the federal mandate and transitioned to the Treasury G-Invoicing solution. Target: Identify or initiate development effort for the implementation of the G- Invoicing platform. (Target Met)	Transition NBS portfolio to a FedRAMP-certified cloud service provider.	Complete assessment and continue the enhancement of the NBS architecture.	N/A
OS-OALM-001 Utilize performance-based contracting (PBC). (ongoing) (Output)	FY 2023: NIH obligated 47 percent of eligible service contracting dollars to PBC. Target: Obligate the FY 2023 goal of eligible service contracting dollars to PBC.	Obligate the FY 2024 goal of eligible service contracting dollars to PBC.	Obligate the FY 2025 goal of eligible service contracting dollars to PBC.	N/A

Measure	Year and Most Recent Result /	FY 2024 Target	FY 2025 Target	FY 2025 Target
	Target for Recent Result / (Summary of Result)			+/-FY 2024 Target
	(Target Met)			
OS-OHR-001 Address diverse workforce recruitment needs to ascertain highly qualified staff to conduct or support biomedical research. (Ongoing) (Output)	FY 2023: The use of industrial-organizational psychologists and advanced assessments has improved hiring outcomes for managers across NIH. Target: Examine key area to enhance recruitment: Examine use of advanced applicant assessments to help improve the quality of applicant pools for highly skilled positions at the NIH and determine whether or not there is an impact on hiring and retention. (Target Met)	Examine key area to enhance recruitment: Examine use of resources created specifically to assist HR Specialists with the promotion of vacancies to underrepresented groups, veterans, etc. in an effort to increase awareness of NIH opportunities among diverse populations and determine whether or not there is an impact on the diversity of NIH's applicant pools.	Examine key area to enhance recruitment: Examine the impact of the change in qualification requirements for the Scientist Administrator positions (e.g., Health Scientist Administrator, Social and Behavioral Scientist Administrator) at NIH to guide future approaches to filling vacancies.	N/A
OS-OIR-001 Reallocate laboratory resources based on external reviews by Boards of Scientific Counselors (BSC). (Output)	FY 2023: 25 percent of Principal Investigators were reviewed, resulting in \$6,540,757 of resources recommended to be reallocated. Target: Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources. (Target Met)	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	Conduct BSC reviews annually of 25 percent of Principal Investigators to assess quality of science and prioritize resources.	N/A
OS-ORF-001 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 2023: 20 of the 27 active projects were under construction. 4 projects were completed, with 2 above and 2 below the final approved project cost.	27 Active Projects	27 Active Projects	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
	(Target Not Met but Improved)			
OS-ORF-002 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 2023: The NIH Building and Facilities project portfolio was modified to include 27 projects due to the availability of funds. NIH managed the design and construction of 25 of the 27 funded projects within plus or minus 10 percent adjustment to the approved scope. Target: 24 Active Projects (Target Met)	27 Active Projects	27 Active Projects	N/A
OS-ORF-003 Reduce the footprint of office and warehouse space in NIH's owned and leased facilities portfolio by one percent annually to comply with guidelines in the Office of Management and Budget (OMB) Memorandum M- 12-12, Promoting Efficient Spending to Support Agency Operations. (Output and Efficiency)	FY 2023: The usable square footage of rentable office and warehouse space was reduced by 0.2 percent. Target: Reduce one percent of FY 2022 usable square feet. (Target Not Met but Improved)	Reduce one percent of FY 2023 usable square feet.	Reduce one percent of FY 2024 usable square feet.	N/A

#### GRANT AWARDS TABLE

	FY 2023 Final <sup>3,a</sup>	FY 2024 CR <sup>3,a</sup>	FY 2025 President's Budget <sup>3,a,b</sup>
Number of Awards	52,601	52,204	53,286
Average Award (in Whole \$s)	\$623,539	\$619,693	\$637,883
Range of Awards (in Whole \$s) <sup>1,2</sup>	\$1,000 to	\$1,000 to	\$1,000 to
	\$32,887,320	\$35,295,545	\$36,244,258

<sup>1</sup> Award range excludes minimum values of zero to under \$1,000 related primarily to no-cost extensions and co-funded actions. Excludes awards under Other Transaction Authority.

<sup>3</sup> Includes 21st Century Cures Act funding.

<sup>a</sup> Figures do not include any awards or funding related to ARPA-H.

<sup>b</sup> Figures include awards or funding related to the Cancer Moonshot.

<sup>&</sup>lt;sup>2</sup> 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.

#### **Budget Summary**

	FY 2023 <sup>2</sup>	FY 2024 <sup>3</sup>	FY 2025 <sup>4</sup>
Notification <sup>1</sup>	\$63,140	\$120,130	\$120,555

(Dollars in Thousands)

<sup>1</sup>Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

<sup>2</sup> Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on September 23, 2022.

<sup>3</sup> Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 19, 2023.

<sup>4</sup> HHS has not yet notified for FY 2025.

#### **Authorizing Legislation:**

Authorization	.Section 223 of Division G of the Consolidated Appropriat	ions Act, 2008
Allocation Method	Direct Federal, Compe	etitive 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.

#### **Budget Allocation FY 2025**

NIH FY 2025 NEF-funded activities consist of the following three projects:

#### **Electrical Power Reliability for the Clinical Center Complex (Phase 4)**

One of NIH's highest facility-related priorities is to support the safety and reliability of the infrastructure that provides utility services to patient-related areas of the Clinical Center Complex (CCC) on the Bethesda Campus. The CCC is composed of three major structures including the original Building 10, Ambulatory Care Research Facility's (ACRF), and Clinical Research Center (CRC) built in 1952, 1980, and 2005, respectively. This four-phase project consists of three major initiatives to achieve electrical power reliability in the CCC, including: 1) new electrical risers and associated equipment; 2) electrical vault decommissioning; and 3) upgrades to existing vaults. This utility project will replace and upgrade aging services with safe, state-of-of the art, cost effective, contiguous, and secure electrical systems. The entire program (all three initiatives) will be executed in four phases. This FY 2025 NEF request is for Phase 4, which will consist of three elements:

<u>Element 1 – Install New Electrical Risers and Associated Equipment</u>: Provide 8 new normal and 13 new emergency electrical distribution risers (total of 21) of varying ampacity in the A, B, C, D, G, H, and J wings of Building 10 (B10) by extending the current installation from the perimeter of the building to full height of distal wings. Each riser will be adjacent to and usurp one of the East and West freight elevators and lobbies. This will enable each riser to reach the highest level of each wing and to house panel boards and switchgear necessary to complete the

system. These new risers will allow: 1) the transfer of all distribution equipment in old B10 for service by these new risers; 2) replacement of panel boards/distribution boards/switchboards/motor control centers that, after evaluation, were determined not suitable to function in the new distribution; 3) installation of new lighting panels and life safety panels on every floor of each distal wings; 4) provision of life safety panels 208V and 480V for egress requirements for the library wing; and 5) replacement of all 208V ballast as necessary in East and West distal wings of old B10 preparing the fixtures for 277V service from dedicated lighting panel boards.

<u>Element 2 – Decommission Existing Vaults</u>: Fully decommission and remove existing equipment in vaults 1, 2, 4, and 5 including environmental requirements for removal of Polychlorinated Biphenyl (PCB) contaminated transformers.

<u>Element 3 – Perform Upgrades to Existing Vaults</u>: Replace and upgrade electrical vaults V6, V7, V8, V9, and V10 one vault at a time while maintaining full functional service to the ACRF facility.

#### **Upgrade Existing Site Electrical Distribution System (Phase 1)**

The NIH mission is dependent upon the reliability of the campus electrical distribution system. To meet this demand, the existing electrical distribution system needs to be upgraded to provide resiliency, redundancy, capacity, and maintainability – the cornerstones of a reliable power system. Upgrading the existing distribution system to a power ring bus configuration by electrically connecting the campus' existing three substations and two switching stations together offers a viable solution to mitigate the impact of power outages and unexpected downtime on mission-critical research. This project is to design and install the interconnection of three existing substations and two existing switching stations in a power ring bus configuration at the NIH Bethesda Campus; these five stations make up the campus' medium voltage (15kV) electrical distribution system. The completed project will allow for any one of the three substations to serve as backup to any other substation and will provide redundant sources of power to the two switching stations. The work will be performed in four phases; this FY 2025 NEF planned project is for phase 1.

## Generator for Campus Emergency Chilled Water Service, Building 105, North Electrical Plant, Research Triangle Park Campus

This project will design and construct a medium voltage standby power generating system in the North Electrical Plant Building 105 Central Utility Plant (CUP) on the Research Triangle Park (RTP), North Carolina campus to provide a critical power source for the campus chilled water service that is both redundant and on emergency power. Construction of an emergency power generating system will: 1) assure continuity of operations, 24 hours per day/7 days a week; 2) safeguard against disruptions to important research and/or loss of computer network equipment; 3) protect research animal welfare, 4) provide critical cooling to expensive research equipment and 5) ensure the future reliability and resiliency of the chilled water service to the RTP campus. This project will design and provide a modernized 13.8 kV Power Supply Yard, with standby power generation capability. Providing increased normal power switching capability for the south campus will strengthen the ability to support 24/7 facility operations and harden the campus power distribution system. The project will also provide the CUP with an emergency

power source sized to provide uninterruptable chilled water production during a power failure and will be expandable as campus needs change.

#### **Budget Allocation FY 2024**

\$26.1 million of FY 2024 NEF funding was allocated to Phase 2 of the Electrical Power Reliability program for the CCC. The Electrical Power Reliability program to replace failing and unreliable electrical power systems in the CCC on the Bethesda campus consists of three major initiatives, to be completed in four phases. This funding is for Phase 2, which will replace Vault 9, rebuild Vault 6, remove the existing freight elevator, and create new floors and electrical rooms, extend the electrical busducts from the West vault to the newly created electrical rooms, and decommission Vault 4.

\$40.0 million of FY 2024 NEF funding was allocated to the Building 11 Chiller & Cooling Tower Replacement Program– Electrical Upgrades. In all, there are six chillers that require replacement under the Building 11 Chiller and Cooling Tower Replacement Program – Chillers 16 through 21 and their associated Cooling Towers. Chillers 16 and 17 and Cooling Towers 16, 17 and 18 were replaced under FPAA Project N-15-007 – Replace R22 Refrigerant Chillers.

\$11.4 million of FY 2024 NEF funding was allocated to Building 11 Provide Sprinkler Protection. This project will provide sprinkler protection in the NIH CUP, Building 11. The CUP is a nearly 70-year-old, 290,488 gross square feet (GSF) building that provides chilled water and steam to cool, heat, and humidify nearly 12 million GSF of space at the NIH Bethesda Campus. The current infrastructure is over 40 years old and is at the end of its useful life; the necessity for an overhaul to the CUP's current sprinkler system is based on the requirements of the National Fire Protection Association (NFPA) 101, Life Safety Code.

\$29.3 million of FY 2024 NEF funding was allocated to Replace Steam and Chilled Water Lines from Vault 2 to Vault 31C. This project will design and replace failed, underground Steam, Chilled Water and Domestic Water piping from existing Valve Vault 2 (VV2) to existing Valve Vault 31C (VV31C) within a new, underground walkable utility tunnel on the Bethesda campus, Maryland. This repair will provide for the final "West" leg of a continuous tunnel, connecting to the ends of the existing Northeast tunnel between VV2 and VV31C.

\$13.4 million of FY 2024 NEF funding was allocated to Repair Parking Garages, Bethesda. This project is a three-phase repair/restoration program of four multi-level parking (MLP) garages located on the NIH Bethesda campus. The MLP garages on the Bethesda campus were built at different times, so their condition and service life vary. However, all have common issues - the structures are deteriorating due to lack of maintenance and poor drainage. To correct and mitigate garage deterioration and safety issues, the NIH is proposing a garage repair/restoration program that will: 1) provide for a complete remediation of the parking structures (including stairs towers) to include concrete and drainage repairs, as well as any other repair necessary to ensure the safety and structure integrity of the parking garage system; and 2) provide a 25-year maintenance/repair plan for the expected service life of each garage. The plan will prioritize the preventative maintenance, repair, and rehabilitation needs for the entire garage system on a yearly basis.

**OVERALL APPROPRIATIONS** 

#### **Budget Allocation FY 2023**

\$22.5 million of FY 2023 NEF funding was allocated to Phase 3 of the Electrical Power Reliability program for the CCC. As noted above, this program consists of three major initiatives, to be completed in four phases. Phase 3 of this project will extend the life safety, emergency, and normal power bus ducts from the East Vault to the "A" Wing of Building 10. The project will provide a new tower on the south side of the "A" Wing for the bus duct risers and closets and offer distribution to all "A" Wing floors. Additionally, the work will upgrade Vault 8 to four 2000 kVA transformers and Vault 9 to four 2500 kVA transformers.

\$40.7 million of FY 2023 NEF funding was allocated to the NIAID Support Facility (Building J), Rocky Mountain Laboratories (RML), Montana. Building J is a multistory addition to existing NIAID Building J for departmental functions including Microscopy, Intramural Administrative Management Branch, Acquisition Management and Operations Branch, Office of Cyber Infrastructure and Computational Biology, and NIH Police. The existing facilities housing the essential support functions of these programs have remained unchanged for many years, while the scientific structure being supported continues to expand. All areas of services have had additional demands placed on them and additional staff have been hired without adequate facilities available to house and support functions and consequently, negatively affect the scientific mission of NIH at RML.

#### **Budget Allocation FY 2022 and prior**

\$212.4 million of FY 2020 and \$225.0 million of FY 2021 NEF funding was allocated to the NIH for the development of enhanced bridging documents and the design build (D/B) construction of the Surgery, Radiology and Lab Medicine Building (SRLM) on the Bethesda campus. This project will construct a new addition and repurpose two floors of the west laboratory wing of the CRC. The project will include the Clinical Center's (CC) Surgical (Department of Perioperative Medicine and Interventional Radiology), Radiology (Radiology and Imaging Sciences), and Laboratory Medicine (Department of Laboratory Medicine) departments now located in the 1982-era ACRF wings S&T and the National Cancer Institute's (NCI) research laboratories located on floors 1W and 3W of the CRC West laboratory wing. These departments involve some of the most advanced and technology dependent cutting-edge programs supporting NIH's Translational Research initiatives. The project is focused on developing a facility that supports medical research initiatives to improve the nation's health and strengthen NIH's biomedical research capacity in close proximity to the CRC. Some of the major deficiencies include the following: 1) functional space inadequacies/inefficiencies; 2) routes of circulation are not efficient; 3) facility has numerous limitations restricting the flexibility/adaptability to address growth and change; 4) infrastructure systems are deficient and unreliable (major areas of concern include normal and emergency power, communication systems, heating, cooling, and ventilation); and 5) structural problems (light steel structure) result in unacceptable vibration levels in some areas of the building. The total project will consist of 630,000 GSF, including new construction of 527,000 GSF and 103,000 GSF of renovation. The new wing will be an eight-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 is located on the west end of the CRC-West Laboratory Wing. Once the new addition is completed, two floors of the West Lab wing (1W and 2W) will be renovated after the existing NCI Research Labs are moved to the new addition. The funds for the Enhanced Bridging Documents and D/B construction have been obligated.

\$12.6 million of FY 2020 NEF funding was allocated to the NIH for the Building Automation System (BAS) Replacement, Building 10, Bethesda. The project is to upgrade and replace the obsolete Johnson Controls, Inc. Building Automation System (BAS) of NIH Bethesda campus Building 10 CRC with a new state-of-the-art, cost-effective, contiguous, simple, and secure system. The CRC is within the Building 10 CCC. 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.

\$63.5 million of FY 2019 NEF funding was allocated to the NIH for construction of the Utility Vault and Patient Parking Garage on the Bethesda campus, providing a new, 330,000 GSF, Utility Vault and Multi-Level Parking Garage to serve the NIH Clinical Center. The project also included several 'enabling' tasks for the construction of the SRLM Building, being built as an addition to the CRC. The enabling tasks included a new 2MW generator and switchgear for the SRLM Building and the Clinical Data Center, replacement of electrical duct bank currently serving the CRC, which is in the footprint of the new SRLM building, 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 and 59A (emergency generators and switchgear) replacement. In all, the new Utility Vault and Parking Garage will: 1) ensure the reliability and long-term sustainability of the electrical power feeds to the 4.5 million square foot hospital and biomedical research complex; 2) mitigate the security risk, personal safety risk, and liability risk associated with the existing underground parking garage; and 3) enable the new SRLM Building addition. This project is complete.

\$19.5 million of FY 2019 NEF funding was allocated to the NIH for Phase 1 of the Electrical Power Reliability program to replace failing and unreliable electrical power systems in the CCC on the Bethesda campus. As noted above, this program consists of three major initiatives, to be completed in four phases. Phase 1 will replace the most critical Vault 10 in the ACRF and provide critical immediate upgrades to Vaults 6 through 9. These funds have been obligated.

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

\$16.5 million of FY 2017 NEF funding was allocated for Emergency Generators to support the CUP. The original scope of this project was to install three 2,500 KW emergency generators and associated electrical gear adjacent and within 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 of power to various substations on the Bethesda Campus, which in turn feeds the CUP. The new scope of work for this project was 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 utility (Pepco). In order to protect the critical mission of 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, through a sequence of electrical relays, 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. This project is complete.

\$162.1 million of FY 2016 NEF funding was allocated for the Renovation of the E-Wing in the NIH Clinical Center (Building 10). Building 10 is a 70-year-old facility built over 2 years beginning in 1950 that provides clinical services, laboratories and supporting office space. With failing infrastructure, the condition of Building 10 has impaired its ability to fully support its role in this mission critical complex. Without major renovation of its infrastructure, NIH is at risk of: 1) impacting accreditation by "The Joint Commission" and "College of Anatomical Pathologists" relating to the close proximity of the Anatomical Pathology area located in the adjoining F wing; 2) failing to provide the necessary functional adjacency to the existing Institutes and the Center's outpatient clinics; and 3) causing the NIH to fail in fulfilling its mission. These funds have been obligated.

\$10.0 million of FY 2015 NEF funding was allocated for National Institute of Environmental Health Sciences (NIEHS) Net-Zero Energy Warehouse in Research Triangle Park North Carolina. The government-owned warehouse facility is located on the NIEHS main campus and replaced an off-site leased facility. This eliminated the need to pay for a continuing lease and provided an increased level of security for the warehouse. The location of the warehouse also routes traffic away from the agency's research and administrative staff facilities, therefore improving the continuity of operations. This project is complete.

### Exhibit A

### (In millions of dollars)

NIH NG	onrecurri	ng Expen	se Fund (	NEF) Ove	erview					
	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY	2024
Project	Received	Received	Received	Received	Received	Received	Received	Received	Rec	eived
		\$M	\$M	\$M	\$M	\$M	\$M	\$M		\$M
E-Wing Renovation, Building 10, Bethesda, MD	\$ 162.10									
R22 Refrigerant Chillers Replacement, Bethesda, MD		\$ 35.27								
Emergency Power Generators to Assure Chilled Water, Bethesda		\$ 16.48								
Surgery, Radiology and Lab Medicine Building (SRLM), Bethesda, MD					\$ 212.40	\$ 225.00				
ORF/ORS/NIAID Support Facilities, RML, MT								\$ 40.65		
Electrical Power Reliability, Building 10, Bethesda. MD				\$ 19.50				\$ 22.49	\$	26.10
Building Automation System (BAS) Replacement, Bldg 10, Bethesda, MD					\$ 12.60					
Utility Vault and Patient Parking Garage, Bethesda, MD				\$ 63.54						
Replace Cooling Towers 18,19 and Chillers 17,18,19									\$	40.00
Building 11 Provide Sprinkler Protection									\$	11.37
Replace Steam & Chilled Water Lines from Vault 2 to Vault 31C									\$	29.30
Repair Parking Garages, Bethesda									\$	13.36
Upgrade Existing Site Electrical Distribution System										
(Connect SWS-B-48 to SS-B-46)										
105, North Electrical Plant, RTP										
Totals:	\$ 162.10	\$ 51.75	\$ -	\$ 83.04	\$ 225.00	\$ 225.00	\$ -	\$ 63.14	\$	120.13