

DEPARTMENT OF HEALTH AND HUMAN SERVICES

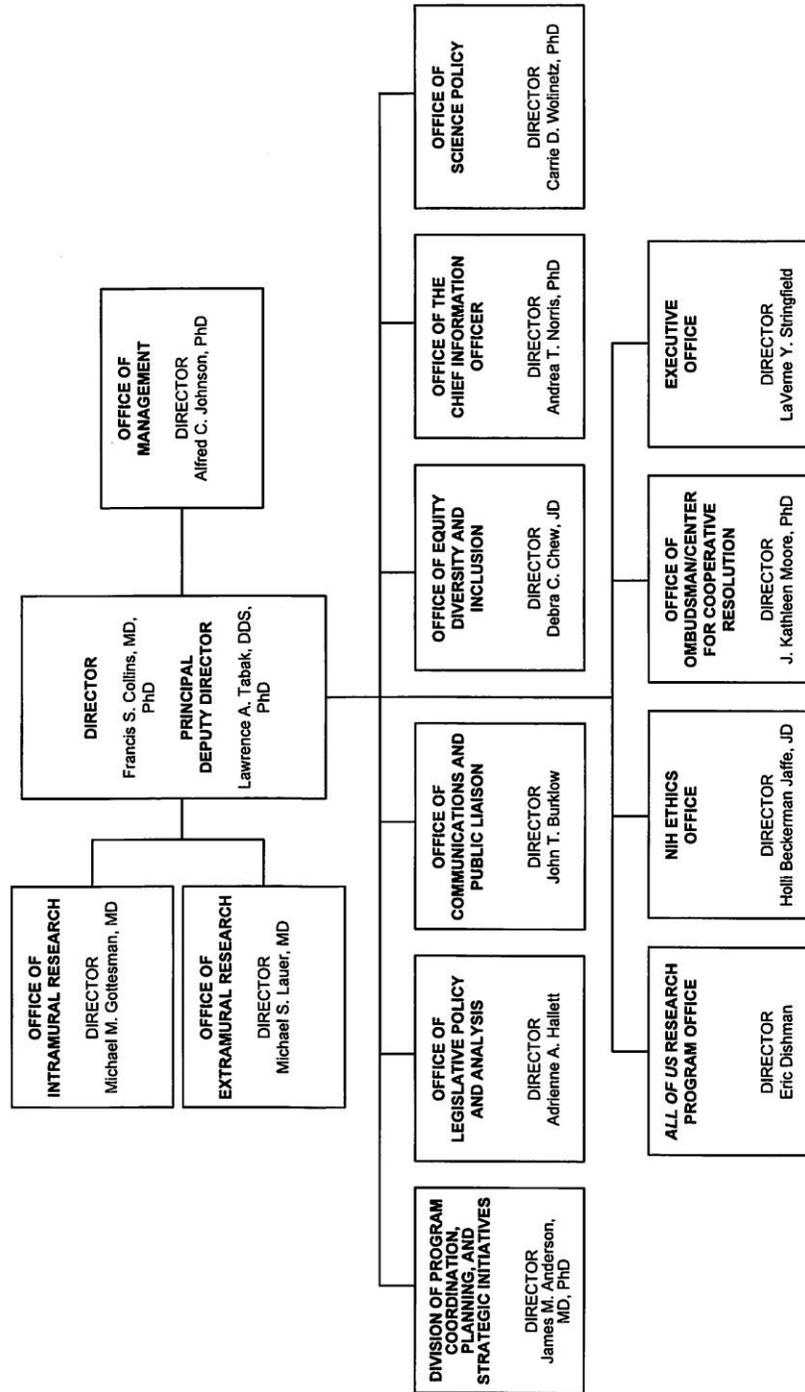
NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

<u>FY 2020 Budget</u>	<u>Page No.</u>
Organization Chart.....	2
Appropriation Language	3
Amounts Available for Obligation.....	6
Budget Mechanism Table	7
Major Changes in Budget Request	8
Summary of Changes	9
Budget Authority by Activity	11
Authorizing Legislation	12
Appropriations History	13
Justification of Budget Request	14
Budget Authority by Object Class	39
Salaries and Expenses	40
Detail of Full-Time Equivalent Employment (FTE)	41
Detail of Positions.....	42

NATIONAL INSTITUTES OF HEALTH

Office of the Director Organization Structure



NATIONAL INSTITUTES OF HEALTH
OFFICE OF THE DIRECTOR
(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH,
[\$1,909,075,000]\$1,756,544,000: *Provided*, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: *Provided further*, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: *Provided further*, That [\$165,000,000]\$157,065,000,000 shall be for the Environmental Influences on Child Health Outcomes study: *Provided further*, That [\$606,566,000]\$520,367,000 shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: *Provided further*, That of the funds provided, \$10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: *Provided further*, That the Office of AIDS Research within the Office of the Director of the NIH may spend up to \$8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act[: *Provided further*, That \$50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities][: *Provided further*, That \$5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further*, That the funds provided in the previous proviso may be transferred from one specified

activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That the Inspector General shall consult with the Committees on Appropriations of the House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2019 and 2020 no later than 30 days after the date of enactment of this Act].

In addition to other funds appropriated for the Common Fund established under section 402A(c) of the PHS Act, \$12,600,000 is appropriated to the Common Fund from the 10-year Pediatric Research Initiative Fund described in section 9008 of title 26, United States Code, for the purpose of carrying out section 402(b)(7)(B)(ii) of the PHS Act (relating to pediatric research), as authorized in the Gabriella Miller Kids First Research Act.

NIH INNOVATION ACCOUNT, CURES ACT
(INCLUDING TRANSFER OF FUNDS)

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, [~~\$711,000,000~~]~~\$492,000,000~~, to remain available until expended: *Provided*, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further*, That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account:

Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Amounts Available for Obligation^{1,2,3}
(Dollars in Thousands)

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation ²	\$1,914,345	\$2,117,675	\$1,926,144
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	0	0	0
Transfer to HHS Office of Inspector General	0	-5,000	
Subtotal, adjusted appropriation	\$1,914,345	\$2,112,675	\$1,926,144
OAR HIV/AIDS Transfers	0	0	0
Subtotal, adjusted budget authority	\$1,914,345	\$2,112,675	\$1,926,144
Unobligated balance, start of year ⁴		47,399	0
Unobligated balance, end of year ⁴	-47,399		0
Subtotal, adjusted budget authority	\$1,866,946	\$2,160,074	\$1,926,144
Unobligated balance lapsing	-210	0	0
Total obligations	\$1,866,737	\$2,160,074	\$1,926,144

¹Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2018 - \$47,655 FY 2019 - \$58,000 FY 2020 - \$60,000

² Includes \$110.0 million in FY 2018, \$196.0 million in FY 2019, and \$157.0 million in FY 2020 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

³ Amounts may not add due to rounding.

⁴ Reflects funds from the NIH Innovation Account not obligated in FY 2018 and available for obligation in FY 2019.

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Budget Mechanism - Total¹
(Dollars in Thousands)

MECHANISM	FY 2018 Final ²		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Grants:</u>								
Research Projects		\$577,522		\$659,602		\$569,667		-\$89,935
Research Centers		211,808		218,675		180,198		-38,477
Other Research		596,166		704,681		649,363		-55,318
Total Research Grants		\$1,385,496		\$1,582,958		\$1,399,228		-\$183,730
Training		\$59,653		\$66,479		\$62,287		-\$4,192
R & D Contracts		53,546		51,831		49,253		-2,578
Intramural Research		23,360		25,474		21,290		-4,184
Res. Management & Support		392,092		385,933		394,086		8,153
Total Other Than Research Grants		\$528,652		\$529,717		\$526,916		-\$2,801
Subtotal, Labor/HHS Budget Authority		\$1,914,345		\$2,112,675		\$1,926,144		-\$186,531
Total, OD		\$1,914,345		\$2,112,675		\$1,926,144		-\$186,531

¹Includes \$110.0 million in FY 2018, \$196.0 million in FY 2019, and \$157.0 million in FY 2020 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

²Includes \$47.4 million of 21st Century Cures Act funding not obligated in FY 2018, and carried over into FY 2019.

Major Changes in the Fiscal Year 2020 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2020 budget request for OD, which is \$186.5 million below the FY 2019 Enacted level for a total of \$1,926.1 million.

Next Generation Researchers Initiative (NGRI) (+\$100.0 million; total \$100.0 million): The FY 2020 budget request for NGRI will establish a dedicated pool of \$100.0 million that Institutes and Centers will be able to draw on to supplement the NGRI efforts undertaken with their own appropriations.

Biomedical and Behavioral Research Facilities (-\$50.0 million; total \$0.0 million): The FY 2020 budget request does not include continued funding to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities.

Environmental Influences on Child Health Outcomes (ECHO) (-\$7.9 million; total \$157.1 million): Within the reduced funding level, ECHO will apply an additional \$15.0 million in FY 2020 to continue efforts to support the IDeA States Pediatric Clinical Trials Network (ISPCTN), a partnership with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of General Medical Sciences (NIGMS).

OD Operations (+\$15.7 million; total \$241.5 million): The FY 2020 budget request for OD Operations includes funding to continue efforts to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural research, research information, IT, finance and administration.

Regenerative Medicine (-\$2.0 million; total \$8.0 million): The FY 2020 President's Budget request for the Regenerative Medicine Innovation Project will facilitate an opportunity to galvanize the field and stimulate a comprehensive and coordinated effort to foster major scientific advances and ensure that regenerative medicine clinical studies are standardized, reproducible, and generalizable. The reduction from FY 2019 reflects the lower authorized level for FY 2020 in the 21st Century Cures Act.

All of Us Research Program (-\$63.4 million; total \$312.6 million): The FY 2020 President's Budget request for the *All of Us* Research Program will be used to continue enrollment and retention activities to achieve the one-million participant cohort by the end of 2024, with a focus on engagement strategies that emphasize diversity. The request includes \$149.0 million of *All of Us* funding authorized in the 21st Century Cures Act, a \$37.0 million reduction from the FY 2019 authorized and enacted level.

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Summary of Changes

(Dollars in Thousands)

FY 2019 Enacted	\$2,112,675
FY 2020 President's Budget	\$1,926,144
Net change	-\$186,531

CHANGES	FY 2020 President's Budget		Change from FY 2019 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority
<u>A. Built-in:</u>				
<u>1. Intramural Research:</u>				
a. Annualization of January 2019 pay increase & benefits		\$4,608		\$35
b. January FY 2020 pay increase & benefits		4,608		12
c. Paid days adjustment		4,608		17
d. Differences attributable to change in FTE		4,608		0
e. Payment for centrally furnished services		0		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		16,682		0
Subtotal				\$64
<u>2. Research Management and Support:</u>				
a. Annualization of January 2019 pay increase & benefits		\$123,641		\$1,302
b. January FY 2020 pay increase & benefits		123,641		434
c. Paid days adjustment		123,641		469
d. Differences attributable to change in FTE		123,641		0
e. Payment for centrally furnished services		1,737		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		258,709		0
Subtotal				\$2,205
Subtotal, Built-in				\$2,269

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Summary of Changes - continued

CHANGES	FY 2020 President's Budget		Change from FY 2019 Enacted	
	No.	Amount	No.	Amount
B. Program:				
<u>1. Research Project Grants:</u>				
a. Noncompeting	295	\$452,821	27	-\$23,693
b. Competing	100	109,864	-52	-65,902
c. SBIR/STTR	19	6,982	-1	-342
Subtotal, RPGs	414	\$569,667	-26	-\$89,936
2. Research Centers	88	\$180,198	-29	-\$38,477
3. Other Research	267	649,363	-32	-55,317
4. Research Training	137	62,287	-35	-4,191
5. Research and development contracts	4	49,253	-1	-2,578
Subtotal, Extramural	910	\$1,510,768	-123	-\$190,500
6. Intramural Research	<u>FTEs</u> 0	\$21,290	<u>FTEs</u> 0	-\$4,248
7. Research Management and Support	781	394,086	0	5,947
8. Construction	0	0	0	0
9. Buildings and Facilities	0	0	0	0
Subtotal, Program	1,691	\$1,926,144	-123	-\$188,800
Total changes				-\$186,531

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Activity¹
(Dollars in Thousands)

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY2019
OD Operations	226,850	225,804	241,500	15,696
<i>NIH Director's Challenge Fund</i>	<i>(1,413)</i>	<i>(1,413)</i>	<i>(1,217)</i>	<i>(-196)</i>
Division of Program Coordination, Planning and Strategic	16,567	16,777	14,445	-2,332
Office of Behavioral & Social Sciences Research	27,823	27,823	23,956	-3,867
Office of AIDS Research	62,256	63,190	54,394	-8,796
Office of Research on Women's Health	43,731	43,731	37,653	-6,079
Office of Disease Prevention	10,494	12,494	10,757	-1,737
Office of Dietary Supplements	25,305	25,305	21,787	-3,517
Office of Research Infrastructure Programs	289,209	289,209	249,009	-40,200
Office of Data Science Strategy	0	30,000	25,830	-4,170
Director's Discretionary Fund	10,000	10,000	8,610	-1,390
Foundation for the National Institutes of Health	1,250	1,250	1,076	-174
Intramural Loan Repayment and Scholarship	7,788	7,788	6,705	-1,083
Nuclear Radiological Chemical Countermeasures	97,128	97,128	83,627	-13,501
Environmental Influences on Child Health Outcomes	165,000	165,000	157,065	-7,935
INCLUDE Project	20,218	32,000	27,552	-4,448
BRAIN Initiative	10,000	10,000	8,610	-1,390
Reception and Representation Fund	10	10	10	0
All of Us Research Program	190,000	190,000	163,590	-26,410
All of Us Research Program - Cures	100,000	186,000	149,000	-37,000
Regenerative Medicine - Cures	10,000	10,000	8,000	-2,000
Common Fund	600,716	619,166	532,967	-86,199
Next Generation Researchers Initiative	0	0	100,000	100,000
Biomedical & Behavioral Research Facilities	0	50,000	0	-50,000
Total	\$1,914,345	\$2,112,675	\$1,926,144	-\$186,531

¹ Items in italics are "non-adds"; for reference only (NIH Director's Challenge Fund amounts are already included in OD Operations budget.)

**NATIONAL INSTITUTES OF HEALTH
Office of the Director**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2019 Amount Authorized	FY 2019 Enacted	2020 Amount Authorized	FY 2020 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$2,117,675,000	Indefinite	\$1,926,144,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$2,117,675,000		\$1,926,144,000

**NATIONAL INSTITUTES OF HEALTH
Office of the Director**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2011	\$1,220,478,000		\$1,268,580,000	\$1,177,300,000
Rescission				\$10,337,395
2012	\$1,298,412,000	\$1,198,412,000	\$1,439,064,000	\$1,461,880,000
Rescission				\$2,762,953
2013	\$1,429,161,000		\$1,431,341,000	\$1,528,181,000
Rescission				\$3,056,362
Sequestration				(\$104,107,715)
2014	\$2,046,346,000		\$2,031,757,000	\$1,400,134,000
Rescission				\$0
2015	\$2,034,825,000		\$1,413,734,000	\$1,946,773,000
Rescission				\$0
2016	\$1,442,628,000	\$2,240,565,000	\$2,080,214,000	\$1,571,200,000
Rescission				\$0
2017 ¹	\$1,623,200,000	\$775,639,000	\$803,142,000	\$1,729,783,000
Rescission				\$0
2018 ¹	\$2,127,666,661	\$792,980,000	\$697,890,000	\$2,526,609,000
Rescission				\$0
Supplemental				\$50,000,000
2019 ¹	\$1,808,306,000			\$2,117,675,000
Rescission				\$0
2020 ¹	\$1,926,144,000			

¹ Includes funding provided in the NIH Innovation Account under the 21st Century Cures Act, after actual and anticipated transfers.

Justification of Budget Request

Office of the Director

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as Amended.

Budget Authority (BA):

	FY 2018 <u>Final</u>	FY 2019 Enacted	FY 2020 President's <u>Budget</u>	FY 2020 +/- <u>FY 2019</u>
BA	\$1,914,345,000	\$2,112,675,000	\$1,926,144,000	-\$186,531,000
FTE	764	781	781	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The Office of the Director (OD) provides scientific and administrative leadership to foster trans-NIH activities through planning, managing, and implementing policies and procedures to facilitate the coordination of cutting-edge biomedical research.¹ The OD coordinates NIH's intramural and extramural research activities, science policy, health information dissemination, legislative activities, technology transfer, and oversight of NIH's stewardship of public funds. The OD manages, prioritizes, and allocates funds for administrative services including budget and financial management, information technology, property management, procurement services, ethics, human resources, extramural and intramural support, and administration of equal employment and diversity management practices. Program descriptions for the OD Operations Offices are provided below. The Program Description and Accomplishments section includes detailed information on the OD's Research Offices and activities with examples of their initiatives in support of the NIH mission.

- **Immediate Office of the Director (IMOD)** directly serves the NIH Director and Principal Deputy Director in a wide range of support functions.
- **Executive Office (ODEO)** provides administrative leadership for the NIH OD on policy, finance, budget, human resources, performance management, property, internal controls, organizational development, IT support, and management analysis.
- **Executive Secretariat (ES)** manages correspondence and documents on behalf of the NIH Director and Principal Deputy Director; facilitates clearance activities; provides information for FOIA requests; coordinates NIH congressional reports; and retains official records.
- **NIH Ethics Office (NEO)** provides leadership and oversight to the NIH Ethics Program to educate employees on and in compliance with ethics statutes, regulations, and policies.
- **Office of the Chief Information Officer (OCIO)** advises the NIH Director and IC

¹ <http://www.nih.gov/institutes-nih/nih-office-director>

leadership on the direction and management of NIH IT activities; establishes NIH-level IT plans, policies, and guidance; assures compliance with policies and promotes best practices in information and IT management across NIH. The OCIO also manages the NIH Security Program (cybersecurity).

- **Office of Equity, Diversity, and Inclusion (EDI)** is a federally mandated policy portfolio whose purpose is to foster an inclusive culture at NIH, increase diversity representation, provide demographic diversity data analyses, and manage the agency's civil rights program.
- **Office of Federal Advisory Committee Policy (OFACP)** is responsible for NIH-wide development and implementation of policies and procedures for the establishment, appointment of members, and management of 153 Federal advisory committees.
- **Office of the Ombudsman/Center for Cooperative Resolution (OOCCR)** serves as a confidential and informal information resource, communications channel, and dispute resolver for NIH employees.
- **The NIH Branch of the HHS Office of the General Counsel's (OGC) Public Health Division** provides advice, representation, and other legal services to NIH. OGC coordinates with the Department of Justice when NIH is involved in litigation, and advises and represents NIH on HHS-wide matters.
- **Office of Communications and Public Liaison (OCPL)** communicates the NIH mission, scientific research results, and health information to the public; provides leadership and guidance to the communications offices at NIH's Institutes and Centers (ICs); and speaks for NIH.
- **Office of Extramural Research (OER)** provides the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH extramural research portfolio. It oversees activities related (but not limited) to high-profile digital platforms, grant compliance, peer review, communications with the extramural community, scientific misconduct, human subjects protection, biomedical research workforce, and laboratory animal welfare.
- **Office of Intramural Research (OIR)** oversees policies that govern intramural research, as well as training conducted within the NIH Intramural Research Program. OIR approves the appointment of NIH principal investigators and is responsible for external review of intramural research, human subjects research protections, animal care and use, research integrity, and technology transfer in the intramural research program.
- **Office of Legislative Policy and Analysis (OLPA)** provides essential information, advice, and guidance on congressional actions affecting NIH to the NIH community, and is the principal point-of-contact and liaison with members of Congress and their staff.
- **Office of Management (OM)** advises, provides leadership, and oversees NIH administration and management, including (but not limited to) areas of budget, human resources, facilities, support services, security operations, logistics and strategic planning. OM represents the Director in working with the ICs on all business management matters, except grants administration.
- **Office of Science Policy (OSP)** is the primary advisor to the NIH Director on matters of biomedical research policy issues that are of significance to the agency, including clinical research, data sharing, biosafety and biosecurity, and technology innovation.
- **Office of the Chief Officer for Scientific Workforce Diversity (SWD)** leads NIH's effort to diversify the national scientific workforce through expanded recruitment and retention.

Overall Budget Policy: The FY 2020 President’s Budget request is \$1,926.1 million, a decrease of \$191.5 million or 9.0 percent compared with the FY 2019 Enacted level. The OD will continue to promote and foster NIH research and research training efforts in the prevention and treatment of disease through the policy oversight of both the extramural grant and contract award functions and the Intramural Research program. The FY 2020 level includes \$157.0 million in the NIH Innovation Account under the 21st Century Cures Act, reflecting the authorized Cures Act level of \$492.0 million after reduction for transfers to the National Cancer Institute, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke for Cures Act initiatives in those Institutes.

Program Description and Accomplishments

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

DPCPSI² provides leadership for identifying, analyzing, funding, and reporting on trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that merit further research and would benefit from collaboration between two or more ICs, or from strategic coordination and planning. The work of the DPCPSI offices is described on pages OD-16 through OD-29 of this narrative.

Within DPCPSI, the Office of Portfolio Analysis (OPA)³ facilitates trans-NIH and Institute and Center portfolio analysis efforts; provides training in the use of portfolio analysis tools; identifies and develops new, sophisticated computational tools, metrics,^{4,5,6} and approaches capable of analyzing a wide range of parameters of biomedical research funding and the resulting impact. OPA activities are intended to enhance the impact of NIH-supported research by enabling NIH research administrators and decision makers to evaluate and prioritize current, as well as emerging, areas of research that will advance knowledge and improve human health. OPA works closely with the Office of Evaluation, Performance and Reporting (OEPR)⁷ which coordinates and leads NIH efforts to better capture, communicate, and enhance the value of biomedical research through strategic planning, performance monitoring, evaluation, and reporting. OEPR works to improve the collection of information and the analysis and reporting on NIH activities, products, outputs and outcomes, and in parallel identifies strategies and opportunities to strengthen NIH’s capacity for performance monitoring and evaluation. The Sexual & Gender Minority Research Office⁸ coordinates and encourages sexual and gender minority (SGM) research across NIH, leads NIH’s efforts to implement the SGM research-related provisions included in the 21st Century Cures Act, collaborates with National Institute on Minority Health and Health Disparities to ensure that the designation of SGMs as a health disparity population for NIH research is integrated throughout the work of the agency, and facilitates implementation of the NIH FY 2016-2020 Strategic Plan to Advance Research on the

² <https://dpcpsi.nih.gov/>

³ <http://dpcpsi.nih.gov/opa>

⁴ Hutchins, B.I., Yuan, X., Anderson, J.M., and Santangelo, G.M. (2016). Relative Citation Ratio (RCR): A New Metric That Uses Citation Rates to Measure Influence at the Article Level. *PLoS Biology* 14, e1002541.

⁵ Naik, G. (2016). The quiet rise of the NIH's hot new metric. *Nature* 539, 150.

⁶ Santangelo, G.M. (2017) Article-level assessment of influence and translation in biomedical research. *Mol. Biol. Cell* 28, 11 1401-1408

⁷ <https://dpcpsi.nih.gov/oepr/index>

⁸ <https://dpcpsi.nih.gov/sgmro>

Health and Well-being of Sexual and Gender Minorities. The Tribal Health Research Office⁹ coordinates NIH activities related to American Indian and Alaska Native (AI/AN) populations, supports the NIH Tribal Advisory Committee, holds annual tribal consultations, and will lead efforts to continue implementation of the FY 2019-2023 Tribal Health Research Strategic Plan.

Budget Policy: The FY 2020 President's Budget request for the DPCPSI Director's office is \$14.4 million, a decrease of \$2.3 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, DPCPSI will continue to coordinate trans-NIH research opportunities through the Common Fund, and offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences, Disease Prevention, Dietary Supplements, Infrastructure Resources, Sexual and Gender Minorities, Tribal Health, and Data Science. In addition, the Division will continue its portfolio analysis, planning, evaluation, and reporting efforts aimed at optimizing future research investments by the ICs and the OD.

Common Fund (CF)/Office of Strategic Coordination (OSC)

The CF supports the biomedical community by providing enabling technologies, databases, and programs; developing essential tools and methodologies; and fostering innovation through high risk/high reward programs.¹⁰ Overseen by OSC and managed as a partnership between OSC and trans-NIH teams, CF programs tackle major challenges in biomedical research that affect many diseases or conditions or that broadly relate to human health. CF programs address challenges and opportunities identified as high priorities for the scientific research community and NIH.

The FY 2020 President's Budget request supports many CF programs and activities that align with NIH-wide priorities. With increased support in FY 2020, the Gabriella Miller Kids First Research program will collaborate with the NIH Data Commons Pilot to establish a Pediatric Data Commons, providing a pathway to efficiently share and analyze trans-NIH pediatric data. In collaboration with the trans-NIH HEAL (Helping to End Addiction Long-term) Initiative, the Acute to Chronic Pain Signatures program aims to identify potential signatures of the transition from acute to chronic pain or resilience to chronic pain. The Transformative High Resolution Cryo-Electron Microscopy program will expand access to state-of-the-art equipment, technical support, and training for cryo-electron microscopy technology. For additional details on these and programs, please see the Common Fund section of the Overview volume.

Budget Policy: The FY 2020 President's Budget request for the Common Fund is \$533.0 million, a decrease of \$86.2 million or 13.9 percent compared with the FY 2019 Enacted level. This decrease reflects an overall budget reduction in accordance with the President's Budget request, in addition to the planned ramping down of several initiatives. This request includes support for the expansion of high priority activities within the Transformative Cryo-Electron Microscopy Program (CryoEM), Human BioMolecular Atlas Project (HuBMAP), and Molecular Transducers of Physical Activity Consortium (MoTrPAC). CryoEM will increase support for national service centers to provide biomedical researchers access to state-of-the-art equipment, technical support, and instruction for cryo-electron microscopy, an advanced technology that provides more accurate pictures of biological molecules. HuBMAP will continue to scale up efforts to build foundational resources that will enable the biomedical research community to

⁹ <https://dpcpsi.nih.gov/thro>

¹⁰ <https://commonfund.nih.gov/>

map the human body at the cellular level. MoTrPAC will increase support for large-scale clinical studies to identify the molecules that underlie the health benefits of physical activity. Finally, this request also includes funds for continued support of the Gabriella Miller Kids First Research Program. For additional details, please see the Common Fund section of the Overview volume.

Office of AIDS Research (OAR)

OAR is Congressionally-mandated to plan, coordinate, evaluate, and manage the trans-NIH HIV/AIDS research program.¹¹ The OAR oversees the development of the comprehensive *NIH Strategic Plan for HIV and HIV-Related Research* which establishes the NIH HIV/AIDS research agenda in the following scientific priority areas: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines, microbicides, and pre-exposure prophylaxis; 2) the development of the next generation of HIV therapies with increased safety and ease of use; 3) research toward a cure for HIV/AIDS; and 4) prevention and treatment of HIV coinfections and comorbidities. The Strategic Plan also includes priorities for cross-cutting research areas, specifically the basic sciences; clinical; epidemiologic; health disparities; and behavioral and social sciences research; implementation science; research training; infrastructure and capacity building; and information dissemination.

In FY 2020, OAR will continue to coordinate and advance NIH HIV/AIDS research by collaborating with the Institutes, Centers, and Offices (ICOs) in establishing strategic partnerships, evaluating NIH-wide HIV/AIDS research outcomes to ensure compliance with the agency's priority areas, and providing support for new research projects in the areas of highest priorities. The NIH-wide HIV research program has achieved unprecedented progress against the global HIV pandemic. HIV/AIDS was discovered more than three decades ago and has been transformed from a fatal condition to a manageable chronic illness. Such a remarkable achievement is due in large part to NIH's significant investments in scientific research, which continue to produce groundbreaking discoveries and advances in our understanding of basic virology, human immunology, HIV pathogenesis, and sociobehavioral dynamics. The advances have led to the development of safe and effective antiretroviral therapies (ART), improved systems of wellness and care, and novel intervention strategies to prevent HIV acquisition and transmission.

OAR will also provide support for urgent and/or emerging scientific needs. After recent data suggested a potential relationship between *in utero* exposure to the drug dolutegravir (an antiretroviral medication) and neural tube (brain and spinal cord) defects, OAR is funding efforts to evaluate the short- and long-term effects of this and other integrase inhibitors. OAR is also focusing on support of interdisciplinary research in HIV neurological complications and Alzheimer's disease. In addition, OAR will invest in innovative information technology tools to perform analyses of the NIH-wide HIV research portfolio. Analyses provide data to guide OAR to identify research gaps and emerging opportunities, and to facilitate budget projections for specific priorities and projects. OAR has integrated new innovative data systems and tools, such as the AIDS Budget System and AIDS Budget System Portfolio Review, to enhance the effectiveness of the budget development, review, and reporting processes.

¹¹ <https://www.oar.nih.gov/>

Budget Policy: The FY 2020 President’s Budget request for OAR is \$54.4 million, a decrease of \$8.8 million or 15.9 percent compared with the FY 2019 Enacted level. OAR will utilize the funds to support initiatives that address the highest HIV/AIDS scientific priorities. In addition, OAR will continue to work closely with the Institutes and Centers to ensure that the HIV/AIDS funding is directed to the highest priority HIV/AIDS research and capitalize on emerging research opportunities for newly identified, highest priority areas of study; build on scientific progress and push for discovery and breakthroughs in the key research areas of prevention, including vaccines; support novel therapeutics to achieve durable viral suppression and improve treatment modalities; and address comorbidities of aging, neurological impairment, cancer, and cardiovascular complications with HIV.

Office of Research on Women’s Health (ORWH)

ORWH provides leadership and coordination of research on the health of women.¹² To this end, ORWH leads the implementation of the *Trans-NIH Strategic Plan for Women’s Health Research* and the NIH policy on Sex as a Biological Variable (SABV). ORWH also fosters the recruitment, retention, reentry, and advancement of women in biomedical careers, and assists ICs, OER, and OIR with monitoring adherence to NIH’s inclusion policies that ensure women and minorities are appropriately represented in NIH-supported clinical research. These efforts incorporate a new NIH policy addressing inclusion across the lifespan, and requirements of the 21st Century Cures Act.

Program Portrait: Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program

FY 2019 Level: \$10.0 million
FY 2020 Level: \$10.0 million
Change: \$ 0.0 million

ORWH, along with its IC partners, created the BIRCWH Program, one of the first institutional training programs to focus on the broad areas that fall within women’s health research. BIRCWH is approaching its 20th anniversary having demonstrated the need for, and resiliency of, interdisciplinary career development for young researchers, both women and men, who are advancing science for the health of women.

BIRCWH projects have spanned the full life course of girls and women, from preconception to advanced age. They have included interdisciplinary basic, translational, behavioral, clinical, and/or health services research relevant to women's health, and, where appropriate, the study of both sexes to better understand the influence of sex as a variable on health and disease.

Budget Policy: The FY 2020 President’s Budget request for ORWH is \$37.7 million, a decrease of \$6.1 million or 13.9 percent compared with the FY 2019 Enacted level. In partnership with NIH Institutes and Centers (ICs), the ORWH will continue implementing the 2019-2023 *Trans-NIH Strategic Plan for Women’s Health Research*. As part of this plan, the ORWH will collaborate with the ICs to advance rigorous research that is relevant to the health of women, and to develop methods and leverage data sources that enhance the dissemination and implementation of evidence to improve the health of women. The plan also promotes training

¹² <https://orwh.od.nih.gov/>

and careers to enhance a well-trained, diverse, and robust workforce to advance science for the health of women and improve evaluation of research that is relevant to the health of women.

Office of Behavioral and Social Sciences Research (OBSSR)

OBSSR furthers the mission of NIH by facilitating research on the behavioral and social determinants of health which account for over half of premature deaths in the U.S. and contribute to disease trajectories and management.¹³ Guided by the OBSSR Strategic Plan (Fiscal Years 2017-2021), the office has led or coordinated several initiatives.

Big data analytic approaches such as computational modeling, predictive modeling, machine learning, and artificial intelligence have contributed to significant advances in a variety of scientific areas. The application of these approaches for understanding social and behavioral phenomena, however, has lagged behind other sciences, partly due to insufficient expertise in the field with these approaches, and partly due to an insufficient number of data sets that contain temporally dense behavioral data that can be shared and integrated. For FY 2020, OBSSR plans to develop and fund a series of efforts that will accelerate the incorporation of these big data analytic methods into the behavioral and social sciences. OBSSR will fund predoctoral training awards (T32s) that will create innovative behavioral and social sciences predoctoral programs focused on training in computational and/or data science analytic approaches.¹⁴ In addition to the predoctoral training in advanced data analytics, OBSSR is working with the NIH data science efforts to support initiatives for research resources and infrastructures that will make large, sharable databases of social and behavioral phenomena from research, administrative, and consumer digital sources available to researchers. Collaborating with other ontologies efforts to use common language to describe and define scientific concepts and their relationships with each other, OBSSR will encourage international development and dissemination of behavioral ontologies for specific research areas with compelling data integration needs.

Program Portrait: Leveraging New Technologies to Understand Health Behaviors

FY 2019 Level: \$1.5 million

FY 2020 Level: \$1.5 million

Change: \$0.0 million

OBSSR is committed to leveraging its funds to improve the use of big data analytic approaches to understand how social and behavioral factors influence individuals over time. Therefore, in FY 2018, OBSSR successfully launched a trans-NIH supported research network for Intensive Longitudinal Analysis of Health Behaviors: Leveraging New Technologies to Understand Health Behaviors.¹⁵ This collaborative network of seven projects and a research coordinating center will study factors that influence key health behaviors using intensive longitudinal data obtained from cutting-edge sensor technologies. Research within the network will cover sensor technology use in mobile assessment of suicide risk and associated behaviors, bipolar disorder, adolescent alcohol and drug-use, smoking cessation, and physical activity. In FY 2020, this network will be performing data analyses, including computational and predictive modeling of these data, and making their data available for other researchers to use.

¹³ www.obssr.od.nih.gov

¹⁴ www.grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-011.html

¹⁵ www.grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-011.html

Budget Policy: The FY 2020 President’s Budget estimate for OBSSR is \$24.0 million, a decrease of \$3.9 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, OBSSR will prioritize its continued research efforts in addressing the social and behavioral factors contributing to the opioid crisis, in concert with the NIH-wide HEAL Initiative.¹⁶ OBSSR will also continue its obligation to support in FY 2020 the National Cooperative on Childhood Obesity Research¹⁷ a collaboration of Federal partners and private entities to support research to reduce childhood obesity. Consistent with the 2017-2021 strategic plan,¹⁸ OBSSR will continue to support ongoing and planned initiatives to advance basic behavioral science, support novel measurement, methodology, and data infrastructure efforts, and to facilitate the adoption of effective social and behavioral interventions in practice. Some of these initiatives, such as the [Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences \(R25\)](#)¹⁹ and the [Predoctoral Training in Advanced Data Analytics for Behavioral and Social Sciences Research \(T32\)](#)²⁰ are to be awarded in FY 2020. With these already planned funding obligations for FY 2020, OBSSR will not plan any additional new initiatives for FY 2020, but will continue to coordinate the behavioral and social sciences at NIH to identify important new research directions and enhance the communication and integration of research and training activities across the NIH.

Office of Disease Prevention (ODP)

The mission of ODP is to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by NIH.²¹ To achieve its goals, ODP collaborates with other Federal agencies, academic institutions, the private sector, and non-governmental organizations in formulating prevention research initiatives. For example, ODP provides scientific leadership and oversight for the implementation of the NIH-FDA (Food and Drug Administration) Tobacco Regulatory Science Program which addresses priority areas of the Family Smoking Prevention and Tobacco Control Act including the manufacture, distribution, and marketing of tobacco products. In FY 2019, ODP released a new strategic plan which includes six priority areas that will guide the activities of the Office from FY 2019-2023.²² The priorities are interconnected, allowing each area to leverage staff expertise and build upon prevention related resources, tools, and initiatives developed across the ODP.

In FY 2020, ODP will work with partners across the NIH to develop metrics for measuring the long-term progress of and changes in NIH investments in prevention research. This information, along with data from ODP efforts to better characterize the NIH prevention research portfolio, will help to inform the decision-making process by NIH Institutes, Centers, and Offices. The ODP will also continue to provide direction for the Pathways to Prevention (P2P) program which includes multi-day workshops designed to identify research gaps, identify methodological and scientific weaknesses, suggest research needs, and move these fields forward through an unbiased, evidence-based assessment. Previous workshops have examined the methods for

¹⁶ <https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative>

¹⁷ <https://www.nccor.org/>

¹⁸ <https://obssr.od.nih.gov/wp-content/uploads/2016/12/OBSSR-SP-2017-2021.pdf>

¹⁹ <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-012.html>

²⁰ <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-011.html>

²¹ <https://prevention.nih.gov/>

²² <https://prevention.nih.gov/about-odp/strategic-plan-2019-2023>

evaluating natural experiments in obesity, and the appropriate use of drug therapies for osteoporotic fracture prevention. Additionally, the ODP will continue to coordinate trans-NIH Prevention Scientific Interest Groups to address gaps in prevention research through the development of targeted initiatives such as new funding opportunity announcements, workshops, and research resources. Recent efforts have resulted in a new funding opportunity announcement to identify and address disparities in the uptake of evidence-based adult screening services within diverse populations; a new database cataloging NIH-wide cohorts containing genetics information that can be used to support the design of new prevention-related studies; and a workshop to stimulate methodological innovation in evaluating the impact of screening on childhood health outcomes.

Program Portrait: Analysis of the NIH Prevention Research Portfolio

FY 2019 Level: \$1.1 million

FY 2020 Level: \$1.1 million

Change: \$0.0 million

Since 2013, ODP has taken a leadership role in developing comprehensive methods to identify the characteristics of NIH-funded prevention research studies. New portfolio analysis approaches were needed that identified key characteristics of studies—rationale, exposures, outcomes, entities studied, setting, population(s) studied, study design, and prevention research category—to provide the information needed to enable the identification of patterns and trends, as well as research areas that may benefit from targeted efforts by NIH Institutes, Centers, and Offices. Initial analyses focused on characterizing NIH investments in primary and secondary prevention research in humans and related methods research.

During FY 2012–2017, ODP estimated that 16.7 percent of projects and 22.6 percent of dollars awarded by NIH through research grants or cooperative agreements were used to support primary and secondary prevention research in humans, together with methods studies to support that research.²³ Most of the leading risk factors for death in the U.S. were reported as outcomes in less than 5 percent of the prevention research portfolio (e.g., alcohol, obesity, diet/nutrition, physical activity), with only tobacco breaking that mark at 5.1 percent. Most studies included an observational study (63.3 percent) or an analysis of existing data (43.4 percent), while many fewer included a randomized intervention (18.2 percent). Because so much is already known about the risk and protective factors that explain a large fraction of the variation in death and life expectancy in the U.S., the nation would be well served by having more of NIH’s prevention resources focused on applying that knowledge to the development and testing of interventions to prevent the leading causes of death by addressing those risk and protective factors. Additional studies are underway examining specific topic areas which will further inform the decision-making process and support efforts to evaluate NIH’s scientific investments.

Budget Policy: The FY 2020 President’s Budget estimate for ODP is \$10.8 million, a decrease of \$1.7 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, ODP will continue to implement key components of its strategic plan.²⁴ Efforts will include continued coordination of an annual survey to identify activities supported by NIH Institutes, Centers, and Offices related to areas of insufficient evidence identified by the USPSTF. The survey provides an opportunity for Institutes and Centers to consider how their current and planned activities are sufficient, or whether additional activity may be warranted to better inform the development of

²³ Murray DM, Villani J, Vargas AJ, Lee JA, Myles RL, Wu JY, Mabry PL, Schully SD. NIH Primary and Secondary Prevention Research in Humans During 2012–2017. (In press 2018) *Am J Prev Med*. 2018. doi: 10.1016/j.amepre.2018.08.006. [Epub ahead of print]

²⁴ https://prevention.nih.gov/sites/default/files/2018-10/ODP_Strategic_Plan_19-23.pdf

USPSTF clinical guideline recommendations. ODP will work to stimulate research to address the leading causes and risk factors for premature mortality and morbidity as a cross-cutting theme of its strategic plan. As part of this effort, ODP will work closely with the Global Burden of Disease Study, which is coordinated by the World Health Organization and the Bill and Melinda Gates Foundation, to generate new age profile data (birth to 70 years) to be included in all future reports. This information will provide ODP and others the ability to study the leading risk factors and causes of premature death. Additionally, ODP will also continue to provide limited co-funding to NIH Institutes and Centers to promote research across a variety of topics, including those addressing the top disease risk factors in the United States, research gaps identified by the USPSTF, and collaborative trans-NIH projects.

Office of Dietary Supplements (ODS)

The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, and disseminating research results.²⁵ Toward this end, three ODS programs are highlighted. First, ODS expands its ability to promote research on dietary supplements through the ODS Grant Co-funding Program²⁶ by providing supplemental funding to existing NIH grants, including the funding of administrative supplements and the NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program (see program portrait). Second, ODS will continue its congressionally mandated Analytical Methods and Reference Materials (AMRM) Program²⁷ which promotes rigorous research and product quality by promoting the development of accurate, precise, and reliable analytical methods for dietary supplement ingredients. The AMRM Program also develops reference materials to enhance the reliability and reproducibility of research in support of the NIH research reproducibility initiative. Third, ODS also supports its Population Studies Program,²⁸ which collects and analyzes data on the use of dietary supplements in the U.S., tracks trends in supplement use over time, identifies changes in the user population, and assesses potential risks and benefits from supplements. The program also estimates total nutrient intake from foods and dietary supplements to identify population groups that may not meet, or may exceed, nutrient recommendations.

²⁵ <https://ods.od.nih.gov>

²⁶ https://ods.od.nih.gov/Funding/Grants__Contracts.aspx

²⁷ <https://ods.od.nih.gov/Research/AMRMProgramWebsite.aspx>

²⁸ <https://ods.od.nih.gov/Research/populationstudies.aspx>

Program Portrait: NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program

FY 2019 Level: \$3.95 million

FY 2020 Level: \$3.95 million

Change: \$0.0 million

The congressionally mandated CARBON Program* is comprised of three Botanical Dietary Supplements Research Centers and two Centers for Advancing Natural Products Innovation and Technology, jointly funded by the NIH Office of Dietary Supplements and the National Center for Complementary and Integrative Health. The program promotes collaborative, transdisciplinary research on safety, effectiveness, and mechanisms of action of botanical dietary supplements with a high potential to benefit human health. The Centers identify and characterize botanicals, assess the bioavailability and bioactivity of their components, explore mechanisms of action, and conduct preclinical and clinical evaluations. The Centers provide a rich environment for training and career development. The Program's research will greatly advance understanding of the potential effects of botanicals on human health. The program will continue to be funded in FY 2020.

* https://ods.od.nih.gov/Research/Dietary_Supplement_Research_Centers.aspx

Budget Policy: The FY 2020 President's Budget estimate for ODS is \$21.8 million, a decrease of \$3.5 million or 13.9 percent compared with the FY 2019 Enacted level. The ODS will be working under its Strategic Plan for 2017-2021.²⁹ In addition to co-funding research grants on dietary supplements, this budget will support a number of major activities including the congressionally mandated Dietary Supplement Label Database, a database of label information from dietary supplements sold in the United States. ODS will continue to support its Analytical Methods and Reference Materials program, also congressionally mandated, in the development, validation, and dissemination of analytical methods and reference materials that are critical tools for quality assurance of dietary supplements. The ODS Vitamin D Initiative and its Vitamin D Standardization Program has proven to be a successful model for identifying nutrients of public health concern. In 2020, the model used for this initiative will be applied to other nutrients such as iron, iodine, and folic acid. ODS, in partnership with NCCIH, leads efforts to advance knowledge of botanical dietary supplements through its congressionally mandated NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program (see Portrait of a Program). The ODS will continue to support the CARBON program in 2020.

Office of Research Infrastructure Programs (ORIP)

ORIP advances the NIH mission by making grant awards that support research infrastructure and research resource programs³⁰ to provide a platform for innovation in basic research and translational and clinical studies. Specifically, ORIP: 1) supports research resources such as animal models of human disease and state-of-the-art biomedical instrumentation; 2) plans, organizes, and conducts workshops to identify and pursue scientific opportunities; and 3) supports research-training opportunities for veterinary scientists that capitalize on their distinct perspective and expertise based on a deep understanding of comparative medicine and insight into animal models of human disease. ORIP's programs support DPCPSI strategic goals of identifying and funding trans-NIH research activities that fill knowledge gaps and benefits from

²⁹ <https://ods.od.nih.gov/pubs/strategicplan/ODSSstrategicPlan2017-2021.pdf>

³⁰ <https://orip.nih.gov>

collaborations among NIH ICs. ORIP has two scientific divisions, the Division of Comparative Medicine and the Division of Construction and Instruments, which play essential roles in supporting and accelerating biomedical discovery.

ORIP's Division of Comparative Medicine (DCM)

DCM provides critical resources for scientists using animal models for basic and biomedical research and supports the development of specialized technologies involving human disease models.³¹ Many major medical advances of the last century involved the use of animal models. Because it would neither be cost effective nor feasible to reproduce these specialized animal resources and expertise at every research institution, these DCM programs are a valuable resource to the entire research community.

DCM funds research to safeguard the health and welfare of all laboratory animal models from invertebrates to mammals. Non-mammalian models such as fish, worms, and fruit flies are often used to advance the understanding of gene function, protein interactions, and metabolic processes related to human health and disease. Genetically-altered mammals such as mice, rats, and pigs enable the discovery of molecular targets and biomarkers (indicators of biological condition) that are both valuable for pre-clinical testing and as potential therapeutic targets for human disease models.

DCM further supports development of a clinician-scientist workforce by providing training and career development in translational science and pathology for veterinary scientists, biomedical researchers who have degrees in veterinary medicine. These clinician-scientists enhance the value of translational research teams while adding diversity to the biomedical research workforce.

DCM supports the National Primate Research Centers (NPRC) program, which facilitates the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research. In FY 2018, the NPRCs facilitated over 1,000 individual research projects involving roughly 2,150 NIH-supported researchers. Research supported by the NPRCs in FY 2018 included significant advances in HIV/AIDS therapy, other infectious diseases, genetic model development, regenerative medicine and undiagnosed and rare diseases. For example, researchers at the Oregon NPRC have identified the first NHP model of a broad class of rare, fatal, and inherited disorders of the nervous system known as Batten disease. The model will allow evaluation of therapeutic strategies for the treatment of this rare disease.

The NIH Chimpanzee Management Program³², managed by ORIP, supports housing and maintenance for chimpanzees at NIH-supported facilities. ORIP provides programmatic oversight of the facilities and ensures that they comply with the Animal Welfare Act and Public Health Service policies. The Chimpanzee Health Improvement, Maintenance, and Protection Act, signed into law in December 2000, required the establishment of a sanctuary system for federally-owned or supported chimpanzees that were no longer needed for research. In November 2015, the NIH announced it will no longer support

³¹ <https://orip.nih.gov/comparative-medicine>

³² https://dpcpsi.nih.gov/orip/cm/chimpanzee_management_program

biomedical research on chimpanzees, and all NIH-owned and NIH-supported chimpanzees that reside outside of the Federal sanctuary are eligible for retirement and relocation to the sanctuary. Animals continue to be relocated as safely and quickly as possible while allowing for optimal transition of each individual chimpanzee with careful consideration of their welfare, including their health and social grouping. ORIP will continue to work with the research facilities and sanctuary to coordinate the safe retirement of the chimpanzees.

Program Portrait: Rigor and Reproducibility in Zebrafish Research - Defined Reference Diets for Zebrafish

Zebrafish are powerful models for studying human development, behavior, genetics, and disease. They are used for investigating the biological mechanisms underlying human health and diseases, and for developing relevant therapeutics approaches. Different facilities and laboratories use a variety of diets and feeding methods to maintain these models. Although nutritional studies indicate that the length, weight, sexual maturation, fecundity, and mortality of zebrafish can vary significantly under different diet formulations, the impact of dietary variation on zebrafish health, behavior, and metabolism and consequently their implications for zebrafish research outcome, are still not well understood. Currently, there is no consensus among aquatic facilities, researchers, and commercial vendors on what optimal diets should be for zebrafish during different developmental stages (*i.e.*, larval, juvenile, and adult) to minimize husbandry variations among aquatic laboratories or facilities. Based on recommendations made by experts at a workshop convened by the ORIP in 2018, the proposed initiative is to address the needs and challenges of developing and implementing reference diets to improve animal husbandry and to promote more rigorous and transparent research in all areas of science involving zebrafish.

ORIP's Division of Construction and Instruments (DCI)

DCI funds grants for the acquisition of expensive state-of-the-art instruments and funds grants to improve existing animal research facilities or construct new research facilities.³³ The DCI Shared Instrumentation Grant programs advance biomedical research by providing access to essential state-of-the-art instruments. In FY 2018, these instrumentation programs funded 120 grants to academic and research institutions coast-to-coast and supported more than 1,000 NIH research projects, which collectively represent the majority of NIH ICs. As an example, modern cryo-electron microscopy instruments have accelerated discoveries allowing scientists to see and understand how proteins, nucleic acids, and other biomolecules function and interact. This makes the development of new drugs and medical treatments possible, as well as the ability to identify disease-causing mechanisms. Using such instruments, researchers have generated a high-resolution 3D image of the Zika virus, finding drug-binding pockets on the virus surface, and paving the way for vaccine design. A second example of important discoveries made by providing tools and technologies is illustrated in precision medicine. Precision medicine is when doctors select treatments based on a genetic understanding of the patient's disease with the hope that customized treatments are more successful than a one-size-fits-all approach. DCI's Shared Instrumentation Grant programs enable researchers to acquire high-end DNA sequencers to conduct pioneering research. Scientists can identify the genetic profiles of diseases and bring precision medicine efforts into the clinical realm. This empowers physician-scientists to rapidly detect

³³ <https://orip.nih.gov/construction-and-instruments>

numerous mutations in patients' tumors and to identify potential new, targeted therapeutic approaches.

ORIP will continue to promote programs that connect NIH partners and the scientific community. These programs uphold scientific priorities and meet the broad needs of the biomedical research continuum. ORIP will continue to advance the NIH mission by supporting research infrastructure and research resource programs to ensure the Nation's capability to improve human health and prevent disease.

Budget Policy: The FY 2020 President's Budget estimate for ORIP is \$249.0 million, a decrease of \$40.2 million or 13.9 percent compared with the FY 2019 Enacted level. The ORIP programs provide support for research and research infrastructure needs, including animal research models and biological materials; training and career development for veterinarian scientists; acquisition of state-of-the-art and shared instrumentation; and grants to modernize biomedical research facilities when construction funds are appropriated.

ORIP's Division of Comparative Medicine (DCM) will continue to interact with NIH partners and the scientific community to maintain scientific priorities that best meet the broad needs of the multidisciplinary biomedical research continuum. DCM programs will include, but are not limited to: (1) the National Primate Research Center program with the goal to facilitate the use of non-human primates as models of human health and disease for basic and translational biomedical research; (2) the Mutant Mouse Resource and Research Centers and other Resources for genetically-altered mammals such as rats and pigs; (3) non-mammalian models such as fish, worms, and fruit flies which are used to advance the understanding of gene function or metabolic processes; and (4) the National Research Service Awards. The proposed budget will result in an approximately 13.9 percent reduction in funding levels of trans-NIH nonhuman primate and other established animal resources-related (including mouse, zebrafish, and fruit fly) awards. Additionally, ORIP's unique veterinarian scientist training programs will be reduced approximately 13.9 percent. Program priorities benefiting all areas of research funded by the NIH ICs, will be carefully reviewed by DCM with orderly terminations of the research project grants.

ORIP's Division of Construction and Instruments (DCI) plans to continue to support the Nation's capacity for the conduct of biomedical research. DCI Instrumentation Programs will provide funding for shared instrumentation grants to enable, enhance, and accelerate NIH-funded research in a broad array of basic, translational, and clinical research. Further, DCI programs provide support for improvements of infrastructure of biomedical research facilities; by providing access to modern instruments and tools, these programs enhance scientific rigor of animal research. The FY 2020 budget will result in an approximately 15 percent reduction in the number of awards. To keep up with the program priorities of benefiting all areas of research funded by the NIH ICs, DCI will reduce the number of awards, proportionally in each category of the supported technologies.

Office of Data Science Strategy

The Office of Data Science Strategy (ODSS)³⁴ is charged with coordinating a broad range of data science activities that align with NIH's priorities and strategic plans. NIH-supported researchers generate large volumes of basic and clinical research data, such as genomic, imaging, and electronic health data. The amount of data generated is increasing, and so is the need to implement processes that seamlessly integrate the use of these data into everyday biomedical research practices. This includes developing and implementing new ways to collect, store, analyze, use, and share data. NIH has much existing expertise in data science and related policy and is funding numerous activities in this field. These activities are spread across the NIH Institutes and Centers. To coordinate these efforts, and to ensure that innovative methods to collect, analyze, and use NIH data are implemented broadly across the agency, NIH has created the ODSS.

To maximize this coordination across NIH, ODSS will plan, organize, oversee, and report on a broad range of initiatives and projects that align with the NIH Strategic Plan for Data Science. ODSS works closely with the NIH Scientific Data Council, and other trans-NIH committees and groups, to implement the strategic plan by: 1) catalyzing the use of new technologies and methods to gain deeper insights from NIH's vast data resources, 2) developing strategic partnerships to promote innovative contributions from computer science, engineering, and other physical science fields, and 3) enhancing competencies and capabilities of the biomedical research workforce to capitalize on new ways of working with large-scale biomedical data and analytic tools.

In FY 2020, ODSS will build on results from previous programs like Big Data to Knowledge and the NIH Data Commons to create interoperability between existing NIH data ecosystems, such as the National Center for Biomedical Informatics and the National Cancer Institute Genomics Data Commons. As part of this process, ODSS will work with the leaders of the STRIDES (Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability) Initiative to further develop partnerships with cloud providers so that access to cloud-based infrastructures is extended across NIH programs and to NIH-supported researchers. ODSS will also assist in efforts to build new systems for access to large, controlled-access NIH datasets hosted on cloud providers and to develop methods for access to data that is a part of published research findings.

In FY 2020 ODSS will launch a new NIH Data and Technology Advancement (DATA) Fellowship to attract data scientists into one- to two-year training appointments at NIH. The DATA Fellowship will recruit experts in computer engineering, mathematics, statistics, and other analytical fields. The fellowship will include opportunities for leading data scientists at various stages of their careers to work at NIH and tackle large-scale, data-intensive projects. Integrating these experts into the NIH workforce will generate creative ways to overcome current obstacles or develop new capabilities that will yield transformational changes to biomedical research.

Budget Policy: The FY 2020 President's Budget request for ODSS is \$25.8 million, a decrease of \$4.2 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, the

³⁴ <https://datascience.nih.gov>

ODSS will prioritize partnerships with cloud providers so that access to cloud-based infrastructures is continued across NIH programs and to NIH-supported researchers. Cloud environments have the potential to streamline NIH data use by allowing rapid and seamless access for a broader community, as well as to improve efficiencies by minimizing infrastructure and maintenance costs. Additionally, the ODSS will prioritize support for indexing and Findable, Accessible, Interoperable, and Reusable (FAIR)-compliant sharing of NIH datasets.

Research for Countermeasures against Nuclear/Radiological/Chemical Threats

Although funding is provided through the Office of Director, NIH's National Institute of Allergy and Infectious Diseases (NIAID) manages both the Radiation and Nuclear Countermeasures Program (RNCP) and the Chemical Countermeasures Research Program (CCRP). There are currently over 300 medical countermeasures (MCMs) at various stages of research and development in the Nuclear/Radiation/Chemical research portfolio.

The RNCP funds the development of MCMs to treat injuries resulting from a radiation public health emergency. As of August 2018, the RNCP has developed two MCM candidates (Neupogen® and Neulasta®) that have been granted FDA approval to increase survival of people acutely exposed to high doses of radiation that damage the bone marrow. The RNCP, working with a commercial partner, is also planning a pivotal, large animal study to demonstrate efficacy of another licensed growth factor for radiation-induced bone marrow injury, to be included in a planned 2019 submission to the FDA. Several other MCMs have been granted Investigational New Drug (IND) status by the FDA and to date, 29 approaches have transitioned to BARDA for advanced product development.

The CCRP is focused on developing antidotes and treatments to mitigate both lethality and/or injuries that can be caused by chemical threat agents. Since its inception in 2006, CCRP-supported researchers have evaluated more than 500 potential MCMs. These efforts have resulted in numerous patents and over 1,500 peer-reviewed scientific articles. Of the many compounds evaluated, six products have transitioned to BARDA for advanced development, including a candidate for protection against the toxic effect of chlorine gas exposure on the lungs and organophosphorus agents on the nervous system. The CCRP is currently working with federal stakeholders at the DoD and HHS as well as commercial partners to evaluate two oncology-related compounds that were recently approved by the FDA as MCMs for acute radiological/nuclear exposure for potential effectiveness against sulfur mustard-induced myelosuppression.

Budget Policy: The FY 2020 President's Budget request to support the development of medical countermeasures (MCM) against Radiological, Nuclear and Chemical threats is \$83.6 million, a decrease of \$13.5 million or 13.9 percent compared with the FY 2019 Enacted level. The Radiation and Nuclear Countermeasures Research Program will continue to support basic and translational research for the development of promising safe and effective therapeutic and diagnostic candidates towards IND and licensure. Basic research will focus on elucidating mechanisms of radiation injuries and identifying potential new (MCM) candidates for measuring, minimizing, mitigating and treating the effects of exposure to external radiation sources. The Chemical Countermeasures Research Program will continue to support basic and translational research directed at the development of promising safe and effective therapeutics and antidotes

for nerve agents, metabolic poisons, pulmonary agents, toxic industrial chemicals, and vesicating (blistering) agents.

INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to understand Down syndromE)

Down syndrome is the most common genetic cause of intellectual disability, the most common autosomal trisomy, and one of the most visible and universally recognized genetic syndromes. Each year there are approximately 5,300 babies born in the U.S. with Down syndrome. Within the past 25 years, the average lifespan for a person with Down syndrome has doubled, from 30 to 60 years. Despite this increase in lifespan, individuals with Down syndrome and their families face significant and changing health challenges.

The Joint Explanatory Statement accompanying the Consolidated Appropriations Act, 2018 included language directing NIH to develop a new trans-NIH initiative on Down syndrome to facilitate scientific discovery with the aim of improving health and neurodevelopment of individuals with Down syndrome and typical individuals at risk for Alzheimer's disease, cancer, cardiovascular disease, immune system dysregulation, and autism, among others.

As a result of this legislation, NIH launched the INCLUDE project in June 2018 to not only expand its current efforts on Down syndrome and commonly co-occurring conditions in individuals with Down syndrome that are also seen in the general population, such as Alzheimer's disease/dementia, autism, cataracts, celiac disease, congenital heart disease, diabetes, and immune system dysregulation, but to build an integrated effort across NIH that will be truly transformative in these areas.

NIH has identified the following three major components for a trans-NIH effort on Down syndrome (INCLUDE), spanning basic to clinical research:

- (1) targeted high risk - high reward basic science studies;
- (2) development of a cohort to perform deep phenotyping and study co-existing conditions; and
- (3) establishing a clinical trials network so that therapies for co-occurring conditions can begin to be tested in the Down syndrome population as soon as possible, while also further supporting and expanding existing clinical trial infrastructure.

An enhanced understanding of the constellation of co-occurring conditions and resiliencies in individuals with Down syndrome will yield a unique opportunity to both address the unmet health needs of individuals with Down syndrome while simultaneously improving the health of all individuals.

NIH dedicated \$20.2 million toward INCLUDE research, bolstering total funding for Down syndrome research in FY 2018 to approximately \$60 million, with further support anticipated in FY 2019 and beyond.

Budget Policy: The FY 2020 President’s Budget request for INCLUDE is \$27.6 million, a decrease of \$4.4 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, NIH will continue to support INCLUDE research efforts.

Foundation for the National Institutes of Health (FNIH)

The Congress created the FNIH, a 501(c)(3) public charity, to support the mission of NIH. Since 1996, the FNIH has raised over \$1.05 billion, generating \$80 per \$1 of NIH support, dramatically leveraging the NIH yearly contribution. Because of its charter, the FNIH serves as a critical and trusted convener of multiple constituencies and has pioneered novel public-private partnerships that have been widely emulated in the U.S. and abroad. For more than a decade, Charity Navigator, a prominent charity watchdog in the U.S., has rated the FNIH as an organization that consistently exceeds industry standards for effective management and efficient use of resources.

In January 2018, the FNIH and NIH teamed with biopharmaceutical, life science and non-profit organizations to overcome obstacles and increase success for advancing promising treatments for Parkinson’s disease (PD). Part of the Accelerating Medicines Partnership (AMP), AMP PD focuses on identifying and validating promising markers of disease that may be useful in tracking the progression of PD and could serve as biological targets for the development of new drugs. A critical component of this partnership is that all members have agreed to make the AMP PD data and analyses publicly available to the broad biomedical community. This is AMP’s fourth disease area leveraging already successful partnerships led by NIH and made possible through the FNIH in Alzheimer’s disease, type 2 diabetes, and the autoimmune disorders of rheumatoid arthritis and systemic lupus erythematosus.

Budget Policy: The FY 2020 President’s Budget request for FNIH is \$1.1 million, a decrease of \$0.2 million or 13.9 percent compared with the FY 2019 Enacted level. This represents a key strategic investment by NIH given the FNIH’s proven ability to leverage funds in furtherance of NIH’s mission. Funding will continue to support direct salary and overhead costs incurred for operations.

Intramural Loan Repayment and Scholarship Programs (ILRSP)

The mission of ILRSP is to develop and manage programs that offer financial incentives and other benefits to attract highly-qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of NIH. There are two education programs offered: the Intramural Loan Repayment Program (ILRP) and the NIH Undergraduate Scholarship Program (UGSP).

ILRP repays outstanding eligible educational debt for postgraduates, and in return, participants must enter into a contractual agreement to conduct qualified research as NIH employees. During FY 2018 the distribution of ILRP awards was as follows:

- 67 awards for the General LRP – 26 new and 41 renewals; and
- Three awards for AIDS LRP – 1 new and 2 renewals.
- One Clinical LRP - Disadvantage background – 1 new and 0 renewals

FY 2018 ILRP awards (71) increased by 10.9 percent compared to FY 2017 awards (64). There was one new Clinical Research LRP applicant during the 2018 cycle and one new AIDS award. UGSP offers competitive scholarships to exceptional college students from disadvantaged backgrounds who are committed to biomedical, behavioral, and social science health-related research careers at NIH. For every year of UGSP scholarship support, recipients are obligated to participate in a ten-week summer internship and one year as a full-time paid employee in an NIH research laboratory. UGSP selected 16 new recipients for the UGSP Scholarship award and 5 UGSP Scholars received scholarship award renewals. In addition, 21 UGSP scholars conducted their yearlong service obligation and 21 completed their summer internship during this same period.

Budget Policy: The FY 2020 President's Budget request for ILRSP is \$6.7 million, a decrease of \$1.1 million or 13.9 percent compared with the FY 2019 Enacted level.

Director's Discretionary Fund (DDF)

The DDF allows the NIH Director to respond quickly to new and emerging high-priority research opportunities and health priorities. In FY 2018, funds were used to support trans-NIH initiatives such as ClinicalTrials.gov, African Postdoctoral Training Initiative, National Academy of Sciences Consensus Study of Temporomandibular Disorders (TMD), HEAL (Helping to End Addiction Long-term) Initiative, and the NIH Workplace Harassment and Climate Communication Strategy.

Budget Policy: The FY 2020 President's Budget request for the DDF is \$8.6 million, a decrease of \$1.4 million or 13.9 percent compared with the FY 2019 Enacted level. In FY 2020, the DDF will continue funding projects to help uncover new knowledge that prevents, detects, diagnoses, and treats disease and disability, from the common cold to the treating of genetic disorders.

Environmental Influences on Child Health Outcomes (ECHO)

Now in its third year, Environmental Influences on Child Health Outcomes (ECHO) is a nationwide program of interconnected observational and intervention research to enhance the health of children for generations to come. In its observational research, ECHO knits together 60+ longitudinal studies of mothers and children into what will become a national research resource during the next 5 years: a single ECHO-wide Cohort comprising around 50,000 children and their families. Its overall goals are to examine how a broad array of early environmental factors interact with biology and genetics to influence outcomes of pregnancy, common childhood conditions such as childhood obesity, asthma, and autism spectrum disorders, and positive attributes of child health.

In the past two years, for example, ECHO Cohort investigators have shown that through epigenetic mechanisms, providing vitamin C supplements to pregnant women who are unable to quit smoking can lower the risk of their children developing breathing problems in the first years of life; among 10-year-olds who had been born extremely prematurely, obesity, asthma, and poor quality of life tend to cluster together; trajectories of growth have the potential to pinpoint timing of interventions to prevent obesity; and life satisfaction is as high among children with chronic disease as those without.

Interventions to prevent or treat pediatric conditions are the purview of ECHO's IDeA States Pediatric Clinical Trials Network (ISPCTN), a partnership with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of General Medical Sciences (NIGMS). The priorities of ISPCTN are to create evidence to influence pediatric practice, programs, and policies through providing access to state-of-the-art clinical trials among children from rural and underserved backgrounds, while enhancing the capacity for pediatric research at institutions in states which historically received low levels of support from NIH.

Within its first 2+ years, having implemented robust approaches to capacity building, the ISPCTN is already undertaking several trials to see how children's bodies absorb and use supplements and medications routinely used in pediatric practice. Also, in collaboration with NICHD, ECHO is supporting three studies addressing the needs of babies (and their families) with neonatal opioid withdrawal syndrome (NOWS), including two clinical trials focused on improving the care of babies with NOWS.

Budget Policy: The FY 2020 President's Budget request for the ECHO is \$157.1 million, a net decrease of \$7.9 million or 4.8 percent compared with the FY 2019 Enacted level. This funding will continue to support efforts to integrate multiple synergistic, longitudinal studies by leveraging existing and new data from maternal/pediatric cohorts. Within the reduced funding level, ECHO will apply an additional \$15.0 million to continue the ISPCTN program, which is currently in its fourth year of operation.

OD Operations

OD Operations is comprised of several OD Offices that provide advice to the NIH Director, policy direction and oversight to the NIH research community, and administer centralized support services essential to the NIH mission. These include the Offices of Extramural Research, Intramural Research, Science Policy, Management, Budget, Communications and Public Liaison, Legislative Policy and Analysis, Federal Advisory Committee Policy, Chief Information Officer, Equity, Diversity and Inclusion, Chief Officer for Scientific Workforce Diversity, Executive Office, Executive Secretariat, NIH Ethics Office, and the Immediate Office of the Director.

Funding will be used to continue efforts to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural research, research information, IT, finance and administration. Below are a few examples of accomplishments and initiatives within OD Operations that will continue to be supported in FY 2019 and beyond:

In FY 2020, the Scientific Workforce Diversity (SWD) office will complete a new Faculty Institutional Recruitment of the Scientists of Tomorrow (FIRST) funding opportunity announcement and will begin implementation of recommendations identified as part of the June 2018 Advisory Committee to the Director Working Group on Diversity (ACD WGD). The SWD office will also continue work associated with the randomized controlled trial, "Grant-Writing Support Effects on Resubmission." The SWD office will develop and launch e-learning implicit bias modules, eligible for continuing education credits, for general NIH audiences and clinical audiences, hiring and recruitment search committees, and grant peer-reviewed wars. SWD also

plans to lead the trans-NIH establishment of the Future Research Leaders Conference (FRLC) and Young Investigator weekly lecture series across all Intramural Research Program (IRP) Institutes and Centers programs; an effort which will link identified presenters to Scientific Directors and ICs for continued follow-up and recruitment. The SWD office will also develop a trans-NIH Results Based Accountability program focused on Scientific Workforce Diversity Strategic Plan metrics and performance monitoring.

In FY 2018, the Office of Extramural Research (OER) implemented and strengthened proactive approaches for addressing research misconduct, ensuring the preservation of the integrity of NIH-supported research. Further, OER regularly works with its Federal partners and the biomedical research community to reinforce the importance of proper stewardship of Federal support and compliance with grant award requirements. As an example, NIH reminded the extramural community in March 2018 of the need to report all sources of financial support, including that from foreign sources, to reduce any potential influences or conflicts which may adversely affect the integrity of the scientific process. NIH is also committed to policies to address sexual harassment issues in NIH-supported extramural research, including holding grantee institutions to the terms of the Grants Policy Statement that outlines possible actions that NIH can take if the institutions fail to comply. In FY 2019, policies related to clinical trials stewardship are being strengthened to ensure that results are reported in a timely manner on public websites such as ClinicalTrials.gov to improve accountability and transparency. Additionally, OER will continue to enhance electronic systems in an effort to improve oversight and stewardship of NIH grant awards while also reducing administrative burden. OER will also continue implementing provisions of the 21st Century Cures Act, including through the Inclusion Across the Lifespan policy, effective January 2019, which requires that individuals of all ages be included in clinical research studies unless there are scientific or ethical reasons to exclude them. In response to another provision in the 21st Century Cures legislation, OER released a Request for Information soliciting feedback on how to reduce administrative burden on investigators that use laboratory animals for research, while also preserving safeguards to protect laboratory animal welfare and maintain scientific integrity.

In FY 2018, the Office of Intramural Research (OIR) worked in concert with the NIH Clinical Center to assure that the highest standards of clinical care and safety were implemented in response to the Red Team Report of 2016. OIR also collaborated with SWD to begin the Distinguished Scholars Program (DSP), aimed to create a more inclusive community among the NIH IRP. Since the inception of Lasker Clinical Research Scholars, supporting outstanding clinical researchers early in their careers to help them transition to independence, the NIH IRP has recruited 15 Lasker Scholars. These dedicated clinician-investigators are conducting research on important health problems including cancer, post-traumatic brain disease, psychiatric disorders, obesity, alcohol and drug addiction, sickle cell disease and other cardiovascular disorders. Due to its success, the program has expanded, and eight new Lasker Scholars were hired from the FY 2018 applicant pool.

The OIR will also continue to manage the NIH Director's Challenge Innovation Fund. These funds are used to foster innovation, accelerate intramural science, and encourage trans-NIH collaboration. OIR's support of the NIH Director's Challenge Innovation Fund has also

bolstered initiation of innovative programs such as the Center on Compulsive Behaviors (CCB)³⁵ and the Genomic Ascertainment Cohort (TGAC).³⁶

In fiscal years 2019 and 2020, the Office of Science Policy (OSP) will work towards instituting a modernized NIH data management and sharing policy which better reflects the NIH's longstanding commitment to proper management, preservation and accessibility of scientific data to stakeholders within the research community and the public. OSP will continue its consultation with stakeholders to determine data management and sharing priorities and implement measures which update the NIH's 2003 policy. In 2019, NIH will release a draft data sharing and management policy that applies to all of its funded and supported research that results in scientific data, consistent with the authorities granted to NIH under the 21st Century Cures Act, with the intent of soliciting additional feedback and finalizing a policy by 2020.

The Office of Management (OM) will enhance workforce planning, hiring, and development to better align with NIH needs. This will be accomplished by better leveraging information technology (IT) systems and employing improved data management across the agency. OM will continue to lend its support to the "Optimize NIH" efforts by reviewing additional enterprise-wide functional areas and harmonizing the administrative functions of travel and property across the NIH. These efforts will contribute to enhanced collaboration, adoption of best practices, and economies of scale. Lastly, OM will be prepared to start construction (when funds become available) of a new addition to the Clinical Research Center for three Clinical Center departments currently housed in substandard facilities: Surgery, Radiology, and Laboratory Medicine.

To further agency and departmental objectives, in FY 2018, the Office of the Chief Information Officer (OCIO) successfully closed 14 data centers, deployed endpoint threat detection to provide real-time alerting and containment of malicious activity, completed deployment of Phase 1 Continuous Diagnostics and Mitigation (CDM) capabilities and increased the Data Center Optimization Initiative (DCOI) score from an F to a C as reflected in the HHS FITARA scorecard. In FY 2019 and beyond, the OCIO will expand NIH's shared services offerings to include the launch of the NIH Enterprise Mobile Devices and Services Program as well as the NIH Enterprise Laptop/Desktop Contract and Value-Added Services Program. In the area of Information Security, OCIO will complete Phase 1 CDM capabilities for hardware and software asset management and also the implementation of Phase 2 CDM capabilities for management and control of account privileges and authentication.

In FY 2018, the Office of Federal Advisory Committee Policy (OFACP) participated in the creation of a more efficient on-boarding process for appointment processes affecting NIH's Special Government Employees (SGEs) serving on National Advisory Councils, Boards of Scientific Counselors, and Program Advisory Committees that support the NIH mission. In FY 2019 and beyond, the revised appointment process components developed in collaboration with subject matter experts and systems programmers across the OD Offices and ICs will enter pre-

³⁵ <https://neuroscience.nih.gov/ccb/CCBHome.aspx>

³⁶ <https://www.nih.gov/news-events/news-releases/nih-pilot-project-will-match-researchers-genes-gene-variants-interest>

testing and/or testing phases to eventually create an entirely online appointment process and allow for the secure flow of information between NIH offices.

In FY 2019, OFACP will continue to lead the NIH Optimize Committee Management effort to modernize the Federal advisory committee arena and help with the recruitment and retention of the next generation of Committee Management professionals. This effort will also improve and streamline processes with the goal of having broad impact at NIH and HHS but possibly also across other agencies and departments who manage Federal advisory committees.

The NIH Ethics Office (NEO) strives to utilize the Optimize NIH focus areas of improved efficiency and effectiveness in tandem with the guiding principles of engagement, empowerment, service, performance, stewardship and sustainability to transform certain ethics-related functions and, also, leverage NIH's comprehensive and secure ethics data platforms to continue to analyze and develop enhanced, streamlined and more efficient business practices. In support of this effort, the NEO oversaw process mapping, collaborated with the Office of Quality Management to supply data for numerous simulations and also surveyed the ethics community to determine areas for improved efficiency. The Confidential Financial Disclosure form, Office of Government Ethics (OGE) 450 has been updated to allow Special Government Employees (SGE) who serve on advisory councils to use the NIH Enterprise Ethics System (NEES) to electronically file their reports. NEO will soon complete the NEES SGE OGE 450 pilot and, based on its findings, will develop the next phase of deployment to include a communication plan and targeted training across committee management and ethics offices. During this phase, NEO will also seek HHS Designated Agency Ethics Official approval to implement the release of the system to all advisory committees. In FY 2020, the NIH Ethics Office will continue its collaborations with the NIH Center for Information Technology to integrate two ethics data systems; the Ethics Management Information System (EMIS) and NEES designed to electronically transmit data and, thus, provide more complete ethics records and efficient data management.

Budget Policy: The FY 2020 President's Budget request for OD Operations is \$241.5 million, an increase of \$15.7 million or 7.0 percent compared with the FY 2019 Enacted level. Funding will be used to continue efforts to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural research, research information, IT, finance and administration.

OD Operations will also continue to support the NIH Director's Challenge Fund. The Office of Intramural Research will use these funds to foster innovation, accelerate intramural science, and encourage trans-NIH collaboration. Initial funding support to the ICs is limited to two years for a pilot project, renewable for up to two more years with additional required support from the host IC depending on progress and competing new applications.

All of Us Research Program

The *All of Us* Research Program³⁷ a key component of the Precision Medicine Initiative (PMI) and the 21st Century Cures Act (P.L. 114-255), is enrolling one million or more U.S. volunteers in an ambitious effort to accelerate health research and medical breakthroughs. By analyzing

³⁷ <https://allofus.nih.gov/>

individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine, an emerging approach for disease prevention and treatment. *All of Us* officially launched on May 6, 2018, after extensive design and testing of the many systems involved. By late January 2019, more than 175,000 people have begun the enrollment process, and more than 100,000 have completed all the steps in the protocol. Of those in the latter group, greater than 75 percent are from communities that have been historically underrepresented in biomedical research, and nearly 50 percent self-identify as belonging to one or more racial/ethnic minority groups.

These data reflect the program's efforts to engage individuals from all walks of life, including those who may not have been asked to participate in research previously. To date, the program has already created the most diverse biomedical research cohort as evaluated by measures of demographics, geography, health status, and data types. This diversity has the power to revolutionize standards for inclusivity in research and for generalizability of biomedical research findings across many communities, with the ultimate goal of spurring discoveries that bring the promise of precision medicine to all of us. *All of Us* participants are partnering with the program by serving on boards, committees, and task forces at the local and national levels. Participants will identify their own preferences on how they would like information returned to them, a transformative approach to participant participation in research. *All of Us* is committed to protecting the data participants contribute while leveraging digital health technologies. The program looks to identify ways to empower individuals with respect to their electronic health records and to responsibly return genetic information. The program relies on continuous testing and will implement features only when ready and right. The FY 2020 budget reflects continued enrollment and retention of participants from across the country to achieve the one-million participant cohort by 2024; continued genotyping and whole genome sequencing on a subset of participants; and support of the *All of Us* Research Hub that will democratize science by allowing researchers, including citizen scientists, to access program data securely.

Budget Policy: The FY 2020 President's Budget request for the *All of Us* Research Program is \$312.6 million, a decrease of \$63.4 million or 16.9 percent compared with the FY 2019 Enacted level. This funding will be used to continue enrollment and retention activities to achieve the one-million participant cohort by the end of 2024, with a focus on engagement strategies that emphasize diversity. FY 2020 funds will be used to collect individual data and biospecimens from participants, and will ensure that the data is shared back with participants according to their preferences. The funding will support the curation, storage, and access of data to ensure that all types of researchers will be able to use the data through a secure enclave. The program will also continue whole genome sequencing and the return of genetic information to a subset of participants. The program will continue to assess whether improvements can be made or additional scientific and/or technological advances can be leveraged to achieve efficiencies and increase value to participants and researchers.

Regenerative Medicine (RM)

Regenerative medicine holds the promise to repair or replace cells and tissues damaged by injury, disease, or aging. RM strategies focus on delivery of therapeutic cells that restore normal structure and function as well as on leveraging and enhancing the body's own innate healing capacity. These strategies include a wide range of technologies such as engineered biomaterials

and tissues as well as gene editing or replacement. Preclinical studies have demonstrated the possibility of these approaches to treat both chronic disease as well as acute injury in a wide range of contexts, including vision loss; hearing loss; development disorders/conditions; heart, lung, and blood disorders; and acute injury to spinal cord, kidney, muscle, and connective tissues.

Budget Policy: The FY 2020 President’s Budget request for Regenerative Medicine is \$8.0 million, a decrease of \$2.0 million or 20.0 percent compared with the FY 2019 Enacted level. These provisions are intended to support “...clinical research to further the field of regenerative medicine using adult stem cells, including autologous cells.” The Act stipulates that NIH, in coordination with FDA, award grants and contracts “...contingent upon the recipient making available non-Federal contributions...in an amount not less than \$1 for each \$1 of Federal funds provided in the award.” The RM Innovation Project offers an opportunity to galvanize the field and stimulate a comprehensive and coordinated effort to foster major scientific advances and ensure that regenerative medicine clinical studies are standardized, reproducible, and generalizable.

To support the RM Innovation Project, NIH is establishing the **Regenerative Medicine Innovation Catalyst** that will provide grantees with key clinical services, including good manufacturing practice assistance, regulatory support, and in-depth stem cell characterization. The Catalyst also will leverage existing Federal investments to support data sharing and analyses that will deepen our scientific and clinical understanding in this field. Costs for administering the Catalyst will be supported by participating NIH Institutes, with 21st Century Cures funds preserved for funding RM science.

Next Generation Researchers Initiative

The Next Generation Researchers Initiative (NGRI) began in FY 2017 to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers. Its goal is to increase funding available for the most promising early-stage investigators, and to provide support for those at risk of losing all NIH funding.

Budget Policy: The FY 2020 President’s Budget request for the Next Generation Researchers Initiative is \$100.0 million, all of which is an increase from the FY 2019 Enacted level. In FY 2020, the Office of the Director will manage a dedicated pool of \$100.0 million that Institutes and Centers will be able to draw on to supplement the NGRI efforts undertaken with their own appropriations. NGRI is one of NIH’s highest priorities, and was authorized by Congress in Section 2021 of the 21st Century Cures Act (adding Section 404M to the Public Health Service Act).

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Object Class
(Dollars in Thousands)

	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total compensable workyears:			
Full-time equivalent	754	754	0
Full-time equivalent of overtime and holiday hours	4	4	0
Average ES salary	\$187	\$187	\$0
Average GM/GS grade	13.0	13.0	0.0
Average GM/GS salary	\$118	\$118	\$0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$137	\$141	\$4
Average salary of ungraded positions	\$159	\$159	\$0
OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
11.1 Full-Time Permanent	75,652	76,966	1,315
11.3 Other Than Full-Time Permanent	13,220	13,193	-27
11.5 Other Personnel Compensation	2,176	2,179	3
11.7 Military Personnel	900	931	30
11.8 Special Personnel Services Payments	1,420	1,426	5
11.9 Subtotal Personnel Compensation	\$93,368	\$94,695	\$1,327
12.1 Civilian Personnel Benefits	32,009	33,048	1,040
12.2 Military Personnel Benefits	489	506	16
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$125,866	\$128,249	\$2,383
21.0 Travel & Transportation of Persons	1,255	1,252	-3
22.0 Transportation of Things	110	110	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	6	6	0
23.3 Communications, Utilities & Misc. Charges	1,152	1,150	-3
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	44,816	38,715	-6,101
25.2 Other Services	89,543	71,633	-17,910
25.3 Purchase of goods and services from government accounts	145,199	169,168	23,969
25.4 Operation & Maintenance of Facilities	2,877	2,877	0
25.5 R&D Contracts	42,870	41,933	-937
25.6 Medical Care	2	2	0
25.7 Operation & Maintenance of Equipment	971	971	0
25.8 Subsistence & Support of Persons	23	23	0
25.0 Subtotal Other Contractual Services	\$328,823	\$327,837	-\$985
26.0 Supplies & Materials	1,175	1,168	-7
31.0 Equipment	7,375	7,374	0
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	1,649,437	1,461,515	-187,921
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$1,986,809	\$1,797,895	-\$188,914
Total Budget Authority by Object Class	\$2,112,675	\$1,926,144	-\$186,531

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	\$75,652	\$76,966	\$1,314
Other Than Full-Time Permanent (11.3)	13,220	13,193	-27
Other Personnel Compensation (11.5)	2,176	2,179	3
Military Personnel (11.7)	900	931	31
Special Personnel Services Payments (11.8)	1,420	1,426	6
Subtotal Personnel Compensation (11.9)	\$93,368	\$94,695	\$1,327
Civilian Personnel Benefits (12.1)	\$32,009	\$33,048	\$1,039
Military Personnel Benefits (12.2)	489	506	17
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$125,866	\$128,249	\$2,383
Travel & Transportation of Persons (21.0)	\$1,255	\$1,252	-\$3
Transportation of Things (22.0)	110	110	0
Rental Payments to Others (23.2)	6	6	0
Communications, Utilities & Misc. Charges (23.3)	1,152	1,150	-2
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	44,816	38,715	-6,101
Other Services (25.2)	89,543	71,633	-17,910
Purchases from government accounts (25.3)	145,199	169,168	23,969
Operation & Maintenance of Facilities (25.4)	2,877	2,877	0
Operation & Maintenance of Equipment (25.7)	971	971	0
Subsistence & Support of Persons (25.8)	23	23	0
Subtotal Other Contractual Services	\$283,429	\$283,387	-\$42
Supplies & Materials (26.0)	\$1,175	\$1,168	-\$7
Subtotal Non-Pay Costs	\$287,127	\$287,073	-\$54
Total Administrative Costs	\$412,992	\$415,322	\$2,330

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2018 Final			FY 2019 Enacted			FY 2020 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	718	7	725	734	7	714	734	7	714
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	718	7	725	734	7	714	734	7	714
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	39	-	39	40	-	40	40	-	40
Total:	39	-	39	40	-	40	40	-	40
Total	757	7	764	774	7	781	774	7	781
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2016	12.9								
2017	12.9								
2018	13.0								
2019	13.0								
2020	13.0								

**NATIONAL INSTITUTES OF HEALTH
Office of the Director**

Detail of Positions¹

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	12	12	12
Total, ES Salary	2,248,662	2,248,662	2,248,662
GM/GS-15	121	123	123
GM/GS-14	163	166	166
GM/GS-13	234	238	238
GS-12	106	108	108
GS-11	43	43	43
GS-10	1	1	1
GS-9	18	18	18
GS-8	1	1	1
GS-7	11	11	11
GS-6	0	0	0
GS-5	1	1	1
GS-4	4	4	4
GS-3	2	2	2
GS-2	1	1	1
GS-1	2	2	2
Subtotal	708	719	719
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	3	3	3
Senior Grade	3	3	3
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	7	7	7
Ungraded	63	63	63
Total permanent positions	646	657	657
Total positions, end of year	768	779	779
Total full-time equivalent (FTE) employment, end of year	764	781	781
Average ES salary	187,388	187,388	187,388
Average GM/GS grade	13.0	13.0	13.0
Average GM/GS salary	117,514	117,514	117,514

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.