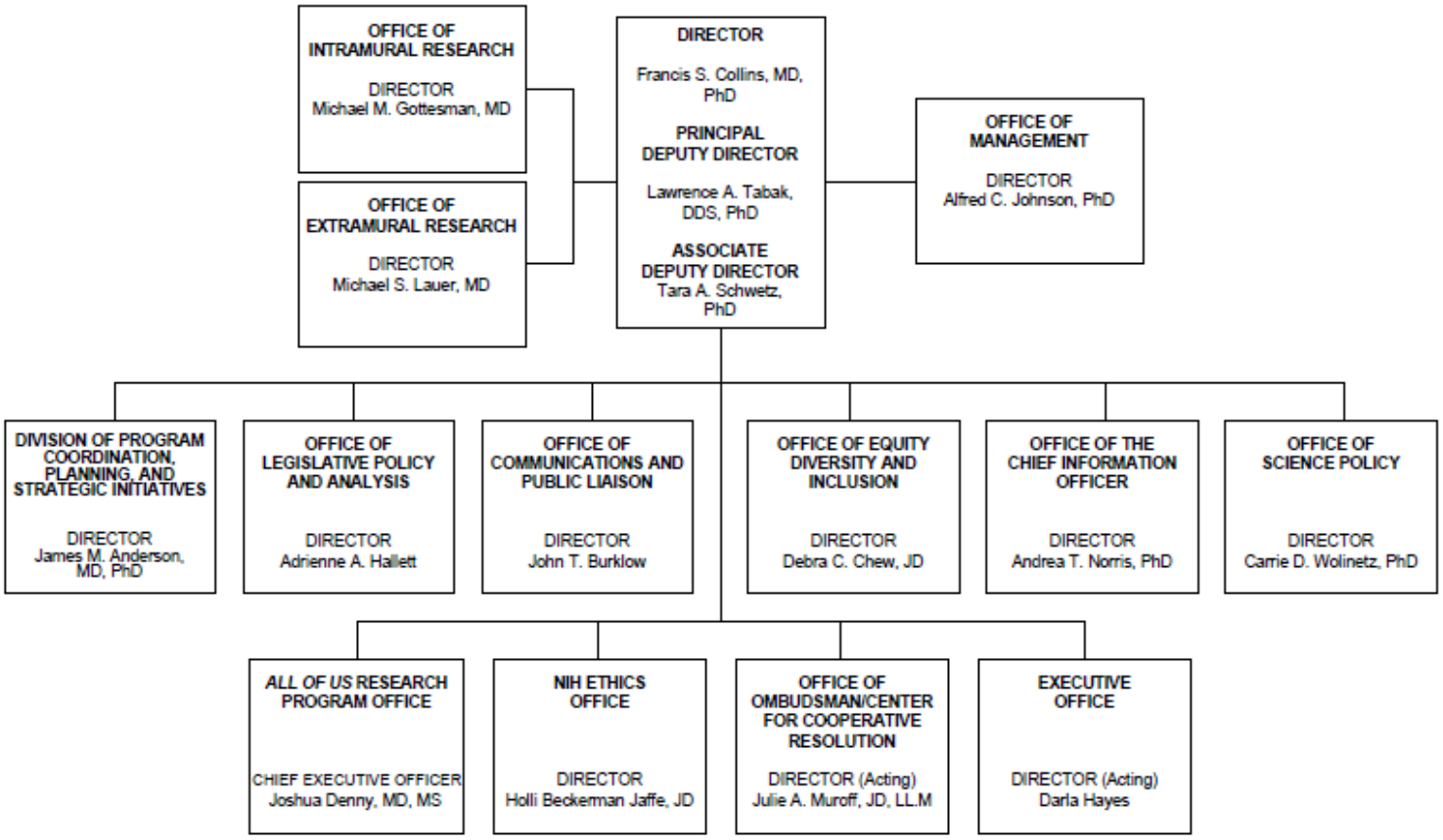
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure



OFFICE OF THE DIRECTOR

(INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, [$2,239,787,000]*$2,086,463,000*: *Provided,* That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: *Provided further,* That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: *Provided further,* That [$180,000,000]*$168,763,500* shall be for the Environmental Influences on Child Health Outcomes study: *Provided further,* That [$626,511,000]*$583,867,000* shall be available for the Common Fund established under section 402A(c)(1) of the PHS Act: *Provided further,* That of the funds provided, $10,000 shall be for official reception and representation expenses when specifically approved by the Director of the NIH: *Provided further,* That the Office of AIDS Research within the Office of the Director of the NIH may spend up to $8,000,000 to make grants for construction or renovation of facilities as provided for in section 2354(a)(5)(B) of the PHS Act[: *Provided further,* That $50,000,000 shall be used to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to biomedical and behavioral research facilities][: *Provided further,* That $5,000,000 shall be transferred to and merged with the appropriation for the "Office of Inspector General" for oversight of grant programs and operations of the NIH, including agency efforts to ensure the integrity of its grant application evaluation and selection processes, and shall be in addition to funds otherwise made available for oversight of the NIH: *Provided further,* That the funds provided in the previous proviso may be transferred from one specified activity to another with 15 days prior approval of the Committees on Appropriations of the House of Representatives and the Senate: *Provided further,* That the Inspector General shall consult with the Committees on Appropriations of the

House of Representatives and the Senate before submitting to the Committees an audit plan for fiscal years 2020 and 2021 no later than 30 days after the date of enactment of this Act]:*Provided further*, That amounts available under this heading are also available to establish, operate, and support the Research Policy Board authorized by section 2034(f) of the 21st Century Cures Act.

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

NIH INNOVATION ACCOUNT, CURES ACT

(INCLUDING TRANSFER OF FUNDS)

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, **[**$492,000,000**]***$404,000,000*, to remain available until expended: *Provided*, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: *Provided further*, That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account:

Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law. (Department of Health and Human Services Appropriations Act, 2020.)

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Amounts Available for Obligation[1,2,3]

(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation[2]	$2,117,675	$2,409,387	$2,208,063
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-6,583	0	0
Transfer to HHS Office of Inspector General	-5,000	-5,000	
Subtotal, adjusted appropriation	$2,106,092	$2,404,387	$2,208,063
OAR HIV/AIDS Transfers	-2,106	0	0
Subtotal, adjusted budget authority	$2,103,986	$2,404,387	$2,208,063
Unobligated balance, start of year	47,853	59,290	0
Unobligated balance, end of year[4]	-59,290		0
Subtotal, adjusted budget authority	$2,092,549	$2,463,677	$2,208,063
Unobligated balance lapsing	-132	0	0
Total obligations	$2,092,417	$2,463,677	$2,208,063

[1]Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2019 - $93,919 FY 2020 - $104,000 FY 2021 - $109,000

[2] Includes $196.0 million in FY 2019, $157.0 million in FY 2020, and $109.0 million in FY 2021 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 2019 and available for obligation in FY 2020.

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2019 Final[2]		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY 2020	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects		$659,307		$760,011		$736,859		-$23,152
Research Centers		245,949		247,210		234,967		-$12,242
Other Research		708,211		804,884		670,558		-$134,326
Total Research Grants		$1,613,467		$1,812,105		$1,642,384		-$169,720
Training		$20,159		$22,758		$18,832		-$3,925
R & D Contracts		53,405		50,946		49,417		-$1,529
Intramural Research		20,617		18,896		12,903		-$5,993
Res. Management & Support		396,338		499,683		484,526		-$15,157
Construction		0		0		0		$0
Total Other Than Research Grants		$490,519		$592,282		$565,678		-$26,604
Subtotal, Labor/HHS Budget Authority		$2,103,986		$2,404,387		$2,208,063		-$196,324
Total, OD		$2,103,986		$2,404,387		$2,208,063		-$196,324

[1]Includes $196.0 million in FY 2019, $157.0 million in FY 2020, and $109.0 million in FY 2021 provided in the NIH Innovation Account under the 21st Century Cures Act (after actual and anticipated transfers).

[2]Includes $52.8 million of 21st Century Cures Act funding not obligated in FY 2019, and carried over into FY 2020.

Major Changes in the Fiscal Year 2021 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 2021 budget request for OD, which is $196.3 million below the FY 2020 Enacted level for a total of $2,208.1 million.

Artificial Intelligence (AI) to Address Chronic Disease (+$50.0 million; total $50.0 million): The FY 2021 budget request will enable NIH to launch an initiative that aims to use AI to gain a deeper understanding of the underlying causes of chronic diseases and to identify successful early treatments This initiative will support the Administration's Industries of the Future initiative.

Biomedical and Behavioral Research Facilities (-$50.0 million; total $0.0 million): The FY 2021 budget request does not include continued funding to carry out section 404I of the PHS Act (42 U.S.C. 283K), relating to support for renovation or construction of extramural biomedical and behavioral research facilities.

All of Us Research Program (-$63.8 million; total $436.2 million): The FY 2021 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 $109.0 million of *All of Us* funding authorized in the 21st Century Cures Act, a $40.0 million reduction from the FY 2020 authorized and enacted level.

Regenerative Medicine (-$8.0 million; total $0.0 million): Consistent with the authorized levels for specific research initiatives in the 21st Century Cures Act, the FY 2021 President's Budget does not request dedicated Cures Act funding for regenerative medicine. NIH will use base resources to continue the Regenerative Medicine Innovation Project, which 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.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes

(Dollars in Thousands)

FY 2020 Enacted	$2,404,387
FY 2021 President's Budget	$2,208,063
Net change	-$196,324

CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2020 pay increase & benefits		$5,388		$18
b. January FY 2021 pay increase & benefits		5,388		177
c. Paid days adjustment		5,388		-20
d. Differences attributable to change in FTE		5,388		0
e. Payment for centrally furnished services		0		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		7,524		274
Subtotal		$29,074		$449
2. Research Management and Support:				
a. Annualization of January 2020 pay increase & benefits		$136,604		$838
b. January FY 2021 pay increase & benefits		136,604		2,021
c. Paid days adjustment		136,604		-489
d. Differences attributable to change in FTE		136,604		0
e. Payment for centrally furnished services		0		0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		348,022		4,794
Subtotal		$894,438		$7,164
Subtotal, Built-in				$7,613

CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	310	$539,434	25	$12,543
b. Competing	139	190,386	-23	-35,180
c. SBIR/STTR	15	7,039	-1	-514
Subtotal, RPGs	464	$736,859	1	-$23,152
2. Research Centers	77	$234,967	-36	-$12,242
3. Other Research	332	670,558	-93	-134,326
4. Research Training	487	18,832	-1	-3,925
5. Research and development contracts	5	49,417	-122	-1,529
Subtotal, Extramural	1,365	$1,710,634	-251	-$175,174
	FTEs		FTEs	
6. Intramural Research	0	$12,903	0	-$6,442
7. Research Management and Support	780	484,526	0	-22,320
8. Construction	0	0	0	0
9. Buildings and Facilities		0		0
Subtotal, Program	780	$2,208,063	-250	-$203,937
Total changes				-$196,324

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Activity
(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY2020
OD Led Science Programs	**595,250**	**771,750**	**684,941**	**-86,809**
INCLUDE Project	*33,000*	*60,000*	*56,232*	*-3,768*
All of Us Research Program	*190,000*	*351,000*	*328,959*	*-22,041*
All of Us Research Program - Cures	*186,000*	*149,000*	*109,000*	*-40,000*
Regenerative Medicine - Cures	*10,000*	*8,000*	*0*	*-8,000*
BRAIN Initiative	*10,000*	*10,000*	*9,100*	*-900*
Environmental Influences on Child Health Outcomes	*165,000*	*180,000*	*168,764*	*-11,237*
Foundation for the National Institutes of Health	*1,250*	*1,250*	*1,172*	*-78*
New Tools in Data Science and Artificial Intelligence	**30,000**	**30,000**	**78,116**	**48,116**
Office of Data Science Strategy	30,000	30,000	28,116	-1,884
Artificial Intelligence to Address Chronic Disease	0	0	50,000	50,000
Building Research Capacity and Collaborations	**1,096,248**	**1,116,859**	**1,040,985**	**-75,874**
Common Fund	619,166	639,111	596,467	-42,644
Division of Program Coordination, Planning and Strategic Initiatives	477,082	477,748	444,518	-33,230
Research Training and Career Development	**19,236**	**19,277**	**18,066**	**-1,211**
Intramural Loan Repayment and Scholarship	7,823	7,864	7,370	-494
NIH Director's Challenge Fund	1,413	1,413	1,324	-89
Director's Discretionary Fund	10,000	10,000	9,372	-628
Research for Countermeasures against Nuclear/Radiological/Chemical Threats	**97,128**	**97,128**	**90,535**	**-6,593**
OD Operations	**266,125**	**369,373**	**295,420**	**-73,953**
Reception and Representation Fund (non-add)	*(10)*	*(10)*	*(9)*	*(-1)*
Biomedical & Behaviorial Research Facilities (non-add)	*(50,000)*	*(50,000)*	*(0)*	*(-50,000)*
Total	**$2,103,986**	**$2,404,387**	**$2,208,063**	**-$196,324**

Note: Amounts in italics are non-add.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2020 Amount Authorized	FY 2020 Enacted	2021 Amount Authorized	FY 2021 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$2,404,387,000	Indefinite	$2,208,063,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$2,404,387,000		$2,208,063,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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			$1,946,773,000
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	$2,111,428,000	$2,118,660,000	$2,117,675,000
Rescission				$0
2020[1]	$1,926,144,000	$2,216,592,000	$2,513,622,000	$2,409,387,000
Rescission				$0
2021[1]	$2,208,063,000			

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

National Institutes of Health

Summary of the Office of the Director

The NIH Office of the Director (OD) serves as the central office of NIH and provides leadership in planning, managing, and coordination across the agency's Institutes and Centers (ICs). With an overarching view of the agency, the OD applies historically successful approaches, guides the agency's present direction, and develops plans to ensure a successful future.

As NIH Director, Dr. Francis Collins plays a vital role in shaping the agency's overarching agenda and outlook. Dr. Collins provides leadership and guidance to all of the 27 ICs, especially in the many scientific and operational efforts that span the agency. The Director is responsible for seeking input from and collaborating with a wide range of stakeholders, including the scientific community, the public, other Federal agencies, and Congress. With this critical perspective, the Director identifies and informs enterprise-wide priorities that advance the NIH mission.

The OD provides scientific and operational guidance to the ICs in setting trans-NIH policy and procedures, developing and maintaining shared resources, coordinating initiatives, programs, and activities, and anticipating new directions for the biomedical research enterprise. The OD continues NIH's stewardship of both public funds and the public trust by overseeing the operational processes of the NIH, such as budget and financial management, technology and property management, procurement services, ethics, and human capital management. The resources of the OD are distributed across all these areas (Figure 1).

The OD maintains and secures the digital and physical infrastructure of the NIH to build a supportive environment for scientific research, management, and agency administration.

With its central role at NIH, the OD has the unique ability to confront emerging, challenging scientific questions, to advance innovative science from bench to bedside, and to promote health nationwide.

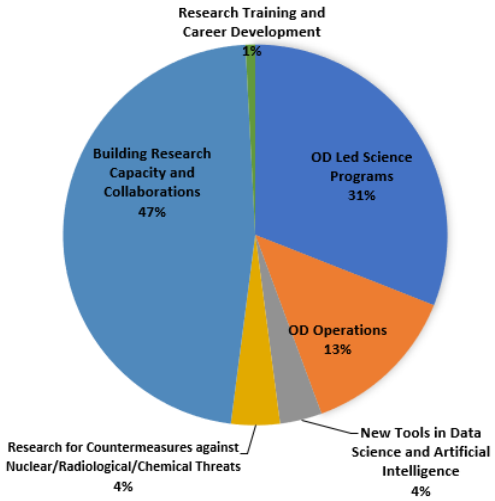


Figure 1: OD budget distribution for FY 2021

Highlights from the Office of the Director

- **Helping to End Addiction Long-term (HEAL) Initiative:** Many OD offices and ICs contribute to the trans-NIH HEAL initiative coordinated through the Immediate Office of the Director to identify scientific solutions to the opioid crisis.
- **Investigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Initiative:** Launched in FY 2018, the trans-NIH INCLUDE Initiative is addressing the unique health and quality-of-life needs of this population and their families. Engaging 13 institutes across NIH, this effort addresses the full spectrum of research from high-risk, high-reward science to increasing access to clinical trials for these individuals.
- **Engaging Leaders from the Extramural Community:** The OD consistently works with leaders in the extramural community to address key issues faced by scientific and clinical workforce. This has led to recommendations and reports on topics key to NIH, including foreign influences on research integrity and the Next Generation Researchers Initiative.
- **Anti-Harassment Efforts at NIH:** The OD has assembled the central offices and leadership across the NIH to address serious concerns about harassment in scientific research. The recent NIH Workplace Climate and Harassment Survey, the Anti-Harassment Steering Committee, and the NIH Civil Program have led to increased visibility of harassment, centralized reporting mechanisms, and new anti-harassment policies.
- **Trans-NIH Coordination of Data Science:** The newly established Office of Data Science Strategy and two new data science fellowships will help coordinate data science activities across the NIH. An ongoing working group of the Advisory Committee to the Director (ACD) is identifying opportunities to harness the potential of artificial intelligence (AI) to support the NIH mission.

The OD provides scientific and administrative leadership to many trans-NIH activities including those listed above. By supporting initiatives and programs across the NIH, the OD fosters innovative research and scientific and health resources to protect and improve health.

NIH…
Turning Discovery into Health

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 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	$2,103,986,000	$2,404,387,000	$2,208,063,000	-$196,324,000
FTE	792	780	780	0

Office of the Director
The mission of the NIH OD, as the agency's central office, is to provide support to the NIH Institutes and Centers in pursuit of their unique goals, and to provide coordination, oversight, and leadership on policies and resources shared across the agency in pursuit of NIH's agency-wide mission.

Director's Overview
The 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. The OD coordinates NIH's extramural and intramural research activities, health information dissemination and outreach, science policy, 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, procurement services, property management, ethics, human resources, intramural and extramural support, and administration of equal employment and diversity management practices.

Policy Initiatives in the Office of the Director: Guiding the Scientific Enterprise, Ensuring Research Stewardship
As the central office at NIH, the OD sets policy across the agency. These policies seek to address major needs and challenges encountered by the biomedical research enterprise by protecting research integrity, building a globally competitive and diverse biomedical workforce, and ensuring that the public receives maximum benefit from its investment in NIH. This section includes selected examples of these activities undertaken by the OD.

Next Generation Researchers Initiative: Investing in the Future of the Biomedical Workforce
The NIH has long recognized that the most critical assets in the biomedical research enterprise are the scientists who comprise its workforce. The biomedical research enterprise relies upon a pipeline of highly trained investigators to convey new insights, develop innovative ideas, and advance the translation of scientific research into improved health for all. In September 2017, with support from the 21st Century Cures Act (P.L. 114-255), the OD launched the Next

Generation Researchers Initiative (NGRI).[1] This initiative aims to bolster opportunities for early-stage investigators (ESIs), those within ten years of completing postgraduate clinical training or their highest advanced research degree. Through this initiative, NIH Institutes and Centers prioritize funding for additional ESIs[2] and track the impact of funding decisions for early-stage investigators to ensure that this new strategy is effectively implemented. As of September 2019, NIH funded 1,292 ESIs, exceeding its goal of funding 1,100 ESIs in FY 2019. Continued NGRI initiatives include prioritizing meritorious R01-equivalent competing applications from ESIs for funding and identifying "at-risk investigators," namely investigators (new or established) who have not received funding through any major award/source of independent NIH funding in the current fiscal year or whose NIH funding will end in the current fiscal year.

NIH is also developing, at the NIH IC level, evidence-based strategies to identify and retain NIH-supported ESIs that consider emerging areas of scientific inquiry, the ICs' portfolios, and projected needs of the scientific workforce. NIH will incorporate guidance from the ACD NGRI Working Group, coordinated by the OD, and the National Academies of Sciences, Engineering, and Medicine (NASEM) report "The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through"[3] in the future design, testing, implementation, and evaluation of policies and programs to enhance the success of the next generation of talented biomedical researchers. Lastly, NIH as a whole will determine the impact of NGRI policies on women and individuals from nationally underrepresented backgrounds in the NIH portfolio. Several sources of data show modest improvements in the representation of women in the biomedical research pipeline, but underrepresentation of women at faculty career levels remains a persistent issue. For example, an investigation of the gender makeup of the NIH-funded research workforce found that female scientists are more likely than their male counterparts to be in the trainee/fellow postdoctoral and career development (K)-awardee pools and are less likely to be in the RPG and R01-equivalent awardee groups.[4] Although ESIs and new investigators (NIs) include a higher proportion of underrepresented minorities, Hispanics, and women than experienced investigators, the share of funding awarded to ESIs and NIs declined between 2009-2016, suggesting these populations may not be well supported.[5] NIH has developed and implemented a range of approaches to address these challenges, outlined in the section below. NIH remains strongly committed to the goals of NGRI to fund more early-career investigators, protect and retain meritorious at-risk scientists, and enhance the diversity of the biomedical research workforce. NIH will continue to identify and pursue activities to improve management of the biomedical research enterprise.

Work-Life Integration Policies

The Office of Research on Women's Health (ORWH) within the OD, the NIH Working Group on Women in Biomedical Careers (WgWBC), the OD Office of Extramural Research, and NIH Institute, Center, and Office (ICO) leadership and staff have developed and implemented a constellation of initiatives and programs to enhance work-life integration for the scientific workforce on behalf of the agency. Approaches in the NIH extramural community include

[1] https://grants.nih.gov/ngri.htm
[2] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html
[3] https://www.nap.edu/catalog/25008/the-next-generation-of-biomedical-and-behavioral-sciences-researchers-breaking
[4] Acad Med. 2016 August; 91(8): 1164–1172. doi:10.1097/ACM.0000000000001209
[5] FASEB J. 2018; 32:6410–6422. doi: 10.1096/fj.201800639

targeted support for investigators with high potential to re-enter an active research career after an interruption for family responsibilities or other qualifying circumstances. The NIH has also strengthened the parental leave policy on National Research Service Awards (NRSAs). The revised policy allows for the recipients, who are predoctoral and postdoctoral fellows, to continue to receive their stipends from their awards during their parental leave. In addition, another key action has been the automatic extension of Early-Stage Investigator status for childbirth, which extends the period during which R01 applications from these investigators are given appropriate consideration for the investigator's less extensive research experience compared to senior investigators.

Historical data detailed in the National Academies report, "Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Sciences and Engineering," provides an overview of the climate, and the report also includes recommendations for addressing challenges for women in science, technology, engineering, and mathematics (STEM) based on the report's findings.[6] This landmark report was the impetus behind the creation of the NIH WgWBC.

As mentioned above, the NIH WgWBC considers barriers for women in science and plans to continue chartering innovative strategies to promote recruitment, entry, retention, and sustained advancement of women in biomedical research careers. Current efforts underway include the development of a portfolio of initiatives to address the underrepresentation of women in biomedical careers. Together, these programs complement ongoing or other nascent programs at the NIH to enhance diversity and comprise a comprehensive approach that targets both individual investigators and institutional change. These initiatives are expected to be released in FYs 2020 and 2021. Moving forward, the WgWBC will periodically review policies and progress related to NIH childcare, the NIH intramural workforce concerning gender, and work-life integration issues. The WgWBC convenes thought leaders to discuss and think through these issues and propose plausible solutions, thus serving as a strong framework by which change can occur.

NIH has also implemented a multitude of policies and programs to address these challenges for those working at NIH. To ensure effective communication about the programs available, the Office of Research Services supports a publicly accessible website that describes the on-site childcare facilities and other resources available to NIH employees, intramural trainees, and contractors. The NIH Office of Human Resources has implemented a range of support tools, including a leave bank program for NIH employees to have access to paid medical leave if they or a family member become sick or for the birth of a child. Specific policies and programs for the NIH Intramural Community developed by the Office of Intramural Research within the OD include paid parental leave extension for NIH intramural trainees from six to eight weeks. In addition, the OD also provides for tenure-clock modification for NIH intramural scientists that automatically incorporates an additional year to accommodate family leave, and the "Keep the Thread" program, an accommodation program for intramural postdoctoral fellows that offers flexible schedule options and part-time work options. Through all of these approaches, both within and outside the agency, NIH is investing ways to continue to develop work-life integration policies that will ensure a competitive and diverse workforce for the biomedical research enterprise now and in the future.

[6] The National Academies Press; 2007. http://www.nap.edu/openbook.php?record_id=11741

NIH Efforts to End Harassment

NIH does not tolerate harassment of any kind, including sexual harassment, whether it is within the agency, at research organizations that receive NIH funding, or anywhere else NIH-funded activities are conducted. The OD is bolstering policies and practices to foster a culture of respect wherever NIH research activities are conducted, and ensure sexual harassment is not tolerated or ignored. Over the last year, NIH leadership has been heavily focused on this issue, with guidance from the NIH Anti-Harassment Steering Committee, coordinated by the OD, and recommendations currently being developed by the ACD Working Group on Changing the Culture to End Sexual Harassment. These actions aim to create a paradigm shift in the scientific culture wherever NIH research activities take place to eliminate sexual harassment and enhance contributions by women and others to scientific advancements.

Through a multi-faceted campaign, NIH has taken actions to address harassment for all staff, including the launch of a new, central website on all NIH anti-sexual harassment activities that comprehensively outlines NIH policies, practices, and initiatives. NIH has also issued two new agency-wide policies that apply to the entire NIH community, including contractors and trainees/fellows, and focus on preventing harassment and inappropriate conduct and addressing personal relationships in the workplace. NIH has also developed a new training module to inform the NIH community of the anti-harassment policy and expanded the existing NIH Civil Program to establish a centralized, independent office to consistently address allegations of harassment, manage related administrative inquiries, and track and report data regularly to the Anti-Harassment Steering Committee and annually to the NIH community. In early 2019, a survey was disseminated to all NIH staff, including contractors and fellows, to assess NIH workplace climate and harassment, with the goal of implementing programs to address sexual harassment in the workplace and set a baseline to evaluate their effectiveness to ensure effective policies and successful implementation.

NIH efforts on harassment at recipient institutions include the launch of a new, central website on its anti-harassment activities that comprehensively outlines NIH policies, practices, and initiatives as a funding agency. NIH has reminded applicants of the requirements for applicant and recipient research institutions to ensure safe and healthful working conditions for their employees and foster work environments conducive to high-quality research. NIH continues to require that institutions notify the NIH if the institution takes an administrative or disciplinary action against its employee(s) that affects the ability of the employee(s) to continue as principal investigator (PI) or other senior key personnel on an NIH award. NIH can take a variety of actions including suspension or termination of the grant if the proposed alternative arrangements are not acceptable. Several different means of communication have been used to publicize these efforts and ensure that NIH expectations are understood and met.

Foreign Influence on Research Integrity

NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. The U.S. biomedical enterprise sets the standard for discovery and innovation excellence for the world. This is made possible because the overwhelming majority of researchers participating on NIH grants, whether U.S. or foreign-born, are honest contributors to the advancement of knowledge that benefits us all. NIH recognizes the importance of scientific

collaborations, including those involving international institutions, to advance its mission. Yet, there are threats to the integrity of the biomedical research enterprise, including the failure by some researchers at NIH-funded institutions to disclose contributions of resources from other organizations, diversion of intellectual property produced by NIH-supported biomedical research to other entities, and sharing of confidential information by peer reviewers with others or otherwise attempting to influence funding decisions.

The OD has taken a multi-pronged approach to address threats to the integrity of biomedical research, including communicating these concerns to over 10,000 recipient institutions within the research community. Since fall 2018, the NIH has also contacted over 70 institutions regarding concerns it has about scientists who may have failed to disclose foreign affiliations, financial conflicts of interest, and/or research support from foreign granting agencies. This approach has proven most effective in both communicating concerns to the extramural research community and gaining compliance with Federal and NIH grants policies. The agency has also extensively communicated the responsibilities of all participants in the NIH peer review process and the consequences of a breach of review integrity. NIH continues to address this issue by implementing recommended approaches made by the NIH ACD Working Group on Foreign Influences on Research Integrity, coordinated by the OD, continuing outreach and communication internally within NIH and externally with the grantee community, and continuing active partnerships with other Federal departments and agencies, scientific professional societies, and grantee institutions to learn from each other and establish best practices to protect the integrity of NIH-supported science.

NIH Data Sharing and Management Policy Update

NIH has a longstanding commitment to making the results and accomplishments of the research that it funds and conducts available to the public.[7] Specifically, sharing of scientific data and results enables researchers to more vigorously test the validity of research findings, strengthen analyses by combining data sets, access hard-to-generate data, and explore new frontiers. Data sharing also informs future research pathways, increases the return on investment of scientific research funding, and accelerates the translation of research results into knowledge, products, and procedures to improve health and prevent disease. Effective data sharing practices rely upon appropriate identification, adoption, and crediting of good data management and sharing practices; thus, NIH encourages data sharing consistent with the FAIR (Findable, Accessible, Interoperable, and Re-usable) data principles.[8] NIH, through the OD, is invested in ensuring that scientific data are managed, preserved, and made accessible in a timely manner for appropriate use by the research community and the public, as outlined in the NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research.[9] In accordance with this plan, NIH is implementing measures to update the agency's 2003 Data

[7] NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources http://grants.nih.gov/grants/sharing.htm; the NIH Intramural Research Program Human Data Sharing (HDS) Policy https://oma1.od.nih.gov/manualchapters/intramural/3016/index.html; the NIH Trans-NIH BioMedical Informatics Coordinating Committee website http://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html

[8] Wilkinson, M., Dumontier, M. et al, The FAIR Guiding Principles for scientific data management and stewardship (2016). https://www.nature.com/articles/sdata201618

[9] National Institutes of Health Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research (February 2015). https://grants.nih.gov/grants/nih-public-access-plan.pdf

Sharing Policy,[10] consistent with Administration priorities[11] and other authorities granted to NIH, such as under the 21st Century Cures Act.

Taking these factors into consideration, the proposed key provisions for an updated NIH data management and sharing policy would build upon NIH's existing policy framework, including informed consent, Human Subjects Protections, Certificates of Confidentiality, etc., and include consideration of exceptions to data sharing where appropriate. Elements for such Data Management and Sharing Plans have also been outlined, and feedback was requested from the community through a recent Request for Information.[12] NIH is committed to fostering a culture of responsible data stewardship and developing a flexible policy for managing and sharing the diverse scientific data generated through NIH funded and conducted research. In November 2019, NIH released a draft NIH Policy for Data Management and Sharing and supplemental draft guidance for public comment through notices in the NIH Guide for Grants and Contracts and the Federal Register. The draft policy proposal promotes effective and efficient data management and sharing while respecting the autonomy and privacy of research participants. Feedback obtained on the draft policy will help inform a final NIH Policy for Data Management and Sharing, which upon the effective date would replace the 2003 NIH Data Sharing Policy.

As a specific example of data-sharing in action, NIH has facilitated a data-sharing and use agreement between the Navajo Nation and NIH grantees of the OD's Environmental influences on Child Health Outcomes (ECHO) Program, which was ratified on March 8, 2019. The agreement enables the Navajo Birth Cohort Study (NBCS) to continue as part of the ECHO program and NBCS individual participant data to be shared with the ECHO Data Analysis Center for approved ECHO multi-cohort analyses. The agreement was created to respect Navajo Nation cultural beliefs, Tribal sovereignty, and community values. It is the first Tribal data-sharing agreement for a nationwide research consortium creating a large-scale database and lays the groundwork for discussion with other Tribal Nations considering participation in biomedical research programs.

Stewardship of NIH-Supported Clinical Trials

Clinical trials are the most publicly visible aspect of the clinical research enterprise, translating laboratory findings into treatments or preventive interventions. NIH is committed to assuring the public of the highest possible levels of stewardship and transparency of its clinical trial portfolio. The OD has launched a multifaceted effort to improve the quality, transparency, and efficiency of all NIH-supported clinical trials by updating the process by which NIH (1) receives information from investigators on proposed clinical trials, (2) reviews and selects clinical trials for support, (3) oversees the progress of research, and (4) promotes transparency in providing public access to information about clinical trials and sharing their summary results. NIH is also improving usability of ClinicalTrials.gov through system enhancements and additional guidance, and has launched the Human Subjects System (HSS), a shared system for PIs, institutional officials, and NIH staff to submit updates related to research with human subjects, thereby

[10] NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources. https://grants.nih.gov/grants/policy/data_sharing/

[11] Office of Science and Technology Policy, National Science and Technology Council. https://www.whitehouse.gov/ostp/nstc/

[12] Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-013.html

reducing data entry burden, improving monitoring, and streamlining compliance. In addition, a Clinical Trials Dashboard for NIH leadership has been developed and deployed, which shows graphical displays and analyses of aggregate data to be used for understanding the clinical trial portfolio at the trans-NIH and IC levels. The NIH has also taken specific steps to address the unique needs of the basic science community in the development and implementation of these enhancements. Specifically, NIH has developed new funding opportunity announcements for basic experimental studies involving humans allowing additional flexibility for registration and reporting. In order to ensure its continued responsiveness to the needs of the basic science community, NIH is also gathering feedback about policy implementation for these types of studies.

Evidence-Based Decision-Making at the NIH

NIH is committed to using its resources effectively to address the many health challenges facing the nation. With a unique perspective on the whole of NIH, several offices within the OD are conducting complementary activities to build and strengthen the use of evidence to inform mission-critical decisions.

The goal of the Office of Evaluation, Performance, and Reporting (OEPR) is to improve organizational stewardship by ensuring that NIH and its stakeholders have the best evidence available on NIH activities and outcomes to inform decision-making. To advance this goal, OEPR has been guiding a trans-NIH effort to develop an evaluation plan to improve the organization's capacity to generate and integrate high-quality evidence from evaluations, monitoring activities, and other studies and analyses into its decision-making processes. This effort has been motivated and reinforced by ongoing calls from Administration officials and Congressional leaders, including the enactment of the Foundations for Evidence-Based Policymaking Act of 2018 (P.L. 115-435) to improve Federal agencies' ability to build and use robust evidence in support of agencies' mission and functions. Concurrently, OEPR has been collaborating with stakeholders from across the NIH to develop tools and resources that aim to facilitate routine monitoring and evaluation and continuous learning and improvement.

The Office of Portfolio Analysis (OPA) has been expanding NIH's analytic capabilities by developing and disseminating new methods, computational tools, and best practices that enable the agency to examine the outputs, influence, and impact of its research investments and to consider how potential investments might address research needs and emerging opportunities that evolve over time in biomedical research. This groundbreaking work of OPA analysts, data scientists, and software engineers within the OD has generated substantial interest both within and outside of NIH. As a result of this increased recognition, OPA now provides methodological and analytical support for data-driven decision-making by NIH senior leadership, NIH ICOs, and extramural stakeholders (e.g., administrators in other US government agencies). OPA has also established collaborations with administrators, analysts, and researchers across the US government and abroad, as well as those in academia and the private sector. Tools developed by OPA enable sophisticated analysis and evaluation of NIH programs and research portfolios to ensure that NIH funding decisions and research directions are data-driven to the greatest extent possible, ensuring stewardship of our resources and program effectiveness. OPA will continue to develop and implement AI approaches to understand the biomedical research landscape.

The Office of Extramural Research (OER) also develops tools and analytical methods to support NIH decision-making. For instance, the Research, Condition and Disease Categorization (RCDC) process, which has analyzed the NIH scientific portfolio and reported public information annually for over a decade, also supported the development of the HEAL initiative to address the opioid crisis. OER is also working across the U.S. Department of Health and Human Services (HHS) to integrate data into NIH grant systems, allowing their activities to be indexed via RCDC methods, find duplicative research ideas, and assist in grant application review processes. NIH grants data have also informed the development and implementation of policy initiatives, such as the Next Generation Research Initiative described above.

Implementing the 21st Century Cures Act

NIH continues its implementation of the 21st Century Cures Act (P.L. 114-255) as coordinated by the OD. Several programs supported by this legislation continue to be flagship initiatives at the NIH, including the Precision Medicine Initiative, BRAIN Initiative, Beau Biden Cancer Moonshot, and Regenerative Medicine, supported through the NIH Innovation Account also established through this legislation. These programs continue in line with the work plan, with input from the NIH ACD, with further details forthcoming in the FY 2019 annual report in early CY 2020. Notably, this legislation also codifies the NIH-Wide Strategic Plan. NIH is currently addressing goals within the existing plan for FYs 2016-2021 and planning for the next strategic plan is already underway, being led by OEPR.

Additionally, the Act includes a FOIA 3b exemption statute that allows for, at the discretion of the Secretary of HHS, the withholding of information derived from the practice of research that is, or has the potential to be, individually identifiable. If NIH receives a FOIA request for such information, NIH has the license to deny the request under this new authority. All NIH Institutes and Centers are working with ORWH and NIMHD to ensure that their research portfolios and strategic plans fully leverage all available means to reduce health disparities and ensure the inclusion of women and under-represented groups in clinical research. To align with the expanded statutory protections and responsibilities detailed in the Act, the NIH has updated its policy for the issuance of Certificates of Confidentiality, which apply to biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected. These enhancements, as authorized by Congress, will help protect the privacy of individuals who are subjects of such research by limiting the disclosure and unauthorized use of sensitive, identifiable information collected during the course of research. Relevant studies funded, either wholly or in part, by the Federal Government are now automatically issued Certificates by the NIH; such studies that are not federally funded may apply to NIH for a Certificate.

Overall Budget Policy: The FY 2021 President's Budget request for the OD is $2,208.1 million, a decrease of $196.3 million or 8.4 percent compared with the FY 2020 Enacted level. Reductions are distributed across all programmatic and research areas. This level also includes an increase of $50.0 million to support Artificial Intelligence to Address Chronic Disease, which will support the Administration's Industries of the Future initiative. This increase will fund the implementation of an initiative that will employ Artificial Intelligence, Machine Learning (ML), Deep Learning (DL), and related approaches to enhance the collection, integration, analyses, and interpretation of data related to the onset and progression of chronic diseases.

The FY 2021 level includes $109.0 million in the NIH Innovation Account under the 21st Century Cures Act, reflecting the authorized Cures Act level of $404.0 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.

Scientific Programs in the Office of the Director: Coordination, Strategic Direction and Investments

The OD plays a multi-faceted role in coordinating scientific research activities across the NIH. In order to provide strategic direction for key scientific programs, the OD contributes to initiatives housed both within the OD and across the ICs.

Scientific Programs from the Office of the Director

The Helping to End Addiction Long-term (HEAL) Initiative, launched in April 2018, is a trans-NIH effort led by the OD with the aim of speeding scientific solutions to the national opioid crisis. To date, HEAL brings together offices within the OD, across the NIH, and private organizations to support research on treatments for opioid abuse, addiction, and pain management. In FY 2019, HEAL funded 24 scientific research projects across 13 ICs and the OD. These projects aim to find new therapeutic targets for both pain and opioid addiction, develop new medical devices for pain treatment, assess the effect of opioids on unique populations, such as women and children, and improve opioid addiction treatment in criminal justice settings. The drug naloxone, a nasal spray used by first responders to prevent opioid overdose deaths, has been a central element of the HEAL Initiative. A new effort, the HEALing Communities Study aims to reduce opioid-related deaths by 40 percent in select communities by studying the impact of giving friends and family access to naloxone. Workshops with HEAL Initiative participants have facilitated trans-NIH success. In the last year, the Critical Evaluation of Animal Pain Models for Therapeutics Development Workshop brought together experts in both animal model research and translational research to discuss best practices in developing new pain treatments.

In the last 25 years, the expected lifespan for people with Down syndrome has doubled, leading to a pressing need to understand the medical needs and challenges faced by individuals with Down syndrome as they age. The Investigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Initiative, a trans-NIH effort, engaged diverse expertise across the agency from 17 participating NIH Institutes and Centers to address the complex nature of Down syndrome and the need for a comprehensive approach. This effort has attracted new investigators into the field and has continued to grow and support Down syndrome research with new opportunities across the spectrum of basic and clinical research, to build a cohort of individuals with Down syndrome across the lifespan and develop outcome measures for impactful clinical trials tailored to these individuals. INCLUDE has also hosted workshops to bring together patients and patient advocates, investigators, clinicians, and NIH staff to better engage the community.

The *All of Us* Research Program, a signature program at NIH, brings together expert collaborators to create a national cohort of one million or more participants to enable research across all aspects of health and disease. The program is currently collecting data on *All of Us*

participants, incorporating historical health data with capture of electronic health records, and developing new methods for biospecimen capture. In addition to leveraging new tools and collaborations, *All of Us* continues to make progress towards its goal of 1 million participants by approximately 2024 and currently enrolls participants 18 years of age or older from all 50 states, D.C., and the 5 populated U.S. territories. The program has a national network of more than 340 partner sites that collect physical measurements and biospecimens. This ultimately will enable thousands of scientific studies to utilize the largest, most diverse dataset of its kind, produce new knowledge, and develop more effective ways to promote health and treat illness.

Regenerative medicine (RM) is perhaps one of the most promising fields of biomedical research because it aims to repair or replace cells and tissues damaged by injury, disease, or aging. It includes a wide range of technologies such as engineered biomaterials and tissues as well as gene editing, replacement, and addition. To encourage the development of safe and effective RM treatments, the 21st Century Cures Act established the RM Innovation Project (RMIP), directing NIH to work in coordination with the Food and Drug Administration (FDA) to support clinical research to advance the field of RM using adult stem cells. Following broad consultation with key RM stakeholders, RMIP has funded both late stage IND/IDE-enabling preclinical studies and early phase clinical trials toward the development and testing of RM cell products and therapies. Furthermore, NIH, working with the FDA and the National Institute of Standards and Technology (NIST), has initiated the RM Innovation Catalyst to support clinical research efforts that exemplify rigorous science, optimal regulatory compliance, and enhanced data sharing to ultimately advance the field of RM.

Circuits of interconnected cells in the brain enable us to think, feel, and act. Dysfunction of these circuits underlies neurological, psychiatric, and substance misuse disorders that impose an enormous burden on society. Because of the extraordinary complexity of the brain, research tools have not been powerful enough to understand how brain circuits work and what goes wrong in these diseases. The BRAIN Initiative is developing and applying new technologies to understand brain circuits, taking advantage of a convergence of opportunities arising from decades of investment across many fields of science and engineering. The Initiative is making dramatic progress on tools to identify all of the brain cell types, monitor activity thousands of cells in a circuit in real time, and precisely manipulate cells' activity. From its inception, the BRAIN Initiative has focused on the normal brain, largely in laboratory animals, with the expectation that this will, in due course, provide the tools and knowledge to combat human brain diseases. To an encouraging extent, technological advances are already opening new avenues for progress against human disease, with interventions now in testing for several neurological and psychiatric disorders.

To enhance the health of children for generations to come, the Environmental influences on Childhood Health Outcomes (ECHO) program aims to study the impacts of environmental exposures on child health and development by aggregating existing and new study populations of pregnant women and their offspring into a large virtual cohort while taking advantage of evolving scientific technologies. ECHO recently announced an ECHO-Wide Cohort Data Collection Protocol to standardize data collection and management across all ECHO Program participants. This will serve as a nation-wide resource for solution-oriented analyses of geographic, physical, chemical, social, behavioral, and biological exposure data with child

development and health outcomes, the intervention component of ECHO. Additionally, NIH has announced renewal funding opportunities for the IDeA States Pediatric Clinical Trials Network (ISPCTN), which aims to enhance pediatric research infrastructure and capacity at institutions in IDeA states with historically low levels of funding from NIH. These opportunities will increase the participation of under-represented children in clinical trials and answer critical questions to improve the health of these populations and bridge important gaps in pediatric care and research.

The Foundation for the National Institutes of Health (FNIH) is a public charitable organization established to support the mission of the NIH. In this role, the FNIH collaborates with offices in the OD and Institutes and Centers across the NIH, as well as the FDA, pharmaceutical and biological sciences companies, and non-profit organizations to establish new partnerships, find ways to overcome obstacles, and improve success rates in research. The Accelerating Medicines Partnership at FNIH, for which the OD is the NIH lead, has utilized these collaborations to speed the process of drug discovery for several major diseases – rheumatoid arthritis and lupus, Alzheimer's disease, Parkinson disease, and diabetes. These projects have advanced the search for therapeutic targets in disease by jointly identifying promising, clinically relevant approaches and increasing financial support for research.

The rigor, reproducibility, and transparency of basic and applied biomedical research has been a growing concern in recent years. The NIH OD, through ORWH and OER, have promoted changes to develop and implement the NIH Sex as a Biological Variable (SABV) policy to prompt researchers to account for sex in study design, analysis, and reporting, thereby enhancing the rigor and reproducibility of biomedical research The intention of the SABV policy is to address the overreliance on male animal models and the inadequate consideration of biological sex as a fundamental variable in biomedical research. ORWH works with the Trans-NIH SABV Working Group and external stakeholders to implement the policy across NIH-funded studies. The ORWH also collaborated with NIH ICOs to incorporate SABV into the Trans-NIH Strategic Plan for Women's Health Research. This continuing effort will help promote rigorous and clinically relevant research, which will benefit and improve the health of women and men.

The ORWH recently published a research project (R01) Funding Opportunity Announcement, titled the Intersection of Sex and Gender Influences on Health and Disease (RFA-OD-19-029).[13] This sex- and gender-focused funding opportunity reflects the NIH's commitment to the consideration of sex and gender influences on health and disease and to the mission of ORWH, which is leading the R01 effort.

The Office of AIDS Research (OAR) plans, coordinates, evaluates, and manages the trans-NIH HIV/AIDS research program. Most recently, OAR developed the first 5-year NIH Strategic Plan for HIV and HIV-Related Diseases for FY 2021-2025 to encompass a longer-term vision for the HIV/AIDS research agenda. The Plan provides a framework and aligns with the *Ending the HIV Epidemic (EHE): A Plan for* America – a once-in-a-generation opportunity to eliminate new HIV infections in our nation. In FY 2021, NIH will build on work started during the "jumpstart" of EHE programming in FY 2019 and FY 2020 to collaborate with community partners to develop locally relevant plans to diagnose, treat, and prevent HIV in areas with some of the highest rates of new HIV cases nationwide.

[13] https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-029.html

Budget Policy: The FY 2021 President's Budget estimate for OD-led science programs is $684.9 million, a decrease of $86.8 million or 11.2 percent compared to the FY 2020 Enacted level. The OD will utilize these funds to pursue promising scientific opportunities across a range of areas from HIV research to sex and gender influences on health and disease. In addition, the OD will continue to lead landmark scientific efforts such as the *All of Us* Research Program and HEAL Initiative. The OD will nucleate trans-NIH efforts, such as INCLUDE and the BRAIN Initiative, which capitalize upon the collective expertise of NIH Institutes and Centers.

New Tools in Data Science and Artificial Intelligence

Advances in data science have presented the NIH with new opportunities in data generation, networking, and algorithms. DNA sequencing, personalized activity and health monitors, and other new technologies have generated vast amounts of data that can be used to study and treat disease. A challenge now faced by NIH is to ensure this data is being used correctly, ethically, and efficiently to improve scientific research and patient outcomes. To address these challenges, the NIH Office of Data Science Strategy (ODSS) is leading trans-NIH efforts to implement the NIH Strategic Plan for Data Science, which will help NIH keep pace with the rapid changes in biomedical data science. Additionally, over 30 trans-NIH teams are currently working on specific data science issues. For example, the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative connects researchers with access to cost-effective cloud industry partners for data storage, and computational infrastructure, tools, and expert support services, and creates the potential for researchers and industry partners to collaborate. Biomedical data stored in the cloud will exceed 50 petabytes by 2020 and includes programs such as the National Cancer Institute's Research Data Commons, the Gabriella Miller Kids First Pediatric Research Program, and Data Resources from the National Center for Biotechnology Information (NCBI).

Another key goal of the NIH Strategic Plan for Data Science is to evaluate the need for generalist data repositories to fill current gaps between the diverse array of data repositories currently used by NIH researchers. To do this, the OD has capitalized on existing standards and tools, such as NIH Figshare, which will provide NIH with information on data depository usage to better inform future depository implementation strategies. NIH is encouraging the adoption of Fast Healthcare Interoperability Resources (FHIR) standards, which will allow NIH-funded researchers to easily access, integrate, and exchange clinical data for research purposes to accelerate innovation in science and data sharing.

Engaging members of the computer and data science communities is a key priority of the NIH Strategic Plan on Data Science. The NIH collaborated with the non-profit organization Coding it Forward to bring Civic Digital Fellows to administrative and extramural offices across NIH. These students spend 10 weeks at NIH gaining hands-on experience tackling biomedical data challenges. The Graduate Data Science Summer Program, organized by the Office of Intramural Training and Education, invites students to the intramural research labs at NIH to learn about biomedical research and provide insights into how computer science can help solve problems faced by researchers. Finally, the ODSS plans to announce in 2020 the Data and Technology Advancement (DATA) National Service Sabbatical Scholar Program, which will recruit experienced computer science professionals with a wide range of technology and data-related

expertise and place them in high impact NIH programs for one to two years. In looking to the future, the OD Office of Strategic Coordination (OSC/Common Fund) is planning a new trans-NIH initiative for FY 2021 and beyond on Harnessing Data Science for Health Discovery and Innovation in Africa. This program would explore whether advances in data science applied in the African context can spur new health discoveries and catalyze innovation in healthcare and health research on the continent.

At NIH, AI has the potential to accelerate and expand biomedical and clinical research and improve clinical care. The NIH OD hosted a workshop, Harnessing Artificial Intelligence and Machine Learning to Advance Biomedical Research, to centralize the NIH's interest in AI and gather feedback from experts in the community. Four major needs in AI were identified – preparing data for AI use, applying AI ethically, increasing engagement with computer science communities, and improving AI methods and interpretation at NIH. In 2019, the NIH Director announced the formation of an AI working group of the ACD. Coordinated by the OD, this ACD Artificial Intelligence Working Group is identifying trans-NIH opportunities in AI, determining how NIH can best collaborate with computer and data science communities, defining approaches for NIH to encourage computer scientists to engage in biomedical research, and identifying the major ethical considerations related to AI in health research and care. The Working Group is currently organizing another workshop, Learning Meaningful Representations of Life, to bring together representatives from biomedical research and computer and data science. Looking to FY 2021, the Common Fund will explore a potential program in Artificial Intelligence based on the upcoming recommendations of the ACD Working Group on Artificial Intelligence (in addition to the proposed Artificial Intelligence to Address Chronic Disease initiative). Lastly, NIH is harnessing the power of AI for use with internal NIH data to support data-driven decision-making. The OPA uses AI-based approaches to support analysis of the biomedical research landscape and inform data-driven decision-making by NIH leadership. For example, OER is currently collaborating with the National Institute on Aging to determine if machine-learning techniques can enhance the current RCDC categorization process for identifying aging-related research activities.

Program Portrait: Common Fund Data Ecosystem

As increasing amounts of data are generated from biomedical research studies, the way that scientists interact with digital data is changing. No longer can large biomedical datasets be stored or analyzed using local computers and servers. The Common Fund is developing a data ecosystem – the Common Fund Data Ecosystem (CFDE) – where new models of making data sets interoperable in the cloud environment will be tested. The CFDE will help to ensure that all Common Fund data sets are Findable, Accessible, Interoperable, and Reusable (FAIR), will provide training for users to operate on the data in a cloud environment, and will ensure that Common Fund data continue to be available after individual programs are completed. The CFDE will amplify the impact of several CF programs by enabling researchers to interrogate multiple disparate data sets, and thereby make new kinds of scientific discoveries that were not possible before. The CFDE is being coordinated with NIH-wide efforts in data science, led by the Office of Data Science Strategy (ODSS). This coordination will ensure that lessons learned and best practices from the CFDE inform NIH-wide data science activities.

Budget Policy: The FY 2021 President's Budget estimate for data science and AI is $78.1 million, an increase of $48.1 million or 160.4 percent compared to the FY 2020 Enacted level. This includes $50.0 million for the Artificial Intelligence to Address Chronic Disease initiative starting in FY 2021, which supports the Administration's Industries of the Future initiative. ODSS will continue to build on partnerships with cloud providers through the STRIDES Initiative to provide cloud-based infrastructures 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. ODSS will also continue to support training opportunities to build capacity in application of AI to biomedical research

Building Research Capacity and Collaborations

Several initiatives within the OD aim to build research capacity and collaborations to innovate tools for future research. The NIH Common Fund and the Office of Research Infrastructure Programs (ORIP) within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), along with ICs, have developed several programs to build and disseminate advanced research tools. For example, the Somatic Cell Genome Editing Program is a community resource of tools for safe and effective genome editing in humans. Widespread dissemination of these tools will enable many researchers in different biomedical sub-fields to accelerate the development of gene-based therapies for a variety of diseases. Through support of national service centers, the Transformative High Resolution Cryo-Electron Microscopy program broadens researchers' access to the improved cryo-electron microscopy and offers relevant training. Additionally, the Zebrafish International Resource Center, National Primate Research Centers, and the Knockout Mouse Project Repository support research laboratories funded by 23 ICs in their work with these animal models. These programs distribute important genetic and phenotypic information to researchers across all areas of biomedical research and are leading to advances in disease treatment and prevention. ORIP fosters the trans-NIH Shared Instrumentation Grant Program by supporting the acquisition of the commercially available, expensive, state-of-the-art instruments requested by investigators. These instruments are indispensable for the advancement of research funded by all NIH ICs.

The table below provides the budget levels for the offices within DPCPSI.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
Budget Summary
(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY2020
Office of the DPCPSI Director	17,091	17,282	16,197	-1,085
Office of Behavioral & Social Sciences Research	27,878	27,956	26,201	-1,756
Office of AIDS Research	62,256	62,256	56,636	-5,620
Office of Research on Women's Health	43,812	43,925	41,167	-2,758
Office of Disease Prevention	12,586	12,700	11,903	-798
Office of Dietary Supplements	25,351	25,415	23,819	-1,596
Office of Research Infrastructure Programs	288,108	288,213	268,596	-19,617
Total	**$477,082**	**$477,748**	**$444,518**	**-$33,230**

To facilitate collaborations between basic research and translational or clinical research, several OD-led initiatives have been designed to bring these communities together. The NIH Bench-to-Bedside Awards fund collaborations between intramural and extramural researchers and the "Opportunities for Collaboration at the NIH Clinical Center" awards support research in collaboration with the NIH Clinical Center. The Sexual and Gender Minority (SGM) Research Office (SGMRO) coordinates sexual and gender minority research and related activities across NIH with the goal of strengthening the community of investigators across the research continuum conducting SGM health research. The SGMRO will continue to encourage SGM-related data collection to improve research on SGM populations. The Tribal Health Research Office (THRO) will continue its efforts, working in partnership with the ICOs, to enhance communication and collaboration, build research capacity, expand research, and enhance cultural competency and community engagement. The Population Studies Program in the Office of Dietary Supplements (ODS) evaluates the use of dietary supplements in the U.S., using data from the National Health and Nutrition Examination Survey, allowing researchers access to data on specific sub-populations, dietary supplements, and nutrition status. The ODS develops validated analytical methods and reference standards for evaluation of dietary supplements and their metabolites in clinical specimens. The ODS also disseminates scientific information on supplements to researchers, clinicians, and consumers through Dietary Supplement Fact Sheets. Through these programs, the OD will ensure continued support for new research tools and partnerships for the advancement of biomedical research. In planning for future fiscal years, the Common Fund is developing a new trans-NIH initiative on Precision Nutrition. To understand individual differences with respect to diet, the Common Fund is planning a study to generate an open source discovery engine that is amenable to artificial intelligence approaches and provides a resource for the collective community to understand individual responses to diet. The goal will be to discover and validate novel algorithms that predict how any individual will respond to different dietary regimens. If successful, this bold, high-risk initiative will enable more tailored dietary recommendations to be provided by physicians, and it will enable the development of tools that will allow individuals to make more informed decisions about healthy food choices.

The Office of Behavioral and Social Sciences Research (OBSSR) leads several programs bringing Institutes, Centers, and OD offices together to accelerate the use of innovative methods

and measures in the behavioral and social sciences. These programs include training for advanced data analytics in the next generation of scientists, developing sustainable training institutes and programs. In addition to training, OBSSR is building collaborations between research institutions via the Intensive Longitudinal Health Behaviors Network,[14] which leverages sensor technologies and advanced data analytics to improve our understanding of how health behaviors change over time, providing critical data for producing more effective health behavior interventions; and the Eureka Platform,[15] a research resource designed to facilitate mobile and internet-based medical or health-related research.

Program Portrait: Maternal Mortality and Morbidity Committee

To combat the rise in maternal mortality and morbidity (MMM) in the United States, the ORWH is coordinating experts across Federal and private partners in a multidisciplinary research initiative focusing on all aspects of maternal health. To that end, the ORWH has facilitated trans-NIH collaborations between 14 ICs and 2 OD programs. To date, funded studies have targeted significant knowledge gaps, such as accurately predicting risk for MMM and investigating the relationship between racial disparities and maternal health. ORWH established an MMM Working Group to facilitate coordination and collaboration of research efforts among NIH Institutes, Centers, and Offices to address MMM. In late 2019, ORWH worked with the Immediate Office of the Director and the National Institute of Child Health and Human Development to stand up a Maternal Mortality Task Force. This task force is seeking bold, innovative approaches and strategic alignment of research efforts across NIH to maximize the impact of the agency's efforts and will identify, recommend, and develop an integrated, NIH-wide approach for establishing new collaborations and funding these priorities.

The MMM Web Portal, a website created by ORWH, acts as a resource for scientists, clinicians, and the public to access information on MMM relevant research at NIH, as well as new funding opportunity announcements and scientific articles and meetings. The site also links to other Federal agency websites and relevant MMM resources.

The ORWH will continue to collaborate with HHS and other agencies to further enhance and expand the Web Portal as a valuable public resource and coordinate trans-NIH research programs to address the growing national concern over MMM. By building a knowledge base that covers basic, translational, and behavioral research, ORWH will advance the multiagency effort to address and prevent MMM.

The Office of Disease Prevention (ODP) worked with the Global Burden of Disease (GBD) Study, which is coordinated by the World Health Organization and the Bill and Melinda Gates Foundation, to generate a new age category – birth to 70 years of age – for the study. The data for this category, which tracks the causes and risk factors for premature death (defined as death before the age of 70) and disability, will now be available in all future GBD results. The GBD is the world's largest systematic, scientific effort to quantify health loss from all diseases, injuries, and risk factors by age, sex, and geographic location over time. However, until ODP's collaboration with the GBD, data on the causes and risk factors for premature death and disability were not regularly available for the U.S. as a whole, or by sex, age, or race/ethnicity.

[14] www.ilhbn.ssri.psu.edu
[15] http://info.eurekaplatform.org/

Now, as a result of this collaboration, NIH and the extramural research community can identify and track the causes and risk factors of premature death and disability in the U.S. over time (both historically and projecting up to 25 years in the future). Premature death is often preventable, so the availability of this data not only improves our understanding of the burden of disease and key health outcomes in the U.S., but it also enhances our ability to focus on the most pressing health challenges facing the nation.

Budget Policy: The FY 2021 President's Budget estimate for this program is $1,041.0 million, a decrease of $75.9 million or 6.8 percent compared to the FY 2020 Enacted level. The offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences, Disease Prevention, Dietary Supplements, Infrastructure Resources, Sexual and Gender Minorities and Tribal Health will continue to serve as focal points for these research areas across NIH, fostering efforts such as a trans-NIH Precision Nutrition initiative, and providing shared resources, such as Dietary Supplement Fact Sheets and Eureka Platform to build capacity in these areas.

Research Training and Career Development at NIH

Through training and career development programs across the OD, NIH is working to develop a skilled biomedical workforce for the future. Increasing representation and diversity in both the NIH intramural and extramural communities is a key goal of several training and workforce-related programs. The Diversity Program Consortium is a trans-NIH program funded by the NIH Common Fund and coordinated by the National Institute for General Medical Sciences to bring together institutions to engage a more diverse field of individuals at the student, faculty, and institutional levels. Additionally, the NIH Distinguished Scholars Program works to build an inclusive community within the NIH Intramural Research Program by providing mentoring and professional development training to yearly cohorts of investigators with diverse backgrounds. The Future Leaders Research conference offers career development opportunities for diverse early-career researchers to share their scientific work and learn from NIH leaders and investigators. Other workforce development programs are designed to support specific areas of scientific expertise. To recruit and sustain trainees in HIV/AIDS research, the ORIP and the OAR jointly support the HIV/AIDS Scholars Program to develop young researchers using non-human primate models. The Training Veterinary Scientists as Biomedical Researchers Program supports the distinct perspective of researchers with expertise in comparative disease models to integrate that knowledge into translational biomedical research. These programs are all part of a multi-pronged approach across NIH to support training and career development, in addition to dedicated funding mechanisms supported across the NIH.

The NIH Intramural Loan Repayment and Undergraduate Scholarship Programs offer financial incentives that include loan repayment and scholarship, along with other benefits to attract highly qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of NIH. The Intramural Loan Repayment Program (ILRP), housed in the Office of Intramural Research, repays outstanding eligible educational debt for NIH Full-Time Equivalent (FTE) employee postgraduates. In return, participants enter into a contractual agreement to conduct qualified research in one of several areas as identified by the ILRP and coinciding with the NIH mission. The Undergraduate Scholarship Program (UGSP), also housed in the Office of Intramural Research, offers competitive scholarships to exceptional undergraduate students from financially disadvantaged backgrounds. Awardees must be

committed to biomedical, social science, or behavioral health-related research career paths. In exchange for each year or partial year of scholarship funding, UGSP award recipients are contractually obligated to participate in a 10-week summer internship and one year as a full-time paid employee of the NIH Intramural Research Program.

Within the Office of Intramural Research (OIR), the NIH Director's Challenge Innovation Award Program provides start-up money to innovative and impactful research projects run by trans-NIH collaborations. The yearlong awards fund new facilities and initiatives which will later be available to the wider Intramural Research Program. In FY 2021, this Award Program will continue to support growing relationships across NIH Intramural Research to improve the ability of NIH investigators to study public health questions.

The Director's Discretionary Fund (DDF) enables the NIH to prioritize new research opportunities and address pressing scientific issues. Previously in FY 2019, funds were applied in support of trans-NIH initiatives and projects including the Cardiovascular Disease Research among Disproportionately Affected Sub-Populations, Africans Post-doctoral Training Initiative, the Sexual Harassment Climate Survey and related activities, a modernization of ClinicalTrials.gov, and a Randomized Controlled Trial on the Impact of Grant-writing Support on R01 Grant-Application Resubmission. In FY 2021, the DDF will continue to fund emerging scientific projects to help discover new solutions to upcoming health problems.

Budget Policy: The FY 2021 President's Budget estimate for this program is $18.1 million, a decrease of $1.2 million or 6.3 percent compared to the FY 2020 Enacted level. In FY 2021, the OD will ensure the future of our biomedical workforce with training and career development opportunities. In addition, the DDF will continue to support nascent scientific opportunities across the agency.

Research for Countermeasures against Nuclear/Radiological/Chemical Threats
The National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, manages both the Radiation and Nuclear Countermeasures Program (RNCP) and the Chemical Countermeasures Research Program (CCRP), with funding provided through the OD. Currently, these 2 Programs have over 400 medical countermeasures (MCMs) at various stages of research and development in their portfolios.

The RNCP supports the development of and FDA approval process for MCMs and biodosimetry approaches to assess, mitigate, and/or treat injuries resulting from a radiation public health emergency. In November 2019, the program met a key milestone in the FDA drug approval process by completing a large animal study that demonstrated the efficacy of Amgen's Nplate® in treating Acute radiation syndrome (ARS). In 2021, RNCP will continue to support a broad range of research activities, including development and maintenance of a strong research infrastructure, funding of large animal and human studies to evaluate MCM safety and efficacy, strengthening collaborations with academic and U.S. Government partners, and issuance of funding opportunities focused on pediatric aspects of radiation medical preparedness and radiation-induced immune-dysfunction.

The CCRP supports the fundamental research and early development of MCMs to prevent lethality and treat immediate and/or long-term injuries after a mass casualty chemical event. Since FY 2006, seven advanced research and development contracts have been awarded by BARDA that transitioned from the CCRP portfolio. These awards advanced critical countermeasures as treatment for poisoning by organophosphorus nerve agents and pesticides, sulfur mustard and chlorine gases, and the procurement of Seizalam® for the SNS, which was initially developed by the CCRP. The CCRP continues to build research resources and collaborations to develop novel MCMs and in FY 2019 managed a comprehensive portfolio of 5 Centers of Research Excellence, 26 Research Cooperative Agreements, 11 Individual Research Grants, 8 Administrative Supplement awards, and 7 Interagency Agreements with the DoD and HHS. In FY2021, the CCRP will continue these initiatives and collaborations and plans to transition several mass casualty amenable MCMs to BARDA for advanced development in higher order animal models and humans to evaluate their safety and/or effectiveness in reversing conditions such as synthetic opioid-induced respiratory depression and systemic toxicities after sulfur mustard gas exposure.

Budget Policy: The FY 2021 President's Budget estimate for this program is $90.5 million, a decrease of $6.6 million or 6.8 percent compared to the FY 2020 Enacted level. Funding will be used to continue leadership of the Radiation and Nuclear Countermeasures Program (RNCP) and the Chemical Countermeasures Research Program (CCRP) for development of safe and effective medical countermeasures (MCMs), targeting areas such as pediatric aspects of radiation medical preparedness and radiation-induced immune-dysfunction, and making advances in MCMs for synthetic opioid-induced respiratory depression and systemic toxicities after sulfur mustard gas exposure.

Operations in the Office of the Director: Transforming Culture and Modernizing Processes
A critical role of the OD is to provide infrastructure and resources for all of NIH while continually striving to streamline operations. Through the work of several offices, OD works to positively transform NIH culture, modernize processes, and enhance transparency.

Transforming Culture
The Optimize NIH effort established an infrastructure and foundation to foster a cultural shift towards continuous improvement at NIH. NIH leveraged organizational change management principles, techniques, and tools to support and maximize employee engagement and process improvement. The Office of Management (OM) and Optimize NIH leadership formed high-performance, cross-organizational work teams composed of volunteers across the NIH community. These efforts have increased efficiencies and improved the effectiveness of prioritized business functions, improving interactions with external customers and enabling NIH staff to focus on high value, mission-critical work, such as improvements to NIH Enterprise Ethics System (NEES) for Special Government Employees (SGEs), launch of FOIAXpress and Portal for receiving and processing FOIA requests, and streamlining and automating Committee Management processes. NIH is continuing to assess additional opportunities to increase efficiency and effectiveness in the administrative business functions of Acquisitions, IT Security, Property, Title 42(f), and Travel. Optimize NIH will graduate from ReImagine HHS in FY 2020, and efforts will continue internally at NIH.

Modernizing Process

OD leadership launched the Strategic Engagement Agenda to increase OD efficiencies to enhance collaboration, communication, and functionality; and to improve engagement and dialogue between the OD and the Institutes and Centers to strengthen relationships, support, and coordination. The initiative involves assessment of OD business, administrative, budget, and other scientific management processes. For example, working with the OD Executive Office and the Office of Federal Advisory Committee Policy, OD began streamlining document management and clearance processes to save staff time and resources.

Efficiencies continue to be made in NIH IT and data management. The Office of the Chief Information Officer (OCIO) was involved in the development of the NIH Data Center Optimization Initiative (DCOI) Strategic Plan and continues to work with HHS and the ICs to track and monitor progress. OCIO has also implemented a project to help ICs evaluate the feasibility of adding power metering in key IC data centers. The NIH Information Security Program has made significant progress in deploying key tools and software to provide better visibility into cybersecurity risks and be able to respond faster to attacks. Some of the tools are required by HHS and/or the Department of Homeland Security and are challenging to deploy in NIH's heterogeneous environment. Deploying these tools centrally will facilitate standardization and has the potential to provide NIH with volume discounts.

In response to increasingly complex challenges in the area of content management and a drive to transition to digital recordkeeping, stemming from Federal records management requirements, policy directives, and the exponential growth of enterprise content in general, OM initiated a pilot of an Enterprise Content Management (ECM) program that will provide organizations across the enterprise with the tools and resources required to effectively manage digital content in a secure and compliant manner. The NIH ECM program is highly focused on delivering solutions that manage content and streamline associated content-centric processes that have significant impact using an approach that is both inclusive and cost-effective. As the program matures beyond the current pilot, governance processes will be enhanced to streamline the intake, review, and prioritization of proposed use-cases from a larger internal audience, and the NIH will realize a reduction in the incremental cost of expanding the program to optimize additional high-value content-centric processes. The results of this pilot will inform the development of an OD-wide platform currently being developed through the Strategic Engagement Agenda that will integrate current siloed systems, simplify business processes, and convert manual processes into an electronic format. The new digital format will optimize efficiency and streamline administrative activities.

OM and other OD offices are leading several additional efforts to improve OD and trans-NIH activities, including improvements in budget processes, hiring and employee accommodation, and leases. NIH has replaced the existing Application Programming Interfaces (API) budget upload with a more robust and integrated application tool, effective with the beginning of FY 2020. In FY 2021, HHS, with NIH Office of Human Resources' leadership, will deploy a new approach to recruiting candidates to the NIH and HHS. All HHS OPDIVs will be able to share recruitments and candidates across organizations in an effort to reduce the time to hire from when a manager identifies a vacancy to the date the position is filled. As a part of their mission to cultivate a culture of inclusion where diverse talent is leveraged to advance health discovery,

the Office of Equity, Diversity, and Inclusion (EDI) launched the NIH Reasonable Accommodation Program and the agency's Language Access Plan, including the coordination of Plans within the ICs through a trans-NIH working group. NIH has also been collaborating with GSA to optimize its footprint of leased space. For example, NIH is strategically consolidating office space in Rockville, Maryland – a major transition for over 1,400 employees from 5 different buildings.

Enhancing Transparency

OER continues to bolster NIH's efforts to enhance transparency through the expansion and modernization of the RePORT suite of web tools, including the NIH Data Book. The RePORT website upholds NIH's commitment to public accountability, providing a one-stop shop for NIH data and reports, and serves as a major avenue of information for NIH stakeholders, including investigators, research organizations, Congress, and the public. The NIH Data Book summarizes answers to the most commonly asked questions about the NIH budget, extramural programs, peer review, and workforce using annually updated data from multiple sources. OER is currently modernizing the RePORT platform to take advantage of new technologies for faster and more interactive approaches to data exploration. Modernization will allow for a consolidated home for dashboards to ensure consistency and reduce redundant information development across NIH. Updates to RePORT also include the publication of IC funding for R01 grants and inclusion data linked to categories. OER has also made updates to the Categorical Spending reports that allow for cross-reference with disease burden data. Additionally, OD, through the work of the Chief Officer for Scientific Workforce Diversity (COSWD), is enhancing transparency and accountability in scientific workforce diversity metrics through a trans-NIH results-based accountability network, online data and reporting tool, and formalization of a trans-NIH committee devoted to this initiative.

Budget Policy: The FY 2021 President's Budget estimate for this program is $295.4 million, a decrease of $74.0 million or 20.0 percent compared to the FY 2020 Enacted level. In FY 2021, funding will be used to provide common infrastructure and resources for NIH institutes and centers, such as NIH IT and data management efforts. The OD will also continue to lead efforts across the agency to streamline processes and improve efficiency, such as through Optimize NIH and OD Strategic Engagement Agenda efforts.

NATIONAL INSTITUTES OF HEALTH
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Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total compensable workyears:				
	Full-time equivalent	780	780	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$197	$202	$6
	Average GM/GS grade	13.1	13.1	0.0
	Average GM/GS salary	$124	$128	$3
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$119	$123	$4
	Average salary of ungraded positions	$188	$194	$6
	OBJECT CLASSES	**FY 2020 Enacted**	**FY 2021 President's Budget**	**FY 2021 +/- FY 2020**
	Personnel Compensation			
11.1	Full-Time Permanent	79,403	84,128	4,724
11.3	Other Than Full-Time Permanent	13,129	13,276	148
11.5	Other Personnel Compensation	2,301	2,327	26
11.7	Military Personnel	942	967	25
11.8	Special Personnel Services Payments	1,926	1,948	22
11.9	**Subtotal Personnel Compensation**	**$97,700**	**$102,646**	**$4,946**
12.1	Civilian Personnel Benefits	35,637	38,660	3,023
12.2	Military Personnel Benefits	668	686	18
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$134,005**	**$141,992**	**$7,987**
21.0	Travel & Transportation of Persons	1,359	1,384	25
22.0	Transportation of Things	114	117	2
23.1	Rental Payments to GSA	1,408	1,436	28
23.2	Rental Payments to Others	66	68	1
23.3	Communications, Utilities & Misc. Charges	637	644	7
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	78,457	72,625	-5,832
25.2	Other Services	127,708	120,195	-7,513
25.3	Purchase of goods and services from government accounts	168,445	152,351	-16,094
25.4	Operation & Maintenance of Facilities	0	0	0
25.5	R&D Contracts	42,259	42,376	117
25.6	Medical Care	65	68	3
25.7	Operation & Maintenance of Equipment	6,286	6,407	121
25.8	Subsistence & Support of Persons	15	16	0
25.0	**Subtotal Other Contractual Services**	**$423,235**	**$394,036**	**-$29,199**
26.0	Supplies & Materials	1,347	1,373	26
31.0	Equipment	5,789	5,904	115
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	1,836,425	1,661,108	-175,316
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	**$2,270,382**	**$2,066,071**	**-$204,311**
	Total Budget Authority by Object Class	**$2,404,387**	**$2,208,063**	**-$196,324**

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

NATIONAL INSTITUTES OF HEALTH
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Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation			
Full-Time Permanent (11.1)	$79,403	$84,128	$4,724
Other Than Full-Time Permanent (11.3)	13,129	13,276	148
Other Personnel Compensation (11.5)	2,301	2,327	26
Military Personnel (11.7)	942	967	25
Special Personnel Services Payments (11.8)	1,926	1,948	22
Subtotal Personnel Compensation (11.9)	**$97,700**	**$102,646**	**$4,946**
Civilian Personnel Benefits (12.1)	$35,637	$38,660	$3,023
Military Personnel Benefits (12.2)	668	686	18
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$134,005**	**$141,992**	**$7,987**
Travel & Transportation of Persons (21.0)	$1,359	$1,384	$25
Transportation of Things (22.0)	114	117	2
Rental Payments to Others (23.2)	66	68	1
Communications, Utilities & Misc. Charges (23.3)	637	644	7
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			0
Consultant Services (25.1)	78,457	72,625	-5,832
Other Services (25.2)	127,708	120,195	-7,513
Purchases from government accounts (25.3)	144,796	128,276	-16,520
Operation & Maintenance of Facilities (25.4)	0	0	0
Operation & Maintenance of Equipment (25.7)	6,286	6,407	121
Subsistence & Support of Persons (25.8)	15	16	0
Subtotal Other Contractual Services	**$357,262**	**$327,518**	**-$29,744**
Supplies & Materials (26.0)	$1,347	$1,373	$26
Subtotal Non-Pay Costs	**$360,786**	**$331,104**	**-$29,683**
Total Administrative Costs	**$494,791**	**$473,095**	**-$21,696**

NATIONAL INSTITUTES OF HEALTH
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Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2019 Final			FY 2020 Enacted			FY 2021 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	741	9	750	729	9	738	729	9	738
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	741	9	750	729	9	738	729	9	738
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	42	-	42	42	-	42	42	-	42
Total:	42	-	42	42	-	42	42	-	42
Total	783	9	792	771	9	780	771	9	780
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
2017	12.9
2018	13.0
2019	13.1
2020	13.1
2021	13.1

NATIONAL INSTITUTES OF HEALTH
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Detail of Positions[1]

GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	11	11	11
Total, ES Salary	2,105,765	2,164,726	2,225,338
GM/GS-15	142	140	140
GM/GS-14	177	174	174
GM/GS-13	269	265	265
GS-12	101	99	99
GS-11	46	45	45
GS-10	0	0	0
GS-9	20	20	20
GS-8	1	1	1
GS-7	8	8	8
GS-6	0	0	0
GS-5	0	0	0
GS-4	3	3	3
GS-3	1	1	1
GS-2	1	1	1
GS-1	1	1	1
Subtotal	770	758	758
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	5	5	5
Senior Grade	3	3	3
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	9	9	9
Ungraded	56	56	56
Total permanent positions	669	657	657
Total positions, end of year	846	834	834
Total full-time equivalent (FTE) employment, end of year	792	780	780
Average ES salary	191,433	196,793	202,303
Average GM/GS grade	13.1	13.1	13.1
Average GM/GS salary	120,814	124,197	127,675

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