

DEPARTMENT OF HEALTH AND HUMAN SERVICES

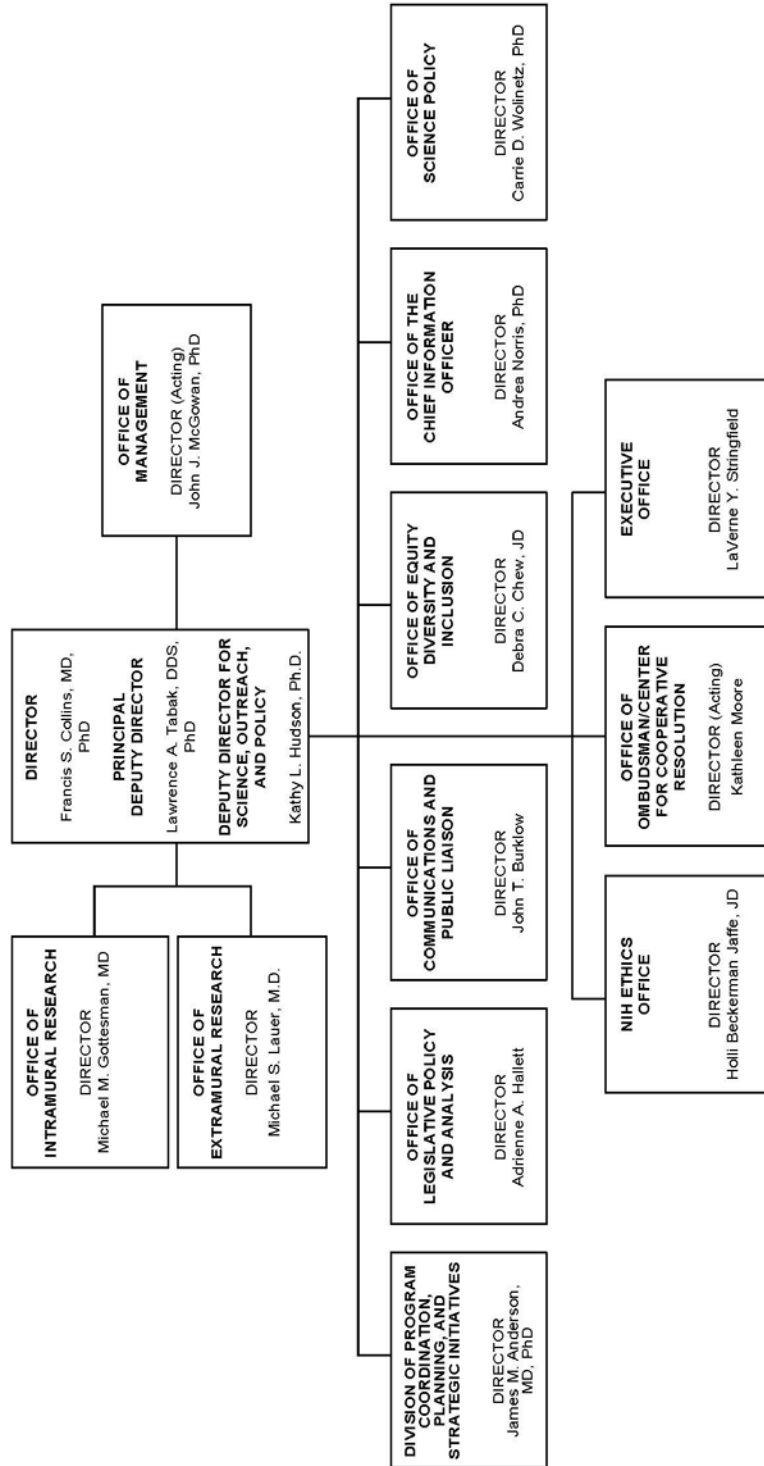
NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

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# NATIONAL INSTITUTES OF HEALTH

## Office of the Director Organization Structure



## NATIONAL INSTITUTES OF HEALTH

### Office of the Director

#### (INCLUDING TRANSFER OF FUNDS)

For carrying out the responsibilities of the Office of the Director, NIH, [~~\$1,558,600,000~~]~~\$1,432,859,000~~, of which up to [~~\$30,000,000~~]~~\$40,000,000~~ may be used to carry out section [215]213 of this Act: Provided, That funding shall be available for the purchase of not to exceed 29 passenger motor vehicles for replacement only: Provided further, That all funds credited to the NIH Management Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: [Provided further, That \$165,000,000 shall be for the National Children's Study Follow-on: Provided further, That NIH shall submit a spend plan on the next phase of the study in the previous proviso to the Committees on Appropriations of the House of Representatives and the Senate not later than 90 days after the date of enactment of this Act:] Provided further, That [~~\$663,039,000~~]~~\$553,039,000~~ 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 up to [~~\$130,000,000~~]~~\$20,000,000~~ of the funds provided to the Common Fund are available to support the trans-NIH Precision Medicine Initiative: [Provided further, That of the amount provided to the NIH, the Director of the NIH shall enter into an agreement with the National Academy of Sciences, as part of the studies conducted under section 489 of the PHS Act, to conduct a comprehensive study on policies affecting the next generation of researchers in the United States:] Provided further, That, [of the funds from Institute, Center, and Office of the Director accounts within "Department of Health and Human Services, National Institutes of Health,"] in order to strengthen privacy protections for human research participants, NIH shall require investigators receiving NIH funding, *from amounts appropriated in this Act to NIH accounts*, for new and competing research projects designed to generate and analyze large volumes of data derived from human research participants to obtain a certificate of confidentiality; *Provided further, That the Director may direct up to 1 percent of the total made available in this or any other Act to all National Institutes of Health discretionary appropriations to activities that the Director may so designate: Provided further, That no such appropriation shall be decreased by more than 1 percent by any such transfers and that the Congress is promptly notified of the transfer.*

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.

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

**Amounts Available for Obligation<sup>1</sup>**  
(Dollars in Thousands)

<b>Source of Funding</b>	<b>FY 2015 Actual</b>	<b>FY 2016 Enacted</b>	<b>FY 2017 President's Budget</b>
Appropriation	\$1,413,734	\$1,571,200	\$1,716,200
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	0	0	0
<i>Other mandatory financing</i>			270,741
Rescission	0	0	0
Sequestration	0	0	0
Subtotal, adjusted appropriation	\$1,413,734	\$1,571,200	\$1,716,200
OAR HIV/AIDS Transfers	0	0	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	\$1,413,734	\$1,571,200	\$1,716,200
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,413,734	\$1,571,200	\$1,716,200
Unobligated balance lapsing	-101	0	0
Total obligations	\$1,413,633	\$1,571,200	\$1,716,200

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:

FY 2015 - \$38,372    FY 2016 - \$40,000    FY 2017 - \$40,000

**NATIONAL INSTITUTES OF HEALTH**  
**Office of the Director**  
**Budget Mechanism - Total <sup>1</sup>**

(Dollars in Thousands)

MECHANISM	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget <sup>2</sup>		Change from FY 2016	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Grants:</u>								
Research Projects		\$521,859		\$546,136		\$607,143		\$61,007
Research Centers		283,581		233,946		241,942		7,996
Other Research		245,401		338,349		371,483		33,134
Total Research Grants		\$1,050,842		\$1,118,430		\$1,220,567		\$102,137
Training		\$19,270		\$33,244		\$36,697		\$3,453
R & D Contracts		60,218		99,337		136,599		37,262
Intramural Research		26,553		29,451		28,148		-1,302
Res. Management & Support		256,749		290,738		294,188		3,450
Total Other Than Research Grants		\$362,791		\$452,770		\$495,633		\$42,863
Cancer Initiative Mandatory Financing		\$0		\$0		\$0		
Other Mandatory Financing		\$0		\$0		-\$270,741		-\$270,741
<b>Total, Labor /HHS Budget Authority</b>		<b>\$1,413,633</b>		<b>\$1,571,200</b>		<b>\$1,445,459</b>		<b>-\$125,741</b>
<b>Proposed Law Funding:</b>								
Cancer Initiative Mandatory Financing		\$0		\$0		\$0		
Other Mandatory Financing		\$0		\$0		\$270,741		\$270,741
<b>Total, OD</b>		<b>\$1,413,633</b>		<b>\$1,571,200</b>		<b>\$1,716,200</b>		<b>\$145,000</b>

<sup>1</sup> All Subtotal and Total numbers may not add due to rounding.

<sup>2</sup> Includes mandatory financing.

# NATIONAL INSTITUTES OF HEALTH

## Office of the Director

### Budget Authority by Activity<sup>1,2</sup>

(Dollars in Thousands)

	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget <sup>3</sup>	FY 2017 +/- FY2016
OD Operations	125,561	143,230	143,230	0
<i>NIH Director's Challenge Fund</i>	<i>(1,413)</i>	<i>(1,413)</i>	<i>(1,413)</i>	<i>(0)</i>
Division of Program Coordination, Planning and Strategic	11,227	13,275	13,275	0
Office of Behavioral & Social Sciences Research	26,094	26,738	26,738	0
Office of AIDS Research	61,923	62,256	62,256	0
Office of Research on Women's Health	40,776	42,023	42,023	0
Office of Disease Prevention	7,910	9,956	9,956	0
Office of Dietary Supplements	24,686	25,297	25,297	0
Office of Research Infrastructure Programs	276,124	277,395	277,395	0
Science Education Partnership Awards/Office of Science	18,541	18,541	18,541	0
Director's Discretionary Fund	10,000	10,000	10,000	0
Foundation for the National Institutes of Health	1,000	1,000	1,000	0
Intramural Loan Repayment and Scholarship	7,145	7,447	7,447	0
Nuclear Radiological Chemical Countermeasures	92,098	93,392	93,392	0
National Children's Study Follow-On	165,000	165,000	165,000	0
BRAIN	0	0	45,000	45,000
Reception and Representation Fund	10	10	10	0
Common Fund	545,639	675,639	775,639	100,000
<b>Total</b>	<b>\$1,413,734</b>	<b>\$1,571,200</b>	<b>\$1,716,200</b>	<b>\$145,000</b>

<sup>1</sup>Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

<sup>2</sup>Items in italics are "non-adds"; for reference only (NIH Director's Challenge Fund amounts are already included in OD Operations budget.)

<sup>3</sup>Includes mandatory financing.

## **Major Changes in the Fiscal Year 2017 President's 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 2017 President's Budget request for OD, which is \$145 million above the FY 2016 Enacted level, for a total of \$1,716.200 million.

### Common Fund (+\$100.000 million; total \$775.639 million):

The FY 2017 budget request for the Common Fund expands support for the Precision Medicine Initiative Cohort Program so that its awardees move toward full implementation of the required infrastructure and programmatic operations needed for the cohort to support initial enrollees.

### BRAIN Initiative (+\$45.000 million; total \$45.000 million):

The FY 2017 budget request for the BRAIN Initiative continues to ramp up the NIH investment pursuant to the long-term plan developed by a working group of the Advisory Committee to the Director. This increase, together with existing funds in the NIH Institutes and Centers, would result in a total FY 2017 budget of \$195.000 million.

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

**Summary of Changes**

(Dollars in Thousands)

<b>FY 2016 Enacted</b>				\$1,571,200	
<b>FY 2017 President's Budget</b>				\$1,716,200	
<b>Net change</b>				\$145,000	
CHANGES	FY 2017 President's Budget <sup>1</sup>		Change from FY 2016		
	FTEs	Budget Authority	FTEs	Budget Authority	
<u>A. Built-in:</u>					
<u>1. Intramural Research:</u>					
a. Annualization of January 2016 pay increase & benefits		\$4,403		\$9	
b. January FY 2017 pay increase & benefits		4,403		35	
c. Two less days of pay		4,403		-34	
d. Differences attributable to change in FTE		4,403		0	
e. Payment for centrally furnished services		0		0	
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		23,746		0	
Subtotal					\$11
<u>2. Research Management and Support:</u>					
a. Annualization of January 2016 pay increase & benefits		\$105,583		\$209	
b. January FY 2017 pay increase & benefits		105,583		786	
c. Two less days of pay		105,583		-756	
d. Differences attributable to change in FTE		105,583		0	
e. Payment for centrally furnished services		2,125		0	
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		223,217		-116	
Subtotal					\$123
Subtotal, Built-in					\$134



**NATIONAL INSTITUTES OF HEALTH**  
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**Summary of Changes-continued**

(Dollars in Thousands)

CHANGES	FY 2017 President's Budget <sup>1</sup>		Change from FY 2016	
	No.	Amount	No.	Amount
<b>B. Program:</b>				
<u>1. Research Project Grants:</u>				
a. Noncompeting	365	\$427,491	60	\$61,360
b. Competing	189	172,414	-1	-353
c. SBIR/STTR	20	7,238	0	0
Subtotal, RPGs	574	\$607,143	59	\$61,007
2. Research Centers	78	\$241,942	0	\$7,996
3. Other Research	660	371,483	44	33,134
4. Research Training	327	36,697	22	3,453
5. Research and development contracts	3	136,599	0	37,262
Subtotal, Extramural		\$1,393,863		\$142,852
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	0	\$28,148	0	-\$1,313
7. Research Management and Support	702	294,188	0	3,327
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	702	\$1,716,200	0	\$144,866
Total changes				\$145,000

<sup>1</sup> Includes mandatory financing.

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

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2016 Amount Authorized</b>	<b>FY 2016 Enacted</b>	<b>2017 Amount Authorized</b>	<b>FY 2017 President's Budget<sup>1</sup></b>
Research and Investigation	Section 301	42§241	Indefinite	\$1,571,200,000	Indefinite	\$1,432,859,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$1,571,200,000</b>		<b>\$1,432,859,000</b>

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

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2007	\$667,825,000	\$667,825,000	\$687,825,000	\$478,650,000
Rescission				\$0
2008	\$517,062,000	\$1,114,422,000	\$1,145,790,000	\$1,109,099,000
Rescission				\$19,720,000
2009	\$1,056,797,000	\$1,255,420,000	\$1,275,281,000	\$1,246,864,000
Rescission				\$0
Supplemental				\$2,636,000
2010	\$1,182,777,000	\$1,168,704,000	\$1,182,777,000	\$1,177,020,000
Rescission				\$0
2011	\$1,220,478,000		\$1,268,580,000	\$1,177,300,000
Rescission				\$10,337,395
2012	\$1,298,412,000	\$1,198,412,000	\$1,439,064,000	\$1,461,880,000
Rescission				\$2,762,953
2013	\$1,429,161,000		\$1,431,341,000	\$1,528,181,000
Rescission				\$3,056,362
Sequestration				(\$76,704,177)
2014	\$1,473,398,000		\$1,463,606,000	\$1,400,134,000
Rescission				\$0
2015	\$1,451,786,000		\$1,413,734,000	\$1,413,734,000
Rescission				\$0
2016	\$1,442,628,000	\$1,552,326,000	\$1,523,537,000	\$1,571,200,000
Rescission				\$0
2017*	\$1,716,200,000			

\* Includes mandatory financing.

## 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:

	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
BA	\$1,413,734,000	\$1,571,200,000	\$1,716,200,000	+\$145,000,000
FTEs	673	679	679	0

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

### Director's Overview

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

The Office of Extramural Research (OER) provides overarching leadership, oversight, and the electronic system to review, administer, and manage NIH extramural research, training, and career development programs.<sup>2</sup> In FY 2015, extramural investments accounted for approximately 81 percent of NIH's budget, and provided funds supporting a scientific workforce of over 300,000 research positions, at over 2,300 institutions worldwide. OER serves as the interface between NIH and the extramural research community and guides institutions and investigators through the NIH processes for application, review, and funding. OER ensures that NIH extramural policies are developed and administered effectively, transparently, and ethically and works in close partnership with the NIH ICs to be accountable for the substantial investment in extramural research. For example, to increase transparency and promote effective use of resources, NIH began reporting the amount of indirect costs paid per grant on its Research Portfolio Online Reporting Tools website.

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

<sup>2</sup> <http://grants.nih.gov/grants/oer.htm>

The Office of Intramural Research (OIR) provides leadership in the development and coordination of NIH Intramural Research Program (IRP) policies to assure that it: 1) achieves a healthy balance between investigator-driven and collaborative team science in a collegial culture that accommodates world-class basic, translational, population-based, and clinical research; 2) has rigorous scientific review of intramural research by outside scientific experts; 3) hires a diverse workforce of outstanding scientists capable of performing independent research; 4) conducts research integrity training; 5) encourages the sharing of resources in the interest of efficient operations; and 6) fosters collaborations across NIH and with outside organizations.<sup>3</sup> Pursuant to these responsibilities, OIR oversees five main offices: Office of Animal Care and Use (OACU); Office of Human Subjects Research Protections (OHSRP); Office of Intramural Training and Education (OITE); Office of Technology Transfer (OTT); and an Office of Communications, which now supervises the Office of NIH History.

OACU manages IRP's Animal Welfare Assurance and related programs in compliance with multiple laws, regulations, and policies for 23 NIH ICs that use animals in their research. OHSRP, through its Human Research Protections Program, protects the rights and safeguards the welfare of human subjects who participate in NIH intramural clinical trials across 23 NIH ICs, 12 Institutional Review Boards (IRBs), the NIH Clinical Center, and the researchers and staff who conduct research involving human subjects. OITE enhances the training experience of the approximately 6,500 students and fellows on all of the NIH campuses and helps them to develop the scientific and professional skills that will enable them to pursue careers in biomedical research community. OTT oversees patenting, licensing, and royalty administration for inventions from NIH, the FDA, and the CDC intramural scientists. In FY 2014, this office executed 222 licenses, administered \$138 million in royalties, filed 358 U.S. patent applications, added 197 issued U.S. patents to the NIH and FDA intellectual property portfolios, and coordinated 77 new Cooperative Research and Development Agreements.

The Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) fulfills requirements of the NIH Reform Act of 2006 by bringing under one administrative home many aspects of trans-NIH program planning and implementation as well as other cross-cutting NIH-wide functions. This includes identifying and reporting on research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between two or more NIH ICs, or would benefit from strategic coordination and planning. The Division also serves as a resource for portfolio analysis and coordinates program evaluation and performance management activities across NIH. DPCPSI is composed of six program offices: Office of Strategic Coordination; Office of AIDS Research; Office of Research on Women's Health; Office of Behavioral and Social Sciences Research; Office of Disease Prevention; and Office of Research Infrastructure Programs.

The Office of Science Policy (OSP) helps advance biomedical research through sound and comprehensive science policy coordination and development on high-priority and cross-cutting issues of significance to NIH and the biomedical research community including areas such as

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<sup>3</sup> <https://oir.nih.gov/sourcebook%20-%20OIR>

basic and clinical research involving recombinant DNA, genomic technologies and genomic data sharing, biosecurity, clinical and translational research, and human subjects protections.<sup>4</sup> OSP focuses on the intersection of science and society and addresses the scientific, clinical, ethical, and societal implications of research advances. OSP prepares analyses and reports for the public and in fulfillment of certain Congressional reporting requirements.

The Office of Communications and Public Liaison (OCPL), is the communications headquarters for NIH and NIH ICs.<sup>5</sup> OCPL leads strategic communications planning for NIH; responds to thousands of media requests every year (more than 4,500 in 2014); and distributes more than 230 news releases annually to hundreds of media outlets worldwide; manages the NIH home page; coordinates communications among NIH ICs and with HHS; assists with NIH Director's communications including the NIH Director's Blog manages the NIH Freedom of Information Act program; provides tours; organizes special events; and provides science-based health information via print, television, and web-based formats.<sup>6,7</sup> NIH produces two regular resources for community health, public health, and science outlets – *NIH News in Health and Research Matters*. OCPL reaches out daily to the general public, scientific community, medical profession, and public and patient advocacy groups. To more effectively maintain this multi-pronged communication effort, OCPL has increased its social media presence through a portal for more than 250 social media sites and works to increase public input and perspective on NIH programs and activities. OCPL is responsible for collaborating across NIH to deal with controversial and complex issues related to funding, new initiatives, budget, animals in research, clinical research, and, in FY 2015, new disease threats including Ebola and enterovirus. NIH's OCPL continues to lead a trans-NIH initiative to improve access to information about clinical research opportunities by working across NIH with Clinical Research Trials and You.<sup>8</sup> In FY 2015, the Office increased resources on the first ever central location for research registries across NIH. OCPL facilitates interviews from NIH's remote actuality studio OCPL on breaking science and health news to give access to the country, saving time and resources and also conducted more than 120 interviews with "young" NIH researchers for a video profile series aimed at encouraging more people to pursue careers in the sciences.

The Office of Legislative Policy and Analysis (OLPA) is the principal congressional liaison for NIH. OLPA provides timely and accurate legislative analysis, insight, and guidance to the Director in support of NIH's mission and the legislative implementation of the Director's vision for NIH. OLPA prepares the NIH Director, Deputy Directors, and other senior NIH staff, and NIH IC Directors for congressional hearings, briefings, and other substantive meetings by monitoring and analyzing pending legislation. OLPA facilitates the strong relationship between NIH and Congress by briefing members of Congress and their staff on NIH priorities and programs, and coordinating congressional interactions with NIH.

The Office of the Associate Director for Data Science (ADDS) leads the development of the overall NIH vision in Data Science and coordinates across the 27 Institutes and Centers in

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<sup>4</sup> <http://osp.od.nih.gov/>

<sup>5</sup> <http://www.nih.gov/icd/od/ocpl/index.html>

<sup>6</sup> <http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison>

<sup>7</sup> [directorsblog.nih.gov](http://directorsblog.nih.gov)

<sup>8</sup> [www.nih.gov/health/clinicaltrials](http://www.nih.gov/health/clinicaltrials)

support of biomedical research as a digital enterprise. In FYs 2014-2016, NIH issued funding announcements aimed at developing, optimizing, and disseminating technologies for biomedical computing, informatics, and big data science, bringing together experts in disparate fields to build solutions to the challenges posed by large biomedical datasets. The Big Data to Knowledge (BD2K) program seeks to promote open science and data sharing by making biomedical big data and tools more findable, accessible, interoperable, and reusable.

The Chief Officer for Scientific Workforce Diversity (COSWD) leads NIH's effort to diversify the national scientific workforce and expand recruitment and retention. COSWD aims to be a model for capturing the diverse talent into biomedical research across our nation through research innovations and data-driven interventions in diversity inclusion policies, processes, and programs.

The Office of the Chief Information Officer (OCIO) provides trans-NIH leadership of investments in information technology capabilities that support world class research and the day to day administrative and management functions that support and advance the NIH mission. OCIO seeks to maximize opportunities to leverage technologies that enable today's scientific advances.

The Office of Management (OM) advises the NIH Director and Deputy Director on all phases of NIH-wide administration and management; ensures compliance with legislative and external policy mandates; provides direction for strategic planning to meet administrative goals; and oversees the enterprise system for all NIH business transactions. OM provides leadership and oversight for diverse areas such as budget and finance; human resources; management assessment, policy, and program integrity; contracts, procurement, and logistics; engineering services and facility management; security operations (police and fire); and a wide range of support services such as lab and radiation safety, ID cards, events management, the NIH library, medical illustration, and others.

### **Program Description and Accomplishments**

**Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI):** The Division serves as a portfolio analysis and research resource for the ICs and the OD through the Office of Portfolio Analysis (OPA). OPA focuses on accurate quantitative assessment of the NIH portfolio and improvement of portfolio analysis methodology by developing and disseminating computational tools and best practices.<sup>9</sup> OPA also offers training courses and consultations to all NIH staff. Collectively, these activities enhance the impact of NIH-supported research by enabling NIH research administrators and decision-makers to evaluate and prioritize current, as well as emerging, areas of research that will advance scientific knowledge and improve human health. New computational tools being designed and tested by OPA include: data retrieval and database services to analyze information about biomedical research funding and associated scientific collaborations and publication records; advanced data mining and knowledge discovery techniques to link people, funding, and research outputs across disparate data sets; innovative methods to facilitate the content analysis of grant applications,

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<sup>9</sup> <https://dpcpsi.nih.gov/opa/index>

publications, and patents; tracking bench-to-bedside clinical advances, thereby linking basic research discoveries to direct impact on human health; mapping knowledge/technology transfer; measuring the dissemination of biomedical knowledge as new publications are added to the literature; and tracking bibliometric information to assess productivity, impact, and influence. The latter includes a powerful web-based tool, *iCite*, which has been released to the public and allows the calculation of Relative Citation Ratios (RCRs) for any analysis group, which can consist of a single publication or a very large collection of publications.<sup>10</sup> A pre-print describing the development of the RCR method (deposited on BioRxiv:) is already being recognized as an important new way to track biomedical scientists' influence on their respective fields (see the American Society for Cell Biology blog). DPCPSI also coordinates reporting on completed evaluation studies and performance reporting under the Government Performance and Results Modernization Act.<sup>11,12</sup>

In FY 2016, two new offices were established in DPCPSI: the Sexual and Gender Minority Research Office (SGMRO) and the Tribal Health Research Office (THRO). SGMRO coordinates sexual and gender minority (SGM) health research activities across NIH; represents NIH at meetings and on groups focused on SGM research; coordinates workshops to inform planning activities; manages information dissemination related to SGM research; and works with ICs to leverage resources or develop initiatives to support SGM health research. The SGMRO is coordinating implementation of the NIH FY 2016-2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities.<sup>13</sup> THRO coordinates tribal health research-related activities across NIH; represents the Agency on tribal health-related committees; coordinates and facilitates the NIH Tribal Consultation Advisory Committee and other tribal consultation activities; organizes manages information dissemination related to tribal health research coordination; and works with NIH ICs to leverage resources or develop initiatives to support tribal health research.

#### Budget Policy:

The FY 2017 President's Budget estimate for the DPCPSI Director's office is \$13.275 million, the same as the FY 2016 Enacted level. In FY 2016, DPCPSI began serving as the NIH focal point for coordinating research related to Sexual and Gender Minorities (SGM) and Tribal Health. The Division will work with the ICs and engage extramural stakeholders and partner with the NIH intramural and extramural research communities in maximize the impact of SGM and Tribal Health focused research efforts. In FY 2017, DPCPSI will continue to coordinate trans-NIH research opportunities through the Common Fund and its Program Offices for research on HIV/AIDS, Women's Health, Behavioral and Social Sciences Disease Prevention, Dietary Supplements, and Infrastructure Resources. In addition, the Division will continue its portfolio analysis efforts aimed at optimizing future research investments by the ICs and in support of the overall effort to help ensure that the NIH research portfolio is balanced, free of unnecessary duplication, identifies emerging scientific opportunities, and takes advantage of collaborative, cross-cutting research.

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<sup>10</sup> <https://iCite.od.nih.gov>

<sup>11</sup> <http://biorxiv.org/content/early/2015/10/22/029629>

<sup>12</sup> <http://www.ascb.org/nature-of-scientific-impact/>

<sup>13</sup> <http://edi.nih.gov/sgm/research/sgm-strategic-plan.pdf>



**Common Fund (CF)/Office of Strategic Coordination (OSC):** CF supports the biomedical community by providing enabling technologies, databases, and programs; developing essential tools and methodologies; and fostering innovation through high risk/high reward programs.<sup>14</sup> CF programs tackle major challenges in biomedical research that affect many diseases or conditions or that broadly relate to human health. Collectively, CF programs address challenges and opportunities that have been identified as high priorities for the scientific research community and NIH as a whole. These programs are described in detail in the Common Fund portion of this document.

OSC oversees the management of CF, working with trans-NIH teams for each of the more than 25 CF programs.<sup>15</sup> These teams ensure that each program meets the criteria of CF programs to synergize with IC-funded research. OSC provides input to these groups to reflect guidance from the NIH and DPCPSI Directors and to maintain goal-driven management practices. As CF programs mature and transition out of CF, evaluations to determine program outcomes are conducted. Program outcome evaluations, along with additional assessments conducted throughout the lifetime of the programs, are expected to deliver lessons learned concerning trans-NIH program management in addition to information concerning the scientific products and utility of the programs to date. Communication and outreach is an important component of all the CF programs, as the products and data generated by each program become ready for dissemination to the community-at-large.

#### Budget Policy:

The FY 2017 President's Budget request for the Common Fund is \$775.639 million, \$100.000 million or 14.8 percent compared to the FY 2016 Enacted level. This increase is attributed entirely to planned increases to the Precision Medicine Initiative – Cohort Program. This request also includes funds for the Gabriella Miller Kids First Research Program.

With this budget level, funds for new programs are limited for FY 2017. In order to continue to support the Human Health and Heredity in Africa Program and the Illuminating the Druggable Genome Program, the Molecular Transducers of Physical Activity in Humans Program will be deferred; the lower costs that have been planned for FY 2016 will now occur in FY 2017. Strategic Planning efforts have led to one potential new Common Fund program that is currently under development for a start in FY 2017, but may be delayed pending funds availability: Enabling the Exploration of the Eukaryotic Epitranscriptome (E4), which will pilot the development of tools and reagents for the research community to study the emerging field of RNA modifications. For additional details, please see the Common Fund section.

**Office of AIDS Research (OAR):** OAR serves a critical role in coordinating and managing the comprehensive trans-NIH AIDS research program encompassing all areas of biomedical, behavioral, and social sciences research on HIV/AIDS and its associated coinfections, comorbidities, and other complications.<sup>16</sup> OAR plans, coordinates, evaluates, and manages the budget for the trans-NIH HIV/AIDS research program. All of the NIH ICs support HIV/AIDS

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<sup>14</sup> <https://commonfund.nih.gov/>

<sup>15</sup> <http://dpcpsi.nih.gov/osc/>

<sup>16</sup> <http://www.oar.nih.gov/>

research. The significant scientific accomplishments and advances in the development of safe and efficacious treatment regimens, successful prevention interventions, and strategies to halt the further spread of the AIDS pandemic have resulted from the comprehensive and coordinated NIH HIV/AIDS research program. Utilizing its legislative authorities, OAR has implemented new trans-NIH planning, portfolio analysis, and budgeting processes to ensure that AIDS dollars are supporting the overarching HIV/AIDS research priorities. OAR is authorized to develop an annual trans-NIH Strategic Plan and develop and allocate the trans-NIH AIDS research budget, which is linked directly to the Strategic Plan. OAR uses its legislative authorities to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that HIV/AIDS research dollars are invested effectively and efficiently. OAR also identifies specific funding for emerging scientific opportunities in HIV/AIDS research and public health needs; manages and facilitates multi-IC and trans-NIH activities to address those needs; stimulates research by designating funds to support pilot program areas; facilitates international AIDS research and training; and sponsors scientific agenda setting workshops to identify new cutting-edge initiatives. The Trans-NIH AIDS Research Budget appears in the Overview section of this document.

#### Budget Policy:

The FY 2017 budget estimate for OAR is \$62.256 million, the same as the FY 2016 Enacted level. OAR will utilize its funds to support initiatives that address the highest scientific priorities based on the OAR Advisory Council Priority-Setting Working Group; the Trans-NIH Plan for HIV-Related Research; and NIH leadership. OAR is providing additional redirected funds to the ICs for new research initiatives to address the overarching AIDS research priorities including: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines; 2) development of the next generation of HIV therapies with increased safety and ease of use; 3) research toward a cure for HIV/AIDS; and 4) prevention and treatment of HIV coinfections and comorbidities. Cross cutting these priorities is basic research, health disparities, and training. OAR will continue its core support for the District of Columbia Partnership for HIV/AIDS Progress. OAR also will facilitate innovative bilateral initiatives for research, infrastructure development, and research training in Africa, the Caribbean, India, China, Brazil, and Russia. OAR will support the HIV Treatment Guidelines Working Groups, including government and non-government experts, who develop the HHS standards for treatment of HIV disease and its associated co-morbidities and coinfections in adults, pregnant women, adolescents, and children. OAR will convene outside expert panels who provide advice and guidance to OAR and the ICs regarding emerging research opportunities. OAR will support initiatives to enhance dissemination of research findings and the HHS treatment guidelines and clinical trial information to the scientific community, healthcare providers, and communities at risk through *AIDSinfo*, a web-based service available at: [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov). OAR will also use its funds to support IC initiatives in the highest priority areas for trans-NIH AIDS research, which are outlined in the trans-NIH AIDS research budget in the Overview section of this document.

**Office of Research on Women's Health (ORWH):** The mission of ORWH is to advance and expand research on women's health and increase the consideration of sex and gender factors in health and disease, to ensure the inclusion of women in NIH clinical research, and to promote the

career development of women in biomedical research.<sup>17</sup> ORWH coordinates these activities through partnerships with the NIH ICs to ensure that the women's health and sex/gender perspectives are incorporated into the broad NIH scientific framework. ORWH activities are guided by the 2010 NIH Strategic Plan for Women's Health Research.<sup>18</sup> This strategic plan outlines six goals to maximize the impact of NIH research efforts: 1) Increase sex differences research in basic science; 2) Consider sex/gender differences in the development and delivery of new technologies, devices, and therapeutics; 3) Actualize personalized prevention, diagnostics, and therapeutics for girls and women; 4) Create strategic partnerships, domestically and globally; 5) Fully utilize new communication and social networking technologies; and 6) Increase diversity in the research workforce. These comprehensive goals support the NIH Director's themes in emphasizing basic research for scientific discovery and health applications, highlighting sex as a fundamental individual characteristic in precision medicine, supporting research that is reproducible, robust and transparent to increase scientific gain and public trust, and supporting a diverse biomedical research workforce. ORWH programs and initiatives amplify and accelerate study of both sexes in research through collaborative efforts that leverage existing resources, thereby expanding the knowledge base for women's health.

**Program Portrait: Administrative Supplements for Research on Sex/Gender Differences**

FY 2016 Level: \$5 million

FY 2017 Level: \$5 million

Change: \$0 million

A landmark Institute of Medicine report Exploring the Biological Contributions to Human Health asserted that biological sex, assigned by chromosomal complement (XX,XY) and defined by reproductive organs and functions, is a fundamental variable that merits consideration in study design and analysis of results in "all areas and at all levels of biomedical and health related research."<sup>19</sup> To support scientists in taking a deliberate approach in considering sex in preclinical research, ORWH developed a program to catalyze exploratory research on sex and gender differences by providing administrative supplements to ongoing NIH-funded research. This approach serves to increase awareness of the need to study both sexes, to demonstrate how research can incorporate sex as a biological variable, and to reinforce the value of taking sex into account as these studies yield results. The projects funded through this mechanism span a wide array of science, including basic immunology, cardiovascular physiology, neural circuitry, and behavioral health. The projects will contribute to the body of sex- and gender-based knowledge, and can improve human health by adding one of the following elements to the original project:

- Addition of animals, tissues, or cells of the opposite sex to allow sex-based comparisons;
- Addition of more subjects of either sex to a sample that already includes both males and females to allow analysis for a sex/gender difference; and
- Analysis of existing datasets containing information from males and females.

Most NIH ICs have funded supplements since the program began in 2013. The expected results of this program will be the cost-effective, value-added expansions of meritorious research projects that will advance the understanding of the role of sex differences in preclinical research and the downstream implications for a variety of diseases and conditions, with the added potential to apply knowledge so derived to the development of more personalized therapeutics.

<sup>17</sup> <http://orwh.od.nih.gov/>

<sup>18</sup> <http://orwh.od.nih.gov/research/strategicplan/index.asp>

<sup>19</sup> <http://www.iom.edu/Reports/2001/Exploring-the-Biological-Contributions-to-Human-Health-Does-Sex-Matter.aspx>

### Budget Policy:

The FY 2017 President's Budget estimate for ORWH is \$42.023 million, the same as the FY 2016 Enacted level. The Office of Research on Women's Health (ORWH), in partnership with NIH IC, will implement the NIH strategic plan, *Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research*, by: 1) providing support to expand consideration of sex/gender factors in basic, biomedical, and behavioral science studies through ORWH research initiatives, policy initiatives, programs and co-funding, and with additional priority in 2017, to the BRAIN Initiative; 2) facilitating the translation of basic science findings to clinical research and to clinical practice through ORWH programs such as the Specialized Centers of Research on Sex Differences; 3) maximizing the domestic and global impact of women's health research through alliances with Federal government programs charged with prevention and policy in areas of public health significance such as violence against women and the intersection of violence and HIV/AIDS; and 4) developing innovative career development models, such as the Building Interdisciplinary Research Careers in Women's Health program to ensure the continued supply of scientists with the skills necessary to be productive in emerging multidisciplinary fields of women's health research.

**Office of Behavioral and Social Sciences Research (OBSSR):** OBSSR furthers the mission of NIH by emphasizing the critical role that behavioral and social factors play in health, health care and well-being.<sup>20</sup> OBSSR coordinates behavioral and social sciences research (BSSR) across NIH and serves as a liaison between NIH, extramural research communities, other Federal agencies, academic and scientific societies, national voluntary health agencies, and the general public on matters pertaining to BSSR. . Following the appointment of Dr. William Riley in August 2015 as Director of OBSSR, the Office initiated a strategic planning process to guide the Office's activities over the next five years. Specifically, OBSSR's goal in launching this effort is to determine the future directions and activities that will ensure that it continues to fulfill its mission. OBSSR's vision is to bring together the biomedical, behavioral, and social science communities to collaboratively work to solve pressing health challenges facing our Nation. OBSSR's strategic goals include: 1) shaping the next generation of basic behavioral and social science research informed by breakthroughs in complementary areas such as genetics and epigenetics, informatics, computer sciences, measurement, methods, and multilevel analysis; 2) facilitating collaborative research across the full range of disciplines and stakeholders necessary to fully elucidate the complex determinants of health and health systems challenges; 3) stimulating systems-based statistical and computational modeling approaches that integrate multiple levels of analysis required to understand the complex and dynamic interactions of individual, contextual, and organizational factors that influence health status; and 4) working with NIH and other Agency partners to identify key problems in population health where scientists, practitioners, and decision makers can work together to accelerate the translation, implementation, dissemination, and adoption of behavioral and social sciences research.

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<sup>20</sup> <http://obssr.od.nih.gov/index.aspx>

**Program Portrait: Intensive Longitudinal Analysis of Health Behavior: Leveraging New Technologies to Understand Health Risk Behaviors**

FY 2016 Level: \$0.0 million

FY 2017 Level: \$2.0 million

Change: +\$2.0 million

Recent technological and methodological advances provide researchers a potentially new approach to understand the best predictors of health behaviors and how they are related. The advent of ecological momentary assessment (EMA), smartphones, and passive sensor technologies have made it possible to perform intensive longitudinal assessments of individuals. For example, via smartphone sensors alone, we are able to detect location, movement, and the number and duration of social contacts via text or voice. The rapidly developing area of passive sensor technologies allows for the detection of a variety of health risk behaviors such as smoking, sedentary behavior, and sunscreen exposure as well as physiological changes and environmental exposures. Experience sampling approaches provide prospective assessment of intrapersonal constructs that currently cannot be objectively observed or sensed. These recent technological and analytical advances provide the capability to collect temporally dense data, and provide computational methods for detecting patterns from these data.

Current research on the theoretical predictors of health behavior has focused predominantly on evaluating differences between individuals. Theories that guide this research are generally evaluated in a cross-sectional nature, with few contextual variables included in the model. To shift the field towards new, intensive, longitudinal approaches utilizing novel sensor technologies and computational dynamic modeling, a concerted programmatic effort is needed. In FY 2017, OBSSR plans to issue a new Funding Opportunity Announcement to solicit research projects that seek to explain and predict risk behaviors in individuals over time with intensive longitudinal, within-person protocols, which leverage recent advances in mobile and wireless sensor technologies and “big data” analytics. This research area addresses two key NIH initiatives: *Harnessing Data and Technology to Improve Health and Translating Discovery into Health*. A transdisciplinary mobile health (mHealth) approach will generate the advances necessary to enhance health effectively and efficiently. OBSSR will capitalize on broad interest in mHealth within the NIH’s ICs and with other Federal partners for partnering on this new initiative.

**Budget Policy:**

The FY 2017 President’s Budget estimate for OBSSR is \$26.738 million, the same as the FY 2016 Enacted level. In FY 2017, OBSSR will complete a number of program evaluation projects begun in FY 2015 to lay the groundwork for a formal strategic planning process that was initiated in August 2016. These program evaluations include an assessment of the outcomes from the various training programs that the office has supported, the decade long development and support of programs utilizing a Community-Based Participatory Research approach, and a comprehensive analysis of the NIH behavioral and social sciences research (BSSR) portfolio. The goal of the portfolio analysis is to help NIH scientific staff gain insights into research funding patterns and the performance of funded projects, including not only publications, but also a range of additional research performance metrics. This project will evaluate the research and training activities, funding plans, and behavioral and social science related applications and funding patterns within and across the NIH Institutes and Centers (ICs) to assess the state of the health-related behavioral and social sciences research portfolio and to identify the most promising avenues for future investments within the context of the NIH mission. Based on these evaluations and consultations with NIH and outside stakeholders and BSSR experts, OBSSR will develop a new strategic plan to guide the Office’s activities for the next five years.

In FY 2017, OBSSR will continue a number of efforts to advance rigorous behavioral and social sciences research. The office will stimulate the development and adoption of new and innovative

behavioral and social science methodologies and measures via new initiatives, workshops, and trainings. In FY2016 the office initiated an NIH-wide work group on emerging behavioral science intervention designs with the goal of determining what research questions can be pursued using these emerging methodologies. Following the work group efforts, an expert panel of methodologists (from non-NIH HHS agencies and academia) will be convened with the task of producing a compendium of methods that is suitable for dissemination to behavioral and social science researchers targeting health outcomes. The compendium will be developed via contract in FY 2017.

In FY 2017, the office plans to continue collaborations to advance mobile and wireless health research, data harmonization, integration, and the development of a common behavioral ontology to promote data sharing in the behavioral and social sciences. Advances in behavioral and social sciences can be facilitated with greater clarity of terms and definitions of behavioral phenotypes, mechanisms, and intervention strategies, particularly with determining the appropriate granularity of these constructs that are related to the neurobiological processes and environmental influences that interact on behavior.

OBSSR, in collaboration with the Agency for Health Research and Quality, jointly produced a book titled Population Health: Behavioral and Social Science Insights, which addressed current status and future directions for research into the various behavioral and social factors on longevity, disability and illness, and quality of life, primarily at the population level. Factors such as access to health care, educational attainment, nutrition, physical activity, use of tobacco products, and non-communicable diseases are considered, along with many other determinants of health and longevity. In FY2017, OBSSR will release a new funding opportunity announcement (FOA) entitled “Education and Health: New Frontiers.” The primary goal of the FOA is to support research that will further elucidate the pathways involved in the relationship between education and health outcomes, identify the specific aspects and qualities of education that are responsible for this relationship, and determine the mediating factors that influence the robust relationship of education and health and contribute to health disparities.

**Office of Disease Prevention (ODP):** The mission of ODP is to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by NIH.<sup>21</sup> ODP collaborates with other Federal agencies, academic institutions, the private sector, non-governmental organizations, and international organizations in formulating prevention research initiatives. To carry out these diverse responsibilities, the Office of Dietary Supplements is included as an administrative unit within ODP and promotes scientific research in this area. ODP leads the NIH Prevention Research Coordinating Committee (PRCC), which serves as a venue for exchanging information related to recent scientific advances in disease prevention; examining the impact of new policies on research; planning new or discussing on-going initiatives; and highlighting program accomplishments. ODP also provides scientific leadership and oversight for the continued implementation of the NIH-FDA Tobacco Regulatory Science Program which addresses priority areas of the Family Smoking Prevention and Tobacco Control Act including the manufacture, distribution, and marketing of tobacco products.

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<sup>21</sup> <http://prevention.nih.gov/>

ODP activities are guided by its Strategic Plan for FYs 2014–2018, which outlines the priorities that the Office will focus on and highlights our role in advancing prevention research at NIH. For example, ODP is leading new efforts to enhance coordination between the NIH and the U.S. Preventive Services Task Force (USPSTF). ODP is the primary liaison with the USPSTF and works to provide input on draft research plans, evidence reports, and clinical practice recommendations. Improved coordination will ensure that recommendations released by USPSTF are based on the most accurate scientific information. ODP is developing a database that contains the USPSTF Insufficient (“I”) recommendations (where there was not enough evidence and/or the quality was not strong enough to balance the benefits and harms of a health service) which can be used by NIH ICs to help them make decisions during the post peer review process to address gaps in research and further expand knowledge within a given area. Additionally, ODP will continue to work to develop a computer-based system to enable a standardized, automated, rapid, and objective characterization of NIH prevention research funding. Such categorization will enable assessment of the progress and changes in NIH-funded prevention research over time to inform program planning and reporting. ODP is also working to make sure the best available methods in prevention research are utilized to move the state-of-the-science forward. In collaboration with the NIH Center for Scientific Review, ODP is developing strategies for identifying experts in prevention science methods who could serve on NIH study sections. These efforts will strengthen the review panels and improve the quality of the prevention research supported by NIH. Finally, ODP will continue to coordinate the implementation of the Pathways to Prevention program which includes workshops designed to identify research gaps, identify methodological and scientific weaknesses, suggest research needs, and move these fields forward through an unbiased, evidence-based assessment.

#### Budget Policy:

The FY 2017 President’s Budget estimate for ODP is \$9.956 million, the same as the FY 2016 Enacted level. In FY 2017, ODP plans to continue to stimulate disease prevention research across the NIH and to coordinate and collaborate on related activities with other federal agencies as well as the private sector. ODP will work with the NIH ICs and other partners to implement key components of its strategic plan in order to advance disease prevention and health promotion science at the NIH. The ODP does not have research grant authority or funds, but will continue its accomplishments through the PRCC and participating in other disease prevention and health promotion activities associated with the US Preventive Services Task Force, the Community Preventive Services Task Force, Healthy People 2020, and the National Prevention Strategy. In collaboration with its partners, ODP will identify needs in prevention research and disseminate information on emerging areas of scientific opportunity and existing knowledge gaps that merit special emphasis. Additionally, the ODP will collaborate with multiple partners and audiences, including the NIH ICs, service providers, and community organizations, to promote the dissemination of evidence-based disease prevention strategies and interventions with the potential to impact public health.

**Office of Dietary Supplements (ODS):** The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an

enhanced quality of life and health for the U.S. population.<sup>22</sup> Toward this end, ODS co-funds research grants with ICs on dietary supplements and sponsors systematic reviews in relevant areas as well as projects to enhance the incorporation of these reviews into nutrition research. ODS, in collaboration with NCCIH, is funding three new Botanical Dietary Supplements Research Centers and two Centers for Advancing Natural Products Innovation and Technology in the five-year program cycle for 2015-2020. ODS leads and sponsors efforts to advance scientific understanding of the importance of vitamin D to health through the Vitamin D Standardization Program, an international effort conducted in collaboration with the National Institute of Standards and Technology, CDC, and the national health surveys of Australia, Canada, Germany, Ireland, Mexico, South Korea, the United Kingdom, and the United States. Recently, USPSTF determined that there is insufficient evidence to assess the benefits and harms associated with screening pregnant women and infants (6-24 months) for iron deficiency as well as routine iron supplementation for pregnant women. In July 2016, ODS will host a workshop to identify the specific research needs related to these topics. ODS has also developed an iodine initiative in response to concerns that some pregnant women may have inadequate intakes of this nutrient at a time of high physiologic demand. To address this issue, Launched in June 2013, the Dietary Supplement Label Database (DSLDD), a joint project of ODS and the National Library of Medicine (NLM), provides the full label contents from dietary supplement products marketed in the United States which is of value to research scientists and health care providers (see the DSLDD Portrait of a Program).

#### Budget Policy:

The FY 2017 President's Budget estimate for ODS is \$25.297 million, the same as the FY 2016 Enacted level. In addition to co-funding research grants on dietary supplements, this budget will support a number of major activities including the congressionally mandated Dietary Supplement Label Database (DSLDD), a database of label information from dietary supplements sold in the United States (see Portrait of a Program: Dietary Supplement Label Database). ODS will continue to support its Analytical Methods and Reference Materials (AMRM) program, also congressionally mandated, in the development, validation, and dissemination of analytical methods and reference materials that are critical tools for quality assurance of dietary supplements. ODS leads efforts to advance knowledge of vitamin D's importance to health and to accurately measure levels of this nutrient in the U.S. population through its Vitamin D Initiative. In 2017, the model used for this initiative may be applied to other nutrients of public health concern such as iron. ODS, in partnership with NCCIH, will continue to support the NIH Botanical Research Centers (BRC) in 2017.

**Office of Research Infrastructure Programs (ORIP):** ORIP advances the NIH mission by making grant awards that support research infrastructure and research-related resources programs, and coordinating NIH's science education efforts.<sup>23</sup> Specifically ORIP: 1) awards grants to support research resources such as animal models of human disease and state of the art biomedical instrumentation; 2) plans, organizes, and conducts workshops, both independently and in collaboration with NIH ICs, to identify and pursue scientific opportunities; 3) supports research-training opportunities for veterinary scientists that capitalize on their distinct

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<sup>22</sup> <http://ods.od.nih.gov/>

<sup>23</sup> <http://dpcpsi.nih.gov/orip/index>



perspective and expertise based in a deep understanding of comparative medicine and insight into animal models of human disease; and 4) supports strategies that bring high quality science, technology, engineering, and mathematics (STEM) educational opportunities for pre-kindergarten to grade 12 (P-12) students with an emphasis on underserved communities to diversify the next generation of biomedical scientists. ORIP is comprised of the Division of Comparative Medicine, the Division of Construction and Instruments, and the Office of Science Education.

**Division of Comparative Medicine (DCM):** DCM provides critical resources for scientists using animal models for basic and biomedical research and supports the development of specialized technologies involving human disease models.<sup>24</sup> There are many complex diseases that must be studied in living organisms leading researchers to develop animal models that provide knowledge about the biological and behavioral mechanisms, causes of disease onset and progression, risk factors, biological markers for diagnosis, and new interventions. The specialized animal colonies, technologies, and training funded by DCM enable the discoveries that improve human health. In fact, virtually every major medical advance of the last century involved the use of animal models. Because it would neither be cost effective nor feasible to reproduce these specialized animal resources and expertise at every research institution, these DCM programs are a valuable resource to the entire research community.

DCM also funds research to safeguard the health and welfare of laboratory animals. The research resources funded by DCM cover the full range of animal models, from invertebrates to mammals. Non-mammalian models such as fish, worms, and fruit flies are often used to advance the understanding of gene function, protein interactions, and metabolic processes related to human health and disease. Genetically-altered mammals such as mice, rats, and pigs enable the discovery of molecular targets and biomarkers (indicators of biological condition) that are both valuable for pre-clinical testing and as potential therapeutic targets for human diseases. In 2015, DCM supported pilot centers for precision disease modeling. These pilot centers have begun establishing demonstration pipelines for scientific discovery, disease modeling and development of new cures and preventative treatments based on innovative animal models, which eventually will be integrated into better diagnostics, care and therapeutic treatment of human patients.

Increasing the number of veterinarians ready to contribute to translational research is a priority for DCM as well-trained veterinarians are key contributors to the success of all animal-based research. DCM funds career development programs that attract veterinarians in such specialties as comparative and laboratory animal medicine and pathology. DCM also provides opportunities in translational science for developing the careers of biomedical researchers who have degrees in veterinary medicine. These programs enhance the value of translational research teams when veterinarians join with other scientists and physicians, thus strengthening and sustaining the biomedical workforce.

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<sup>24</sup> <http://dpcpsi.nih.gov/orip/CM/index>

**Program Portrait: One Health: Integrating the Veterinarian-Scientist into the Biomedical Research Enterprise**

FY 2016 Level: \$0 million

FY 2017 Level: \$2 million

Change: +\$2 million

One Health is the integrative effort of multiple disciplines working together to attain optimal health for humans, animals and the environment. Veterinarian-scientists, biomedical scientists with a veterinary degree, are integral to application of One Health concepts to interdisciplinary research projects. Veterinarian-scientists, based on their training and knowledge of animal diseases and physiology, have made key research findings and have identified many animal models that inform pre-clinical studies. These scientists are trained to compare and evaluate different animal models of human disease and to provide a distinct perspective of use to multidisciplinary biomedical research teams. Because of their comparative approach and specialized training in laboratory animal medicine, pathology and zoonotic infections, veterinarian-scientists are key players in an integrated, multidisciplinary approach to biomedical research, as exemplified by the concept of One Health.

DCM proposes a new initiative that will facilitate participation in interdisciplinary teams and career advancement for veterinarian-scientists utilizing the One Health perspective. The overall goal of the program will be to fund research that will link the veterinarian-scientist to interdisciplinary teams, aid veterinarian-scientists in attaining independent research careers, and further promote their integration into multidisciplinary biomedical research teams. This initiative is the result of presentations and discussions of veterinarian-scientists, translational researchers and clinical experts at a workshop convened by DCM in 2015.

New areas of emphasis in FY 2017 will include: 1) developing new “precision animal models” to address the unique requirements of individual patients or groups of patients; 2) revitalizing veterinarian-scientist, a subset of clinician-scientist, training to further strengthen and sustain the biomedical workforce; and 3) enhancing rigor and transparency in disease models through consideration of biological variables such as the sex of research animals and cultured cells as well as environmental factors such as the “microbiome” (the community of microorganisms living on, and inside, humans and animals).

DCM supports the National Primate Research Centers (NPRCs), which facilitate the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research. NPRCs, which house approximately 23,000 NHPs, provide animals for research, and expertise in all aspects of NHP biology and husbandry to biomedical researchers nationwide. In FY 2015, NPRCs facilitated more than 1,000 individual research projects involving approximately 1,500 researchers. Major areas of research benefiting from the resources of NPRCs include: vaccine development for a number of infectious agents, Parkinson’s disease, diabetes, asthma, and women’s health. Research supported by NPRCs in FY 2015 included significant advances in vaccine development for tuberculosis and various viral agents, HIV/AIDS, and regenerative medicine. Researchers using NPRC resources developed a novel aerosol-based vaccine for tuberculosis that is a promising candidate to replace the current vaccine, which is only marginally effective in humans, particularly in areas with a high burden of the disease. Other researchers developed novel vaccines against west Nile virus, Ebola virus and congenital cytomegalovirus. In the field of HIV/AIDS research, investigators developed a positron emission tomography scan system for visualizing the dynamics of HIV infection in the whole animal. This system will allow detailed analysis of viral reservoirs remaining after treatment with antivirals, essential for understanding the “cure” of HIV infection in humans. Lastly, in the area of regenerative medicine, researchers demonstrated that neurons derived in

vitro from induced pluripotent stem cells can improve motor function when injected into Parkinsonian monkeys, suggesting the utility of stem-cell based approaches for the treatment of Parkinson's disease in humans.

**Division of Construction and Instruments (DCI):** DCI supports programs that improve and expand the Nation's capacity to conduct biomedical research by funding grants for the acquisition of expensive state-of the-art instrumentation and to modernize existing animal research facilities, or to construct new research facilities, when funds are available.<sup>25</sup>

The Shared Instrumentation (SIG) and the High-End Instrumentation (HEI) Grant Programs (Instrumentation Programs) promote advances in biomedical research that would be impossible without access to the appropriate tools and instruments. New and improved technologies emerge continuously, so that the research instrumentation infrastructure requires regular updating to permit NIH-supported investigators to continue the discovery process. DCI's Instrumentation Programs are unique among the NIH grant programs in that they give groups of NIH-funded investigators the funds needed to purchase and share cutting-edge instruments. These instruments are typically too expensive for an individual investigator to acquire. In addition, certain modern technologies are so complex and demand such special technical skills to operate that it actually takes a team of experts to fully realize the potential of the instrument. Each new generation of instrumentation technologies accelerates NIH research programs across a broad array of basic, translational, and clinical investigations. The Instrumentation Programs provide funds for a wide array of instruments able to conduct investigations at the level of molecules, organelles, cells, organs, and whole organisms as well as to enable such investigations and to analyze their results. For example, certain new microscopes have the capability to take fast and accurate measurements at near atomic levels; multi-modal light microscopes can measure several molecular processes simultaneously; and multi-modality brain scanners can capture the localization of metabolites and neuronal activation, and then superimpose these measurements over measurements of anatomical structures. Such instruments can generate very large volumes of data so that computer clusters are required to collect, store, and process these data to extract the meaningful relationship.

The Instrumentation Programs address critical needs across all disciplines and all NIH ICs. The instruments funded by these programs advance biomedical research by allowing investigators to conduct studies not previously possible. The fact that the programs require sharing of the instrument among multiple research projects assures a higher return on the initial investment. In FY 2015, the Instrumentation Programs funded 120 grants at academic and research institutions coast-to-coast and supported more than 1,000 NIH research projects, which collectively represent the majority of NIH ICs.

The Extramural Research Facilities Improvement Program provides support to institutions for the modernization of laboratory animal facilities to enhance animal care and assist institutions in complying with regulations related to the care and use of laboratory animals. The program focuses on improvements, renovations, and equipment upgrades. These improvements enable more accurate monitoring and control of conditions in animal facilities, as well as improving

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<sup>25</sup> <http://dpcpsi.nih.gov/orip/diic/index>

animal handling and general animal welfare. In addition, these improvements result in increased security and minimize exposure of research personnel to animal allergens or infectious agents. Equipment upgrades can also improve the efficiency of animal facilities. When Congress makes funds available, the extramural construction program supports new buildings and laboratory space for NIH-funded research. Such newly constructed facilities for biomedical or behavioral research purposes must be utilized for 10 or 20 years following completion and occupancy.

ORIP's DCI plans to continue to expand the Nation's capacity for the conduct of biomedical research. Specifically, DCI programs provide funding for SIG and HEI grants to NIH-supported investigators that increase the quality of their funded programs and accelerate a broad array of basic, translational, and clinical research. Further, DCI programs provide support for renovations or improvement of laboratory animal facilities to enhance animal care and insure success of animal-based biomedical research programs.

**NIH Chimpanzee Management Program (ChiMP):** ChiMP supports long-term, cost-effective housing and maintenance at NIH-supported facilities for chimpanzees.<sup>26</sup> ORIP provides programmatic oversight of the facilities and ensures they comply with the Animal Welfare Act, PHS policies concerning laboratory animal care and use, and the new chimpanzee research policies implemented by NIH and found in NOT-OD-15-097.<sup>27</sup> The Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act) (section 404K of the Public Health Service Act), signed into law in December 2000, required the establishment of a national sanctuary system for federally-owned or supported chimpanzees that were no longer needed for research.<sup>28</sup> In 2013, the CHIMP Act Amendments were introduced "to enable the National Institutes of Health to operate more efficiently and economically by decreasing the overall Federal cost of providing for the care, maintenance, and transportation of chimpanzees."<sup>29</sup> These amendments have allowed NIH to continue providing for high quality lifetime care of chimpanzees that it currently owns or supports at both research and sanctuary facilities. The same amendments also required two separate reports to Congress. In 2014, NIH provided a detailed "current status" report on the state of the NIH Chimpanzee Management Plan to Congress. In 2015, NIH worked closely with the Government Accountability Office as they developed a report on the research status and costs of the NIH-owned chimpanzee population and supported facilities.

**Science Education Partnership Award (SEPA) Program:** SEPA supports NIH's mission to enhance health, lengthen life, and reduce illness and disability as well as supporting the early pipeline for workforce development.<sup>30</sup> SEPA's P-12 Science, Technology, Engineering, and Mathematics (STEM) education projects provide information and resources pertaining to health-related career opportunities for students and teachers in minority, underserved, and rural communities. SEPA will continue Small Business Innovation Research and Small Business Technology Transfer (SBIR and STTR) funding for Serious STEM Games for learning and behavioral change. In FY 2017, SEPA will continue to be coordinated with the CoSTEM P-12

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<sup>26</sup> [http://dpcpsi.nih.gov/orip/cm/chimpanzee\\_management\\_program](http://dpcpsi.nih.gov/orip/cm/chimpanzee_management_program)

<sup>27</sup> <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-097.html>

<sup>28</sup> <http://www.gpo.gov/fdsys/pkg/PLAW-106publ551/html/PLAW-106publ551.htm>

<sup>29</sup> <http://www.gpo.gov/fdsys/pkg/BILLS-113s1561is/html/BILLS-113s1561is.htm>

<sup>30</sup> [https://dpcpsi.nih.gov/orip/ose/sepa/science\\_education\\_partnership\\_awards\\_index](https://dpcpsi.nih.gov/orip/ose/sepa/science_education_partnership_awards_index)

Implementation Working Group to ensure that program activities and products are aligned with ongoing P-12 reform efforts. SEPA provides a unique funding source at the NIH for health-related informal science education exhibits at science centers and museums. These interactive exhibits and other outreach activities educate the community on the relationship between lifestyle and health. Through these community health literacy activities SEPA supports NIH's role in improving the health of the Nation. Many SEPA grantees have partnered with their State's Institutional Development Award (IDeA) programs so that students "graduate" from SEPA activities to fill the undergraduate pipeline at IDeA institutions, thereby contributing to the NIH workforce diversity efforts.

SEPA requires individual projects to conduct rigorous evaluation to measure effectiveness. Classroom-based projects must employ randomized control trials or well-matched case comparison evaluation tools. Evaluation data are then used to modify SEPA program goals and to identify SEPA projects that can be replicated at other sites.

ORIP's SEPA Program will continue to be funded at \$18.541 million in FY 2017 to continue to improve life science literacy throughout the Nation through innovative educational programs. SEPA-supported projects create partnerships among biomedical and clinical researchers and P-12 teachers and schools, museums and science centers, media experts, and other educational organizations.

#### Budget Policy:

The FY 2017 President's Budget estimate for ORIP is \$277.395 million, the same as the FY 2016 Enacted level. The ORIP programs provide support for research and research infrastructure needs, including animal research models and biological materials; training and career development for veterinarian scientists; acquisition of state-of-the-art and shared instrumentation; grants to expand or renovate existing research facilities or construct new research facilities; and support for science education programs to attract young people into biomedical and behavioral science careers and to enhance science literacy.

ORIP's DCM will continue to interact with NIH partners and the scientific community to maintain scientific priorities that best meet the broad needs of the multidisciplinary biomedical research continuum. DCM programs will include, but are not limited to: (1) the NPRCs program with the goal to facilitate the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research; (2) the MMRRC (Mutant Mouse Resource and Research Center) and other Resources for genetically-altered mammals such as rats and pigs; (3) non-mammalian models such as fish, worms, and fruit flies which are used to advance the understanding of gene function and metabolic processes; and (4) the National Research Service Awards, including plans to fund approximately 150 full-time training positions.

ORIP's DCI plans to continue to expand the Nation's capacity for the conduct of biomedical research. Specifically, DCI programs provide funding for SIG and HEI grants to NIH-supported investigators that increase the quality of their funded programs and accelerate a broad array of

basic, translational, and clinical research. Further, DCI programs provide support for renovations or improvement of laboratory animal facilities to enhance animal care and insure success of animal-based biomedical research programs.

ORIP's SEPA Program will continue to be funded at \$18.541 million in FY 2017 to continue to improve life science literacy throughout the nation through innovative educational programs. SEPA-supported projects create partnerships among biomedical and clinical researchers and P-12 teachers and schools, museums and science centers, media experts, and other educational organizations.

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

ILRP repays outstanding eligible educational debt for postgraduates, and in return, participants must enter into a contractual agreement to conduct qualified research as NIH employees. During FY 2015 the distribution of ILRP awards was as follows:

- 65 awards for the General LRP – 31 new and 34 renewals; and
- Four awards for AIDS LRP – 1 new and 3 renewals.

FY 2015 ILRP awards (69) decreased by 13.75 percent compared to FY 2014 awards (80). It must be noted that there were no Clinical Research LRP applicants during the 2015 cycle. UGSP offers competitive scholarships to exceptional college students from disadvantaged backgrounds that are committed to biomedical, behavioral, and social science health-related research careers at NIH. For every year of UGSP scholarship support, recipients are obligated to participate in a ten-week summer internship and one year as a full-time paid employee in an NIH research laboratory. UGSP selected 11 new recipients for the UGSP Scholarship award and 8 UGSP Scholars received scholarship award renewals. In addition, 30 UGSP scholars conducted their yearlong service obligation and 21 completed their summer internship during this same period.

Budget Policy:

The FY 2017 President's Budget estimate for ILRSP is \$7.447 million, the same as the FY 2016 Enacted level. The ILRSP awards and administrative costs are as follows:

## Intramural Loan Repayment and Scholarship Programs (ILRSP)

(Dollars in Millions)

Program	FY2013 Awards	FY2013 Amount	FY2014 Awards	FY2014 Amount	FY2015 Awards	FY2015 Amount	FY2016 Awards	FY2016 Amount	FY2017 Awards	FY2017 Amount
NIH Clinical Loan Repayment Program	3	\$0.039	1	\$0.121	0	\$0.00	2	\$0.204	2	\$0.204
NIH General Loan Repayment program	58	\$2.912	76	\$4.089	65	\$3.450	65	\$3.633	65	\$3.633
AIDS Loan Repayment Program	4	\$0.123	3	\$0.200	4	\$0.080	4	\$0.542	4	\$0.542
Undergraduate Scholarship Program	17	\$0.232	22	\$0.323	11	\$0.266	19	\$0.266	15	\$0.260
ILRSP Administrative Cost		\$2.585		\$2.412		\$3.349		\$2.802		\$2.808
Totals	82	\$7.048	102	\$7.145	80	\$7.145	90	\$7.447	86	\$7.447

**Director's Discretionary Fund (DDF):** DDF allows the NIH Director to respond quickly to new and emerging high-priority research opportunities and Health priorities. In FY 2015, funds were used to support trans-NIH initiatives such as the BRAIN Initiative, Clinical Genome Resource (ClinGen), Accelerating Curation Pipelines, Pain Research Coordinating Committee, National Academies study on "Strengthening the Disaster Preparedness of Academic Biomedical Research Communities," and Antimicrobial Resistance Diagnostic Challenge Prize.

### Budget Policy:

The FY 2017 President's Budget estimate for DDF is \$10.000 million, the same as the FY 2016 Enacted level. In FY 2017, the DDF will continue funding projects to help uncover new knowledge that prevents, detects, diagnosed, and treats disease and disability, from the common cold to the treating of genetic disorders.

**Research for Countermeasures against Nuclear/Radiological/Chemical Threats:** The Radiation and Nuclear Countermeasures Program (RNCP) managed by NIH/NIAID funds the development of medical countermeasures (MCM) that can be used to mitigate and treat injuries caused by the exposure to nuclear and radiological threat materials due to terrorist attacks or accidents. The multi-element program supports initiatives that conduct basic, translational, and product development support services that provide capabilities for drug development toward FDA licensure. NIAID encourages collaborative efforts between academic, industry, and Federal laboratories. RNCP also supports the development of oral drugs to remove internal radionuclide contamination from the body and the development of biodosimetry approaches for triage and radiation injury assessment. Five MCM candidates have progressed to the Investigational New Drug (IND) submission stage and one MCM candidate (Neupogen) has been received FDA licensure for the radiation nuclear public health emergency indication. This is the first radiation medical countermeasure to be licensed by FDA for the acute radiation syndrome. RNCP accomplishments since initiation of the program in FY 2005 include over 900 scientific articles, 40 patents, and over 150 medical countermeasure candidates in discovery and early development phases. The targeted SBIR program for Radiological/Nuclear Medical Countermeasure Product Development was extended in 2015. Twenty-nine SBIR grants have been funded since FY 2009, including five grants that transitioned from SBIR Phase I to SBIR Phase II.

The Chemical Countermeasures Research Program is designed to prevent, diagnose, and treat the conditions caused by exposure to potential and existing chemical agents of terrorism and chemicals that may be released from transportation and storage facilities by industrial accidents or during a natural disaster. The program includes collaborative efforts with academia and industry, as well as agencies of the Federal Government such as the U.S. Army Medical Research Institute of Chemical Defense, the Defense Technical Information Center, and seven participating NIH ICs. A comprehensive research network has been established which includes center grants focused on countermeasures against chemical threats, individual research grants and projects, exploratory research projects, SBIR grants, contracts, and Interagency Agreements. Accomplishments include patents, and more than 30 MCM candidates in discovery and research phases, including midazolam (a countermeasure against nerve agents), cobinamide (cyanide), Tissue Plasminogen Activator (sulfur mustard), AEOL10150 (for pulmonary edema or pulmonary stress), and Doxycycline (for ocular exposure to sulfur mustard). Midazolam has spanned basic and translational research and has now been transitioned to the Biomedical Advanced Research and Development Authority (BARDA) for advanced product development. Cobinamide will be the next candidate planned for transition to BARDA in FY 2017.

Budget Policy:

The FY 2017 President's Budget estimate to support the development of MCMs against Radiological, Nuclear and Chemical threats is \$93.392 million, the same as the FY 2016 Enacted level. The RNCP will continue to support basic and translational research for the development of promising safe and effective therapeutic and diagnostic candidates towards IND and licensure. Basic research will focus on elucidating mechanisms of radiation injuries and identifying potential new MCM candidates for measuring, minimizing, mitigating and treating the effects of exposure to external radiation sources. The Chemical Countermeasures Research program will continue to support basic and translational research directed at the development of promising safe and effective therapeutics and antidotes for nerve agents, metabolic poisons, pulmonary agents, toxic industrial chemicals, and vesicating (blistering) agents.

**Foundation for the National Institutes of Health (FNIH):** The Congress created FNIH as a 501(c)(3) public charity to support the mission of NIH. Since 1996, FNIH has raised almost \$800 million, generating \$86 per \$1 of NIH support, dramatically leveraging the modest NIH yearly contribution. Because of its charter, FNIH serves as a critical and trusted convener of multiple constituencies and has pioneered novel public-private partnerships that have been widely emulated in the United States and abroad. Examples include the Alzheimer's Disease (AD) Neuroimaging Initiative, where private industry, academia, and patients have joined to create the world's largest network of publicly available online AD data and the Accelerating Medicines Partnership, which enables the biomedical research community to find and validate new drug targets in AD, Diabetes, and Rheumatoid Arthritis/Lupus. For 10 years, Charity Navigator, a prominent charity watchdog in the United States, has rated FNIH as an organization that consistently exceeds industry standards for effective management and efficient use of resources.

Budget Policy:

The FY 2017 President's Budget estimate for the FNIH is \$1 million, the same as the FY 2016



Enacted level. This represents a key strategic investment by NIH given FNIH's proven ability to leverage funds in furtherance of NIH's mission. Funding will continue to support direct salary and overhead costs incurred for operations.

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

Budget Policy:

The FY 2017 President's Budget estimate for OD Operations is \$143.230 million, the same as the FY 2016 Enacted level. This level includes sufficient funds to support the FY 2017 annual pay raise increase. Funding will also be used to strengthen program integrity and reduce risk. The Office of Extramural Research will enhance efforts to provide comprehensive support and maintenance of many compliance oversight activities for grants management and laboratory animal welfare. Compliance oversight activities are part of the bedrock of ensuring the scientific integrity and fiscal responsibility of the NIH extramural research portfolio. The Division of Financial Advisory Services in the Office of Acquisition Management and Policy, the centralized office that supports HHS contracts, grants and program officials will use additional resources to keep pace with the annual volume of proposals requiring negotiation of indirect cost rates received from for-profit contractors and grantees. This will enable the review of 100 percent of the proposals received each year from for-profit contractors and grantees. In addition, these reviews may identify unallowable costs charged to HHS contracts and grants, which can then be redirected to other HHS program initiatives. The Office of Management Assessment's Division of Program Integrity will increase the number of forensic audits on allegations of misuse of NIH grant and contract funding.

The OD will continue to support high priority bioethics research that has applicability across all of the NIH Institutes and Centers. The overarching goal of this program is to integrate bioethics across the spectrum of the NIH research portfolio and to expand the evidence base to inform sound practice and policy. For the past four years, appropriated funds for bioethics research have been used to support research designed to inform NIH policies on ethical issues in research involving human subjects. In FY 2012, NIH funded competing supplements and in FY 2013, NIH supported administrative supplements for studies that would provide data and evidence to inform NIH policy efforts in the areas of participant perspectives about the use of broad consent for unspecified, future research with specimens and data and ethical issues surrounding research done within the standard of care. Funded investigators have been assessing the perceived impact of proposed reforms to HHS regulations governing the protection of human research subjects to require consent for research on de-identified human data and biospecimens in research; studying which practices in biobanking are likely to affect willingness to participate in research using broad consent; examining ethical issues associated with the use of electronic medical records; gathering participant perspectives about broad consent for future use of biospecimens and data; assessing how autonomy influences participation in randomized clinical trials; and assessing how

patients, surrogates, the general public, and institutional review board members view the ethical implications of randomization within the standard of care. In FY 2014 and 2015, awards were made for new research exploring the principles and characteristics of models of central institutional review board review, and participant preferences for research using clinical records and data. Awardees are evaluating models for central IRB review; assessing performance metrics for central IRB review of local context issues; and studying patients' willingness to share their clinical data for research use. In FY 2016, OD funds may be used to support research to enhance the oversight of clinical research and clinical trials. For example, specific topics may include the development of tracking systems for monitoring and coordinating recruitment at multiple site; electronic systems to track informed consent for secondary research; enhancements to security safeguards for biospecimens and data; or tools to link reliance agreements and other documentation across multi-site studies.

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

**National Children's Study (NCS) Follow-On:** Previous efforts to carry out the National Children's Study as a study of environmental influences on child health and development in a national birth cohort of 100,000 were halted in 2014 in response to recommendations of a Working Group of the Advisory Committee to the NIH Director. Accordingly, NIH conducted an orderly shutdown of NCS in FY 2015 and FY 2016. Participant follow-up in the NCS Vanguard pilot was discontinued and the NCS Program Office was closed. To make data from NCS Vanguard available for use by scientific researchers, NIH is completing review and processing of all data and samples collected in NCS Vanguard. These data and samples will populate the National Children's Study (NCS) Data and Sample Archive, expected to open in FY 2016. In FY 2017, limited staff and funding will be required to support the NCS Vanguard sample repository and the operation and ongoing development of the NCS Archive. In FY 2015, \$144 million of former NCS funds were redirected to activities that address the original goals of the National Children's Study, including the Human Placenta Project, Developing Paradigm-Shifting Innovations for in vivo Human Placental Assessment in Response to Environmental Influences (NICHD), Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS; NIBIB), Children's Health Exposure Analysis Resource (CHEAR; NIEHS), Validation of Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium (NIAMS), Collaborative Activities to promote High Dimensional Molecular Analyses in NIEHS-supported Children's Environmental Health Studies (NIEHS), and the Tox21 Developmental Toxicity Program (NIEHS).

#### Budget Policy:

The FY 2017 President's Budget estimate for the NCS Follow-On is \$165.000 million, the same as the FY 2016 Enacted level. This funding will be used continue support of a new program called Environmental influences on Child Health Outcomes (ECHO) established in FY 2016 that will support multiple synergistic, longitudinal studies by leveraging extant maternal/pediatric cohorts. These cohorts will represent a broad range of environmental exposures (e.g., physical, chemical, biological, behavioral, social). ECHO will focus on four key pediatric outcomes with

high public health impact, including upper and lower airway; obesity; pre-, peri-, and postnatal outcomes; and neurodevelopment. All ECHO studies will collect a standardized, targeted set of data (Core Elements) including demographics, typical descriptors of early health and development, genetic background, environmental factors, and patient/person reported outcomes. An additional opportunity exists to create an IDeA States Pediatric Clinical Trials Network by embedding clinical trials experts at IDeA state locations and facilitating partnership with outside academic institutions. ECHO was designed to take full advantage of existing resources, and is intended to be a multi-year program that continues beyond FY 2017. Additionally, starting in FY 2017, the plan will be assessed to determine whether improvements can be made or additional scientific and/or technological advances can be leveraged. This will be informative in FY 2017, in particular, as it will provide insight into the successes and areas of opportunity during the inaugural year of the program, which could drive its future direction significantly.

**BRAIN Initiative:** The NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is an ambitious effort to develop new tools and technologies to enable scientists to decode the language of the brain, i.e. neural circuitry activity. It includes 125 ongoing scientific projects, guided by the *BRAIN 2025* report produced by the expert working group of the Advisory Committee to the NIH Director. NIH-funded BRAIN research is also unfolding in partnership with DARPA, FDA, IARPA, NSF, and multiple private foundations and universities. Many of the FY 2014 and FY 2015 NIH awards were for three-year pilot projects, intended to seed development of new technologies and new interdisciplinary teams of scientists.

#### Budget Policy:

The FY 2017 President's Budget estimate for this component of the BRAIN Initiative is \$45.000 million, all of which is an increase from the FY 2016 Enacted level. The total FY 2017 budget for the BRAIN Initiative is \$195.000 million. FY 2017 is a watershed year, when the first round of pilot projects will end and new awards will build on them as large scale, bold efforts to uncover fundamental insight about how the nervous system functions in health and disease. One such project builds on new high-throughput, single-cell genetic analysis technology to create a census of all cells in the mouse brain – a remarkable goal in its own right, which will also serve as preparation for completing a census of the roughly 85 billion cells in the human brain. To manage a plethora of brain data and increase the value of that data for the broader scientific community, NIH aims to stand up a data repository/sharing system for BRAIN Initiative data. Also, since dissemination of novel neurotechnologies is critical to the success of the BRAIN Initiative, NIH intends to fund BRAIN labs to teach other investigators to use the new technologies. Additional experimental goals for FY 2017 and beyond would enable unprecedented understanding of the brain: elucidation of function of particular brain circuits in mammals or entire brain circuits in lower animals; understanding the computations that brain circuits perform on a continuous basis; and studies extending to humans – both healthy and suffering from conditions such as epilepsy and Parkinson's disease – examining the effects of external brain stimulation on brain circuit activity, and public-private partnerships to develop and refine human brain recording and stimulation technologies.

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

**Budget Authority by Object Class<sup>1</sup>**

(Dollars in Thousands)

	<b>FY 2016 Enacted</b>	<b>FY 2017 President's Budget<sup>2</sup></b>	<b>FY 2017 +/- FY 2016</b>
Total compensable workyears:			
Full-time employment	679	679	0
Full-time equivalent of overtime and holiday hours	4	4	0
Average ES salary	\$181	\$184	\$3
Average GM/GS grade	13.0	13.0	0.0
Average GM/GS salary	\$113	\$115	\$2
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$116	\$118	\$2
Average salary of ungraded positions	\$170	\$172	\$2
<b>OBJECT CLASSES</b>	<b>FY 2016 Enacted</b>	<b>FY 2017 President's Budget<sup>2</sup></b>	<b>FY 2017 +/- FY 2016</b>
Personnel Compensation			
11.1 Full-Time Permanent	\$66,480	\$66,987	\$506
11.3 Other Than Full-Time Permanent	11,205	11,290	85
11.5 Other Personnel Compensation	1,535	1,547	12
11.7 Military Personnel	805	811	6
11.8 Special Personnel Services Payments	952	959	7
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$80,977</b>	<b>\$81,594</b>	<b>\$617</b>
12.1 Civilian Personnel Benefits	\$27,310	\$27,851	\$541
12.2 Military Personnel Benefits	537	541	4
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$108,824</b>	<b>\$109,985</b>	<b>\$1,162</b>
21.0 Travel & Transportation of Persons	\$1,195	\$1,216	\$22
22.0 Transportation of Things	149	152	3
23.1 Rental Payments to GSA	6	6	0
23.2 Rental Payments to Others	13	13	0
23.3 Communications, Utilities & Misc. Charges	1,320	1,344	24
24.0 Printing & Reproduction	2	2	0
25.1 Consulting Services	\$5,505	\$5,604	\$99
25.2 Other Services	61,085	60,760	-325
25.3 Purchase of goods and services from government accounts	144,368	145,390	1,022
25.4 Operation & Maintenance of Facilities	\$460	\$468	\$8
25.5 R&D Contracts	92,076	128,695	36,619
25.6 Medical Care	22	23	1
25.7 Operation & Maintenance of Equipment	604	615	11
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$304,121</b>	<b>\$341,556</b>	<b>\$37,435</b>
26.0 Supplies & Materials	\$998	\$1,016	\$18
31.0 Equipment	2,918	2,971	53
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	1,151,652	1,257,937	106,284
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	2	2	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$1,462,376</b>	<b>\$1,606,215</b>	<b>\$143,838</b>
<b>Total Budget Authority by Object Class</b>	<b>\$1,571,200</b>	<b>\$1,716,200</b>	<b>\$145,000</b>

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

<sup>2</sup> Includes mandatory financing.

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**Salaries and Expenses**

(Dollars in Thousands)

<b>OBJECT CLASSES</b>	<b>FY 2016 Enacted</b>	<b>FY 2017 President's Budget</b>	<b>FY 2017 +/- FY 2016</b>
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$66,480	\$66,987	\$506
Other Than Full-Time Permanent (11.3)	11,205	11,290	85
Other Personnel Compensation (11.5)	1,535	1,547	12
Military Personnel (11.7)	805	811	6
Special Personnel Services Payments (11.8)	952	959	7
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$80,977</b>	<b>\$81,594</b>	<b>\$617</b>
Civilian Personnel Benefits (12.1)	\$27,310	\$27,851	\$541
Military Personnel Benefits (12.2)	537	541	4
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$108,824</b>	<b>\$109,985</b>	<b>\$1,162</b>
Travel & Transportation of Persons (21.0)	\$1,195	\$1,216	\$22
Transportation of Things (22.0)	149	152	3
Rental Payments to Others (23.2)	13	13	0
Communications, Utilities & Misc. Charges (23.3)	1,320	1,344	24
Printing & Reproduction (24.0)	2	2	0
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	5,505	5,604	99
Other Services (25.2)	61,085	60,760	-325
Purchases from government accounts (25.3)	137,111	138,185	1,074
Operation & Maintenance of Facilities (25.4)	460	468	8
Operation & Maintenance of Equipment (25.7)	604	615	11
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$204,765</b>	<b>\$205,632</b>	<b>\$867</b>
Supplies & Materials (26.0)	\$998	\$1,016	\$18
<b>Subtotal Non-Pay Costs</b>	<b>\$208,442</b>	<b>\$209,376</b>	<b>\$934</b>
<b>Total Administrative Costs</b>	<b>\$317,266</b>	<b>\$319,361</b>	<b>\$2,095</b>

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**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2015 Actual			FY 2016 Est.			FY 2017 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	624	4	628	630	4	634	630	4	634
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	624	4	628	630	4	634	630	4	634
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	45	-	45	45	-	45	45	-	45
Total:	45	-	45	45	-	45	45	-	45
Total	669	4	673	675	4	679	675	4	679
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
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2013	12.7								
2014	12.7								
2015	13.0								
2016	13.0								
2017	13.0								

**NATIONAL INSTITUTES OF HEALTH**  
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**Detail of Positions<sup>1</sup>**

<b>GRADE</b>	<b>FY 2015 Actual</b>	<b>FY 2016 Enacted</b>	<b>FY 2017 President's Budget</b>
Total, ES Positions	11	11	11
Total, ES Salary	1,968,442	1,994,032	2,024,939
GM/GS-15	115	116	116
GM/GS-14	143	145	145
GM/GS-13	186	188	188
GS-12	99	100	100
GS-11	33	33	33
GS-10	2	2	2
GS-9	26	26	26
GS-8	1	1	1
GS-7	12	12	12
GS-6	2	2	2
GS-5	3	3	3
GS-4	1	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	623	629	629
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	3	3	3
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	72	72	72
Total permanent positions	639	645	645
Total positions, end of year	683	683	683
Total full-time equivalent (FTE) employment, end of year	673	679	679
Average ES salary	178,949	181,276	184,085
Average GM/GS grade	13.0	13.0	13.0
Average GM/GS salary	111,313	112,760	114,508

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.