

DEPARTMENT OF HEALTH AND HUMAN SERVICES

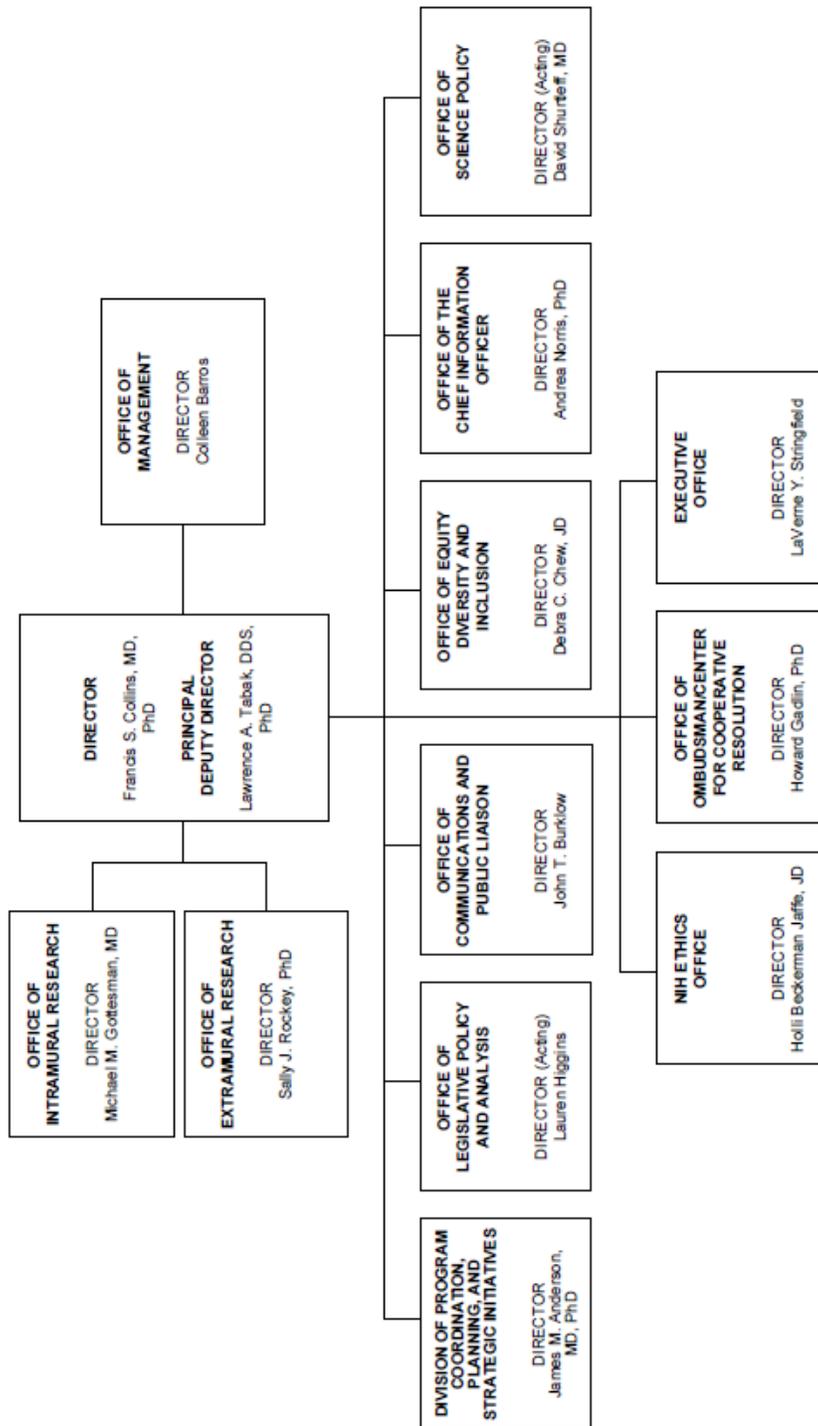
NATIONAL INSTITUTES OF HEALTH

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, [\$1,401,134,000]~~\$1,430,028,000~~, of which up to [\$25,000,000]~~\$30,000,000~~ may be used to carry out section [213]212 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 ("NCS") or research related to the Study's goals and mission, and any funds in excess of the estimated need shall be transferred to and merged with the accounts for the various Institutes and Centers to support activity related to the goals and objectives of the NCS: Provided further, That NIH shall submit a spend plan on the NCS's next phase 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 [\$533,039,000]~~\$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 NIH shall contract with the National Academy of Sciences for a Blue Ribbon Commission on Scientific Literacy and Standing: Provided further, That NIH shall submit to Congress an NIH-wide 5-year scientific strategic plan as outlined in sections 402(b)(3) and 402(b)(4) of the PHS Act no later than 1 year after enactment of this Act]*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 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 Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$1,400,134	\$1,413,734	\$1,442,628
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-3,515	0	0
FY 2014 Second Secretary's Transfer	-275	0	0
Subtotal, adjusted appropriation	\$1,396,344	\$1,413,734	\$1,442,628
OAR HIV/AIDS Transfers	0	0	0
National Children's Study Transfers	-93,330	0	0
Subtotal, adjusted budget authority	\$1,303,014	\$1,413,734	\$1,442,628
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$1,303,014	\$1,413,734	\$1,442,628
Unobligated balance lapsing	-90	0	0
Total obligations	\$1,302,953	\$1,413,734	\$1,442,628

¹ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2014 - \$751,484 FY 2015 - \$60,000 FY 2016 - \$60,000

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

(Dollars in Thousands)

MECHANISM	FY 2014 Final		FY 2015 Enacted		FY 2016 President's Budget		Change FY 2016 +/- FY 2015	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Grants:</u>								
Research Projects		\$445,408		\$567,591		\$573,857		\$6,267
Research Centers		238,368		284,140		270,333		-\$13,807
Other Research		194,618		203,889		234,945		\$31,056
Total Research Grants		\$878,395		\$1,055,619		\$1,079,136		\$23,516
Training		\$10,349		\$22,008		\$33,022		\$11,014
R & D Contracts		139,414		57,395		46,270		-\$11,125
Intramural Research		28,013		28,013		28,013		\$0
Res. Management & Support		246,844		250,699		256,188		\$5,488
Total Other Than Research Grants		\$424,620		\$358,115		\$363,492		\$5,378
Total, OD		\$1,303,014		\$1,413,734		\$1,442,628		\$28,894

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Budget Authority by Activity^{1,2}

(Dollars in Thousands)

	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
OD Operations	125,061	125,561	130,161	4,600
<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	11,221	11,227	12,227	1,000
Office of Behavioral & Social Sciences Research	26,081	26,094	26,094	0
Office of AIDS Research	61,896	61,923	61,923	0
Office of Research on Women's Health	40,756	40,776	40,776	0
Office of Disease Prevention	5,807	7,910	9,910	2,000
Office of Dietary Supplements	26,773	24,686	24,686	0
Office of Research Infrastructure Programs	275,988	276,124	276,124	0
Science Education Partnership Awards/OSE	18,532	18,541	18,541	0
Director's Discretionary Fund	10,000	10,000	10,000	0
Foundation for the National Institutes of Health	500	1,000	1,000	0
Intramural Loan Repayment and Scholarship	7,142	7,145	7,145	0
Nuclear Radiological Chemical Countermeasures	92,053	92,098	93,392	1,294
National Children's Study	70,020	20,000	7,000	-13,000
Strategic Pediatric Research	0	145,000	158,000	13,000
Reception and Representation Fund	10	10	10	0
Common Fund	531,174	545,639	565,639	20,000
Total	\$1,303,014	\$1,413,734	\$1,442,628	\$28,894

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

² Items in italics and brackets are non-add entries.

Major Changes in the Fiscal Year 2016 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 2016 budget request for OD, which is \$28.894 million above the FY 2015 Enacted level, for a total of \$1,442.628 million.

Common Fund (+\$20.000 million; total \$565.639 million):

The FY 2016 budget request for the Common Fund expands support for the Big Data to Knowledge initiative and will enable the development of two potential new Common Fund programs which are currently under development (and therefore subject to change): Enabling the Exploration of the Eukaryotic Epitranscriptome (E4), which aims to enable the systematic study of RNA modifications and their roles in human health and disease, and Mechanisms of Benefit of Physical Activity, which will deliver a human data set of biochemical and physiologic measures from people exposed to a variety of physical activity regimens.

OD Operations (+\$4.600 million; total \$130.161 million):

The FY 2016 budget request for OD Operations will 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. The Division of Financial Advisory Services in the Office of Acquisition Management and Policy will use additional resources to keep pace with the rising annual volume of proposals requiring negotiation of indirect cost rates received from for-profit contractors and grantees. The Division of Program Integrity in the Office of Management Assessment will increase the number of forensic audits on allegations of misuse of NIH grant and contract funding.

Office of Disease Prevention (+\$2.000 million; total \$9.910 million):

The FY 2016 budget request for the Office of Disease Prevention will be used to enhance the activities guided by its Strategic Plan for Fiscal Years 2014–2018, which outlines the priorities that the Office will focus on over the next five years and highlights the ODP's role in advancing prevention research at the NIH.

Division of Program Coordination, Planning, and Strategic Initiatives (+\$1.000 million; total \$12.226 million):

The FY 2016 budget request for the Division of Program Coordination, Planning, and Strategic Initiatives will be used to enable the Division to serve as the NIH focal point for coordinating research to advance the health and wellbeing of sexual and gender minorities (SGM).

Nuc/Rad/Chemical Countermeasures (+\$1.294 million; total \$93.392 million):

The FY 2016 budget request for Nuclear/Radiation/Chemical Countermeasures will support basic and translational research aimed at the development of medical countermeasures for the diagnosis, evaluation, and treatment of injury from exposure to radiological, nuclear and/or chemical agents. NIAID will continue to support the research infrastructure and product development support services necessary to facilitate the development toward FDA licensure of these medical countermeasures.

National Children's Study (-\$13.000 million, total \$7.000 million):

Strategic Pediatrics Research (+\$13.000 million, total \$158.000 million):

The FY 2016 budget request includes a funding shift from the National Children's Study (NCS) to Strategic Pediatrics Research as FY 2015 funding for the NCS shut-down is no longer needed.

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

Summary of Changes

(Dollars in Thousands)

FY 2015 Enacted				\$14,137,340
FY 2016 President's Budget				\$1,442,628
Net change				\$28,894
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
<u>A. Built-in:</u>				
<u>1. Intramural Research:</u>				
a. Annualization of January 2015 pay increase & benefits		\$0		\$0
b. January FY 2016 pay increase & benefits		0		0
c. One more day of pay (n/a for 2015)		0		0
d. Differences attributable to change in FTE		0		0
e. Payment for centrally furnished services		0		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		0		0
Subtotal				\$0
<u>2. Research Management and Support:</u>				
a. Annualization of January 2015 pay increase & benefits		\$100,354		\$292
b. January FY 2016 pay increase & benefits		100,354		1,100
c. One more day of pay (n/a for 2015)		100,354		51
d. Differences attributable to change in FTE		100,354		
e. Payment for centrally furnished services		2,100		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		317,177		-1,443
Subtotal				0
Subtotal, Built-in				0

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

Summary of Changes- continued

(Dollars in Thousands)

CHANGES	FY 2016 President's Budget		Change from FY 2015	
	No.	Amount	No.	Amount
<u>B. Program:</u>				
1. Research Project Grants:				
a. Noncompeting	0	\$399,553	0	\$16,189
b. Competing	0	167,144	0	-10,022
c. SBIR/STTR	0	7,180	0	100
Subtotal, RPGs	0	\$573,857	0	6,267
2. Research Centers	0	\$270,333	0	-13,807
3. Other Research	0	234,945	0	31,056
4. Research Training	0	33,022	0	11,014
5. Research and development contracts	0	46	0	-11,125
Subtotal, Extramural		1,112,158		23,405
6. Intramural Research	<u>FTEs</u> 0	\$28,013	<u>FTEs</u> 0	\$0
7. Research Management and Support	0	256,187	0	5,489
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	0	\$1,443,628	0	\$28,894
Total changes				\$28,894

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

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2015 Amount Authorized	FY 2015 Enacted	2016 Amount Authorized	FY 2016 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$1,413,734,000	Indefinite	\$1,442,628,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$1,413,734,000		\$1,442,628,000

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

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2006 Rescission	\$385,195,000	\$532,216,000	\$537,434,000	\$532,395,000 (\$4,829,000)
2007 Rescission	\$667,825,000	\$667,825,000	\$687,825,000	\$478,650,000 \$0
2008 Rescission	\$517,062,000	\$1,114,422,000	\$1,145,790,000	\$1,109,099,000 (\$19,720,000)
2009 Rescission Supplemental	\$1,056,797,000	\$1,255,420,000	\$1,275,281,000	\$1,246,864,000 \$0 \$2,636,000
2010 Rescission	\$1,182,777,000	\$1,168,704,000	\$1,182,777,000	\$1,177,020,000 \$0
2011 Rescission	\$1,220,478,000		\$1,268,580,000	\$1,177,300,000 (\$10,337,395)
2012 Rescission	\$1,298,412,000	\$1,198,412,000	\$1,439,064,000	\$1,461,880,000 (\$2,762,953)
2013 Rescission Sequestration	\$1,429,161,000		\$1,431,341,000	\$1,528,181,000 (\$3,056,362) (\$76,704,177)
2014 Rescission	\$1,473,398,000		\$1,463,606,000	\$1,400,134,000 \$0
2015 Rescission	\$1,451,786,000		\$1,413,734,000	\$1,413,734,000 \$0
2016	\$1,442,628,000			

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 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2015 +/- FY 2014
BA	\$1,303,014,342	\$1,413,734,000	\$1,442,628,000	+\$28,894,000
FTEs	664	669	669	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 and guidance that foster trans-NIH activities by strategically planning, managing, and implementing policies and procedures to facilitate the coordination of cutting-edge biomedical research. As a key participant in shaping the overall NIH research agenda, OD coordinates NIH's extramural and intramural research activities, science policy, technology transfer, health information dissemination, legislative activities, and oversight of the agency'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. Examples of initiatives pursued by OD programs 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. In FY 2014, extramural investments accounted for approximately 83 percent of NIH's budget, and provided funds supporting a scientific workforce of over 300,000 research positions, at over 2,500 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 (NIH RePORT).

The Office of Intramural Research ([OIR](#)) provides leadership in the development and coordination of NIH Intramural Research Program (IRP) policies that address major topics,

including research review, ethical conduct of research, training, technology transfer, and others. OIR oversees IRP 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; 6) fosters collaborations across NIH and with outside organizations; and 7) provides essential services within and outside the IRP. 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 the 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. This program coordinates activities among 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 become leaders in the biomedical research community. OTT oversees patenting, licensing, and royalty administration for inventions from NIH, the Food and Drug Administration (FDA), and the Centers for Drug Control and Prevention (CDC) intramural scientists. In FY 2013, this office executed 180 licenses, administered \$116 million in royalties, filed 303 U.S. patent applications, added 122 issued U.S. patents to the NIH and FDA intellectual property portfolios, and coordinated 77 new Cooperative Research and Development Agreements (CRADAs). The Office of NIH History advances historical understanding of NIH biomedical research through preservation of records of significant NIH achievements and development as well as installation of innovative exhibits.

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. DPCPSI's mandate 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 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 the 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 activities of these offices are described in the Program Description and Accomplishments section.

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 basic and clinical research involving recombinant DNA, genomic technologies and genomic data sharing, clinical and translational research, and comparative effectiveness research. OSP focuses on the intersection of science and society and attends to 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. OSP also manages the Congressionally-mandated Scientific Management Review Board (SMRB), which was established to conduct comprehensive organizational reviews of the NIH and to provide expert advice to the NIH Director on organizational and management matters.

The Office of Communications and Public Liaison ([OCPL](#)), is the communications headquarters for NIH and its ICs. 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 ICs and with HHS; assists with NIH Director's communications including the new NIH Director's Blog ([directorsblog.nih.gov](#)) manages the NIH Freedom of Information Act activities; provides tours; organizes special events; and provides science-based health information via print, television, and web-based formats. 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 200 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, this year, 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 ([www.nih.gov/health/clinicaltrials](#)). This year, the office added the first ever central location for research registries across the Agency. OCPL facilitated more than 130 interviews from the NIH's remote actuality studio, including approximately 60 on Ebola in the first two weeks of the emergency, designed to ensure that the public received both accurate and reassuring information. OCPL 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 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 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.

This Overview provided highlights of OD's role in shaping the Agency's research agenda. For more information on OD program initiatives and accomplishments, please visit the OD's web page at: <http://www.nih.gov/icd/od/index.htm>.

Program Description and Accomplishments

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI): [DPCPSI](#) was created by the NIH Reform Act of 2006. The Division provides leadership for identifying, reporting, and funding trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that merit further research and would benefit from collaboration between two or more ICs, or from strategic coordination and planning.

DPCPSI serves as a portfolio analysis and research resource for the ICs and the OD. The Division is developing innovative methods to facilitate the content analysis of grant applications; developing and testing new computational tools to further information research portfolio analysis and management, and conducting bibliometric analyses to assess productivity, impact, and influence. DPCPSI manages the Agency's evaluation program and coordinates reporting under the Government Performance and Results Act. Another primary function of DPCPSI is to encourage and facilitate collaboration and help ensure coordination and planning of research between and among the NIH ICs.

DPCPSI includes major programmatic offices that coordinate and support research and activities related to HIV/AIDS, women's health, behavioral and social sciences, disease prevention, dietary supplements, tobacco regulatory science, and research infrastructure and science education. Described below are FY 2016 planned activities.

Budget Policy:

The FY 2016 President's Budget estimate for the DPCPSI Division office is \$12.227 million, \$1.000 million or 9 percent above the FY 2015 Enacted level. Beginning in FY 2016 DPCPSI will serve as the NIH focal point for coordinating research to advance the health and wellbeing

of sexual and gender minorities (SGM). 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-focused research efforts. The Division will also serve as the focal point for tribal consultation activities, including ensuring that Indian tribal representatives have meaningful and timely input in the development of relevant NIH policies, programs, and priorities. In FY 2016, 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, Disease Prevention, Behavioral and Social Sciences, and Infrastructure Resources. In addition, the Division will expand its portfolio analysis efforts that include identifying, developing, and applying new tools that expand and improve NIH-wide efforts in portfolio analysis, providing training on the use of portfolio analysis tools, promoting trans-NIH coordination on portfolio analysis, and collaborating with other Federal agencies and the private sector on projects of mutual interest.

Common Fund/Office of Strategic Coordination (OSC): The [Common Fund](#) 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. Common Fund programs tackle major challenges in biomedical research that affect many diseases or conditions or that broadly relate to human health. Collectively, Common Fund 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 the Common Fund, working with trans-NIH teams for each of the more than 25 Common Fund programs. These teams ensure that each program meets the criteria of Common Fund 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 Common Fund programs mature and transition out of the Common Fund, 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 Common Fund programs, as the products and data generated by each program become ready for dissemination to the community-at-large.

Big Data to Knowledge (BD2K)

As biomedical tools and technologies rapidly improve, researchers are producing and analyzing an ever-expanding amount of complex biological data called “big data.” As one component of an NIH-wide strategy, the Common Fund, in concert with NIH ICs, is supporting the Big Data to Knowledge (BD2K) program (<http://commonfund.nih.gov/bd2k/>), which aims to facilitate broad use of biomedical big data, develop and disseminate analysis methods and software, enhance training in techniques associated with big data usage, and establish a network of collaborating centers of excellence. The expectation is that implementation of BD2K will enable cultural changes in the way the biomedical research community shares, accesses, queries, cites, and analyzes data.

It is anticipated that in FY 2016, BD2K will be running at full capacity with coordinated efforts underway and the biomedical community engaged with NIH in increasing the accessibility and reuse of biomedical big data and the training of data scientists.

In FY 2016, the Common Fund will increase its support for the BD2K program by \$19.495 million or 44.9 percent above the FY 2015 contribution level. This estimated increase in funding will be used to support activities described above, including increases in the Centers of Excellence for Biomedical Big Data and enhanced efforts in training and data coordination.

Budget Policy:

The FY 2016 President's Budget request for the Common Fund is \$565.639 million, \$20.000 million or 3.7 percent above the FY 2015 Enacted level. Strategic planning for new FY 2016 Common Fund programs began in spring 2014. NIH ICs submitted ideas for pressing challenges and emerging opportunities where Common Fund investment could have a transformative impact. Promising ideas will be developed through FY 2015 as possible new program areas for the Common Fund in FY 2016. Two potential new Common Fund programs are currently under development (and therefore subject to change): Enabling the Exploration of the Eukaryotic Epitranscriptome (E4), which aims to enable the systematic study of RNA modifications and their roles in human health and disease, and Mechanisms of Benefit of Physical Activity, which will deliver a human data set of biochemical and physiologic measures from people exposed to a variety of physical activity regimens. Additionally, two ongoing Common Fund programs, Illuminating the Druggable Genome and Knockout Mouse Phenotyping Project, are being considered for a second phase of support. The request includes \$12.6 million, the same as FY 2015, from the Pediatric Research Initiative Fund created by the Gabriella Miller Kids First Research Act and funded with an initial \$38 million. For additional details, please see the Common Fund section.

Office of AIDS Research (OAR): [OAR](#) serves as a model of trans-NIH planning and management, vested with primary responsibility for overseeing all NIH AIDS-related research, and thus allowing the NIH to pursue a united research front against the global AIDS epidemic. The challenges posed by AIDS exceed the mission of any individual Institute. AIDS is a multi-system and multi-organ disease, involving malignancies, opportunistic infections, and cardiovascular, neurological, gynecological, dermatological, gastrointestinal, and other clinical complications and co-morbidities. It affects people across the life span from infancy to old age. Both behavioral and biomedical interventions are required to prevent new infections. Consequently, nearly all NIH ICs are involved in conducting or supporting AIDS research. OAR functions as an "institute without walls" to plan, coordinate, evaluate, and budget the trans-NIH AIDS research program. OAR is authorized to develop an annual trans-NIH Strategic Plan and to develop and allocate the trans-NIH AIDS research budget, explicitly tied to the Plan. Utilizing its legislative authorities, OAR has established comprehensive trans-NIH planning, portfolio analysis, and budgeting processes to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently. OAR also identifies specific funding for emerging scientific opportunities and public health challenges that require focused attention; manages and facilitates multi-Institute and trans-Institute activities to address those needs; fosters research by designating funds and supplements to jump-start or 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 2016 budget estimate for OAR is \$61.923 million, the same as the FY 2015 Enacted level. OAR will utilize its operating funds to support initiatives that address: the highest scientific priorities reaffirmed and outlined by the OAR Advisory Council Priority-Setting Working Group; key priorities of the President's National HIV/AIDS Strategy and Continuum of Care initiative; and the White House Initiative on the Intersection of Violence and HIV Risk. OAR has the leadership responsibility to implement the President's initiative to increase research focused on a cure for HIV (the NIH HIV Cure Initiative). OAR is providing additional redirected funds to the ICs for new research initiatives toward an HIV cure, providing support for public-private partnerships, and leading efforts to expand international collaborations in research toward an HIV cure. This includes encouraging young investigators from other disciplines to enter the field. OAR will continue its support for initiatives in Hispanic communities and core support for the District of Columbia Partnership for HIV/AIDS Progress. OAR will facilitate innovative bilateral initiatives for research, infrastructure development, and medical, nursing, and research training in Africa, the Caribbean, India, China, Brazil, and Russia. OAR will support and convene panels of outside experts who provide guidance to OAR and the ICs regarding emerging research opportunities, as well as provide support for the HIV Treatment Guidelines Working Groups, comprised of government and non-federal experts who develop federal standards for treatment of HIV disease and its associated co-morbidities. OAR will support initiatives to enhance dissemination of research findings and the dissemination of the federal treatment guidelines and clinical trial information to the scientific community, healthcare providers, and communities at risk through *AIDSinfo*, a web-based service that provides information for caregivers and patients (available at www.aidsinfo.nih.gov). OAR will also use its operating funds to facilitate and support IC initiatives in the areas of highest priority 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): Since its creation in 1990, [ORWH](#) has worked to ensure the inclusion of women in NIH clinical research, to advance and expand women's health research, and to promote advancement of women in biomedical careers. ORWH is the focal point for NIH women's health research and works in partnership with the NIH ICs to incorporate a women's health and sex differences research perspective into the NIH scientific framework. ORWH activities are guided by the 2010 [NIH Strategic Plan for Women's Health Research](#). This strategic plan outlines six goals to maximize impact of NIH research effort: 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, and underscoring the importance of 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: Applying a Sex Perspective to Neuroscience Research

FY 2015 Level: \$3.0 million

FY 2016 Level: \$4.0 million

Change: +\$1.0 million

A landmark IOM 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.” The report’s authors presented examples of sex differences in the brain and in brain disorders. Despite this, sexual dimorphisms in brain structure and function remain incompletely characterized. Currently neuroscience is receiving renewed NIH focus. The NIH [Brain Initiative](#) aims to develop and apply new technologies to produce dynamic pictures of the brain, with advances in imaging technology and bioinformatics anticipated to provide new understanding of brain connectivity. A related effort, the NIH [Human Connectome Project](#), states as its objectives “major advances in our understanding of what makes us uniquely human” and in understanding “abnormal brain circuits in many neurological and psychiatric disorders.”

The Office of Research on Women’s Health, working in collaboration with NIH ICs, will build on successful investments in science to understand sexual dimorphisms in health and disease and support an initiative that expands on findings from the NIH Brain Initiative. Using the [NIH Strategic Plan for Women’s Health Research](#) as a scientific framework, through trans-NIH activities, ORWH will work to increase understanding of the influence of sex in brain development and in brain disorders, using a variety of approaches including structural and functional imaging and brain mapping connectivity approaches as well as mechanistic studies of sex-specific neural diversity, epigenetics, and molecular biology approaches. The expected results of the initiative will be the cost-effective, value-added expansions of meritorious research projects that will advance the understanding of women’s health and sex differences in brain development and in a variety of diseases and conditions, with the added potential to apply knowledge so derived to the development of more personalized therapeutics.

Budget Policy:

The FY 2016 President’s Budget estimate for ORWH is \$40.776million, the same as the FY 2015 Enacted level. The Office of Research on Women’s Health (ORWH), in partnership with NIH Institutes and Centers, 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) Expanding consideration of sex/gender factors in basic, biomedical, and behavioral science studies through ORWH research initiatives, programs and co-funding, and with additional priority in 2016, 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 (SCOR) 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 (BIRCWH) 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. OBSSR coordinates behavioral and social sciences research across the NIH and serves as a liaison between NIH and the extramural research communities, other Federal agencies, academic and scientific societies, national voluntary health agencies, and the general public on matters pertaining to behavioral and social sciences research. OBSSR’s vision is to

bring together the biomedical, behavioral, and social science communities to work more collaboratively to solve the 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, 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 decisionmakers can work together to accelerate the translation, implementation, dissemination, and adoption of behavioral and social sciences research.

Program Portrait: Mobilizing Research

FY 2015 Level: \$2.0 million

FY 2016 Level: \$2.0 million

Change: +\$0.0 million

The Mobilizing Research initiative supports the development of research in mobile and wireless technology (mHealth) to improve health. Cellphones and wireless technologies have become both ubiquitous and capable of a range of complex functions. mHealth offers the potential to transform and advance research, prevent disease, improve diagnosis treatment, and adherence. Medical research in behavioral and social sciences has historically struggled with tailoring interventions to individual needs, capturing intensive longitudinal data, achieving accurate recall of behavior (such as daily food intake) and creating sustainable and scalable behavioral interventions. Real-time, continuous behavioral, biological, and environmental data collected by mHealth technologies can be used to rapidly and accurately assess and modify behavior, biological states, and contextual variables. This capability has tremendous potential to transform medical research and improve public health by reducing disparities, increasing access to health services, and lowering healthcare costs in ways previously unimaginable. Existing mHealth technologies, however, often have limited value because they neither incorporate knowledge of the science of behavior change or social behavior nor have they been developed with an understanding of the health care system, patients, and providers. Further, because of industry or technology programs' proprietary considerations, researchers also miss an important opportunity to include mHealth technologies in their research to strengthen ongoing and future scientific efforts.

Breakthroughs in mobile technologies in the United States require a transformative approach that brings together teams of engineers, medical researchers and behavioral and social scientists to address critical public health issues. OBSSR plans to issue a new Funding Opportunity Announcement (FOA) on *Mobilizing Research: A Research Resource to Enhance mHealth Research*. This FOA will develop a research resource that works with wireless carriers to create a registry of potential participants to facilitate observational and clinical mHealth research across a variety of populations, diseases, and settings, allowing more efficient and rapid evaluation of mHealth technologies. OBSSR plans to support Mobilizing Research for development of the resource infrastructure and transition to sustainability. OBSSR also plans to complement this infrastructure by issuing a FOA for a competitive revision for supplementing existing grants to validate mobile devices in existing NIH-funded studies. This research addresses two key NIH initiatives: *Harnessing Data and Technology to Improve Health and Translating Discovery into Health*. A transdisciplinary mobile health approach will generate the advances necessary to enhance health effectively and efficiently. OBSSR will capitalize on broad interest in mHealth within the NIH's Institutes and Centers and with other federal partners for partnering on this new initiative.

Budget Policy:

The FY 2016 President's Budget estimate for OBSSR is \$26.094 million, the same as the FY 2015 Enacted level. Along with voluntary contributions from various NIH Institutes and Centers in FY 2016 for specific Funding Opportunity Announcements (FOAs), the Office will also continue to support the NIH Basic Behavioral and Social Science Opportunity Network (OppNet), a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research across the NIH.

In FY 2016, OBSSR will complete a number of program evaluations begun in FY 2015 to lay the groundwork for a formal strategic planning process following the appointment of a new OBSSR Director. These program evaluations include an assessment of the outcomes from the various training programs that the office has supported, 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 survey the research and training activities, funding plans, behavioral, social science related applications and funding patterns within and across the NIH ICs to assess the state of the health-related behavioral and social sciences research portfolio, and identify the most promising avenues for future investments within the context of the NIH mission. Based on these evaluations, OBSSR will develop, in FY 2016, a new strategic plan to guide the Office's activities for the next five years.

In FY 2016, 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. The office also plans to continue collaborations to advance data harmonization, integration, and the development of a common behavioral ontology to promote data sharing in the behavioral and social sciences. OBSSR will continue to play a lead role in mobile and wireless health research, including the development and validation of objective sensor technologies for assessing behavior and its influences, the support of research and development of technologies that expand the reach and scalability of behavioral interventions, and the evaluation of tech-based behavioral interventions.

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. 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 ongoing initiatives; and highlighting program accomplishments. ODP also provides scientific leadership and oversight for the continued implementation of 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.

ODP activities are guided by its Strategic Plan for Fiscal Years 2014–2018, which outlines the priorities that the Office will focus on over the next five years and highlights the ODP’s role in advancing prevention research at the NIH. For example, the 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 the 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 the 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. Other efforts led by the ODP are addressing major public health issues that are of interest to multiple NIH Institutes and Centers. ODP recently released two Funding Opportunity Announcements (FOAs) to encourage innovative research on how to increase and maintain health-enhancing physical activity. These announcements will encourage multi-level interventions that have the potential to be scalable, implementable, and sustained in real-world settings. The FOAs were released in collaboration with NCCIH, NCI, NIA, NIAAA, NICHD, NIDA, OBSSR, and ORWH. Additionally, ODP will continue to work closely with the DPCPSI Office of Portfolio Analysis to develop a computer-based system to enable a standardized, automated, rapid, and objective characterization of NIH prevention research funding. This tool will enable identification of patterns and trends in NIH prevention research funding, as well as research areas that may benefit from targeted investments by the NIH ICs. 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. In addition, in late 2015, ODP will host two Pathways to Prevention workshops focused on integrated worker health and suicide prevention, respectively. These workshops are designed to identify research gaps in these areas, identify methodological and scientific weaknesses, suggest research needs, and move these fields forward through an unbiased, evidence-based assessment.

Budget Policy:

The FY 2016 President’s Budget estimate for ODP is \$9.910 million, \$2.000 million or 25.3 percent above the FY 2015 Enacted level. In FY 2016, 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. Toward this end, ODS cofunds 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. Through its Communications program, ODS makes accurate and up-to-date scientific information about dietary supplements available to researchers, healthcare providers, and the public. To leverage its resources, ODS makes extensive use of its many collaborative partners both in and outside of NIH. For example, ODS leads and sponsors efforts to advance scientific understanding of the importance of vitamin D to health through the Vitamin D Standardization Program (VDSP), an international effort conducted in collaboration with the National Institute of Standards and Technology (NIST), the Centers for Disease Control and Prevention (CDC), and the national health surveys of Australia, Canada, Germany, Ireland, Mexico, South Korea, the United Kingdom, and the United States. In another example, ODS established the Nutrition and Dietary Supplement Interventions for Inborn Errors of Metabolism initiative, in collaboration with the NIH Office of Rare Diseases Research, NCATS. This initiative will identify gaps in research on the safety, efficacy, and effectiveness of nutritional treatments, including dietary supplements, for rare metabolic and mitochondrial disorders. These activities fit into the broader context of public health because they will likely lead to better approaches to manage more common conditions that affect millions of people. Launched in June 2013, the Dietary Supplement Label Database (DSLDB), 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 and maintains an archive of products and formulations. The database is of value to research scientists and health care providers, and even to consumers who can identify and compare products of interest. By 2016, the DSLDB will include more than 55,000 labels, voluntarily submitted by companies. The eventual goal is to incorporate most of the estimated 85,000 supplement products available on the U.S. market.

Program Portrait: Analytical Methods and Reference Materials Program

FY 2015 Level: \$2.0 million

FY 2016 Level: \$1.8 million

Change: -\$0.2 million

Since the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994, the number of dietary supplement products in the U.S. marketplace has grown from an estimated 4,000 to more than 85,000. ODS's Congressionally-mandated Analytical Methods and Reference Materials Program (AMRM) was developed to provide critical tools that will help assure the quality of these products, including chemical methods to verify ingredient identity and amount as well as standard reference materials (SRMs) to improve ingredient measurements. Accurate, precise, and reliable analytical methods and matching reference materials enhance consumer confidence in the quality of the supplements they buy and improve the conduct of scientific research on these products.

Program needs are identified through open stakeholder meetings and met through collaborative efforts in which industry, government, not-for-profit groups, and academic institutions work to identify needs and set priorities. For example, the AMRM program supports two of its major activities through collaborations with other Federal agencies:

Methods Development: This activity develops, and increases the availability and use of, validated, reliable, and accurate analytical methods for quantitative and qualitative characterization of specific dietary supplements and their ingredients. ODS supports this effort through an Interagency Agreement with the U.S. Department of Agriculture that provides funding to support the development of techniques that will verify the identity of botanicals.

SRMs: This AMRM activity supports the development of SRMs through an Interagency Agreement with the National Institute of Standards and Technology (NIST). NIST creates SRMs for dietary supplement raw materials and finished products (including nutrients) and for nutrient biomarkers in biological matrices such as blood and saliva. ODS also supports NIST's development and implementation of laboratory quality-assurance programs for supplements and for nutrient and nutrient biomarker measurements in clinical specimens.

Website Reorganization: ODS updated its website to make information about AMRM and the resources it provides more accessible to stakeholders. The revised section now includes a search function to locate published and available reference materials, methods, and resources on specific plants, compounds, and matrices.

Budget Policy:

The FY 2016 President's Budget estimate for ODS is \$24.686 million, the same as the FY 2015 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 Analytical Methods and Reference Materials (AMRM) program in the development, validation, and dissemination of analytical methods and reference materials that are critical tools for quality assurance of dietary supplements (See Portrait of a Program: Analytical Methods and Reference Materials program). ODS will continue to lead 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 2016, the model used for this initiative may be applied to other nutrients of public health concern such as iodine and folic acid. ODS, in partnership with NCCIH, anticipates making awards for the recompetition of the NIH Botanical Research Centers (BRC) in June 2015. ODS will also continue to support its program to build and maintain databases about dietary supplement products and their ingredients.

Office of Research Infrastructure Programs (ORIP): [ORIP](#) provides support for research into model systems of human diseases and a variety of research infrastructure needs. ORIP supports a number of repositories of animal (mouse, rat, fish, fruit flies, etc.) models, biological materials, genetic information, and human biospecimens. ORIP also makes grant awards to fund the purchase of expensive state-of-the-art scientific instruments and to modernize animal

research facilities. ORIP supports training and career development awards for veterinarians engaged in biomedical research and the diversity of the future workforce by investing in pre-kindergarten to grade 12 (P-12) and museum based science education programs.

Division of Comparative Medicine (DCM): DCM provides critical resources for scientists using animal models for biomedical research and supports the development of specialized technologies involving human disease models. There are many complex diseases that must be studied in living organisms leading researchers to develop animal models that mimic human pathologies. 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-funded research creates, develops, improves, and preserves a broad array of high-quality animal models and related biological materials. 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. DCM has promoted the use of advanced genome editing tools such as CRISPRs (Clustered Regularly Interspaced Short Palindromic Repeats), which enhance the ability of scientists to induce very specific mutations in a variety of animal species, such as fruit flies, zebrafish, mice, rats, and pigs. This technology has opened the possibility of creating “precision” animal models that more closely resemble specific human diseases than was ever possible before. In 2013 DCM organized a workshop on “Animal Models and Personalized Medicine” that resulted in a new effort to support pilot centers for precision disease modeling.

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 primate clinical medicine and laboratory animal medicine. 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.

Program Portrait: Linking Disease Model Phenotypes to Human Conditions

FY 2015 Level: \$0.0 million

FY 2016 Level: \$4.0 million

Change: +\$4.0 million

The major challenge in translational medicine today continues to be closing the gap that exists between biomedical research and clinical medical practice. Somehow, the wealth of data generated in the research laboratory must be converted into clinically relevant knowledge, permitting the physician to make the best decisions. Advancing scientific developments allow biomedical investigators to define the complex aligned networks of molecular interactions, biochemical pathways, and physiological mechanisms that characterize disease processes.

Understanding the normal and abnormal workings of these minute pieces of the human blueprint are beginning to allow scientists to define, very precisely, the recognizable characteristics that distinguish a healthy state from a pathological one. The composite of the recognizable characteristics of a disease constitute its “phenotype” (e.g., fever and a sore throat). Our increasing ability to recognize the minute alignments, and misalignments, that characterize various diseases now allow us to define a “molecular phenotype.” And it is the molecular phenotype, once we are able to characterize it with sufficient fidelity, which will allow us to understand what makes each disease unique.

Disease models (animals, cells, and tissues) comprise some of the most important tools of biomedical research. The efficacy of their use is based upon the principles of evolutionary conservation, including conservation of pathogenic disease mechanisms. However, “conservation,” in this context, is a relative term since no disease process or phenotype is absolutely conserved between any two species. Understanding this fact elucidates the importance of defining these molecular phenotypes so we can precisely define similarities and differences between the disease model and the actual human condition (resulting in a more predictive model). One of the historic impediments to understanding disease processes in humans using the recognizable phenotypes in animal models is the lack of alignment of these phenotypes among various species, including humans. The availability of more precise molecular phenotypes for diseases, along with increasing uniformity in how these phenotypes are described and how that information is organized, will provide a way around the aforementioned “historic impediment.” We should now be able to bridge the “phenotype gap” and design an approach to return the *disease* molecular phenotype to the *normal* molecular phenotype.

DCM proposes a new initiative to support research and development of projects that will advance the current state of the human clinical phenotype ontology and terminology along with its associated data annotation. Areas of emphasis will include association of disease-relevant phenotypes with physiological pathways and networks; clinical and experimental biology data integration, and the positioning of molecular phenotypes in the emerging field of precision medicine; and resources for submission, representation, analysis and sharing phenotypic and genomic information. This initiative is the result of presentations and discussions of translational researchers and clinical experts at the Tenth Comparative Medicine Resource Directors Meeting convened by the DCM in 2014.

Through interactions with its NIH partners and the scientific community, DCM will support the scientific priorities that best meet broad needs of the biomedical research community. DCM will assume a leadership role in assessing and promoting new animal-based technologies that provide more accurate models of human disease. New areas of emphasis in FY 2016 will include:

- 1) Developing new “personalized animal models” that reflect specific human genotypes and phenotypes; 2) Improving animal disease models for stem cell-based regenerative medicine; and 3) Enhancing reproducibility in disease models through consideration of a variety of biological variables such as the sex of research animals and cultured cells as well as the “microbiome” (the community of microorganisms living on, and inside, humans and animals).

DCM also 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 26,000 NHPs, provide animals for

research, and expertise in all aspects of NHP biology and husbandry to biomedical researchers nationwide. In FY 2014, the NPRCs facilitated more than 1000 individual research projects involving approximately 1500 researchers. Major areas of research benefiting from the resources of NPRCs include Alzheimer's Disease, Parkinson's disease, diabetes, asthma, women's health, regenerative medicine, and emerging infectious diseases, such as avian flu. Research supported by NPRCs in FY 2014 included significant advances in HIV/AIDS, emerging pathogens, and the microbiome. For example, researchers using NPRC resources demonstrated that a new long-lasting injectable antiviral compound protects monkeys from infection by the simian immunodeficiency virus (the monkey analog of human HIV). The first studies assessing the efficacy of this compound in humans are planned in late 2014. NPRCs have also developed an improved influenza vaccine formulation that protects elderly monkeys from infection, suggesting that a similar approach will protect high-risk elderly humans. Lastly, researchers have shown that breastmilk-fed and formula-fed infant monkeys develop markedly different immune systems that persist for at least six months after weaning. These studies link infant diets and resulting differences in the gut microbiome to potential resistance to pathogens in early life.

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.

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 Institutes. 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 2014, the Instrumentation Programs funded 113 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 institutes.

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 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.

NIH Chimpanzee Management Program

The NIH Chimpanzee Management Program supports long-term, cost-effective housing and maintenance at NIH-supported facilities for chimpanzees. ORIP provides programmatic oversight of the facilities and ensures they comply with the Animal Welfare Act and PHS policies concerning laboratory animal care and use. Historically, research that used chimpanzees led to critical advances, including developing vaccines for hepatitis A and B, and establishing the safety and efficacy of therapeutic monoclonal antibodies. In December 2011, the Institute of Medicine (IOM) released a report concluding that alternate research models have rendered chimpanzees largely unnecessary as research subjects. The NIH Director accepted the IOM recommendations and charged a working group of the NIH Council of Councils to advise him on the implementation. As part of the implementation, the “NIH plans to retain but not breed up to 50 chimpanzees for future biomedical research” and the remaining chimpanzees will be retired as federal sanctuary space becomes available. The 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. 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.” These amendments will allow the NIH to continue providing for high quality lifetime care of chimpanzees that it currently owns or supports whether they are kept at research facilities or the sanctuary.

Science Education Partnership Award (SEPA) Program

The SEPA Program supports NIH’s mission to enhance health, lengthen life, and reduce illness and disability as well as supporting the early pipeline for workforce development. 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. In FY 2016, the SEPA Program will continue to be coordinated with the Department of Education to ensure that program activities and commercialized 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 and health-related outreach activities at science centers and museums. These interactive exhibits educate the community on the important relationship between lifestyle and health. Through community education SEPA supports NIH's role in improving the health of the nation. Many SEPA grantees have partnered with the nearby Institutional Development Award (IDeA) programs so that students "graduate" from SEPA activities to fill the undergraduate pipeline at IDeA institutions. These partnerships contribute to NIH workforce diversity efforts such as the Common Fund initiative *Enhancing the Diversity of the NIH-Funded Workforce*.

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

Budget Policy:

The FY 2016 President's Budget estimate for ORIP is \$276.124 million, the same as the FY 2015 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 Division of Comparative Medicine (DCM) will continue to interact with NIH partners and the scientific community to maintain scientific priorities that best meet the broad needs of the multidisciplinary biomedical research continuum. DCM programs will include, but are not limited to: (1) the National Primate Research Centers (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 KOMP2 (Knock Out Mouse Phenotyping Program) Repository and Resources for other 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 (NRSA), including plans to fund approximately 150 full-time training positions.

ORIP's Division of Construction and Instruments (DCI) plans to continue to expand the Nation's capacity for the conduct of biomedical research. Specifically, DCI programs provide funding for Shared Instrumentation (SIG) and High-End Instrumentation (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 2016 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 K-12 teachers and schools, museums and science centers, media experts, and other educational organizations.

Intramural Loan Repayment and Scholarship Programs (ILRSP): The mission of the 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).

The 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 2014 the distribution of ILRP awards was as follows:

- One award for the Clinical LRP – 1 renewal;
- 76 awards for the General LRP – 31 new and 45 renewals; and
- Three awards for the AIDS LRP –3 renewals.

FY 2014 ILRP awards (80) increased by 19 percent compared to FY 2013 awards (65).

The NIH Undergraduate Scholarship Program (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 16 new recipients for the UGSP Scholarship award and 8 UGSP Scholars received scholarship award renewals. In addition, 26 UGSP scholars conducted their yearlong service obligation and 22 completed their summer internship during this same period.

Budget Policy:

The FY 2016 President's Budget estimate for ILRSP is \$7.145 million, the same as the FY 2015 Enacted level. The FY 2015 program plans are flat at \$7.145 million and include the UGSP and Loan Repayment projected new and renewal awards and administrative costs. The FY 2015 awards and administrative costs are as follows:

(Dollars in Millions)

Program	FY2012	FY2012	FY2013	FY2013	FY2014	FY2014	FY2015	FY2015	FY2016	FY2016
	Awards	Amount	Awards	Amount	Awards	Amounts	Awards	Amounts	Awards	Amounts
NIH Clinical Loan Repayment Program	7	\$0.293	3	\$0.039	1	\$0.121	3	\$0.149	3	\$0.149
NIH General Loan Repayment Program	77	\$4.089	58	\$2.912	76	\$4.089	100	\$4.103	100	\$4.103
AIDS Loan Repayment Program	5	\$0.194	4	\$0.123	3	\$0.200	5	\$0.128	5	\$0.128
Undergraduate Scholarship Program	17	\$0.232	17	\$0.232	22	\$0.323	19	\$0.380	19	\$0.380
ILRSP Administrative Cost		\$2.585		\$2.585		\$2.412		\$2.385		\$2.385
Totals	106	\$7.393	84	\$7.048	107	\$7.145	127	\$ 7.145	127	\$ 7.145

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 2014, funds were used to support trans-NIH initiatives such as Enhanced Grants Closeout System Policy, Development of Next Generation GM Workbooks, Rare Disease Clinical Research Networks, Inclusion Management System (IMS) Phase II and Pain Consortium.

Budget Policy:

The FY 2016 President's Budget estimate for DDF is \$10.000 million, the same as the FY 2015 Enacted level. In FY 2016, 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 which conduct basic, applied, translational, and product development support services that provide capabilities for drug development toward FDA licensure leading to new MCMs. NIAID encourages collaborative efforts between academic, industry, and federal laboratories. The RNCP also supports the development of oral drugs to remove internal radionuclide contamination from the body. Three MCM candidates have progressed to the Investigational New Drug (IND) submission stage and one MCM candidate has been reviewed by an FDA Advisory Committee for safety and efficacy. RNCP accomplishments since initiation of the program in FY 2005 include hundreds of scientific articles, patents, and over 150 medical countermeasure candidates in discovery and early development phases. A targeted SBIR program for Radiological/Nuclear Medical

Countermeasure Product Development will be extended in 2015. Twenty-five SBIR grants have been funded since FY 2009, including four 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 eight participating NIH Institutes. 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 11 MCM candidates in discovery and research phases, including midazolam (a countermeasure against nerve agents), cobinamide (cyanide), Tissue Plasminogen Activator (sulfur mustard) and AEOL10150 (for pulmonary edema or pulmonary stress. 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 transitioned candidate.

Budget Policy:

The FY 2016 President's Budget estimate to support the development of MCMs against Radiological, Nuclear and Chemical threats is \$93.400 million, \$1.294 million or 1.4 percent above the FY 2015 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): 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 U.S. 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 2016 President's Budget estimate for the FNIH is \$1.000 million, the same as the FY 2015 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 2016 President's Budget estimate for OD Operations is \$130.161 million, \$4.600 million or a 3.7 percent increase over the FY 2015 Enacted level. This level includes sufficient funds to support the FY 2016 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 and training projects across the NIH ICs. 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 three years and in FY 2015, appropriated funds for bioethics research are being used to support research designed to inform NIH policies on ethical issues in research involving human subjects. In FY 2013, NIH asked relevant networks supported by NIH to develop administrative supplements to propose studies that would aid gathering 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 their 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 that would require consent for research on de-identified human data and specimens in biobank research; study which biospecimen and biobanking-related research practices are likely to affect willingness to participate in research under broad consent; examine

the ethical, legal, and social issues involved in the use of electronic medical records for genomic research; gather participant perspectives about broad consent for future use of their specimens and data; assess how treatment autonomy influences patients' and providers' willingness to participate in randomized clinical trials; and assess how patients, their surrogates, the general public, and institutional review board members view the ethical implications of randomization within the standard of care. In FY 2014, three awards were made for new research exploring the principles and characteristics of central Institutional Review Board models and consent and participant preferences for research using clinical records and data. Because funds were limited in FY 2014 due to non-competing obligations from the previous year, the FY 2015 FOA will use unobligated funds to award additional new research on the same two topics.

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): The National Children's Study (NCS), a proposed national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on child health and development, was reviewed by the Institute of Medicine in June 2014, and by an expert working group of the Advisory Committee to the NIH Director (ACD) in December 2014. The ACD working group recommended that, while the overall goals of the NCS should remain a priority for future scientific support, NCS was not feasible as outlined currently. Accordingly, NIH is pursuing an orderly shut-down of NCS. In FY 2015, NCS staff are beginning the process to complete the collection and transmission of data from the field operations; evaluate and produce data sets for all of the NCS Vanguard Study participants in preparation for long term storage for future use by scientists; collect information on the procedures and activities undertaken during the NCS; and centralize the records from the NCS. In FY 2016, minimal staff and funding will be required to support the repository of the specimens from the Vanguard Study and the data storage and access in order to ensure that the data and specimens previously collected are responsibly maintained and made available for future research.

Budget Policy:

The FY 2016 President's Budget estimate for the NCS is \$7.000 million, a \$13.000 million reduction below FY 2015 Enacted level. This funding will be used to ensure the maintenance of the repository of the specimens from the Vanguard Study and the data storage and access in order to ensure that the data and specimens previously collected are responsibly maintained and made available for future research.

Strategic Pediatrics Research: While NCS is being phased out, the Congress instructed NIH to apply the funds to NCS or other programs that could address the same goals. For FY 2015, NIH has been working diligently to identify efforts to address challenges at the intersection of pediatric and environmental health through alternative approaches, including establishing compelling new programs, integrating existing programs, and enhancing programs by incorporating (more comprehensive) environmental assessments. A major focus of the programs will be tool development to enhance measurement of environmental exposures, with additional projects and programs studying the influence of the environment on *in utero* development and expansion of existing studies of environmental influences on later child development.

Budget Policy:

The FY 2016 President's Budget estimate for Strategic Pediatric Research is \$158.000 million, \$13.000 million or a 9.0 percent increase over the FY 2015 Enacted level. For FY 2016, NIH will continue to expand programs on tool development, whilst integrating the results into the extant programs broadened in FY 2015. These programs also will be evaluated to determine more clearly their anticipated impact on the field, and to identify areas ripe with opportunity for possible integration into existing projects or expansion of particularly effective components.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Budget Authority by Object Class¹

(Dollars in Thousands)

	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Total compensable workyears:			
Full-time employment	669	669	0
Full-time equivalent of overtime and holiday hours	4	4	0
Average ES salary	\$179	\$181	\$2
Average GM/GS grade	12.8	12.8	0.0
Average GM/GS salary	\$109	\$110	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$106	\$107	\$1
Average salary of ungraded positions	\$169	\$170	\$2
OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Personnel Compensation			
11.1 Full-Time Permanent	\$64,849	\$65,746	\$897
11.3 Other Than Full-Time Permanent	10,351	10,495	143
11.5 Other Personnel Compensation	1,598	1,620	22
11.7 Military Personnel	982	995	14
11.8 Special Personnel Services Payments	821	832	11
11.9 Subtotal Personnel Compensation	\$78,601	\$79,688	\$1,087
12.1 Civilian Personnel Benefits	\$25,663	\$25,920	\$257
12.2 Military Personnel Benefits	670	679	9
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$104,933	\$106,287	\$1,353
21.0 Travel & Transportation of Persons	\$945	\$960	\$15
22.0 Transportation of Things	505	513	8
23.1 Rental Payments to GSA	2	2	0
23.2 Rental Payments to Others	27	27	0
23.3 Communications, Utilities & Misc. Charges	1,425	1,448	23
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	\$5,452	\$5,602	\$150
25.2 Other Services	53,071	54,384	1,312
25.3 Purchase of goods and services from government accounts	114,821	118,597	3,776
25.4 Operation & Maintenance of Facilities	\$429	\$429	\$0
25.5 R&D Contracts	50,066	37,681	-12,385
25.6 Medical Care	765	784	19
25.7 Operation & Maintenance of Equipment	513	521	8
25.8 Subsistence & Support of Persons	8	8	0
25.0 Subtotal Other Contractual Services	\$225,126	\$218,007	-\$7,119
26.0 Supplies & Materials	\$577	\$590	\$13
31.0 Equipment	2,567	2,637	70
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	1,077,627	1,112,158	34,530
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$1,308,801	\$1,336,341	\$27,541
Total Budget Authority by Object Class	\$1,413,734	\$1,442,628	\$28,894

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

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Personnel Compensation			
Full-Time Permanent (11.1)	\$64,849	\$65,746	\$897
Other Than Full-Time Permanent (11.3)	10,351	10,495	143
Other Personnel Compensation (11.5)	1,598	1,620	22
Military Personnel (11.7)	982	995	14
Special Personnel Services Payments (11.8)	821	832	11
Subtotal Personnel Compensation (11.9)	\$78,601	\$79,688	\$1,087
Civilian Personnel Benefits (12.1)	\$25,663	\$25,920	\$257
Military Personnel Benefits (12.2)	670	679	9
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$104,934	\$106,287	\$1,353
Travel & Transportation of Persons (21.0)	\$945	\$960	\$15
Transportation of Things (22.0)	505	513	8
Rental Payments to Others (23.2)	27	27	0
Communications, Utilities & Misc. Charges (23.3)	1,425	1,448	23
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	5,452	5,602	150
Other Services (25.2)	53,071	54,383	1,312
Purchases from government accounts (25.3)	107,492	110,008	2,516
Operation & Maintenance of Facilities (25.4)	429	429	0
Operation & Maintenance of Equipment (25.7)	513	521	8
Subsistence & Support of Persons (25.8)	8	8	0
Subtotal Other Contractual Services	\$166,965	\$170,951	\$3,986
Supplies & Materials (26.0)	\$577	\$590	\$13
Subtotal Non-Pay Costs	\$170,444	\$174,489	\$4,045
Total Administrative Costs	\$275,378	\$280,776	\$5,398

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

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2014 Actual			FY 2015 Est.			FY 2016 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	610	6	616	619	6	625	619	6	625
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	610	6	616	619	6	625	619	6	625
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	48	-	48	44	-	44	44	-	44
Total:	48	-	48	44	-	44	44	-	44
Total	658	6	664	663	6	669	663	6	669
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2012	12.7								
2013	12.7								
2014	12.8								
2015	12.8								
2016	12.8								

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

Detail of Positions¹

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	11	11	11
Total, ES Salary	1,952,636	1,972,162	1,991,884
GM/GS-15	111	112	112
GM/GS-14	128	129	129
GM/GS-13	174	175	175
GS-12	101	102	102
GS-11	32	33	33
GS-10	4	4	4
GS-9	26	26	26
GS-8	4	4	4
GS-7	7	7	7
GS-6	0	0	0
GS-5	6	6	6
GS-4	2	2	2
GS-3	2	2	2
GS-2	0	0	0
GS-1	1	1	1
Subtotal	598	603	603
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	4	4	4
Senior Grade	1	1	1
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	6	6	6
Ungraded	70	70	70
Total permanent positions	571	576	576
Total positions, end of year	685	690	690
Total full-time equivalent (FTE) employment, end of year	664	669	669
Average ES salary	177,512	179,287	181,080
Average GM/GS grade	12.8	12.8	12.8
Average GM/GS salary	107,852	108,931	110,020

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