DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

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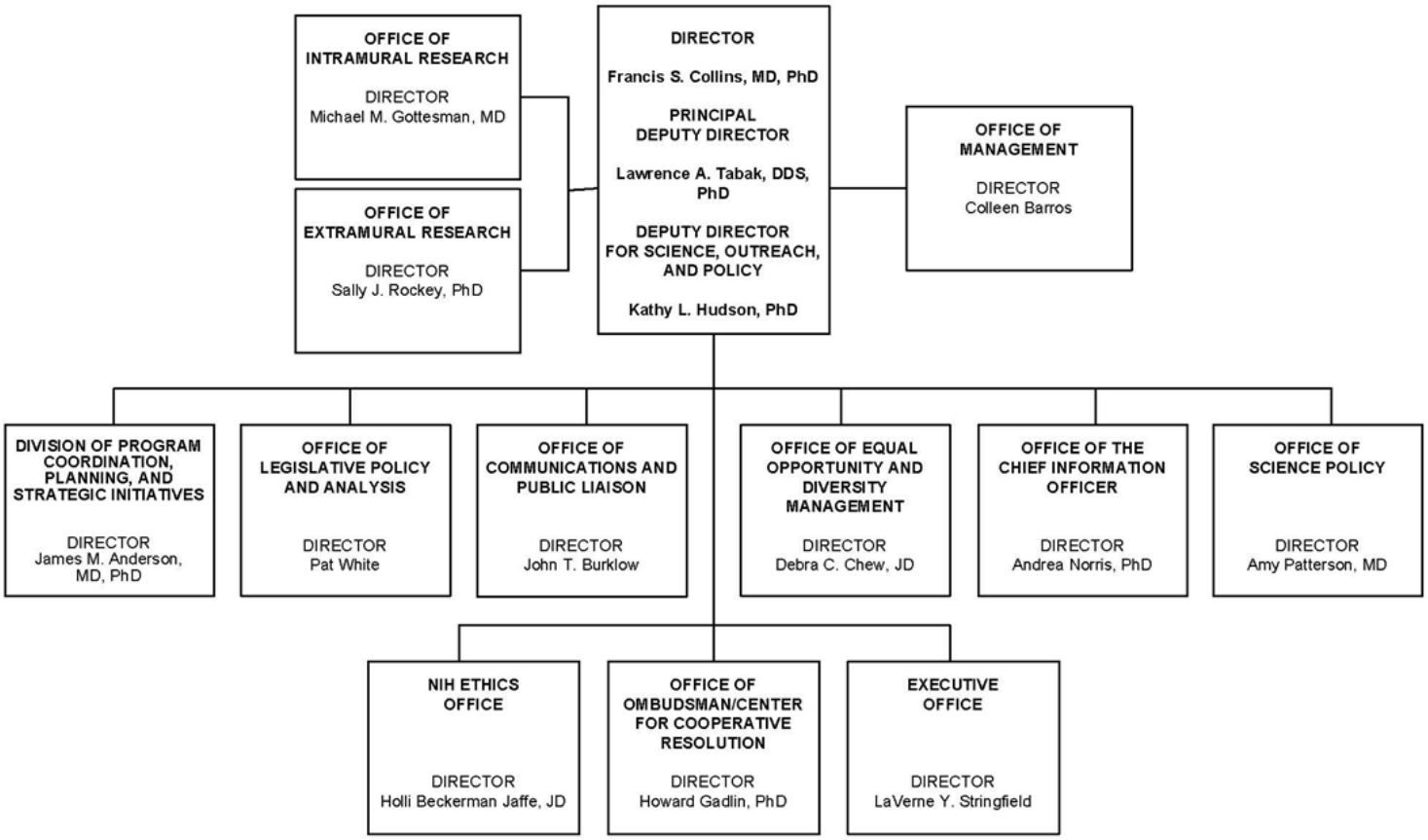
NATIONAL INSTITUTES OF HEALTH

Office of the Director
Organization Structure



NATIONAL INSTITUTES OF HEALTH

Office of the Director

For carrying out the responsibilities of the Office of the Director, NIH, [$1,400,134,000] *$1,451,786,000*, of which up to [$25,000,000] *$30,000,000* shall 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 NIH is authorized to collect third-party payments for the cost of clinical services that are incurred in NIH research facilities and that such payments shall be credited to the NIH Management Fund: *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"), except that not later than July 15, [2014] *2015*, the Director shall estimate the amount needed for the NCS during fiscal year [2014] *2015*, and any funds in excess of the estimated need shall be transferred to and merged with the accounts for the various Institutes and Centers in proportion to their shares of total NIH appropriations made by this Act: *Provided further*, That [$533,039,000] *$583,039,000* 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 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*.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Appropriation	$1,528,181	$1,400,134	$1,451,786
Type 1 Diabetes	0	0	0
Rescission	-3,056	0	0
Sequestration	-76,704	0	0
Subtotal, adjusted appropriation	$1,448,420	$1,400,134	$1,451,786
FY 2013 Secretary's Transfer	-12,790	0	0
OAR HIV/AIDS Transfers	0	0	0
Comparative transfers to NLM for NCBI and Public Access	-1,705	-381	0
National Children's Study Transfers	-23,410	0	0
Subtotal, adjusted budget authority	$1,410,515	$1,399,753	$1,451,786
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$1,410,515	$1,399,753	$1,451,786
Unobligated balance lapsing	-117	0	0
Total obligations	$1,410,399	$1,399,753	$1,451,786

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2013 - $765,154 FY 2014 - $797,134 FY 2015 - $797,134

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

MECHANISM	FY 2013 Actual		FY 2014 Enacted[1]		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects		$423,016		$420,246		$452,842		$32,596
Research Centers		275,924		268,557		241,449		(27,108)
Other Research		199,360		193,807		273,602		79,795
Total Research Grants		$898,300		$882,610		$967,893		$85,283
Training		$7,961		$9,305		$8,172		(1,133)
R & D Contracts		219,429		212,150		185,784		(26,366)
Intramural Research		39,698		28,755		29,122		367
Res. Management & Support		245,127		263,418		260,815		(2,603)
Total Other Than Research Grants		$512,215		$513,628		$483,893		(29,735)
Total, OD		$1,410,515		$1,399,753		$1,451,786		$52,033

[1] The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Budget Authority by Activity

(Dollars in Thousands)

	FY 2013 Actual	FY 2014 Enacted[2]	FY 2015 President's Budget
OD Operations	$ 118,706	$ 125,061	$ 125,800
NIH Director's Challenge Fund [1]	*1,500*	*1,500*	*1,500*
Division of Program Coordination, Planning and Strategic Initiatives	7,737	11,138	11,138
Office of Behavioral & Social Science Research	25,741	26,094	26,094
Office of AIDS Research	60,718	61,923	61,923
Office of Research on Women's Health	40,349	40,903	40,903
Office of Disease Prevention	5,782	5,861	5,861
Office of Dietary Supplements	26,424	26,786	26,786
Office of Research Infrastructure Programs	273,797	275,654	275,654
Science Education Partnership Awards/OSE	19,373	18,541	18,541
Strategic Initiatives	78,691	-	-
Director's Discretionary Fund	9,981	10,000	10,000
Foundation for the National Institutes of Health	500	500	500
Intramural Loan Repayment and Scholarship	7,048	7,145	7,145
Nuclear/Radiological/Chemical Countermeasures	90,851	92,098	93,392
National Children's Study	131,331	165,000	165,000
Reception and Representation Fund	9	10	10
Common Fund	513,476	533,039	583,039
Total	$ 1,410,515	$ 1,399,753	$ 1,451,786

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

[2] The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

Major Changes in the Fiscal Year 2015 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 2015 budget request for OD, which is $52.033 million above the FY 2014 Enacted level, for a total of $1,451.786 million.

Common Fund (+$50.000 million; total $583.039 million):
The FY 2015 budget request for the Common Fund will enable the initiation of new programs and the expansion of some existing programs, such as a $31.1 million increase to the Big Data to Knowledge (BD2K) program. This program will ramp up in FY 2015, with new initiatives aimed at developing policies, standards, software, and training for biomedical big data, as well as establishing Centers of Excellence for Biomedical Big Data. The increased level of support requested will also be critical for the establishment of new programs that represent trans-NIH challenges and opportunities. Programs under consideration for FY 2015 include 3D Nucleome, Bioelectronics, Citizen Science, Glycomics, and Mechanisms Underlying Benefits from Physical Activity. For more details on these and other Common Fund programs, please refer to the Common Fund section of the FY 2015 Congressional Justification.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes[1]

(Dollars in Thousands)

FY 2014 Enacted				$1,399,753
FY 2015 President's Budget				$1,451,786
Net change				$52,033
	FY 2015 President's Budget		**Change from FY2014**	
CHANGES	**FTEs**	**Budget Authority**	**FTEs**	**Budget Authority**
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2014 pay increase & benefits		$831		-$34
b. January FY 2015 pay increase & benefits		831		0
c. Zero more days of pay (n/a for 2015)		831		0
d. Differences attributable to change in FTE		831		0
e. Payment for centrally furnished services		0		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		7,772		0
Subtotal				-34
2. Research Management and Support:				
a. Annualization of January 2014 pay increase & benefits		100,780		1,219
b. January FY 2015 pay increase & benefits		100,780		407
c. Zero more days of pay (n/a for 2015)		100,780		0
d. Differences attributable to change in FTE		100,780		0
e. Payment for centrally furnished services		0		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		133,102		-1,592
Subtotal				34
Subtotal, Built-in				0

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes - continued[1]

CHANGES	FY 2015 President's Budget		Change from FY2014	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	0	$278,743	0	$22,413
b. Competing	0	174,099	0	10,183
c. SBIR/STTR	0	0	0	0
Subtotal, RPGs	0	452,842	0	32,596
2. Research Centers	0	241,449	0	-27,108
3. Other Research	0	273,602	0	79,795
4. Research Training	0	8,172	0	-1,133
5. Research and development contracts	0	185,784	0	-26,366
Subtotal, Extramural		1,161,849		57,784
	FTEs		FTEs	
6. Intramural Research	0	29,122	0	367
7. Research Management and Support	664	260,815	0	-2,603
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	0	$1,451,786	0	$52,033
Total changes				$52,033

[1] The amounts in the Change from FY 2014 column take into account funding reallocations, and therefore may not add to the net change reflected herein.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2014 Amount Authorized	FY 2014 Enacted	2015 Amount Authorized	FY 2015 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$1,399,753,000	Indefinite	$1,451,786,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$1,399,753,000		$1,451,786,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2005	$359,645,000	$359,645,000	$364,100,000	$361,145,000
Rescission				($3,099,000)
2006	$385,195,000	$532,216,000	$537,434,000	$532,395,000
Rescission				($4,829,000)
2007	$667,825,000	$667,825,000	$687,825,000	$478,650,000
Rescission				$0
2008	$517,062,000	$1,114,422,000	$1,145,790,000	$1,109,099,000
Rescission				($19,720,000)
2009	$1,056,797,000	$1,255,420,000	$1,275,281,000	$1,246,864,000
Rescission				$0
Supplemental				$2,636,000
2010	$1,182,777,000	$1,168,704,000	$1,182,777,000	$1,177,020,000
Rescission				$0
2011	$1,220,478,000		$1,268,580,000	$1,177,300,000
Rescission				($10,337,395)
2012	$1,298,412,000	$1,198,412,000	$1,439,064,000	$1,461,880,000
Rescission				($2,762,953)
2013	$1,429,161,000		$1,431,341,000	$1,528,181,000
Rescission				($3,056,362)
Sequestration				($76,704,177)
2014	$1,473,398,000		$1,463,606,000	$1,400,134,000
Rescission				$0
2015	$1,451,786,000			

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 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
BA	$1,410,515,689	$1,399,753,000	$1,451,786,000	+$52,033,000
FTEs	649	664	664	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 leadership and guidance in scientific and administrative matters 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, the 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. The 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 2013, 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 2,400 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 Institutes and Centers to be accountable for the substantial investment in extramural research. For example, to increase transparency and promote effective use of resources, the 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 the NIH intramural research program's policies, training programs, and

technology transfer. OIR pursues and assures (1) rigorous scientific research review, (2) research integrity training, (3) sharing of resources, and (4) collaborations across NIH to enable scientists to conduct innovative biomedical research to prevent, treat, and reduce the burden of human disease. Pursuant to these responsibilities, the 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 Animal Welfare Assurance and related programs in compliance with multiple laws, regulations, and policies for 24 NIH institutes and centers that use animals in their research. Similarly, 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 27 NIH institutes and centers, 12 Institutional Review Boards (IRBs), and the researchers and staff who conduct and support research involving human subjects. OITE enhances the training experience of the approximately 7,000 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 handles the patenting, licensing, and royalty administration for inventions from NIH and FDA intramural scientists. In FY 2012, this office executed 198 licenses, administered $111 million in royalties, filed 300 U.S. patent applications, added 130 issued U.S. patents to the NIH and FDA intellectual property portfolios, and coordinated 93 new Cooperative Research and Development Agreements (CRADAs). The Office of NIH History advances historical understanding of biomedical research originating from the NIH through preservation of records of significant NIH achievements, installation of innovative exhibits, and creation of educational programs and resources.

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 Institutes and Centers, 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 programs offices: the Office of Strategic Coordination, the Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, and the 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 the agency and the biomedical research community including areas such as basic and clinical research involving recombinant DNA, biosafety and biosecurity, 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 NIH's Office of Communications and Public Liaison (OCPL), is the communications headquarters for NIH and its Institutes and Centers. OCPL leads strategic communications planning for NIH; responds to thousands of media requests every year (more than 4,100 in 2013); distributes more than 300 news releases annually to hundreds of media outlets worldwide; manages the NIH web home page; coordinates communications among Institutes and Centers and with HHS; assists with NIH Director 's communications including the new NIH Director's Blog; manages the NIH Freedom of Information Act activities; provides tours; organizes special events; and provides science-based health information via print, TV, radio, 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. The office also manages the NIH Director's Council of Public Representatives (COPR) that works to increase public input and perspective on NIH programs and activities. OCPL is responsible for collaborating across the agency to deal with controversial and complex issues related to funding, new initiatives, budget, animals in research, clinical research, and, this year, new disease threats. Recently, NIH's OCPL continues to lead a trans-NIH initiative to improve access to information about clinical research opportunities by working across the agency with Clinical Trials and You http://www.nih.gov/health/clinicaltrials/. OCPL engaged in a trans-NIH effort to create a single, universal mark for the agency that was successfully trademarked in order to protect the NIH identity and save costs from a continuing proliferation of logos that were often confusing the public.

The Office of Legislative Policy and Analysis (OLPA) is the principal Congressional liaison for the 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 the NIH. OLPA prepares the NIH Director, Deputy Directors, and other senior NIH staff, and the Institute and Center 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 and management support for Information Technology (IT) activities, including IT strategic planning; information security; IT policy; capital planning and investment control; enterprise architecture; accessibility; and project and portfolio management. OCIO seeks to develop IT strategies that will promote efficiency and leverage economies of scale for NIH's IT needs.

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. The 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 Strategy Initiatives (DPCPSI): DPCPSI was created by the NIH Reform Act of 2006. DPCPSI 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 Institutes or Centers (ICs), or from strategic coordination and planning.

DPCPSI serves as a resource for the ICs and the NIH Office of the Director for portfolio analysis by developing, using, and disseminating data-driven approaches and sophisticated computational tools. These portfolio analysis efforts inform the assessment of current, and identification of emerging, areas of research that will advance knowledge and lead to improvements in human health. Data from these analyses also help inform priority setting. The Division coordinates the agency's evaluation set-aside program and reporting under 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.

The Division 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 2015 planned activities.

Budget Policy:
The FY 2015 President's Budget estimate for DPCPSI is $11.138 million, the same as the FY 2014 Enacted level. In FY 2015, 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 intensify its portfolio analysis efforts in FY 2015. These efforts 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 the NIH as a whole. These programs are described in detail in the Common Fund portion of this document.

The 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.

Budget Policy:
The FY 2015 President's Budget request for the Common Fund is $583.039 million, $50.000 million or 9.3 percent above the FY 2014 Enacted level. Strategic planning for new FY 2015 Common Fund programs began in spring 2013. NIH ICs submitted ideas for pressing challenges and emerging opportunities where Common Fund investment could have a transformative impact. Ideas gathered during previous rounds of strategic planning, including ideas generated via discussions with internal and external scientists as well as the general public, were also considered. Promising ideas will be developed through FY 2014 as possible new program areas for the Common Fund in FY 2015. For additional details, please see the Common Fund section.

Office of AIDS Research (OAR): The NIH 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. OAR functions as an "institute without walls" to plan, coordinate, evaluate, and budget the trans-NIH AIDS research program, which is carried out in nearly every IC. 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. OAR is authorized to develop

an annual trans-NIH Strategic Plan and trans-NIH AIDS research budget, explicitly tied to the Plan. The Trans-NIH AIDS Research Budget appears in the Overview section of this document.

Budget Policy:
The FY 2015 budget estimate for OAR is $61.923 million, the same as the FY 2014 Enacted level. OAR will utilize its operating funds to support initiatives that address scientific priorities reaffirmed by the OAR Advisory Council and a working group of non-government experts as well as key priorities of the President's National HIV/AIDS Strategy, the President's Continuum of Care initiative, and the White House Initiative on the Intersection of Violence and HIV Risk. Among these are OAR initiatives in Hispanic populations 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, 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 support 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 also 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 AIDS*info*, a web-based service that provides information for caregivers and patients (available at www.aidsinfo.nih.gov). Funds will be devoted to efforts to build international collaborations and public-private partnerships on research toward a cure, including encouraging young investigators from other disciplines to enter the field. 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 science for health breakthroughs, highlighting sex as a fundamental individual characteristic in precision medicine, and underscoring the importance of a diverse biomedical workforce. ORWH programs and initiatives magnify sex differences considerations 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 2014 Level: $2.8 million
FY 2015 Level: $3.5 million
Change: +$0.7 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 2015 President's Budget estimate for ORWH is $40.903 million, the same as the FY 2014 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*, http://orwh.od.nih.gov/research/strategicplan/index.asp, by: 1) Expanding consideration of sex/gender in basic, biomedical, and behavioral science studies through ORWH research initiatives, programs and co-funding, and with additional priority in 2014, to studies that develop and advance a sex perspective in brain research; 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 interpersonal 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 the NIH by emphasizing the critical role that behavioral and social factors play in health, health care and well-being. OBSSR 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) fostering the next generation of data and analysis methods; 2) strengthening the role of behavioral and social science in an evolving health care system; and 3) training the next generation of behavioral and social scientists.

Technology to Improve Medication Adherence Measurement and Intervention Research

FY 2014 Level: $0.8 million
FY 2015 Level: $1.0 million
Change: +$0.2 million

Medication adherence is the extent to which patients use medications as prescribed by their health care providers. Poor adherence is one of the best predictors of patients failing to receive the full benefit of their medical care. In controlled clinical trials, adherence rates range from 43 to 78 percent for adherence to a single medication. Adherence rates in clinical practice and for more complex regimens are thought to be even lower. Thus, the long standing challenge of patient non-adherence is in need of new solutions, because, in the words of former Surgeon General C. Everett Koop, "Drugs don't work in patients who don't take them".

Because the issue of adherence behavior is critical to the NIH mission of improving population health, OBSSR launched in 2007 the NIH Adherence Network to advance adherence research across the NIH and to strengthen the science of adherence assessment, monitoring, and support. The ultimate goal is to improve health outcomes through the identification of evidence-based approaches to assess and support patient adherence.

Recent years have seen exponential growth in the use of technologies to address medication adherence. Various examples include electronic monitoring of prescription refills, wireless electronic drug monitoring (e.g., Medication Event Monitoring Systems or MEMS caps), pills that wirelessly detect drug ingestion, and cellphone text messaging (SMS) and smartphone/tablet-based programs to promote medication adherence. These advances in technologies provide novel capacities for active monitoring of adherence behavior, improved delivery of medication adherence reminders, patient-centered education on medication and requirements, provision of feedback to patients and providers, and individually-tailored adherence interventions that "fit right into your pocket." The rapid development of these adherence technologies is outpacing both the evidence as well as communication about what is and is not effective. There has been little research on the optimal use of these new technologies, either to better assess adherence, especially to complex regimens, or to intervene to improve adherence behaviors.

To address this gap, OBSSR, in collaboration with the NIH Adherence Network, will develop and issue in 2015 a funding opportunity announcement (FOA) to support research projects that systematically assess medication adherence using technologies, especially in the area of multiple medications. This FOA will also support efforts to identify new areas for changing adherence behavior including, but not limited to, ways to enhance medication literacy, patient-doctor communication and reduction of adherence barriers.

Budget Policy:

The FY 2015 President's Budget estimate for OBSSR is $26.094 million, the same as the FY 2014 Enacted level. Along with voluntary contributions from NIH Institutes and Centers in FY 2015, the Office will 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. Basic behavioral and social sciences studies illuminate mechanisms and processes that influence behavior at the individual, group, community and

population levels (http://obssr.od.nih.gov/about_obssr/BSSR_CC/BSSR_definition/definition.aspx#bfr) and lead to new approaches for reducing risky behaviors and improving the adoption of healthy practices. In addition, OBSSR will advance two new initiatives in FY 2015. *Technology to Improve Medication Adherence Measurement and Intervention Research* will support research projects that systematically assess medication adherence using technologies, especially in the area of multiple medications. This funding opportunity announcement will also support efforts to identify new areas for changing adherence behavior including, but not limited to, ways to enhance medication literacy, patient-doctor communication and reduction of adherence barriers (see program portrait below). A second initiative aligns with the NIH director's goal of strengthening the biomedical workforce. Behavioral and social scientists are increasingly engaging in collaborations with a non-traditional partners, including engineers, computer scientists, physicists, and mathematicians, requiring a new training model that incorporates team science, analytic approaches to understand big data, and evolving research methods. These collaborations require a different set of skills than those offered in most behavioral and social science graduate school curricula. In collaboration with the Office of Science and Technology Policy, OBSSR will launch a new initiative on training the next generation of behavioral and social scientists. Specifically, we plan a multi-pronged approach: 1) to better understand the nature of the current behavioral and social sciences research (BSSR) workforce, training pipeline and their dynamics, OBSSR will join the National Institute of General Medical Sciences' Scientific Workforce Analysis and Modeling initiative to commission the development of BSSR workforce-specific models. 2) Using the models developed in #1, we will probe the likely intended and unintended consequences of a variety of potential efforts to improve the fitness of the BSSR workforce for the 21st century. 3) Informed by model results, develop Funding Opportunity Announcements, training initiatives or other interventions to facilitate achieving the desired size, composition, and characteristics of the BSSR workforce. OBSSR will continue to fund multi-year programs, including a program to enhance the behavioral and social sciences content of medical school curricula; research to develop and translate basic behavioral and social science research into effective health behavior interventions; dissemination and implementation science; and application of systems science methodologies to address complex research questions at the nexus between the behavioral and social sciences and health. Finally, the Office will support training for extramural researchers on the following topics: Systems science, randomized controlled trials involving behavioral interventions; dissemination and implementation research; and mobile health technologies.

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 the 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 on-going 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.

In early FY 2014, ODP released its first strategic plan. The ODP Strategic Plan for Fiscal Years 2014–2018 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. The six priority areas included in the plan chart new directions for the ODP and at the same time build upon and expand established programs. To develop the plan, the ODP implemented an extensive and inclusive stakeholder engagement process which included input from NIH Institutes and Centers, academia, industry, healthcare professionals, patient advocates and advocacy organizations, scientific and professional organizations, federal agencies, and other interested members of the public. ODP also launched new efforts to enhance coordination between the NIH and the U.S. Preventive Services Task Force (USPSTF). The 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. Additionally, the ODP continues to work closely with the NIH Office of Portfolio Analysis to develop new tools to better characterize the prevention research portfolio and improve program planning and reporting. Information resulting from these efforts will be shared with collaborators within and outside the NIH to further advance prevention research. Finally, in late 2014, ODP will host two workshops examining the long-term use of opioids for chronic pain and Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, 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 2015 President's Budget estimate for ODP is $5.861 million, the same as the FY 2014 Enacted level. In FY 2015, 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 co-funds

research grants with ICs on dietary supplements and sponsors systematic reviews in relevant areas as well as projects to enhance the incorporation of these reviews into nutrition research. 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 (NDSI-IEM) initiative, in collaboration with the NIH Office of Rare Diseases Research of the National Center for Advancing Translational Sciences, to identify gaps in research on the safety, efficacy, and effectiveness of nutritional treatments, including dietary supplements, for IEM. The NDSI-IEM is developing models suitable for the study of all rare disorders and evaluating the safety and efficacy of dietary interventions for IEM. These activities fit into the broader context of public health because they will likely lead to better approaches to manage more common diseases that affect millions of people.

Program Portrait: Dietary Supplement Databases
FY 2014 Level: $2.2 million
FY 2015 Level: $2.4 million
Change: +$0.2 million

ODS has an active program to build and maintain databases of information about dietary supplement products and their ingredients sold in the United States that are useful to the scientific research community and not available elsewhere. These four databases are currently in use:

Dietary Supplement Label Database: Launched in June 2013, the DSLD is a searchable database of information taken from the labels of more than 20,000 dietary supplement products. It is a joint project of ODS and the National Library of Medicine (NLM) in collaboration with USDA, CDC, FDA, and DoD. Users can search the database to identify supplements, for example, by label photograph, brand name, ingredients, and health-related claims. About 1,000 new product labels are entered into the DSLD each month so that in time almost all of the more than 55,000 dietary supplements in the marketplace will be included.

Dietary Supplement Ingredient Database: The DSID provides analytically derived estimated levels of ingredients in dietary supplement products. It was developed by the Nutrient Data Laboratory at USDA in collaboration with, and with funding from, ODS. The DSID currently includes multivitamin/multimineral dietary supplements for adults and children. Content of the DSID will be expanded with estimated levels of ingredients in over-the-counter prenatal dietary supplements and omega-3 fatty acid products.

Computer Access to Research on Dietary Supplements: The CARDS database contains information on research with ingredients in dietary supplements funded by USDA, DoD, and NIH. Created for fiscal accounting, management, and control of cross-agency dietary supplement research activities, CARDS identifies the ingredients studied, health outcomes measured, and type of research study.

PubMed Dietary Supplements Subset: Developed in collaboration with NLM, this resource has been available since December 2010. The Subset limits search results from PubMed to citations from a broad spectrum of the scientific literature on dietary supplements, including vitamin, mineral, phytochemical, ergogenic, botanical, and herbal supplements in both human nutrition and animal models.

Budget Policy:
The FY 2015 President's Budget estimate for ODS is $26.786 million, the same as the FY 2014 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 program in the development, validation, and dissemination of analytical methods and reference materials that are critical tools for quality assurance of dietary supplements. 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 2015, the model used for this initiative will be applied to other nutrients of public health concern including iodine and folic acid. ODS, in partnership with the National Center for Complementary and Alternative Medicine 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. (See Portrait of a Program: Dietary Supplement Databases.)

Office of Research Infrastructure Programs (ORIP): ORIP provides support for research and a variety of research infrastructure needs, including animal models and facilities; research models, biological materials, and human biospecimens; training and career development for veterinarians engaged in research; the acquisition of state-of-the-art and shared and high-end instrumentation; and research resources grants to expand, re-model, renovate, or alter existing research facilities or to construct new research facilities.

Division of Comparative Medicine (DCM)

This Division provides critical resources for investigators using animal models for biomedical research and supports technology development involving disease models. The specialized animal colonies, research facilities, tools, and training funded by DCM enable health-related discoveries. Animal models are critical for the success of biomedical research, because they bridge the gap between basic and clinical science. Many diseases need to be studied in living organisms. Therefore, researchers have developed animal models that mimic human conditions. In fact, virtually every major medical advance of the last century involved the use of animal models.

Comparative Medicine – General

DCM funds research to create, develop, characterize, preserve, and study a broad array of high-quality animal models and biological materials. This funding also supports research to safeguard the health and welfare of laboratory animals and provides career development opportunities in specialized areas of translational/biomedical science, with an emphasis on support of researchers who have degrees in veterinary medicine. 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. Mice and other genetically-altered mammals such as rats and pigs provide opportunities for the discovery of molecular targets and biomarkers for pre-clinical testing and the development of therapies for human diseases.

DCM organizes workshops that result in new initiatives in animal-related research areas that are particularly topical. For example, new Funding Opportunity Announcements in the area of

animal stem cell technologies resulted from the recommendations of the workshop entitled "Improving Animal Models for Regenerative Medicine" convened by DCM in 2012.

Properly trained veterinarians are key contributors to the success of all animal-based research. DCM funds career development programs that attract and train graduate veterinarians in such specialties as primate clinical medicine and laboratory animal medicine, to enhance the value of veterinarians on translational research teams. Increasing the number of qualified research veterinarians and ensuring that veterinarians are recognized partners on translational research teams remains a priority.

Through interactions with its NIH partners and the scientific community, DCM plans to support scientific priorities that best meet the broad needs of the multidisciplinary biomedical research community and to take the lead in assessing and promoting new animal-based technologies. New areas of emphasis in FY 2015 will include: 1) Developing new animal models that reflect specific human genotypes and phenotypes ("personalized animal models"), and 2) Facilitating the development of the zebrafish as an emerging animal model for many areas of translational research, including high throughput drug screening.

Program Portrait: New Initiative - Preclinical Models for Precision Medicine

FY 2014 Level: $0.0 million
FY 2015 Level: $4.0 million
Change: +$4.0 million

Recent advances in diverse areas of biomedical science and breakthroughs in technology such as affordable whole genome sequencing and molecular profiling provide a unique opportunity to study the genetics and pathogenesis of a wide variety of human diseases with the eventual goal of using this information to inform clinical practice. Heterogeneity of patient populations and the absence of effective means to interpret patient genetic/omic information for clinical use are significant obstacles toward achieving this goal. Creating optimally informative animal models to generate reliable preclinical data for human studies is a fundamental aspect of this challenge. This initiative is based on recommendations made to ORIP and the NIH Institutes by translational researchers and clinical experts at workshops convened by the DCM in 2012 and 2013.

The overall goal of the program is to establish a working pipeline for pre-clinical scientific discovery, disease modeling and development of interventions. This eventually will be integrated into diagnostics, care and personalized treatment of patients. DCM proposes a new initiative to provide support for research and development projects that will increase the predictive value of preclinical studies based on the use of a new generation of precision animal and *ex vivo* models, thus providing guidance for subsequent clinical trials. The distinguishing features of the proposed collaborative effort will be tight association with patient-specific knowledge environments, the use of state of the art model systems, including animal-based models and complementary ex vivo models, and focused efforts aimed at coordinating and integrating activities and information. This approach recognizes the need for centralized resources that will: collect process and collate genetic and omics information; improve phenotype-disease ontologies; and create genetically modified animals of different species and interspecies somatic hybrids. The goal will be to rigorously assess both useful and limiting characteristics regarding the utility of specific models for specific human disorders.

National Primate Research Centers (NPRCs)

The goal of the NPRC program is to facilitate the use of non-human primates (NHPs) as models of human health and disease for basic and translational biomedical research. The eight NPRCs provide animals for research, facilities, and expertise in all aspects of NHP biology and

husbandry. To facilitate biomedical investigations, the NPRCs house 26,000 NHPs, 70 percent of which are rhesus monkeys, the most widely used NHP for HIV research and translational studies. It is neither cost effective nor feasible to reproduce these specialized facilities and expertise at every research institution, so the NPRCs are a valuable resource to the research community. Major areas of research benefiting from the resources of the NPRCs include AIDS, avian flu, Alzheimer's disease, Parkinson's disease, diabetes, asthma, women's health, and regenerative medicine. Examples of some major research topics pursued at the NPRCs in FY 2013 include the following: 1) HIV/AIDS. Using the rhesus monkey model for HIV/AIDS, researchers have demonstrated that a vaccine based on a cytomegalovirus vector not only controls infection, but can completely eliminate virus over time. Aside from very rare examples in humans, this is one of the first indications that a specific type of vaccine can fully eliminate HIV-type virus from the body. 2) Neurobiology. Approximately 12 percent of human mothers who bear children with autism spectrum disorder (ASD) contain antibodies directed against fetal brain proteins, suggesting that these antibodies may be a cause of ASD in some cases. Investigators injected these antibodies into pregnant monkeys and demonstrated that offspring had behavioral changes suggesting ASD-like symptoms and changes in brain structure, relative to controls. These results suggest the possibility of developing a monkey model of ASD that can be used to understand etiology and to test therapies. 3) Regenerative Medicine. Neural progenitor cells were derived from induced pluripotent stem cells in vitro and injected into the brains of Parkinsonian monkeys. The stem cells survived for up to six months and differentiated into neurons and other neural cell types in the brain. This is an important step toward developing monkey models of personalized stem-cell based therapies for neurological disorders such as Parkinson's disease. These are just a few of the many examples of the contribution of the NPRCs and their collaborators toward investigating major health-related problems.

Division of Construction and Instruments

This Division supports programs to expand the Nation's capacity for the conduct of biomedical research; grants for the acquisition of state-of the-art biomedical research instrumentation and integrated instrument systems; and grants to expand, re-model, renovate, or alter existing research facilities, or to construct new research facilities or complete shell space, when funds are available.

Shared Instrumentation (SIG) and High-End Instrumentation (HEI) Grant Programs

NIH-supported investigators frequently require access to advanced instrumentation to carry out their research projects. Typically, such instrumentation is too expensive for an individual investigator to purchase and may be too complex for a sole investigator to operate to achieve optimal scientific benefits. Furthermore, new and improved technologies capable of further enhancing scientific discovery emerge continuously, so that the research instrumentation infrastructure requires regular updating to hone the competitive edge of NIH-supported investigators. For example, many up-to-date scientific endeavors such as gene sequencing and genotyping cannot be accomplished without the use of modern technologies. Imaging of brain and neuronal activity relies on very sophisticated hardware platforms. Such experiments generate an abundance of data and powerful computer systems are necessary to collect it, analyze it, and interpret it.

To fulfill the objective of enabling scientific discovery, the Shared Instrumentation (SIG) and High-End Instrumentation (HEI) grant programs are providing groups of NIH-supported investigators with essential cutting-edge instrumentation in a cost effective manner through sharing of such resources. These two shared instrumentation programs are unique in the NIH and address critical needs across all disciplines and all NIH Institutes. The new generation instrumentation technologies enable, advance, and accelerate NIH research programs across a broad array of basic, translational, and clinical investigations. The SIG Program funds equipment in the $100,000 - $600,000 range; the HEI Program supports instrumentation from $750,000 - $2 million. These specialized instruments advance biomedical research, because they allow investigators to conduct studies that could not be previously done. The program design of sharing among multiple research projects assures a cost effective and high impact outcome. In FY 2013, the SIG and HEI programs funded 120 instruments, supporting more than 1,500 NIH research projects awarded by most of the NIH ICs.

Extramural Research Facilities Improvement Program

This program provides support to institutions for renovations 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 alterations, renovations, and equipment upgrades. This program enables the investigators to increase animal housing space, increase security, and minimize exposure of personnel to animal allergens or infectious agents. In addition, equipment upgrades can improve the efficiency of the animal facilities. When funds are available, the extramural construction program supports new construction and completion of shell space used in NIH-funded research. These facilities must be utilized for biomedical or behavioral research purposes for which they were improved 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 policies concerning laboratory animal care and use. NIH procured and bred these chimpanzees at a time when AIDS was an emerging epidemic; a disease for which there were no known animal models that would allow scientists to understand the disease pathway or point the way toward therapeutics and vaccines. Historically, research using chimpanzees has led to critical advances, including the development of vaccines for polio, hepatitis A and B, and therapeutic monoclonal antibodies. In December 2011, the Institute of Medicine (IOM) released a report concluding that alternate research tools have rendered chimpanzees largely unnecessary as research subjects. The NIH Director accepted the recommendations and charged the NIH Council of Councils to advise him on the implementation. Senate Bill 252 (the CHIMP Act Amendments of 2013) was enacted on November 27, 2013, and authorizes the funding for the care, maintenance, and transportation of federally-owned retired chimpanzees.

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 support of the early pipeline component of workforce development. SEPA's K-12 STEM projects provide resources for research-related career opportunities for the students and professional development opportunities for the teachers in minority, underserved, and rural communities. In FY 2015, the SEPA Program will be coordinated with the Department of Education to ensure that program activities and commercialized products are aligned with ongoing P-12 reform efforts, and refocused to emphasize biomedical education research interventions. SEPA projects will continue to be required to conduct rigorous evaluation to measure effectiveness. SEPA projects are encouraged to collaborate with Institutional Development Award (IDeA) programs where graduating SEPA students fill the undergraduate pipeline at IDeA institutions, thus continuing NIH's efforts in Enhancing Diversity in the Biomedical Workforce.

Budget Policy:
The FY 2015 President's Budget estimate for ORIP (including the SEPA Program) is $294.195 million, the same as the FY 2014 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 in both children and adults through the Science Education Partnership Program (SEPA).

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 Science Education Partnership Awards (SEPA) program plans will 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 2013 the distribution of ILRP awards was as follows:

- Three awards for the Clinical LRP – one new and two renewals;
- 58 awards for the General LRP – 20 new and 38 renewals; and
- Four awards for the AIDS LRP – one new and three renewals.

FY 2013 ILRP awards were decreased by 27 percent compared to FY 2012 due to the impact of sequestration .

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 19 new recipients for the UGSP Scholarship award and four UGSP Scholars received scholarship award renewals. In addition, 24 UGSP scholars conducted their yearlong service obligation and 14 completed their summer internship during this same period.

Budget Policy:
The FY 2015 President's Budget estimate for ILRSP is $7.145 million, the same as the FY 2014 Enacted level. The FY 2014 program plans include the UGSP and Loan Repayment projected new and renewal awards and administrative costs. The FY 2014 awards and administrative costs are as follows:

(Dollars in Millions)

Program	FY2011 Awards	FY2011 Amount	FY2012 Awards	FY2012 Amount	FY2013 Awards	FY2013 Amounts	FY2014 Awards	FY2014 Amounts
NIH Clinical Loan Repayment Program	4	$0.060	7	$0.293	3	$0.039	3	$0.121
NIH General Loan Repaymen Program	75	$4.510	77	$4.089	58	$2.912	77	$4.089
AIDS Loan Repayment Program	7	$0.230	5	$0.194	4	$0.123	5	$0.200
Undergraduate Scholarship Program	17	$0.230	17	$0.232	19	$0.303	22	$0.323
ILRSP Administrative Cost				$2.585		$3.671		$2.412
Totals	103	$5.040	106	$7.393	84	$7.048	105	$7.145

***NOTE: The Administrative Costs were not included in FY 2011.

Director's Discretionary Fund (DDF): The DDF allows the NIH Director to respond quickly to new and emerging high-priority research opportunities and Health priorities. In FY 2013, funds were used to support trans-NIH initiatives such as Environment Science Rapid Research Response, Early Psychosis Prediction, Pathophysiology, and Prevention, and Recombinant DNA.

Budget Policy:
The FY 2015 President's Budget estimate for DDF is $10.000 million, the same as the FY 2014 Enacted level. In FY 2015, the DDF will continue funding projects to help uncover new knowledge that prevents, detects, diagnoses, and treats disease and disability, from the common cold to the treating of genetic disorders.

Countermeasures against Nuclear/Radiological Threats and Chemical Countermeasures Research: The Radiation and Nuclear Countermeasures Program (RNCP) managed by NIH/NIAID develops medical countermeasures that can be used to mitigate and treat injuries caused by the exposure to nuclear and radiological threat materials. The multi-element program supports collaborative efforts with academic, industry, and federal laboratories. Ongoing initiatives include the Centers for Medical Countermeasures against Radiation (CMCRs), which conduct basic, translational, and applied research leading to new medical countermeasures against radiological and nuclear exposures due to terrorist attacks; and product development support services that provide capabilities for drug development toward FDA licensure. The RNCP also supports the development of oral drugs to remove internal radionuclide contamination from the body. A RNCP contract with the Radiation Effects Research Foundation in Hiroshima, Japan, enables the study of effects of radiation and aging on immune senescence.

RNCP accomplishments since initiation of the program in FY 2005 include over 600 scientific articles published in peer-reviewed journals, over 40 patents, and over 120 medical countermeasure candidates in discovery and development phases. A targeted SBIR program for Radiological/Nuclear Medical Countermeasure Product Development was extended in 2012. Twenty-two 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 the 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 medical countermeasure candidates in discovery and research phases, including the benzodiazepine midazolam and cobinamide. Midazolam, a countermeasure against nerve agents, is a specific initiative that 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, a cyanide countermeasure, will be the next candidate to transition.

Budget Policy:
The FY 2015 President's Budget estimate to support the development of medical countermeasures against Radiological, Nuclear and Chemical threats is $93.392 million, an increase of $1.294 million or a 1.4 percent increase over the FY 2014 Enacted level. The Radiation and Nuclear Countermeasures Program will continue to support basic and translational research for the development of promising safe and effective therapeutic and diagnostic candidates towards IND and licensure. Basic research will focus on elucidating mechanisms of radiation injuries and identifying potential new medical countermeasure candidates for measuring, minimizing, mitigating and treating the effects of exposure to external radiation sources. Important programs, such as "Centers for Medical Countermeasures Against Radiation " and "Product Development Support Services" will be renewed. The Chemical Countermeasures Research program will also 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 in 1996 as a 501(c)(3) public charity to support the mission of NIH. Since inception, FNIH has raised $700 million or $84 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 created novel public-private partnerships that support the mission of the NIH. One such example is ADNI, 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. ADNI-like partnerships now have been formed all over the world. FNIH raises funds from companies, foundations and individuals.

Budget Policy:
The FY 2015 President's Budget estimate for the FNIH is $0.500 million, the same as the FY 2014 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, Executive Office, Executive Secretariat, NIH Ethics Office, and the Immediate Office of the Director.

Budget Policy:
The FY 2015 President's Budget estimate for OD Operations is $125.800 million, an increase of $0.739 million or a 0.6 percent increase over the FY 2014 Enacted level. This level includes sufficient funds to support annual payroll costs. Funding will also be used to reduce vulnerabilities to risks that exist in all areas at the NIH, including both extramural and intramural research, research information, IT, finance and administration.

The OD will continue to support high priority bioethics research and training projects across the NIH ICs. These funds are part of a broader initiative, which is managed by the Office of Science Policy, aimed at integrating bioethics across the spectrum of the NIH research portfolio and expanding the evidence base to inform sound practice and policy. 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 persepectives 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. After reviews for merit and program relevance, five applications were selected for award. Funded investigators will assess 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. The OD has developed an FOA for FY 2014 to solicit 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.

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 is funded through the NIH Office of the Director and led by the Eunice Kennedy Shriver National Institute of Child Health and Human Development in collaboration with a consortium of federal government partners. The NCS is a longitudinal birth cohort observational study with the goal of improving child health and well-being and identifying antecedents of healthy adulthood by examining the effects of a broad range of environmental, behavorial, and biological factors. The NCS plan is to enroll approximately 100,000 children from across the U.S. and follow them until age 21 years. It is designed to produce an unprecedented amount of information about factors that contribute to growth, development, health, and disease. The NCS consists of a pilot study (the "Vanguard Study") begun in 2009 and a Main Study anticipated to begin field work in FY 2015. Per Congressional directive, the Institute of Medicine (IOM) is currently reviewing the proposed methodologies for the Main Study, with a preliminary report targeted for July or August 2014. The NCS is authorized to initiate acquisitions for Main Study activities 60 days following that release.

Budget Policy:
The FY 2015 President's Budget request for NCS is $165 million, the same as the FY 2014 Enacted level. With these funds, the OD will support continuation of the Vanguard Study and initiation of the Main Study in FY 2015. For both the Vanguard Study and Main Study, the budget will support community outreach and communications efforts, bio-specimen and environmental collections, information management systems, and logistics. The Vanguard Study will continue as the pilot for each phase of the Main Study, providing reliable field data to inform Main Study science, operations, and costs, and verifying that the Main Study methods and measures will be feasible, acceptable to participants (critical for retention), and cost-effective. The FY 2015 budget request is based on the currently proposed design, which would enroll participants at multiple points of entry from preconception to birth. Recruitment would occur through health care providers, utilizing hospitals and birthing centers as locations to enroll a birth stratum of newborn children, and community prenatal care providers and clinics to enroll a prenatal stratum of pregnant women. If the IOM report supports the current proposed Main Study design, or suggests only modest refinements, both FY 2015 and budget projections for the next several years would be consistent with the current President's Budget request.

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Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Total compensable workyears:				
	Full-time employment	664	664	0
	Full-time equivalent of overtime and holiday hours	4	4	0
	Average ES salary	$176,421	$178,185	$1,764
	Average GM/GS grade	12.7	12.7	0.0
	Average GM/GS salary	$106,435	$107,499	$1,064
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$109,429	$110,523	$1,094
	Average salary of ungraded positions	$170,431	$172,135	$1,704
	OBJECT CLASSES	**FY 2014 Enacted[2]**	**FY 2015 President's Budget**	**FY 2015 +/- FY 2014**
	Personnel Compensation			
11.1	Full-Time Permanent	$63,342	$63,975	$633
11.3	Other Than Full-Time Permanent	9,975	10,076	101
11.5	Other Personnel Compensation	860	868	8
11.7	Military Personnel	702	709	7
11.8	Special Personnel Services Payments	1,115	1,126	11
11.9	**Subtotal Personnel Compensation**	**$75,994**	**$76,754**	**$760**
12.1	Civilian Personnel Benefits	23,665	24,493	828
12.2	Military Personnel Benefits	360	364	4
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$100,019**	**$101,611**	**$1,592**
21.0	Travel & Transportation of Persons	1,305	1,327	22
22.0	Transportation of Things	100	101	1
23.1	Rental Payments to GSA	17	18	1
23.2	Rental Payments to Others	67	68	1
23.3	Communications, Utilities & Misc. Charges	1,591	1,618	27
24.0	Printing & Reproduction	4	4	0
25.1	Consulting Services	4,475	4,550	75
25.2	Other Services	57,649	53,462	-4,187
25.3	Purchase of goods and services from government accounts	119,734	119,843	109
25.4	Operation & Maintenance of Facilities	328	334	6
25.5	R&D Contracts	212,150	185,784	-26,366
25.6	Medical Care	0	0	0
25.7	Operation & Maintenance of Equipment	3,062	3,114	52
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$400,482**	**$370,223**	**-$30,259**
26.0	Supplies & Materials	860	875	15
31.0	Equipment	2,962	3,012	50
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	891,915	976,065	84,150
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	**$1,296,219**	**$1,350,175**	**$53,956**
	Total Budget Authority by Object Class	**$1,399,753**	**$1,451,786**	**$52,033**

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

[2] The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation			
Full-Time Permanent (11.1)	$63,342	$63,975	$633
Other Than Full-Time Permanent (11.3)	9,975	10,076	101
Other Personnel Compensation (11.5)	860	868	8
Military Personnel (11.7)	702	709	7
Special Personnel Services Payments (11.8)	1,115	1,126	11
Subtotal Personnel Compensation (11.9)	**$75,994**	**$76,754**	**$760**
Civilian Personnel Benefits (12.1)	$23,665	$24,493	$828
Military Personnel Benefits (12.2)	360	364	4
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**100,019**	**101,611**	**1,592**
Travel & Transportation of Persons (21.0)	$1,305	$1,327	$22
Transportation of Things (22.0)	100	101	1
Rental Payments to Others (23.2)	67	68	1
Communications, Utilities & Misc. Charges (23.3)	1,591	1,618	27
Printing & Reproduction (24.0)	4	4	0
Other Contractual Services:			
Consultant Services (25.1)	4,475	4,550	75
Other Services (25.2)	57,649	53,462	-4,187
Purchases from government accounts (25.3)	119,734	119,843	109
Operation & Maintenance of Facilities (25.4)	328	334	6
Operation & Maintenance of Equipment (25.7)	3,062	3,114	52
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$188,315**	**$184,421**	**-$3,894**
Supplies & Materials (26.0)	860	875	15
Subtotal Non-Pay Costs	**$189,175**	**$185,296**	**-$3,879**
Total Administrative Costs	**$289,194**	**$286,907**	**-$2,287**

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

OFFICE/DIVISION	FY 2013 Actual			FY 2014 Est.			FY 2015 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Appropriated									
Direct:	596	5	601	611	5	616	611	5	616
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	596	5	601	611	5	616	611	5	616
Reimbursable									
Direct:	-	-	-	-	-	-	-	-	-
Reimbursable:	48		48	48		48	48		48
Total:	48		48	48		48	48		48
Total	644	5	649	659	5	664	659	5	664
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.									

FISCAL YEAR	Average GS Grade
2011	12.6
2012	12.7
2013	12.7
2014	12.7
2015	12.7

NATIONAL INSTITUTES OF HEALTH
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Details of Positions

GRADE	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Total, ES Positions	13	13	13
Total, ES Salary	2,270,762	2,293,470	2,316,404
GM/GS-15	117	117	117
GM/GS-14	121	126	126
GM/GS-13	159	164	164
GS-12	102	107	107
GS-11	32	32	32
GS-10	5	5	5
GS-9	29	29	29
GS-8	8	8	8
GS-7	10	10	10
GS-6	2	2	2
GS-5	3	3	3
GS-4	8	8	8
GS-3	4	4	4
GS-2	0	0	0
GS-1	0	0	0
Subtotal	600	615	615
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	0	0	0
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	5	5	5
Ungraded	68	68	68
Total permanent positions	586	586	586
Total positions, end of year	702	717	717
Total full-time equivalent (FTE) employment, end of year	649	664	664
Average ES salary	174,674	176,421	178,185
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	105,381	106,435	107,499

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