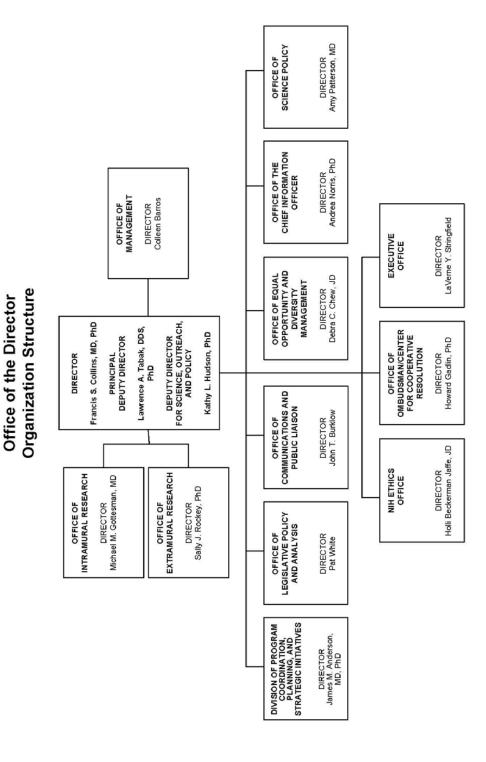
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of the Director (OD)

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NATIONAL INSTITUTES OF HEALTH



NATIONAL INSTITUTES OF HEALTH

Office of the Director

For carrying out the responsibilities of the Office of the Director, NIH, \$1,473,398,000, of which up to \$25,000,000 shall be used to carry out section 211 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 \$572,948,000 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 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	1,461,880	1,468,047	1,473,398
Rescission	(2,763)	0	0
Subtotal, adjusted appropriation	1,459,117	1,468,047	1,473,398
Secretary's Transfer for Alzheimer's disease (AD)	(200)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	(416)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(1,333)	(1,727)	0
Subtotal, adjusted budget authority	1,457,168	1,466,320	1,473,398
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	1,457,168	1,466,320	1,473,398
Unobligated balance lapsing	(221)	0	0
Total obligations	1,456,947	1,466,320	1,473,398

Excludes the following amounts for reimbursable activities carried out by this account: FY 2012 - \$757,710 FY 2013 - \$763,712 FY 2014 - \$1,023,286

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Budget Mechanism - Total (Dollars in Thousands)

MEGNANYGA		FY 20		FY 2013		FY 2014		Change vs. FY 2012		_		
MECHANISM	No.	Actual No. Amount		CR No. Amount		PB No. Amount		No. Amount				
Research Grants:	110.	7.1	inoun	110.		ranount	110.		7 HIROGIL	110.		moun
Research Projects:		\$	438,491		\$	455,008		\$	479,192		\$	40,701
Research Centers			293,079			249,928			241,742			(51,337)
Other Research			175,439			193,791			225,463			50,024
Total, Research Grants		\$	907,009		\$	898,727		\$	946,397		\$	39,388
Training			7,316			7,670			8,023			707
R& D Contracts			253,577			263,178			226,842			(26,735)
Intramural Research			41,300			50,298			41,139			(161)
Res. Mgmt. and Support			247,966			246,447			250,997			3,031
Total Other Than Research Grants		\$	550,159		\$	567,593		\$	527,001		\$	(23,158)
Total, OD		\$ 1.	,457,168		\$	1,466,320		\$	1,473,398		\$	16,230

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Budget Authority by Activity (Dollars in Thousands)

	FY 2 Act	-	F	FY 2013 CR	Y 2014 lent's Budget
OD Operations	\$	123,438	\$	124,586	\$ 128,346
NIH Director's Challenge Fund ¹		1,500		1,500	1,500
Division of Program Coordination, Planning and Strategic Initiatives		8,116		8,166	8,191
Office of Behavioral & Social Sciences Research		27,001		27,166	27,251
Office of AIDS Research		63,802		64,192	64,392
Office of Research on Women's Health		42,324		42,583	42,716
Office of Disease Prevention		6,065		6,102	6,121
Office of Dietary Supplements		27,717		27,887	27,974
Office of Research Infrastructure Programs		283,243		285,029	286,314
Science Education Parternship Awards		20,282		20,406	-
Office of Science Education		3,980		4,004	-
Strategic Initiatives		-		-	30,886
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		7,393		7,438	7,461
Nuclear/Radiological/Chemical Countermeasures		95,298		95,298	95,298
National Children's Study		193,098		194,698	165,000
Common Fund		544,930		548,265	572,948
Total	\$ 1,	457,168	\$	1,466,320	\$ 1,473,398

 $^{1/}I tems \ in \ italics \ are \ "non-adds"; for \ reference \ only \ (NIH \ Director's \ Challenge \ Fund \ amounts \ are \ already \ included \ in \ OD \ Operations \ budget.)$

Major Changes in the Fiscal Year 2014 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 2014 budget request for OD, which is \$16.2 million above the FY 2012 Actual level, for a total of \$1,473.4 million.

National Children's Study (NCS) (-\$28.098 million; total \$165.0 million): The FY 2014 budget request for NCS will support the continuation of the Vanguard Study and the beginning of the Main Study. NIH is evaluating alternative sampling approaches that will reduce costs by building on existing infrastructure, and streamlining administrative components.

Common Fund (+\$28.018 million; total \$572.948 million): The FY 2014 budget request for the Common Fund will enable the initiation of new programs and the expansion of some existing programs, such as an \$8.2 million increase to the NIH Director's Early Independence Awards. The increased level of support requested will be critical for the establishment of new initiatives, such as the Big Data to Knowledge (BD2K) program. As the ability to produce data has far outpaced the ability to analyze it, the scientific community has repeatedly called for coordinated investments to overcome this challenge. To be launched from the Common Fund at a level of \$40.891 million in FY 2014, BD2K represents a major NIH-wide initiative that will benefit the entire biomedical research enterprise.

Science Education Partnership Awards (-\$15.4 million; total \$0) and Office of Science Education (-\$2.2 million; total \$0): In order to better coordinate Federal Science, Technology, Engineering, and Mathematics (STEM) education efforts, improve outcomes, train and generate many more STEM teachers and graduates, the FY 2014 Budget proposes a major reorganization of government-wide STEM programs. Within the OD, this means that the FY 2014 budget eliminates the Science Education Partnership Awards (SEPA) program and the Office of Science Education (OSE). The programmatic portion of prior funding for SEPA (\$15.4 million) and OSE (\$2.2 million) would be consolidated outside NIH, while the remaining portion would be reallocated within OD.

NATIONAL INSTITUTES OF HEALTH

Office of the Director Summary of Changes

(Dollars in Thousands)

FY 2012 Actual				\$1,457,168
FY 2014 President's Budget				\$1,473,398
Net change				\$16,230
		014		
	Preside	nt's Budget	Change from	n FY 2012
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January				
2012 pay increase & benefits		\$4,838		\$12
b. January FY 2014 pay increase & benefits		4,838		36
c. One more day of pay		4,838		18
d. Differences attributable to change in FTE		4,838		0
e. Payment for centrally furnished services		0		0
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		36,301		C
Subtotal				\$66
2. Research Management and Support:				
a. Annualization of January				
2012 pay increase & benefits		\$93,716		\$233
b. January FY 2014 pay increase & benefits		93,716		693
c. One more day of pay		93,716		354
d. Differences attributable to change in FTE		93,716		0
e. Payment for centrally furnished services		2,887		52
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		154,394		-1,398
Subtotal				-\$66
Subtotal, Built-in				\$0

NATIONAL INSTITUTES OF HEALTH Office of the Director

Summary of Changes--continued

		2014		
	Presid	ent's Budget	Change f	rom FY 2012
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research Project Grants:				
a. Noncompeting	0	\$290,007	0	\$10,750
b. Competing	0	189,185	0	29,951
c. SBIR/STTR	0	0	0	0
Total	0	\$479,192	0	\$40,701
2. Research Centers	0	\$241,742	-104	-\$51,337
3. Other Research	0	225,463	-333	50,024
4. Research Training	0	8,023	-137	707
Research and development contracts	0	226,842	0	-26,735
Subtotal, Extramural		\$1,181,262		\$13,360
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	0	\$41,139	0	-\$161
7. Research Management and Support	659	250,997	4	3,031
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	659	\$1,473,398	4	\$16,230
Total changes				\$16,230

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Authorizing Legislation

	PHS Act/	U.S. Code	2013 Amount	_	2014 Amount	FY 2014
	Other Citation	Citation	Authorized	CR	Authorized	PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				\$1,466,320,000		\$1,473,398,000
Office of the Director	Section 401(a)	42§281	Indefinite		Indefinite	
Total Budget Authority				\$1,466,320,000		\$1,473,398,000

Office of the Director

Appropriations History

Fiscal	Budget Estimate to			
Year	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				-
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				-
Supplemental				\$2,636,000
2010	\$1,182,777,000	\$1,168,704,000	\$1,182,777,000	\$1,177,020,000
Rescission				-
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	-
Rescission				-
2014	\$1,473,398,000	-	-	-

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	
	FY 2012	FY 2013	President's	FY 2014 +/-
	Actual	CR	Budget	FY 2012
BA	\$1,457,168,000	\$1,466,320,000	\$1,473,398,000	+\$16,230,000
FTEs	655	659	659	+4

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 in support of the NIH mission. The OD strategically plans, manages, and implements 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 science policy and related social, ethical, and legal issues; technology transfer; health information dissemination and education functions; legislative activities; oversight of the agency's stewardship of public funds; and extramural and intramural research activities. 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. The OD Offices and examples of their initiatives 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 2012, extramural investments accounted for approximately 82 percent of NIH's budget, and provided funds supporting a scientific workforce of over 300,000 investigators at over 3,000 organizations, including universities, medical schools, hospitals, and other research facilities. 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 (ICs) to be accountable for the substantial investment in extramural research. For example, to increase transparency and promote effective use of resources, the NIH will begin reporting the amount of indirect costs paid per grant on its Research Portfolio Online Reporting Tools website (NIH RePORT) by October 1, 2013.

The Office of Intramural Research (OIR) provides leadership in the development and coordination of NIH's 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. The Office of Technology Transfer (OTT) manages collaborations among intramural scientists and colleagues from academia and industry. In FY 2012, on behalf of the NIH and Food and Drug Administration (FDA) Intramural Research Programs, OTT executed 198 licenses; administered \$111 million in royalties; filed 482 patent applications worldwide; added 381 issued-patents worldwide to the NIH and FDA intellectual property portfolios; and coordinated 93 new Cooperative Research and Development Agreements. Currently, there are 61 Clinical Phase I to Phase III licensed technologies in the product development pipeline.

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 NIH. DPCPSI is composed of six program 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 development on high priority and cross-cutting issues of significance to the agency and the biomedical research community in areas such as, clinical and translational research, comparative effectiveness research, biosafety and biosecurity, genomic technologies, and genomic data sharing, as well as in areas that may warrant special attention and/or oversight such as dual use research of concern and research involving recombinant DNA. 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 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 2012); 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 led a trans-NIH initiative to improve access to information about clinical research opportunities working across the agency with Clinical Trials and You http://www.nih.gov/health/clinicaltrials/ In the summer of 2012, OCPL worked extensively with OLPA and the Deputy Director for Science, Outreach, and Policy and staff to create and carry out the "Celebration of Science--NIH Day"-an unprecedented, compelling series of presentations about the value of medical research and its impact on patients and their families. The event included bipartisan participation by members of Congress.

The Office of Legislative Policy and Analysis (<u>OLPA</u>) is the principal Congressional liaison for the NIH Director and Deputy Director, senior staff of the Office of the Director, and the NIH's 27 ICs. 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, other senior NIH staff, and the 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 staffs 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 provides 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 and provides leadership for identifying, reporting, and funding of trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that merit further research and would benefit from collaboration between two or more ICs, or from strategic coordination and planning. The Division coordinates and oversees the planning, implementation, and evaluation of a series of trans-NIH programs that are supported by the NIH Common Fund. These catalytic programs help support research throughout the biomedical community by providing enabling technologies, services and programs; developing essential tools and methodologies; and fostering innovation through high risk/high reward programs. The Division includes major programmatic offices that coordinate research and activities related to AIDS, behavioral and social sciences, women's health, disease prevention, and dietary supplements, research infrastructure, and science education.

DPCPSI is responsible for developing new approaches to analyzing the NIH research portfolio and the development and use of informatics tools for this purpose. The Division also manages NIH-wide evaluation and performance assessment activities, including coordination and preparation of plans and reports required by 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. Planned activities in FY 2013 are summarized below.

Budget Policy: The FY 2014 President's Budgetestimate for DPCPSI is \$8.191 million, \$0.075 million or 0.9 percent over the FY 2012 Actual level. In FY 2014, DPCPSI will continue to coordinate a wide range of 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 implement enhancements to its portfolio analysis efforts and coordinate and collaborate on related activities with other Federal agencies and the private sector. The \$30.866 million for Strategic Initiatives will allow DPCPSI to coordinate and manage a new Biomedical Innovation Opportunities-Fund (BIO-F) and support such initiatives. The BIO-F will enable the NIH to jump start new research that will lead to new knowledge and innovative technologies that can result in improvements in diagnostics, prevention strategies, treatments, and even cures. Successful development of prevention strategies, diagnostics, and therapeutics will require new investments in research across the spectrum from basic science to clinical trials, as well as new partnerships between the public and private sectors. Some research initiatives are planned, implemented, and funded over several years in response to long-standing needs or opportunities. In contrast, other opportunities for significant progress emerge unexpectedly and require a more rapid response and sometimes only a catalytic time-limited investment. The BIO-F will be a mechanism to enable both an agile response to emerging scientific opportunities and the support of strategic initiatives. Establishment of the BIO-F in DPCPSI would facilitate our response to new ideas. As one example, an investment in the recently proposed Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative would enable the scientific community to create new technologies that would allow scientists to take a major step toward understanding brain function.

Common Fund/Office of Strategic Coordination (OSC): The <u>Common Fund</u> supports the biomedical community by providing enabling technologies, services and programs, developing essential tools and methodologies, and fostering innovation through high risk/high reward programs. 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 20 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. FY 2014 marks the 10 year anniversary of the Common Fund, an important milestone since Common Fund programs are intended to achieve high impact goals within a 10 year timeframe. As early Common Fund programs are maturing and transitioning out of the Common Fund, evaluations to determine program outcomes are being conducted. Program outcome evaluations, along with additional evaluations 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.

<u>Budget Policy</u>: The FY 2014 President's Budget request for the Common Fund is \$572.948 million, \$28.018 million or 5.1 percent above the FY 2012 Actual level. Strategic planning for FY 2014 programs began in May 2012 with a brainstorming session with leading external panel members, and two public meetings to gather ideas from a broad group of stakeholders. Ideas discussed at and following these meetings will be developed during FY 2013 as possible new program areas for the Common Fund in FY 2014. For additional details, 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 has established unique trans-NIH planning, portfolio analysis, and budgeting processes to enhance collaboration across ICs, minimize duplication of effort, and ensure that AIDS research dollars support research in the highest priority areas of scientific opportunity that will lead to new tools to fight the global AIDS pandemic. This budget request is informed by the FY 2014 Trans-NIH Plan for HIV-Related Research. The process established by OAR to develop the annual strategic plan, involving both government and non-government experts, results in the identification of clear,

overarching AIDS-research priorities and specific research objectives and strategies. These priorities are aligned with the goals of the President's National HIV/AIDS Strategy as well as the NIH Director's themes. OAR is mandated to develop the annual trans-NIH AIDS research budget in partnership with the ICs and explicitly tied to the objectives of the Strategic Plan. Dollars are allocated to the ICs based on the priorities of the Plan, scientific opportunities, and the ICs' capacity to absorb and expend resources for the most meritorious science—not on a formula. 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 supports a number of initiatives to enhance dissemination of research findings to researchers, physicians, institutions, communities, constituency groups, and patients in the U.S. and around the world. OAR has placed high priority on research and community outreach initiatives to address the disproportionate impact of the epidemic on racial and ethnic minority communities in the United States. The Trans-NIH AIDS Research Budget, developed by OAR, appears in the Overview section of this document.

Budget Policy: The FY 2014 President's Budget estimate for OAR is \$64.392 million, \$0.590 million or 0.9 percent above the FY 2012 Actual level. In FY 2014, OAR will place priority on initiatives to (1) expand basic discovery research; (2) enhance vaccine and microbicide research; (3) improve disease outcomes, including innovative research toward a cure; (4) reduce HIVrelated disparities; and (5) translate research from bench to bedside to the community. OAR will support: development and testing of new vaccine candidates; basic science and therapeutic research to eliminate viral reservoirs that could lead to a cure; initiatives on the use of genomics and other high throughput technologies in the study of host genetics and other factors that affect HIV transmission and disease progression; studies of HIV-related coinfections, comorbidities, and other complications, such as issues related to neurologic and neurocognitive manifestations of HIV disease and aging, that have become more prevalent in HIV-infected individuals; initiatives to address the AIDS epidemic in the United States, particularly among racial and ethnic populations, women, adolescents, and men who have sex with men, including new initiatives in Hispanic populations and an initiative with the District of Columbia; "bench-tobedside" research initiatives that will facilitate the translation of proven HIV prevention strategies and treatment regimens into the community; and research, infrastructure development, and training initiatives in international settings to better address the global AIDS pandemic, including efforts in Africa, the Caribbean, India, China and Russia. OAR will convene the Aging and HIV Research Working Group and the Microbicides Research Working Group, two panels of outside experts who provide guidance to OAR and the ICs. OAR will continue support for the Guidelines Working Groups, comprised of government and non-government experts who develop federal standards for treatment of HIV disease and its associated co-morbidities. OAR will continue to support the NIH AIDS Research Loan Repayment Program and the Intramural AIDS Research Fellowship program, which help to ensure an adequate number of trained AIDS researchers at NIH; and will support a number of initiatives to enhance dissemination of research findings to the scientific community, healthcare providers, and communities at risk and the dissemination of federal treatment guidelines and clinical trial information through AIDSinfo, a web-based service that provides information for caregivers and patients (available at www.aidsinfo.nih.gov).

Office of Research on Women's Health (ORWH): Since its creation in 1990, the NIH ORWH has worked to ensure the inclusion of women in clinical research, to advance and expand women's health and sex differences research, and to promote advancement for women in biomedical careers. ORWH is the NIH focal point for 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 NIH strategic plan for women's health and sex differences research, *Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research*. This strategic plan

outlines six goals to maximize impact of ORWH effort and support: 1) increase sex differences research in basic science, 2) incorporate sex/gender differences in 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, translational science, and the importance of a diverse biomedical workforce. The ORWH signature interdisciplinary research and career development programs have a positive influence on increasing the number of early stage investigators studying women's health, magnifying sex differences research initiatives through collaborative efforts and leveraging existing resources, and expanding the knowledge base for women's health.

Budget Policy: The FY 2014 President's Budget estimate for ORWH is \$42.716 million, \$0.392 million or 0.9 percent above the FY 2012 Actual 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 the consideration of sex/gender in basic science studies. ORWH-generated research initiatives, consistent with the goals outlined in the aforementioned NIH strategic plan, will be directed at promoting sex differences research in basic biomedical and behavioral studies, and in the design and application of new technologies, medical devices and therapeutic drugs. A trans-NIH initiative will be focused on the application of high throughput and emerging technologies in sequencing, data acquisition, bioengineering and bioinformatics, as well as modeling and computational approaches, across diverse scientific fields, to identify and understand sex differences at molecular and systems levels; 2) Facilitating the interdisciplinary translation of basic science to inform clinical care and pave the way for improved health outcomes for women of all ages and backgrounds. The ORWH-sponsored Specialized Centers of Research (SCOR) on Sex Differences program is designed to drive basic research to translation into clinical practice. These centers maximize public health benefit by accelerating the application of research results to the clinical care of diverse populations. The studies focus on developing sexand gender-appropriate prevention, diagnostics and therapeutics that are accessible, accurate and personalized for patient; 3) Maximizing the domestic and global impact of women's health research. Through collaborative alliances, ORWH will develop domestic and global scientific strategies to address women's health issues such as environmental health effects; and 4) Developing models for sustained advancement in science careers. Through its career development programs such as the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program, ORWH will implement interdisciplinary research career development approaches to address the organizational, institutional, and systemic factors that impede the progress of scientific careers of both women and men.

Program Portrait: Applying a Sex Perspective to Current Research Investments

FY 2012 Level: \$3.5 million **FY 2014 Level:** \$4.0 million **Change:** +\$0.5 million

The Office of Research on Women's Health, working in collaboration with the NIH ICs, is building upon its investment in sex differences research by issuing a program announcement for administrative supplements to currently funded NIH research. The advantage of this program of administrative supplements is that the infrastructure for the research is already in place, which maximizes the use and value of the funds for the stated research objectives of the supplement. The approach of applying a sex/gender perspective to NIH funded research, as scientifically appropriate, is compatible with the mission of each NIH IC and Office, and congruous with the NIH leadership's pledge to improve the health of the nation through research. Using the NIH strategic plan for women's health as a scientific framework, this initiative seeks to increase sex differences research in basic science studies; to incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutics; and to create strategic alliances and partnerships maximizing the domestic and global impact of this research to actualize personalized prevention, diagnostics, and treatment for girls and women of diverse populations. Importantly, this initiative will leverage current scientific advances and study data through integration of a sex and gender perspective that includes the consideration of the effect of sex/gender on the outcome or question under study. The trans-NIH focus will encourage the development of information systems needed for collecting, sharing, and comparing clinical data for diseases and conditions of women and girls. The expected results of this initiative will be the cost-effective, value-added, expansion of meritorious research projects that will advance the understanding of women's health and promote the study of sex and gender differences to improve health outcomes for females and males across the lifespan.

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 leads the coordination and development of policies, goals, and objectives related to strengthening research in the behavioral and social sciences at NIH. OBSSR is also a liaison between NIH and the extramural research communities, other federal agencies, academic and scientific societies, national voluntary health agencies, the media, 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 plan includes facilitating 1) the next generation of data and analysis methods; 2) behavioral and social science in an evolving health care system, and 3) training the next generation of behavioral and social scientists.

Budget Policy: The FY 2014 President's Budget estimate for OBSSR is \$27.251 million, \$0.250 million or 0.9 percent above the FY 2012 Actual level. In FY 2014, the Office will 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 research studies mechanisms and processes that influence behavior at the individual, group, community and population levels (see http://obssr.od.nih.gov/about_obssr/BSSR_CC/BSSR_definition/definition.aspx#bfr for a complete definition). Findings from basic behavioral and social sciences research lead to new approaches for reducing risky behaviors and improving the adoption of healthy practices. In addition, OBSSR will support two new initiatives in FY 2014. The first, Shared Medical Decision Making, focuses on the development and use of tools to optimize joint medical decision making by patients and health care providers. The second will support basic research on the exposome to 1) identify and measure behavioral and social environmental exposures across the life course, including the development of applications for mobile devices and sensor

technologies to do so; and 2) develop analytic methods to infer meaning about the contributions of interactions among environmental exposures and biological factors to disease risk and resilience. In addition, the Office will continue to fund multi-year programs, including research to reduce or eliminate health disparities; 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; and application of systems science methodologies to the behavioral and social sciences and health. OBSSR will also continue to support research that applies systems approaches to health disparities through the Network on Inequality, Complexity, and Health. Finally, the Office will offer annual summer training institutes on the following topics: Systems science methodology and health; randomized clinical trials involving behavioral interventions; dissemination and implementation research in health; mobile health; and research methods in the behavioral and social sciences.

Program Portrait: Understanding the Exposome through Basic Behavioral and Social Science

FY 2012 Level: \$0.0 million FY 2014 Level: \$3.0 million Change: +\$3.0 million

Understanding the Exposome through Basic Behavioral and Social Science. The mapping of the human genome was a magnificent scientific contribution to understanding vulnerability to disease. There are also abundant data indicating that environmental exposures influence health and disease. We now recognize, however, that health risk and resilience are more complex than genetic or environmental contributions alone and hinge on the dynamic interplay between genes and the environment. At the behest of the National Institute on Environmental Health Sciences and the Environmental Protection Agency, the National Academy of Sciences (NAS) recently published a report on the exposome (i.e. the totality of all exposures of an individual over the life course and across geographical space): Exposure Science in the 21st Century: A Vision and a Strategy (http://dels.nas.edu/Report/Exposure-Science-21st-Century/13507). Consistent with recommendations contained in this report, basic research on the exposome is needed to understand how environmental exposures interact with individual characteristics, such as genetics, physiology, and epigenetics, to influence health. Focusing on the behavioral and social environment, while much is known about how variation in individual behaviors (e.g., diet, physical activity) or in the social environment (e.g., neighborhood) are linked to health outcomes, we lack reliable, validated tools to measure the interactions between individual behaviors and the population-level social environmental exposures in real time and across the life course. Nor do we understand how these behavioral and social exposures interact with biological variables, over time, to influence health.

In FY 2014 OBSSR will partner with interested NIH ICs to begin to address these gaps in our knowledge. Specifically, we will issue a funding opportunity announcement (FOA), *Understanding the Exposome through Basic Behavioral and Social Science*. This multi-IC initiative will flow from and expand on the recommendations in the NAS report. Specifically, the FOA will solicit research in two key areas: 1) identification and measurement of the vast array of behavioral and social environmental exposures across the life course, including the development of applications for mobile devices and sensor technologies to do so; and 2) development of analytic methods to infer meaning about the contributions of interactions among environmental exposures and biological factors to disease risk and resilience from the enormous amount of exposure, genomics, and epigenomics data that are generated from ongoing and future studies. The proposed initiative is congruent with OBSSR's priority to support research related to the next generation of data and analysis methods. It also contributes to the NIH Director's Theme 1: *Today's Basic Science for Tomorrow's Breakthroughs*, especially the subthemes on *Epigenomics* and *Opportunities and Challenges Associated with Big Data*.

Office of Disease Prevention (ODP): The mission of ODP is to foster, coordinate, and assess research in disease prevention and health promotion as a means to improve public health. ODP collaborates with other federal agencies, academic institutions, the private sector, non-governmental organizations, and international organizations in formulating research initiatives and policies that promote public health. 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 high-lighting program accomplishments. As a trans-NIH, trans-agency committee, the PRCC provides a broad perspective on the current state-of-the-science and actively disseminates information about prevention-related activities sponsored by federal and non-federal organizations to the ICs.

ODP continues to serve as the focal point for evidence-based assessments of medical practice. In October 2012, it convened an independent, objective panel in a consensus development process to weigh the scientific evidence available to address specific challenges in the screening and diagnosis of gestational diabetes mellitus. ODP also worked to identify important emerging areas of research that could be pursued through focused efforts. In December 2012, ODP hosted a meeting examining the major psychological, behavioral, social, and environmental barriers to the adoption of existing physical activity guidelines. Participants examined what is known about evidence-based interventions and the achievement of long-term behavior change in diverse populations. ODP also coordinated a workshop on polycystic ovary syndrome to identify methodological and scientific weaknesses in the study of the disease to help move the field forward through an unbiased and evidence-based assessment of this complex clinical issue.

Budget Policy: The FY 2014 President's Budget estimate for ODP is \$6.121 million, \$0.056 million or 0.9 percent above the FY 2012 Actual level. In FY 2014, 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 NIH ICs and other partners to implement key components of its new strategic plan in order 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 disseminate information on emerging areas of scientific opportunity and existing knowledge gaps that merit special emphasis. Other activities will include coordination of evidence-based workshops on chronic fatigue syndrome and the use of opioids in chronic non-cancer pain conditions.

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, ranging from in vitro laboratory and animal experiments to human studies and clinical trials; and sponsors systematic reviews in relevant areas as well as projects to enhance the incorporation of these reviews into nutrition research, working with the Agency for Healthcare Research and Quality and its Evidence-based Practice Center program. Through its Communications program, ODS makes accurate and up-to-date scientific information about dietary supplements available to researchers, healthcare providers, and the public. ODS also works to create opportunities for dietary supplement and nutrition-related research training and career development for young investigators.

Budget Policy: The FY 2014 President's Budget estimate for ODS is \$27.974 million, \$0.257 million or 0.9 percent above the FY 2012 Actual 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 both the U.S. population and in foods through its Vitamin D Initiative. In 2014, the model used for this initiative will be applied to other nutrients of public health concern including iodine and folic acid. ODS will also support the continued expansion of the number of dietary supplement product labels included in the Congressionally mandated database of dietary supplement labels. ODS, in partnership with NCCAM and NCI, will continue its support of the five NIH Botanical Research Centers (BRC) (see Portrait of a Program: Botanical Research Centers). In 2014, ODS will also work to establish a new strategic plan for the five-year period of 2015 to 2019.

Program Portrait: Botanical Research Centers Program

FY 2012 Level: \$4.144 **FY 2014 Level:** \$4.144 **Change** \$0.000

Approximately one in six Americans use botanical dietary supplements, yet much research is still needed to address the challenges of reproducibly identifying and characterizing these inherently complex and variable products, and even more is needed to understand their biological and clinical effects. ODS, in collaboration with the National Center for Complementary and Alternative Medicine (NCCAM), initiated the Botanical Research Centers (BRC) Program in 1999. The BRC Program promotes collaborative, interdisciplinary research on botanical dietary supplements that has high potential for being translated into practical benefits for human health. Current areas of research focus include cutting-edge research on methods to better characterize botanical products, and research on the safety and mechanisms of action of botanicals that are commonly used for or show potential to benefit women's health, metabolic syndrome, and immune function. In addition to conducting interdisciplinary research on botanicals as they relate to human health, the BRC also provide a rich environment for academic training and career development.

ODS, in partnership with NCCAM and the National Cancer Institute, currently supports five centers:

- Pennington Biomedical Research Center, Louisiana State University System (in partnership with Rutgers, the State University of New Jersey);
- The University of Illinois at Chicago;
- The University of Illinois at Urbana-Champaign (in partnership with the University of Mississippi National Center for Natural Product Research, the National Center for Toxicological Research in Arkansas, and Oregon State University);
- The University of Missouri (in partnership with the Missouri Botanical Garden); and
- Wake Forest University Health Sciences (in partnership with Brigham and Women's Hospital, University of Colorado Health Sciences, and the Bent Creek Institute (NC)).

During FY 2013, the BRC Program will be evaluated by an expert panel to help determine future research directions and collaborations.

Office of Research Infrastructure Programs (ORIP): <u>ORIP</u> 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 instrumentation;

and research resources grants to expand, re-model, renovate, or alter existing research facilities or to construct new research facilities.

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 and terrifying epidemic; a disease for which there were no known animal models that would allow us to understand pathogenesis or point the way toward therapeutics and vaccines. Historically, research using chimpanzees has led to some critical advances, including the development of vaccines for hepatitis A and B, and 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 a working group of the NIH Council of Councils to advise him on the implementation.

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 no longer needed for research. The CHIMP Act also caps federal funding to the sanctuary system at an aggregate total of \$30 million, which includes spending on construction, housing, and care of the chimpanzees. Since enactment of the Chimp Act, NIH has obligated more than \$29 million to the sanctuary system.

NIH is responsible for the lifetime care of its chimpanzees whether they are kept at research facilities or the sanctuary. In order to care for the NIH chimps already in the sanctuary and to accommodate the anticipated reduction in the number of chimps needed for research, NIH is requesting that Congress amend the cap requirement to permit appropriate federal expenditure for the lifetime care and housing of federally-owned retired chimpanzees. NIH does not need additional funds, only the ability to provide funds for the care of the federally-owned chimpanzees at the sanctuary beyond the \$30 million cap. The Budget requests language in the HHS General Provisions (Sec. 218) to permanently eliminate the cumulative cap on NIH spending for the care of former research chimpanzees in the sanctuary system.

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.

DCM funds research to create, develop, characterize, preserve, and study a broad array of high-quality animal models and biological materials, such as cell cultures. 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. 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 genetic disorders. Experimental results on a given disease or topic obtained in different animal models must also be correlated and combined in a single source to be of greatest utility to biomedical researchers. Accordingly, DCM has developed and continues to populate an electronic directory of existing animal models for disease. The current emphasis is to link, through gene networks, relevant model features to appropriate human conditions.

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 specialties such as primate clinical medicine and laboratory animal medicine to enhance the value of veterinarians on translational research teams. In addition, DCM sponsors programs for senior research veterinarians designed to enhance current skills or develop new biomedical research potential. Increasing the number of qualified research veterinarians and ensuring that veterinary scientists 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 2014 will include 1) facilitating regenerative medicine using animal stem cells; 2) developing new animal models that reflect specific human genotypes and phenotypes ("personalized animal models"); and 3) facilitating the development of the zebrafish as a modality for high throughput drug screening.

Program Portrait: New Initiative- Development of induced pluripotent stem cells and related reagents from large animal species for use in regenerative medicine.

FY 2012 Level: \$2.0 million **FY 2014 Level:** \$2.0 million **Change:** \$0.0 million

Researchers and medical practitioners attempting to study and use human stem cells for *in vivo* therapies face significant technical and ethical challenges. Animal stem cells as model systems are extremely helpful to fill gaps in knowledge and to help understand such fundamental issues as stem cell maintenance, homing *in vivo*, reprograming, and the nature of the pluripotent state. Studies utilizing animal stem cells will facilitate the development of new therapeutic approaches for regenerative medicine, including evaluation of safety and efficacy for future clinical applications. A 2012 NIH workshop sponsored by ORIP emphasized the potential utility of "large" (i.e., non-rodent) animal models for studying various problems related to stem cell biology and regenerative medicine. Understanding the properties of stem cells from animals such as swine, monkeys, sheep and goats will increase the potential for the use of the most appropriate models for particular applications. These species also provide important advantages for xenotransplantation studies relative to rodents, including large size, similarity to human physiology and pathology, longer life span, and more direct translation to procedures in humans. The use of large animal stem cells as models for human cells in procedures related to regenerative medicine requires in-depth understanding of common regulatory pathways and species-specific properties and their impact on potential therapeutic applications. Reliable sources of well characterized and standardized stem cell lines and related biomaterials are required for these investigations.

ORIP proposes to provide support for Resource Related Research Project and Animal Model Resource grants to develop, characterize, and distribute stable induced pluripotent stem cell (iPSC) lines and related products from large animal species, e.g., swine and monkeys. These studies will support the development of optimized and standardized protocols to prepare, purify, characterize, and store cells, and provides to the research community biomaterials, protocols for manipulation, species-specific reagents, and genetic tools. Supported activities will solve problems already identified regarding the use of large animal species for regenerative medicine, such as heterogeneity of cell populations, genetic instability, high mutation rate during *in vitro* manipulations, epigenetic memory of differentiated iPSCs, and immune responses induced after stem cell transplantation. The development of assays that predict the potential immunogenicity of transplants and the tumorigenicity or metastatic potential of iPSC lines is of particular interest.

The initiative will facilitate investigations aimed at solving many problems associated with the eventual use of iPSCs for human therapies.

National Primate Research Centers (NPRCs): Within DCM, 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 NPRCs provide animals for research, facilities, and expertise in all aspects of NHP biology and husbandry through funding to eight institutions. 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 national resource to the research community. Major areas of research benefiting from the NPRCs' resources 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 2012 include the following. 1) Studies aimed at elucidating the mechanisms of immunodeficiency virus pathogenesis, with the goal of developing novel anti-HIV vaccines and microbicides. These studies are facilitated by a comprehensive set of primate models, assays, genetic tests, reagents, and expertise developed by the NPRCs, as well as the NPRC facilities to perform experiments on site. 2) Elucidation of changes in bacteria or viruses harbored in the gut of monkeys infected

with HIV-like viruses (called SIVs) or monkeys fed various diets. For example, it has been demonstrated that SIV infection results in increases in pathogenic viruses in the gut, which may explain the pathologies of the intestine that occur in human HIV patients. 3) Preservation of fertility in females monkeys following radiation treatment. Researchers infused an inhibitor of apoptosis (programmed cell death) into ovaries of monkeys prior to irradiation. The treated animals were able to conceive normal offspring following the radiation treatment. These studies provide a promising approach for treatments to preserve fertility of human females following cancer treatment. 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, including laboratory animal facilities.

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

These unique, competitive programs provide new generation technologies to NIH-supported investigators that increase the quality of their funded programs and accelerate a broad array of basic, translational, and clinical research. The instruments are too expensive to be obtained on regular research grants. The SIG Program funds equipment in the \$100,000 - \$600,000 range; the HEI Program funds instrumentation in the \$750,000 to \$2 million range. The specialized instruments, with the latest technological capabilities, are key tools in advancing biomedical research because they allow studies that could not be carried out previously and open-up new

research opportunities for individual investigators. Both these programs are cost effective and have high impact. In FY 2012, the program funded the acquisition of 114 instruments supporting more than 3,000 NIH research projects with a total yearly support of approximately \$1.5 million.

Extramural Research Facilities Improvement Program: This program provides support to institutions for renovations of laboratory animal facilities to enhance animal care and insure success of animal-based biomedical research programs; assists institutions in complying with regulations related to care and use of laboratory animals; and purchases equipment for animal care, transgenic animal resources, and similar activities. In FY 2012, 15 renovation awards were made that benefitted 1,600 active animal-based research grants worth a total of \$656 million, a powerful 100-fold leverage effect. These facilities – currently about 500 in total – are monitored for either 10 or 20 years following completion and occupancy.

<u>Budget Policy</u>: The FY 2014 President's Budget estimatefor ORIP is \$286.314 million, \$3.071 million or 1.1 percent above the FY 2012 Actual 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 coordination of science education activities at the NIH.

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 139 full-time training positions. To facilitate research ORIP/DCM continues to develop and populate an electronic directory of existing animal model for disease. The current emphasis is to link, through gene networks, relevant model features to appropriate human conditions.

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.

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 (IRP) and the NIH Undergraduate Scholarship Program (UGSP).

The IRP 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 2012, the distribution of LRP awards was as follows:

- Two awards for the Clinical LRP zero new and two renewals;
- 76 awards for the General LRP 35 new and 41 renewals; and
- Five awards for the AIDS LRP two new and three renewals.

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 10 new recipients for the UGSP Scholarship award and four UGSP Scholars received scholarship award renewals. In addition, 23 UGSP scholars conducted their yearlong service obligation and 13 completed their summer internship during this same period.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for ILRSP is \$7.461 million, \$0.068 million or 0.9 percent above the FY 2012 Actual level. The FY 2013 program plans include the UGSP and Loan Repayment projected new and renewal awards. The awards are as follows:

(Dollars in Millions)

Program	FY2010		FY2011		FY	<u>′12</u>	<u>FY13</u>		
	Awards	Amount	Awards	Amount	Awards	Amount	Awards	Amount	
NIH Clinical Loan Repayment Program	5	\$0.309	4	\$0.064	7	\$0.293	7	\$0.293	
NIH General Loan Repayment Program	72	\$4.409	75	\$4.512	95	\$5.500	106	\$6.300	
AIDS Loan Repayment Program	7	\$0.285	7	\$0.234	7	\$0.329	7	\$0.329	
Undergraduate Scholarship Program	15	\$0.165	17	\$0.232	17	\$0.255	15	\$0.300	
TOTALS	99	\$5.168	103	\$5.042	126	\$6.377	135	\$7.222	

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 2012, funds were used to support trans-NIH initiatives such as the Hold Still – Developing Brain-Imaging Technology for Young Children, Alzheimer's Funding, Support of RePORT, the Human Frontier Science Program, and increase NIH Network Capacity.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for DDF is \$10.0 million, \$0.019 million or 0.2 percent above the FY 2012 Actual level. In FY 2014, 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 nuclear and radiological exposures. 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. Additional programs support research and development of medical countermeasures for gastrointestinal acute radiation syndrome (ARS), radiation-induced thrombocytopenia, pulmonary radiation injury, cutaneous radiation injury, and combined radiation injuries. The RNCP also supports the development of oral drugs to remove internal radionuclide contamination from the body. An 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 550 scientific articles published in peerreviewed journals, over 40 patents, and over 120 medical countermeasure candidates in discovery and development phases. The product development support services effort includes evaluation agreements with 20 biopharmaceutical companies, development of animal models for screening and pivotal efficacy studies, identification of potential medical countermeasures for hematological ARS (22) and gastrointestinal ARS (15), identification of lead candidates for radionuclide decorporation (5), and confirmation of efficacy of a medical countermeasure candidate in an animal model of ARS. A targeted SBIR program for Radiological/Nuclear Medical Countermeasure Product Development was extended in 2012. Twenty 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 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 conducts basic, translational, and clinical research aimed at the discovery and/or identification of improved therapeutic and diagnostic medical countermeasures against chemical threat agents. The overarching goal of the chemical program is to enhance our medical response capabilities for a diverse civilian population during an emergency. The program, entering its seventh year of funding, includes collaborative efforts with academia and industry, as well as eligible 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 over 450 scientific articles published in peer-reviewed journals, 10 patents, and over 10 medical countermeasure candidates in discovery and research phases, including the benzodiazepine midazolam. Midazolam, a countermeasure against nerve agents, is an example of one of the program's specific initiatives that has spanned basic and translational research. As of this fiscal year, midazolam has been transitioned to the Biomedical Advanced Research and Development Authority for advanced product development.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for Countermeasures against Radiological/Nuclear Threats and Chemical Countermeasures Research is \$95.298 million, the same amount as the FY 2012 Actual level. Funding will continue to span basic, translational and applied research to develop new products for measuring, minimizing, mitigating and treating the effects of exposure to external radiation sources and internal contamination of radionuclides. In addition, NIH will expand research to identify and characterize biomarkers that are predictive of organ and tissue damage due to acute radiation exposure. The Chemical Countermeasures Research program will continue clinical safety and efficacy trails directed at promising drugs and antidotes for nerve agents, poisons, toxic industrial chemicals and vesicating (blistering) agents.

Foundation for the National Institutes of Health (FNIH): The FNIH is a 501(c)(3) public charity established by Congress in 1996 as the sole entity to support the NIH mission by forming partnerships for biomedical research, education, and training. FNIH raises funds for and establishes partnerships to advance biomedical initiatives that can benefit from financial and scientific collaboration among the public, non-profit, and private sectors. FNIH serves as a convener of a wide variety of stakeholders, bringing interested sectors together to address particular pressing health needs or issues. In this way, stakeholders are able to participate in the scientific direction of partnerships such as the Biomarkers Consortium, the Alzheimer's Disease Neuroimaging Initiative (ADNI), the Observational Medical Outcomes Partnership (OMOP), and the Sports and Health Research Program. There is also an extensive global health portfolio.

FNIH also raises funds for education, with the highest priority being placed on a new NIH Medical Research Scholars Program (MRSP).

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the FNIH is \$0.500 million, the same amount as the FY 2012 Actual level. Funding will continue to support direct salary and overhead costs incurred by the FNIH in its efforts to explore and develop public private partnerships for the benefit of NIH. The FNIH will continue serving both the public and private sectors in areas of mutual interest in order to advance the mission of the NIH.

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.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for OD Operations is \$128.346 million, \$4.908 million or 4.0 percent above the FY 2012 Actual 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. In FY 2012, and in light of the exploration underway by the Department of Health and Human Services and the Office of Science and Technology Policy of possible revisions in the HHS regulations governing human subjects research, NIH issued a request for applications to stimulate research on the effectiveness of current regulations, rules, and policies governing human subjects research and the use of broad, prospective consent for research use of human specimens and data. The knowledge generated from this research will inform evaluations of the adequacy and effectiveness of current regulations, rules, and policies governing research with human subjects and will serve as the basis for potential reforms. After reviews for merit and program relevance, four applications were selected for award. Funded investigators will carry out research on the effectiveness of easy-to-read informed consent documents in clinical trials; harmonized procedures for informed consent for the use of biospecimens and repository operations; participant preferences for models of consent for secondary research use of biospecimens, effects of using various consent models on donation of biospecimens in diverse population; and technological solutions for monitoring consent for data-sharing that allow patients to select preferences for the use of their clinical data in research.

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. Study partners include the National Institute of Environmental Health Sciences of the NIH, the Centers for Disease Control and Prevention, and the Environmental Protection Agency. The NCS is a longitudinal birth cohort observational study with the overall goal of improving the health and well-being of children and of identifying antecedents of healthy adulthood, by examining the effects of a broad range of environmental influences and biological factors. Approximately 100,000 children from across the U.S. will be enrolled in the NCS and followed from before birth until age 21 years. The NCS will produce an unprecedented amount of information that will provide a foundation for analyzing factors that contribute to growth, development, health, and disease, guiding future science and policy.

Budget Policy: The FY 2014 President's Budget estimate for NCS is \$165 million, a decrease of -\$28.098 million or -14.6 percent from the FY 2012 Actual level. The NCS has streamlined the Vanguard Study from over forty contractors to four, producing data collection cost savings that will accomplish the budget reduction. In FY 2014, the OD will support continuation of the Vanguard Study and initiation of the Main Study. The Vanguard Study will continue to function as the pilot for each phase of the Main Study, providing reliable field data to inform Main Study methods, operations, and costs, and verifying that the methods and measures used in the Main Study will be feasible, acceptable to participants (critical for retention), and cost-effective. The FY 2014 budget request will allow the NCS to begin the Main Study data collection, enrolling participants at multiple points of entry along the continuum from preconception to birth. Recruitment would occur through health care providers, utilizing hospitals and birthing centers as locations to enroll a birth stratum and community prenatal care providers and clinics to enroll a prenatal stratum. 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 study logistics.

NATIONAL INSTITUTES OF HEALTH Office of the Director

Budget Authority by Object Class

(Dollars in Thousands)

		FY 2012	FY 2014	Increase or
		Actual	PB	Decrease
Total c	ompensable workyears:			
	Full-time employment	655	659	4
	Full-time equivalent of overtime and holiday hours	4	4	0
	Average ES salary (in dollars)	\$176,476	\$179,132	\$2,656
	Average GM/GS grade	12.7	12.7	0.0
	Average GM/GS salary (in dollars)	\$105,771	\$107,363	\$1,592
	Average salary, grade established by act of	0110.00 5	0120.115	41.701
	July 1, 1944 (42 U.S.C. 207) (in dollars)	\$118,336	\$120,117	\$1,781
	Average salary of ungraded positions (in dollars)	\$149,262	\$151,508	\$2,246
		EV 2012	EW 2014	T
	OD IECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or
	OBJECT CLASSES Personnel Compensation:	Actual	ГD	Decrease
11.1	Full-time permanent	\$61,729	\$63,088	\$1,359
	Other than full-time permanent	8,232	8,414	182
I	Other personnel compensation	1,776	1,815	39
11.7	Military personnel	528	539	11
11.8		808	823	15
11.0	Total, Personnel Compensation	\$73,073	\$74,679	\$1,606
12.0	Personnel benefits	\$23,187.12	\$23,671	\$484
12.2		199	204	5
13.0		0	0	0
10.0	Subtotal, Pay Costs	\$96,459	\$98,554	\$2,095
21.0		\$1,326.78	\$1,327	\$0
22.0		117	117	(0)
23.1		0	0	0
23.2	Rental payments to others	92	92	0
23.3	Communications, utilities and			
	miscellaneous charges	1,559	1,559	0
24.0	Printing and reproduction	509	509	(0)
25.1	Consulting services	3,909	112	(3,797)
25.2		54,104	58,862	4,758
25.3	Purchase of goods and services from			
	government accounts	159,114	161,314	2,200
I	Operation and maintenance of facilities	1,017	1,017	(20, 122)
	Research and development contracts	214,656	185,534	(29,122)
	Medical care	0	2 277	0
25.7 25.8	Operation and maintenance of equipment	3,377	3,377 0	(0)
	11 1	\$436,178	\$410,216	(\$25,962)
25.0 26.0	,	\$3,421.20	\$3,421	(\$0)
31.0	11	3,177	3,178	(30)
	Land and structures	0,177	0	(0)
	Investments and loans	0	0	0
41.0		914,325	954,420	40,095
42.0		0	0	0,079
43.0		5	5	(0)
44.0		0	0	0
	Subtotal, Non-Pay Costs	\$1,360,709	\$1,374,844	\$14,135
	Total Budget Authority by Object Class	\$1,457,168	\$1,473,398	\$16,230

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)

	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$61,729	\$63,088	\$1,359
Other than full-time permanent (11.3)	8,232	8,414	182
Other personnel compensation (11.5)	1,776	1,815	39
Military personnel (11.7)	528	539	11
Special personnel services payments (11.8)	808	823	15
Total Personnel Compensation (11.9)	\$73,073	\$74,679	\$1,606
Civilian personnel benefits (12.1)	\$23,187	\$23,671	\$484
Military personnel benefits (12.2)	199	204	5
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$96,459	\$98,554	\$2,095
Travel (21.0)	\$1,327	\$1,327	\$0
Transportation of things (22.0)	117	117	0
Rental payments to others (23.2)	92	92	0
Communications, utilities and			
miscellaneous charges (23.3)	1,559	1,559	0
Printing and reproduction (24.0)	509	509	0
Other Contractual Services:			
Advisory and assistance services (25.1)	3,909	112	(3,797)
Other services (25.2)	54,104	58,862	4,758
Purchases from government accounts (25.3)	120,730	120,485	(245)
Operation and maintenance of facilities (25.4)	1,017	1,017	0
Operation and maintenance of equipment (25.7)	3,377	3,377	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$183,137	\$183,853	\$716
Supplies and materials (26.0)	\$3,421	\$3,421	\$0
Subtotal, Non-Pay Costs	\$190,162	\$190,878	\$716
Total, Administrative Costs	\$286,621	\$289,432	\$2,811

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Details of Full-Time Equivalent Employment (FTEs)

	FY 2012 Actual		FY 2013 CR			FY 2014 PB			
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director	(02	4	507	(07	4	611	607	4	C11
Direct: Reimbursable: Total:	603 48 651	4 - 4	607 48 655	607 48 655	4 - 4	48 659	48 655	4 - 4	611 48 659
Total	651	4	655	655	4	659	655	4	659
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								
2010 2011 2012 2013 2014	12.6 12.6 12.7 12.7 12.7								

NATIONAL INSTITUTES OF HEALTH Office of the Director

Detail of Positions

	FY 2012	FY 2013	FY 2014
GRADE	Actual	CR	PB
Total, ES Positions	12	12	12
Total, ES Salary	2,117,714	2,128,303	2,149,586
GM/GS-15	113	114	114
GM/GS-14	130	131	131
GM/GS-13	160	162	162
GS-12	85	85	85
GS-11	38	38	38
GS-10	5	5	5
GS-9	32	32	32
GS-8	8	8	8
GS-7	8	8	8
GS-6	3	3	3
GS-5	3	3	3
GS-4	1	1	1
GS-3	4	4	4
GS-2	3	3	3
GS-1	0	0	0
Subtotal	593	597	597
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	4	4	4
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	72	72	72
Total permanent positions	575	579	579
Total positions, end of year	680	684	684
Total full-time equiv (FTE) at YE	655	659	659
Average ES salary	176,476	177,358	179,132
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	105,771	106,300	107,363

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