

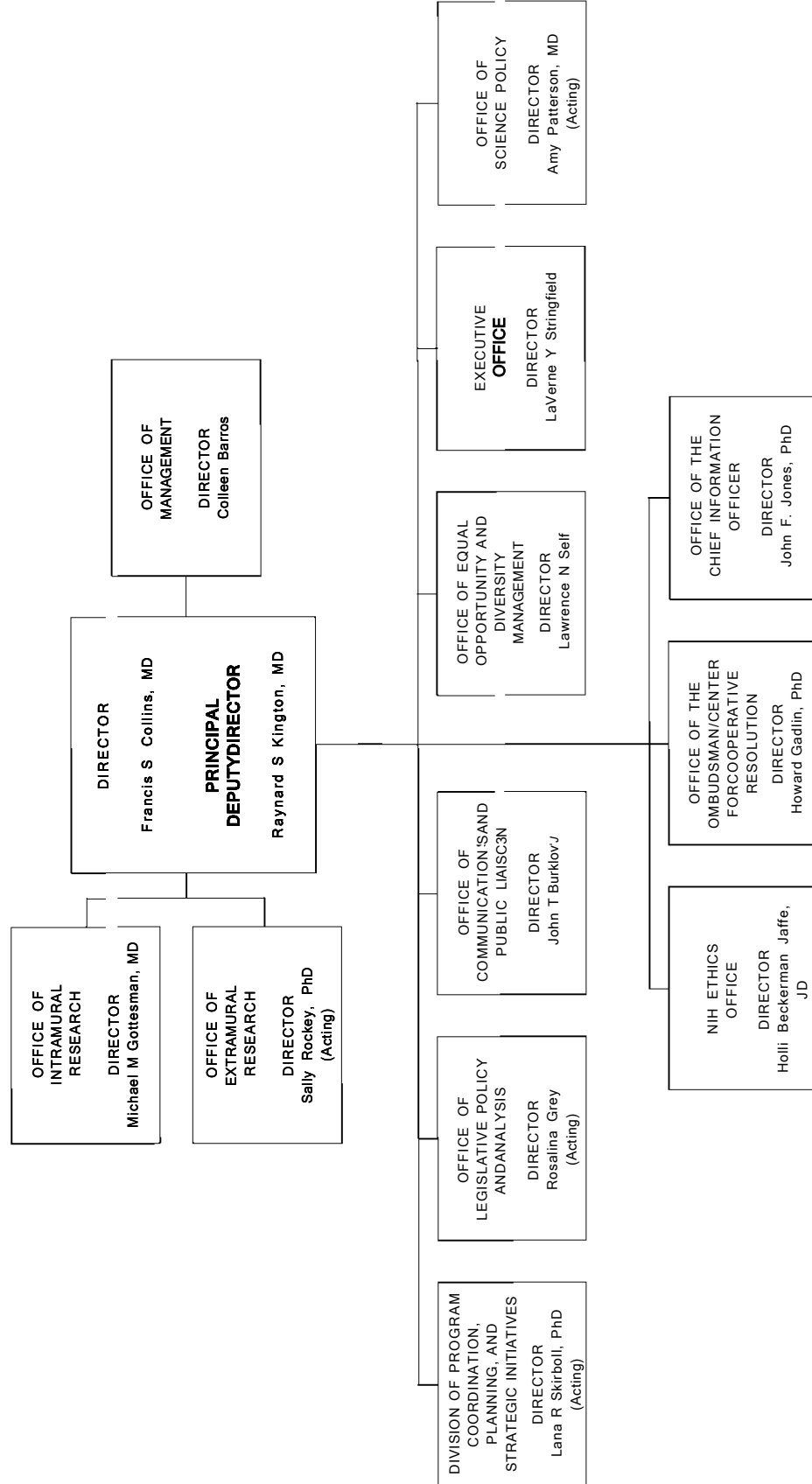
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Office of the Director

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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, National Institutes of Health ('NIH'), [\$1,177,300,000] **\$1,220,478,000**, of which up to \$25,000,000 shall be used to carry out section 214 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 the 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 such Fund shall remain available for one fiscal year after the fiscal year in which they are deposited: *Provided further*, That up to [\$193,880,000] **\$194,400,000** shall be available for continuation of the National Children's Study: *Provided further*, That [\$544,109,000] **\$561,629,000** shall be available for the Common Fund established under section 402A(c)(1) of the Public Health Service Act ('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.

**National Institutes of Health
Office of the Director**

Amounts Available for Obligation 1/

Source of Funding	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
Appropriation	\$1,246,864,000	\$1,177,300,000	\$1,220,478,000
Subtotal, Adjusted Appropriation	1,246,864,000	1,177,300,000	1,220,478,000
Real Transfer to O A R	625,000	0	0
Comparative Transfer to N L M	-197,000	-280,000	
Subtotal, adjusted budget authority	1,247,292,000	1,177,020,000	1,220,478,000
Unobligated balance lapsing	-61,000	0	0
Total obligations	1,247,231,000	1,177,020,000	1,220,478,000

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

FY 2009 - \$694,009,000 FY 2010 Estimate - \$742,375,000 FY 2011 Estimate - \$830,061,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director
(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2009 Actual		FY 2009 Recovery Act Actual		FY 2010 Recovery Act Estimated		FY 2010 Eshmate		FY 2011 PB		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Grants:</u>												
Research Projects:		\$463,435		\$ 425,991		\$ 636,477		\$ 464,442		\$ 514,080		\$ 49,638
Research Centers		187,127		37,887		4,753		130,681		134,581		3,900
Other Research		97,782		10,699				48,585		38,873		-9,712
Total, Research Grants		748,344		474,577		641,230		643,708		687,534		43,826
Training		14,046						13,224		9,907		\$ (3,317)
R& D Contracts		192,064		26,170		12,700		219,002		210,224		-8,778
Intramural Research		36,911						36,950		38,065		1,115
Res. Mgmt. and Support		255,927		136,538		45,622		264,136		274,748		\$ 10,612
Cancer Control		0						0		0		0
Construction		0						0		0		0
Total		498,948		162,708		58,322		533,312		532,944		(368)
OD Operations		0						0		0		0
Total, OD		1,247,292		637,285		699,552		1,177,020		1,220,478		43,458

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

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Budget Mechanism - OP FFA

	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
OD Operations	\$151,173,000	\$151,036,000	\$158,420,000
NTH Director's Challenge Fund	(1,500,000)	(1,500,000)	(1,500,000)
Division of Program Coordination, Planning and Strategic Initiatives			
Office of Behavioral & Social Sciences Research	27,009,000	27,401,000	38,166,000
Office of AIDS Research	63,616,000	64,241,000	65,525,000
Office of Research on Women's Health	42,338,000	42,952,000	44,335,000
Office of Rare Diseases	16,079,000	18,062,000	18,644,000
Office of Dietary Supplements	27,726,000	28,128,000	29,034,000
Director's Discretionary Fund	9,996,000	10,000,000	10,000,000
Foundation for the National Institutes of Health	500,000	500,000	500,000
Nuclear/Radiological/Chemical Countermeasures	96,711,000	96,711,000	99,825,000
NTH Director's Bridge Award	91,243,000	0	0
National Children's Study	179,768,000	193,880,000	194,400,000
Common Fund	541,133,000	544,109,000	561,629,000
Total	1,247,292,000	1,177,020,000	1,220,478,000

NATIONAL INSTITUTES OF HEALTH
Office of the Director
BA by Program
(Dollars in thousands)

	FY 2007		FY 2008		FY 2009		FY 2009		FY 2010		FY 2011		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research														
<u>Detail:</u>														
Res. management & support	586	1,047,48;	614	1,111,735	629	1,247,292	629	1,247,292	642	1,177,020	671	1,220,478	29	43,458
TOTAL	586	1,047,435	614	1,111,735	629	1,247,292	629	1,247,292	642	1,177,020	671	1,220,478	29	43,458

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

Major Changes in the Fiscal Year 2011 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 2010 budget request for OD, which is +\$43.458 million over the FY 2011 Estimate, for a total of \$1,122.478 billion.

Common Fund (+\$17.520 million; total \$561.629 million): The OD will provide Roadmap with resources to address trans-NIH research priorities, and help fill knowledge gaps in FY 2011.

OD Operations (+\$7.384 million; total \$158.420 million): The OD will provide support to expand the Therapeutics for Rare and Neglected Diseases (TRND) program to encourage and speed the development of new drugs for rare and neglected diseases. The OD will fund the NSLS-II, a new DOE synchrotron facility that will replace NSLS at Brookhaven National Laboratory. The OD will continue enhancement of various new and ongoing strategic management, policy and oversight activities.

Office of Behavioral & Social Sciences Research (+\$10.765 million; total \$38.166 million): The OD will provide \$10.000 million to support the NIH Basic Behavioral and Social Sciences Opportunity Network (OppNet). OppNet is a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research (b-BSSR). Launched with OD Recovery Act funding in FY 2010, the program will be transitioned in FY 2011 from OD ARRA support to base appropriations funding through the OD/ICs.

NATIONAL INSTITUTES OF HEALTH
Office of the Director
Summary of Changes

FY 2010 estimate		\$1,177,020,000	
FY 2011 estimated budget authority		1,220,478,000	
Net change		43,458,000	
CHANGES	F Y 2010		
	Estimate Base	Change from Base	
	Budget		Budget
	FTEs	FTEs	Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January 2010 pay increase		SO	SO
b. January 2011 pay increase		0	0
c. Payment for centrally furnished services		0	0
d. Increased cost of laboratory supplies, materials, and other expenses		0	0
Subtotal			0
2. Research Management and Support:			
a. Annualization of January 2010 pay increase		\$90,517,000	\$3,707,000
b. January 2011 pay increase		90,517,000	819,000
c. Payment for centrally furnished services		0	0
d. Increased cost of laboratory supplies, materials, and other expenses		100,192,000	(4,526,000)
Subtotal			0
Subtotal, Built-in			0

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Summary of Changes—continued

CHANGES	FY 2010			
	Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting		\$656,932,000		\$40,509,000
b. Competing		0		0
c. SBIR/STTR		0		0
Total		656,932,000		40,509,000
2. Research centers		0		0
3. Other research		0		0
4. Research training		0		0
5. Research and development contracts		219,002,000		(8,778,000)
Subtotal, extramural				31,731,000
6. Intramural research	<u>FTEs</u>	36,950,000	<u>FTEs</u>	1,115,000
7. Research management and support	642	264,136,000	29	10,612,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		1,177,020,000		43,458,000
Total changes				43,458,000

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 2009 <u>Omnibus</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget</u>	FY 2011+/- 2010 <u>Appropriation</u>
BA	\$1,247,292,000	\$1,177,020,000	\$1,220,478,000	+\$43,458,000
FTE	629	642	671	+29

This document provides justification for the Fiscal Year (FY) 2011 activities of the Office the Director (OD), including HIV/AIDS activities. Details of the FY 2011 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" section of the Overview. Details on the Common Fund are located in the Overview, Volume One. 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 science policy and related social, ethical, and legal issues; technology transfer; health information dissemination and education; 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. An overview of some innovative and cutting-edge initiatives pursued by OD programs in support of the NIH mission is provided below.

Fulfilling the requirements of the NIH Reform Act of 2006, the OD established the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), the Scientific Management Review Board, the electronic coding system for research grants, and the "Biennial Report of the Director" to Congress. DPCPSI's Office of Strategic Coordination (OSC) oversees the management of the Common Fund and organizes the trans-NIH effort to identify, plan, and implement the NIH Roadmap for Medical Research

initiatives supported by the Common Fund. Several Roadmap initiatives have been launched since FY 2007 to accelerate important, cross-cutting discovery and the translation of knowledge into effective prevention strategies and new treatments.

In addition to OSC, DPCPSI is also the home of four other OD programmatic offices: the Office of Behavioral and Social Sciences Research (OBSSR), the Office of Disease Prevention (ODP), the Office of Research on Women's Health (ORWH), and the Office of AIDS Research (OAR). These programs have championed many noteworthy initiatives in support of the NIH mission. For example,

- OBSSR provides leadership and direction to advance behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into other NIH biomedical research activities. This organization develops initiatives to stimulate research and training in the behavioral and social sciences and facilitates communication and collaboration among NIH behavioral and social science programs.
- ODP coordinates disease prevention research across the NIH, other Federal agencies, and the private sector. Within ODP, the Office of Rare Diseases Research recently initiated the Collaboration, Education, and Genetic Test Translation program to diagnose and combat rare diseases. This Office has funded the development of more than two dozen genetic tests, and has made them available to patients and public clinics. Currently 35 more tests have been approved for development translation from the research bench to use in the clinic.
- ORWH has expanded its programs to support interdisciplinary career development and comprehensive research initiatives that explore the understanding of gender factors in women's health. ORWH is completing a national series of public hearings and scientific workshops, increasing awareness of women's health research, and informing future approaches to ensuring the participation of women in clinical and translational research, and career development for the advancement of women in biomedical careers.
- OAR coordinates the scientific, budgetary, legislative, and policy elements of the trans-NIH research program on AIDS and its wide spectrum of associated malignancies, co-infections, and clinical complications. This diverse research portfolio requires an unprecedented level of scientific planning and management and this has resulted in groundbreaking advances in AIDS research, although serious challenges remain. These advances also have benefitted other areas of disease investigation, providing an entirely new model for drug design, development, and clinical trials to treat viral infections, and developing powerful treatments and novel approaches to fight diseases in seemingly unrelated fields.

The Office of Intramural Research (OIR) directs and coordinates NIH's intramural research program's policies, training programs, and technology transfer. OIR supports the successful recruitment, training, mentoring, and diversity of a new cadre of scientists in biomedical research for the 21st century. This office ensures that NIH's intramural research programs provide an environment supportive of the creative scientists conducting biomedical research using innovative approaches in human and non-human

models. OIR facilitates new ways to diagnose and personalize approaches to preempt, treat and reduce suffering from human disease. This organization assures rigorous scientific review, research integrity training, sharing of resources, and development of collaborations across NIH. OIR also facilitates collaborative interactions between NIH scientists and their colleagues from industry and academia in the joint pursuit of common research goals. Managing these collaborations is OIR's Office of Technology Transfer (OTT). In FY 2008, OTT executed approximately 263 licenses; administered over \$87.7 million in royalties; filed 674 patent applications worldwide; added 305 issued patents worldwide to NIH's intellectual property portfolio; and coordinated 40 new Cooperative Research and Development Agreements (CRADAs).

Parallel to OIR but extramurally focused, the Office of Extramural Research (OER) provides strong leadership, oversight, tools, and guidance to develop, administer, and manage NIH grants, including those awarded using funds from the American Recovery and Reinvestment Act. Annually, extramural grants have accounted for approximately 85 percent of NIH's budget, and have been awarded to over 3,000 institutions worldwide. OER serves as the interface between NIH and the extramural research community and has guided institutions and investigators through NIH processes for training, application, and funding. OER ensures that NIH extramural policies are developed and administered effectively, transparently, and ethically.

Another important NIH policy arm, the Office of Science Policy (OSP), helps sustain and advance the biomedical research enterprise through the development of sound and comprehensive science policies. OSP carries out science policy, analysis, and development on cross-cutting issues of significance to the agency and the medical research community, and prepares analyses and reports in fulfillment of certain Congressional reporting requirements, including the "Biennial Report of the Director." OSP is a focal point for the analysis and development of policies related to the scientific, clinical, ethical, legal, and societal implications of research involving recombinant DNA, genetic technologies, and dual use research. OSP analyzes issues related to the conduct and oversight of clinical research and promotes the harmonization of clinical research policies, including adverse event reporting. OSP also develops and distributes model K-12 and other public science education resources. OSP played a key role in NIH's efforts to support additional comparative effectiveness research (CER), which is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in real-world settings. CER helps improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers about which interventions are most effective for which patients under specific circumstances.

In addition to supporting OSP's science education program, NIH's central communications organization, the Office of Communications and Public Liaison (OCPL), supports NIH in the dissemination and exchange of science-based information in medicine and health and coordinates outreach efforts across the 27 NIH Institutes and Centers. OCPL also successfully uses technology advances to innovatively

communicate information about NIH programs and accomplishments to the general public, the scientific community, the medical profession, and public advocacy groups. In FY 2009, OCPL handled some 3,500 press calls and finalized more than 368 news releases used by hundreds of media outlets throughout the country and around the world each day. NIH websites were accessed more than a billion times last year by health professionals, scientists, and the public. OCPL has intensively evaluated the principal NIH website to ensure the reliability and accessibility of consumer health information for the one million unique, daily visitors to the NIH website. OCPL has enhanced the social media elements of its communication program and increased its reach to the public through a remote actuality studio that makes experts available to a worldwide audience on a few moments notice. This facility has been used extensively during the H1N1 alert.

Highly committed to communicating with the public and the NIH community, but with a unique role, is the Office of Legislative Policy and Analysis (OLPA). As NIH's principal legislative liaison with the Congress, OLPA monitors and helps inform the NIH community about important research issues with a legislative component, such as public access to the findings of NIH-supported research, conflict of interest policies in the extramural community, disease-specific legislation, and human embryonic stem cell policies. OLPA briefs and prepares NIH leadership before they participate in congressional hearings, briefings, and other meetings on crosscutting and highly sensitive issues.

The Office of the Chief Information Officer (OCIO) strategically directs and manages significant enterprise Information and Information Technology (I&IT) program and policy activities, including information security, capital planning and investment control, enterprise information architecture, and program/project management. OCIO's I&IT security program for NIH is recognized as a model for HHS and other Federal Agency programs, and is a source of expertise within the information security community. Other accomplishments include: leading the NIH implementation of the HHS Enterprise Performance Life Cycle (EPLC) project management methodology to foster sound management of all I&IT investments; making significant improvements in compliance with requirements for web accessibility; establishing I&IT goals and a plan for their accomplishment; and greatly expanding our ability to collaborate with other researchers through use of federated identity technology including participation in two major federation consortia, in Common and OpenID.

The Office of Management (OM) advises the Director and Deputy Director, NIH, 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 NIH Business System enterprise 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 has provided some of the highlights of OD's role in shaping the agency's research agenda. For more information on other OD program initiatives and accomplishments, please visit the OD's web page at <http://www.nih.gov/icd/od/index.htm>.

Overall Budget Policy: The FY 2011 request for OD is \$1,220.478 billion, an increase of \$43.458 million or +3.7 percent over the FY 2010 enacted level. Resources will be directed towards ongoing high priority projects and initiatives that foster collaborations across the NIH Institutes and Centers. This will include support for outreach efforts to address the five major themes of the NIH Director in the context of sex and gender determinants. Funding support will continue for NIH AIDS research and training activities to include specific funding for emerging scientific opportunities and public health challenges that require focused attention. Support will continue for disease prevention research and the Undiagnosed Diseases Program to advance medical knowledge about rare and common diseases. Funds will support continued development of the Dietary Supplements Label Database and expansion in the area of behavioral and social sciences to support formative research and development projects to establish "community health laboratories". Additional resources will support continued enhancements of new and ongoing strategic management and oversight activities. Funds are included in R&D contracts to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program (TRND), the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory, as well as increased support for other HHS agencies through the program evaluation set-aside.

FY 2011 Justification by Activity Detail

Program Description and Accomplishments

Division of Program Coordination, Planning, and Strategy Initiatives (DPCPSI):

DPCPSI identifies, reports and funds trans-NIH research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special attention. Such research benefits from collaboration between two or more NIH Institutes and Centers, or from strategic coordination and planning. The Division coordinates and oversees the planning, implementation, and evaluation of a series of trans-NIH programs known collectively as the NIH Roadmap for Medical Research, and are supported by the NIH Common Fund. The Division includes major programmatic offices that coordinate research and activities related to AIDS, behavioral and social sciences, women's health, disease prevention, rare diseases, and dietary supplements. DPCPSI also is responsible for developing new approaches to analyzing the NIH research portfolio and the development and use of informatics tools for this purpose. Additional functions of the Division include managing NIH-wide evaluation and performance assessment activities, including the Evaluation Set-Aside program and the Government Performance and Results Act plans and reports.

Program Description and Accomplishments

Office of AIDS Research (OAR): The NIH OAR operates as an "institute without walls" to plan, coordinate, evaluate, and budget the trans-NIH AIDS research program, which is carried out in every Institute and Center (IC). The OAR has established unique and comprehensive 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. The process to develop the annual Trans-NIH 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 AIDS Strategy.

Budget Policy: The FY 2011 budget estimate for OAR is \$65.525 million, a \$1.284 million or 2 percent increase from the FY 2010 estimate. In FY 2011, OAR will place priority on initiatives to (1) expand basic discovery research; (2) enhance prevention science (3) improve disease outcomes; (4) reduce HIV-related disparities; and (5) translate research from bench to bedside to the community. In addition to allocating funds to the ICs for their NIH AIDS research and training activities, OAR has identified specific funding for emerging scientific opportunities and public health challenges that require focused attention; will manage and facilitate multi-Institute and trans-Institute activities to address those needs; foster research by designating funds and supplements to jump-start or pilot program areas; and sponsor scientific agenda setting workshops to identify new cutting-edge initiatives. To assist NIH in these efforts, OAR will convene the Microbicides Research Working Group and the newly established Genomics Research Working Group, two panels of outside experts who provide guidance to OAR, the ICs, and other entities on these critical areas of research. OAR will support: 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 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, and men who have sex with men, including new initiatives in Hispanic populations; "bench-to-bedside" 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 India and Russia. OAR will continue to support the NIH AIDS Research Loan Repayment Program and the newly established Intramural AIDS Research Fellowship program, which help to ensure an adequate number of trained AIDS researchers at NIH; and support a number of initiatives to enhance dissemination of research findings, including sponsorship of the scientific panels that develop the AIDS prevention and treatment guidelines and the distribution of those guidelines through

AIDSinfo, a web-based service that provides information for caregivers and patients (available at www.aidsinfo.nih.gov).

Program Description and Accomplishments

The Office of Research on Women's Health (ORWH) was established in 1990, in response to the NIH Revitalization Act of 1993. ORWH also serves as the NIH focal point for women's health research. ORWH works in partnership with the NIH Institutes and Centers (ICs) to ensure that women's health research is part of the scientific framework at the NIH and throughout the scientific community. ORWH leads efforts on research addressing the study of sex/gender factors in health and disease, ensures IC compliance with the NIH policy on the inclusions of women and minorities in clinical research, and develops opportunities for the recruitment, retention, re-entry and sustained advancement of women in biomedical careers, as well as both women and men in women's health research careers. Through the efforts of ORWH and the NIH Working Group on Women in Biomedical Careers, the NIH workplace incorporates ongoing improvements in NIH policies, practices and programs that promote a family-friendly atmosphere. In a series of scientific workshops titled, "*Moving into the Future- New Dimensions and Strategies for Women's Health Research for the NIH,*" ORWH is addressing gaps in knowledge and forging interdisciplinary connections in women's health research through evolving technologies and innovative methodologies in all aspects of research.

Budget Policy: The FY 2011 budget estimate for ORWH is \$44.335 million, a \$1.383 million or 3.2 percent increase from the FY 2010 estimate. In FY 2011, ORWH will be implementing new initiatives for research based on prevailing themes derived from our strategic planning efforts and focused on capitalizing on nascent scientific advances that can result in improved, comprehensive and accessible health care for girls and women. Recognizing the influence of biological sex characteristics as a basic component of personalized medicine, ORWH will focus its priorities and outreach efforts to address the five major themes of the NIH Director in the context of sex and gender determinants. **High Throughput Technologies:** In an initiative (\$4M) to study sex and gender issues from the nanobiology and molecular biology levels to the societal and community levels, ORWH will support R21 developmental research projects that specifically emphasize the definition and application of newly derived scientific technologies such as those applied to women's health and expanding the understanding of sex and gender factors. **Translation of NIH Science into Practice:** In FY 2011, ORWH will conclude an evaluation of the Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health (\$10M) to determine how effective these projects have been in translating basic science into clinical practice. Based upon the demonstrated effectiveness of these Centers, ORWH will issue a new R F A for future SCORs that can more effectively translate basic research into clinical practice using lessons learned from the previous program. A planned initiative, New Paradigms in Women's Health Research Across the Lifespan (\$10M) will have an emphasis on

translational research. **Healthcare Reform:** The research programs and initiatives that ORWH will implement and support can define parameters of sex and gender as well as population disparities that will be important considerations for healthcare reform. **Global Health:** ORWH, through its collaborative efforts with NIH institutes and centers as well as other agency initiatives, will continue to focus its research and career development programs toward the global community, especially in breast and other cancers in the developing world, career development for women in resource poor countries, and leadership in research on sex and gender in healthcare (\$1M). **Stable Careers for Researchers:** ORWH will enhance its programs to develop and advance both men and women as researchers in the science of sex and gender, including expanding the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program (\$9M), which recognizes and retains scientists in such careers. In addition, ORWH will implement new initiatives to support and advance biomedical careers for women based upon concepts explored and developed during the strategic planning process.

Portrait of a Program: Integrating the Interdisciplinary Research Continuum across the Lifespan

FY 2010 Level: \$ 3 million

FY 2011 Level: \$10 million

Change: \$ 7 million

The Office of Research on Women's Health is implementing new paradigms and directions for women's health research and the study of sex and gender factors based on its comprehensive multiyear strategic planning effort in collaboration with the NIH ICS. A new program announcement will be issued to invite scientists to evaluate and explore an array of anticipatory risk and preventive factors for complex chronic diseases across the life span, with an emphasis on the implications of molecular to behavioral influences for clinical applications and public health policies. Areas for consideration may include: molecular contributions to sex differences in maturation and aging; the role of the intrauterine environment in lifespan health and disease; epigenetics as it applies in particular to women; influences of the individual's microbiome in women's health and disease; and the application of developing technologies and other novel techniques across a broad range of systems biology. Special consideration will also be given to how these new approaches to women's health research will be relevant in the coming age of personalized medicine such that it can be sex and gender appropriate.

Program Description and Accomplishments

Office of Behavioral and Social Sciences Research (OBSSR): This Office furthers the mission of NIH by emphasizing the critical role that behavioral and social factors play in health, health care and well-being. OBSSR provides senior advisory leadership and serves as the focal point for 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 the NIH intramural and extramural communities, other federal agencies, academic and scientific societies, national voluntary health agencies, the biomedical research community, 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: (a) the next generation of basic behavioral and social science research; (b) trans-disciplinary "team science" that integrates biomedical, behavioral and social-ecological perspectives; (c) research that looks at how individual, group, and societal factors interact; and (d) the translation, implementation, dissemination and maintenance of best practices and proven strategies that reduce the burden of chronic disease and eliminate inequities in health and health care.

Budget Policy: The FY 2011 budget estimate for OBSSR is \$38.166 million, a \$10.765 million or 39.3 percent increase from the FY 2010 estimate. In FY 2011, the Office will support the NIH Basic Behavioral and Social Sciences Opportunity Network (OppNet), a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research (b-BSSR) for \$10.000 million. In addition, OBSSR will support two new initiatives in FY 2011. The first will focus on the science of adherence, taking a transformative approach that utilizes the latest behavioral and social sciences tools and methodologies to deepen our understanding of and address low rates of compliance with agreed upon prevention, treatment or maintenance/rehabilitation strategies. The second will support formative research and development projects to establish "community health laboratories." Community health labs are local informatics resources tied into a national Internet based network or cyber-infrastructure that integrates information/data and applications relevant to the health of community populations. Improving the health of community populations requires an integrated approach that adapts the delivery of advances in medical technologies and health care to community conditions, while simultaneously adapting community institutions and environments to support good health. 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; community-based participatory research programs supporting intervention research methods to disease prevention and health promotion in medically underserved areas; research on social networks and health; and studies using systems science methodologies to address policy resistant problems in public health. The Office will offer its annual summer training institutes (systems science methodology and health; behavioral interventions in randomized clinical trials; social work research methods), and host the fourth annual trans-NIH conference on the science of dissemination and implementation.

Portrait of a Program: The Science of Adherence

FY 2011 Level: \$3.0 million

Poor adherence to prescription medications and treatments has been labeled a "worldwide problem of striking magnitude" (World Health Organization, 2003). Research over the last 40 years has documented universally poor adherence to prescription medications and behavioral treatments/recommendations (e.g., improvements in dietary intake and physical activity to combat obesity; smoking cessation; cancer screening). Up to 20 percent of patients do not even fill a new prescription and 50 percent of people with chronic conditions discontinue their medication within six months. No more than 30 percent quit smoking

at the doctor's request, even among those affected with lung conditions. Access to health care is vitally important, but it must be coupled with improved compliance with medical recommendations if we are to improve health outcomes. In numerous discussions within and outside of NIH, the facilitation of a new science of adherence has emerged as a critical research need, one that is also consistent with the Office of Behavioral and Social Sciences Research (OBSSR) strategic goals of stimulating "next generation" basic science, interdisciplinary study, and generating science that yields a population impact.

Scientific breakthroughs to improve adherence require a transformative approach that utilizes the latest technological, behavioral and social science tools. In FY 2011, OBSSR plans to issue a new Funding Announcement Opportunity (FOA) on *The Science of Adherence*. The FOA will target trans-disciplinary, basic and applied research on adherence across diseases and the lifespan. Examples of specific basic research areas include: the science of self-report; how beliefs and attitudes affect adherence behavior; and self-management of health and illness. Innovative approaches that employ knowledge from emerging disciplines such as behavioral economics - which merges the fields of decision-making, economics and marketing - are especially amenable to improving our understanding of adherence. In addition, emphasis will be placed on exploration of novel ways to use technology (e.g., virtual social networks like Facebook and Twitter; smart phones) as platforms to transform adherence measurement and to design interventions to improve it. These multimodal, multilevel approaches will generate the advances necessary to enhance adherence and improve population health. OBSSR will capitalize on broad Institute and Center interest in the science of adherence for partnering on this new initiative.

Program Description and Accomplishments

Office of Disease Prevention (ODP): The mission of ODP is to foster, coordinate and assess research in prevention as a cost-effective means to improve public health in the nation and the world. ODP collaborates with other federal agencies, academic institutions, the private sector, non-governmental organizations and international organizations in the formulation of research initiatives and policies that promote public health. To carry out these diverse responsibilities, ODP has three administrative units: the Office Medical Applications of Research, Office of Dietary Supplements, and the Office of Rare Diseases. ODP is developing Healthy People 2020, which will reflect assessments of major risks to health and wellness, changing public health priorities, and emerging issues related to our nation's health preparedness and prevention. The development process strives to maximize transparency, public input and stakeholder dialogue to ensure that Healthy People 2020 is relevant to diverse public health needs and seizes opportunities to achieve its goals. Since its inception, Healthy People has become a broad-based, public engagement initiative with thousands of citizens helping to shape it at every step along the way. Drawing on the expertise of a Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020, public input and a Federal Interagency Workgroup, Healthy People will provide a framework to address risk factors and determinants of health and the diseases and disorders that affect our communities.

Budget Policy: The FY 2011 budget estimate for ODP is \$1.417 million, a \$.044 million or 3.2 percent increase from the FY 2010 estimate. In FY 2011, 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. The immediate office does not have research grant authority or funds, but will continue its accomplishments through regularly convening the trans-NIH, trans-Agency Prevention Research Coordinating Committee. ODP will also serve as the focal point of NIH to Complete Healthy People 2020 planning. ODP will also regularly convene joint meetings with the National Health and Nutritional Examination Survey (NHANES) staff of CDC to nurture collaborations. The office will also develop the evaluation plan of the HHS Secretary's Prevention and Wellness Fund, funded through ARRA.

Program Description and Accomplishments

Office Medical Applications of Research (OMAR) This Office is the focal point for evidenced-based assessments of medical practice and state-of-the-science on behalf of the medical community and the public. It assesses, translates and disseminates the results of biomedical research that is used in the delivery of important health services to the public. OMAR annually presents a free training opportunity to help develop journalists' and editors' ability to evaluate and report on medical research. Now in its eighth year, the course curriculum builds on the best of prior years' offerings to create an intensive learning experience with hands-on application. The course examines the challenges and opportunities inherent in the process of communicating the results of medical research to the public.

Budget Policy: The FY 2011 budget estimate for OMAR is \$4.935 million, a \$.154 million or 3.2 percent increase from the FY 2010 estimate. In FY 2011, OMAR will continue to support consolidation and translation of research with the NIH ICs including such items as cancer screening and population health, nutrition science, maternal-fetal medicine and neuroscience by the State of the Science Conferences and Consensus Development Conferences such as; Enhancing Use and Quality of Colorectal Cancer Screening, Lactose Intolerance and Health, Vaginal Birth After Cesarean: New Insights, Preventing Alzheimer's Disease and Cognitive Decline and Inhaled Nitric Oxide for Preterm Infants.

Program Description and Accomplishments

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 ODS leads 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. ODS sponsors conferences and workshops on vitamin D and leads a federal working group to identify research needs and how to meet them. ODS also funded the development of standard reference materials to assess vitamin D status in the population and sponsored evidence-based reviews that will inform decisions regarding recommended dietary allowances and safe levels of intake for vitamin D.

Budget Policy: The FY 2011 budget estimate for ODS is \$29.034 million, a \$.906 million or 3.2 percent increase from the FY 2010 estimate. In FY 2011, major activities that this budget would support will include the continued development of the database of dietary supplements label. ODS will continue to co-fund research grants with NIH ICs on dietary supplements, ranging from in vitro laboratory and animal experiments to human studies and clinical trials. It will also work to create opportunities for dietary supplement- and nutrition-related research training and career development for young investigators. This program provides critical tools for quality assurance of dietary supplements. The program promotes development, validation, and dissemination of analytical methods and reference materials for commonly-used dietary supplements. In June 2009, ODS conducted its third annual Dietary Supplements Research Practicum. The goals of the 5-day practicum were to provide a comprehensive overview of issues, concepts, controversies, and unknowns about dietary supplements and their ingredients; show the importance of scientific investigations to evaluate the efficacy and safety of these products; and supply information and resources that would enable attendees to provide more instruction about dietary supplements at their academic institutions. ODS will continue to offer this course annually to faculty and graduate students in all relevant health-related disciplines. ODS will continue to fund systematic reviews in relevant areas as well as projects to enhance the incorporation of systematic reviews into nutrition.

Portrait of a Program: Population Studies Program

FY 2010 Level: \$250,000

FY 2011 Level: \$250,000

Change: \$ 0

There is a recognized need for programs that evaluate the biological measures of nutritional status and their association with health outcomes in large, nationally representative populations, such as the National Health and Nutrition Survey (NHANES) conducted by the National Center for Health Statistics at the CDC. Dietary supplements can contribute to the total nutrient intake and thus can influence overall nutrient status. A recent addition to the Office of Dietary Supplements (ODS), the Population Studies Program will focus on the evaluation of dietary supplement use, including the assessment of biological measures of supplement exposure and associated health effects in nationally representative populations. The efforts of this program will build our capacity to analyze population data, such as those from NHANES.

The program has the following goals: (1) Expand and increase research on the benefits and risks of dietary supplements through NIH grant funding mechanisms and the organization of and participation in seminars, conferences and scientific meetings; (2) Design, conduct and publish research on the benefits and risks of dietary supplements using representative populations; (3) Provide epidemiological and statistical expertise and support ODS staff; and (4) Develop an ODS postdoctoral research training program in nutritional epidemiology. Initial work has been focused on vitamin D through a series of collaborative research projects with several universities and other government agencies.

Program Description and Accomplishments

Office of Rare Diseases Research (ORDR): The mission of the ORDR is to coordinate, and support collaborations in biomedical research to respond to the needs of 25 to 30 million patients who have any one of the more than 6,800 rare diseases. In FY 2009, ORDR collaborated with seven NIH institutes to support phase II of the Rare Diseases Clinical Research Network to increase the number of research consortia from 10 to 19. This second 5-year phase of the network expands the exploration of the natural history, epidemiology, diagnosis, and treatments to more than 95 rare diseases. The Rare Diseases Clinical Research Consortia and a Data Management Coordinating Center will be awarded a total of approximately \$117 million between FY 2010 - FY 2014.

Budget Policy: The FY 2011 budget estimate for ORDR is \$18.644 million, a \$.582 million or 3.2 percent increase from the FY 2010 estimate. ORDR will focus additional efforts on collaborating with other entities inside and outside of the NIH to develop scientific conferences on particularly urgent areas in rare diseases research. ORDR, in collaboration with seven NIH Institutes, renewed and will support for the next five years the Rare Diseases Clinical Research Network (RDCRN), increasing the number of participating consortia from 10 to 19 to study more than 95 rare diseases in research institutions in approximately 30 states across the nation and in other countries. Another continuing program of great impact is the Undiagnosed Diseases Program which is cosponsored by the ORDR, the National Human Genome Research Institute (NHGRI), the Clinical Center (CC), and the NIH ICs. In the first 14 months, the program received 2350 inquiries, reviewed 950-1000 sets of medical records, and accepted 200 patients into protocols. More than 50 NIH intramural research experts representing over 30 medical specialty and sub-specialty areas participated in the reviews. Also continuing is the Collaboration, Education, and Genetic Test Translation (CETT) pilot project that develops and provides access for the public to quality genetic tests. The Collaboration, Education and Test Translation Program (CETT) has resulted in new or improved testing for 67 rare genetic diseases that were previously not available in the clinic. The CETT Program Review Board composed of external experts has approved the translation of new or improved testing for 110 genes involving 67 rare diseases. The program has also resulted in increased research opportunities for rare diseases through the posting of clinical and genetic testing data in databases accessible to researchers. ORDR collaborations also involve the new NIH initiative, the Therapeutics for Rare and Neglected Diseases (TRND) program. TRND is a collaborative drug discovery and development program with the NIH ICs. The program will be located in NHGRI with governance and oversight provided by ORDR. Other ongoing ORDR programs that continue to consistently contribute to research advances include collaborations with ICs in supporting rare diseases Bench-to-Bedside program grants; co-funding with ICs of more than 85 scientific conferences each year to explore scientific research opportunities; support in collaboration with the NHGRI for the Genetic and Rare Diseases Information Center (GARD) which provides comprehensive information on rare and genetic diseases in English and

Spanish to the public; co-sponsoring with NIH ICs the National Disease Research Interchange's Program for Human Tissues and Organs for Research (HTOR) to advance research by procuring and making available human biospecimens; development and distribution of a rare diseases educational module for middle school science classes; collaboration with the World Health Organization (WHO) to review the International Classification of Diseases (ICD) for placement of rare diseases in the appropriate classification of the ICD XI; collaboration with the National Library of Medicine (NLM) to include rare diseases into the NLM's MeSH subject heading tree to facilitate integration into and access to data bases and published literature by researchers; and funding an analysis by the Institute of Medicine (IOM) of challenges in the rare diseases community.

Portrait of a Program: The Rare Diseases Clinical Research Network (RDCRN)

FY 2010 Level: \$11.459 million

FY 2011 Level: \$11.459 million

Change: \$ 0.000 million

Since the 1980s, there has been a continuous expressed need for a nation-wide network of centers for rare diseases. There are approximately 25 to 30 million people in the US with a rare disease, and there are more than 6,500 rare diseases known today. In response to this great need, the Office of Rare Diseases Research (ORDR) and NIH institutes and centers collaborated and, in 2003, created the Rare Diseases Clinical Research Network (RDCRN). In 2009, during phase 2 of the RDCRN, several advances were made: seven institutes provided approximately \$11.9 million and considerable administrative assistance in addition to the ORDR funds; the number of RDCRN consortia increased from 10 to 19; the central data management and coordinating center continued; the new network expanded the exploration of the natural history, epidemiology, diagnosis, and treatment to more than 95 rare diseases.

The consortia are unique in their approach to addressing rare diseases as a group of related rare diseases. Usually, NIH's Institutes and centers fund research on individual rare diseases in their respective disease-type or organ domains. The RDCRN is the first program that aims to create a specialized infrastructure to support rare diseases research. The network is designed to facilitate patient recruitment by fostering collaboration among scientists and shared access to geographically distributed research resources. Collaboration is a critical element of the network and is fostered among investigators from multiple research sites, among participating patient advocacy groups, and between investigators and patient advocate groups. The direct involvement of patient advocacy groups in network operations, activities, and strategy is a major feature of the network.

Program Description and Accomplishments

The Office of Science Education (OSE): Develops programs, instructional materials, and career resources that serve our nation's science teachers, their students (kindergarten through college), and the public. These activities are conducted through strategic partnerships with internal and external organizations. OSE also advises NIH leadership on education policy issues, coordinates related activities with NIH extramural and intramural offices, and represents NIH in federal education initiatives. OSE's efforts are critical to achieve the NIH Director's goal to reinvigorate and empower the biomedical research community and enhance America's competitiveness in the global economy. These efforts foster a pool of talented students well prepared in math and science who can then choose to pursue medical science, health, and other challenging careers. Engaging scientists in K-16 education -- through resource and program development -- is the office's newest focus. The LifeWorks Web site and

SciLife programs encourage students to explore health and medical careers and learn how to achieve their career goals. The LifeWorks E-Mentors program matches students with scientists for one-on-one career guidance. The NIH Curriculum Supplements are lessons on current health science topics that help students develop the workforce skills they need to succeed in the 21st century. Since FY 2000, OSE has distributed more than 350,000 supplements in response to teacher requests. A randomized controlled study found that instruction with an NIH curriculum supplement improved student science achievement over traditional instruction on the same content. These resources reach a diverse national audience, and a special effort is made to reach out to underrepresented populations.

Budget Policy: The FY 2011 budget estimate for OSE is \$4.169 million, a \$.130 million or 3.2 percent increase from the FY 2010 estimate. During FY 2011, OSE will continue to work with the White House Office of Science and Technology Policy through the National Science and Technology Council Education Subcommittee, and by helping to implement and promote the proposed National Lab Day and National STEM Week. Additionally, OSE will work with professional societies and academic institutions to engage scientists in improving K-12 science education. Efforts will include developing tools and resources for individual scientists, and a model program for scientist-teacher partnerships. OSE will print and begin to distribute the two curriculum supplements developed in FY 2009 and FY 2010. The SciLife program will be expanded to enhance the long-term impact on participants and to form additional sponsoring partnerships. To improve its Web-based programs, OSE will add new materials and implement redesign recommendations from a Web analytics strategic plan (completed in FY 2010). The Office will also continue its Section 508 web site remediation efforts.

Program Description and Accomplishments

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 the NIH. There are two education programs offered. The Intramural Loan Repayment Program repays outstanding eligible educational debt for postgraduates, and in return, participants must enter into a contractual agreement to conduct qualified research as NIH employees. 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 the 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. During FY 2009, the distribution of awards for the Intramural Loan Repayment Programs (LRP) was as follows: a total of 3 awards for the Clinical LRP—3 renewals; a total of 73 awards for the General LRP—39 new and 37 renewals; and a total of 4 awards for the AIDS LRP—4 renewals. The grand total of LRP awards for FY 2009 was 80. The Undergraduate Scholarship Program (UGSP) selected 11 new recipients for the UGSP Scholarship award and 5 UGSP Scholars received scholarship

award renewals. In addition, 29 UGSP Scholars conducted their yearlong service obligation during this same period.

Budget Policy: The FY 2011 budget estimate for ILRSP is \$7.745 million, a \$.242 million or 3.2 percent increase from the FY 2010 estimate. The program plans for FY 2011, along are as follows:

(Dollars in Millions)

	FY 2008		FY 2009		FY 2010		FY 2011	
	# Awards	Amount	# Awards	Amount	# Awards	Amount	# Awards	Amount
NIH Clinical Loan								
Repayment Program	9	\$0.309	3	\$0.077	9	\$0.361	9	\$0.361
NIH General Loan								
Repayment Program	74	4.409	73	4.972	80	4.767	80	5.000
AIDS Loan Repayment								
Program	6	0.329	4	0.048	13	0.720	13	0.720
Undergraduate								
Scholarship								
Program	19	0.380	18	0.280	22	0.400	24	0.440

Program Description and Accomplishments

Director's Discretionary Fund: The Director's Discretionary Fund (DDF) allows the NIH Director to respond quickly to new and emerging high-priority research opportunities and health priorities. In FY 2009 funds were used to support trans-NIH initiatives such as Stem Cell Task Force activities, the Human Frontier Science Program, FDA/NIH Clinical Trials Interface and the Undiagnosed Disease Program to assist patients with unknown disorders and to discover new diseases that provide insight into biochemical pathways and cell biology.

Budget Policy: The FY 2011 budget estimate for DDF is \$10 million, the same as the FY 2010 estimate. In FY 2011, 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 rarest genetic disorder.

Program Description and Accomplishments

Common Fund: The Common Fund supports the programs that collectively compose the NIH Roadmap for Medical Research. These programs catalyze 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. In FY 2009, a new high risk/high reward initiative, the Transformative Research Projects (TR01) initiative, was launched to encourage investigator-initiated research that has the potential to significantly impact a broad area of science by overturning a fundamental scientific paradigm in that field. The program is being expanded in FY 2010 and will support a new cadre of investigators in FY 2011. In addition, a new program, Genotype-Tissue Expression

(GTE_x), began funding in FY 2010 as a two-year pilot to collect and analyze multiple human tissues from many donors to establish links between genetic sequence variation and changes in gene activity. The Common Funds also will provide a nimble source of funds for the NIH Director to develop new programs that address challenges and opportunities as they emerge.

Budget Policy: The FY 2011 budget estimate for Common Fund is \$561.629 million, a \$17.529 million or 3.2 percent increase from the FY 2010 estimate. This budget will allow new programs to be supported as described in the Common Fund section of this document. Changes in existing programs will also occur, reflecting the ongoing needs of those programs.

Program Description and Accomplishments

Countermeasures against Nuclear/Radiological Threats and Chemical

Countermeasures Research: This program develops nuclear and radiological medical countermeasures that mitigate or treat injury and restore damaged tissue. This includes supporting collaborative efforts with for-profit and non-profit organizations, as well as eligible agencies of the Federal Government, such as the Armed Forces Radiobiology Research Institute (AFRRI), the National Cancer Institute (NCI), the National Institute on Aging (NIA), and the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK). Ongoing initiatives include support for the Centers for Medical Countermeasures against Radiation (CMCR), which support basic, translational, and applied research leading to new medical countermeasures against radiological and nuclear exposures due to terrorist attacks, as well as a grants program for research and development on medical countermeasures for gastrointestinal acute radiation syndrome (ARS), radiation-induced thrombocytopenia, pulmonary radiation injury, cutaneous radiation injury and combined radiation injuries. NIAID funds contracts for product development support services, the development of oral radionuclide decorporation agents, and the study of immune senescence with the Radiation Effects Research Foundation in Hiroshima, Japan. The CMCRs have entered their fifth year of funding. Accomplishments since inception (FY2005) include 163 scientific published in peer-review journals, 24 patents, and over 100 candidate medical countermeasures in discovery and research phases. The product development support services efforts include interaction with over 90 pharmaceutical and biotechnology companies, development of animal models for screening and pivotal efficacy studies, identification of potential medical countermeasures for hematological ARS (5) and gastrointestinal ARS (2), identification of lead candidates for radionuclide decorporation (5), and confirmation of efficacy of a growth factor in a non-pivotal animal model of ARS. A targeted Small Business Innovation Research (SBIR) program for Radiological/Nuclear Medical Countermeasure Product Development was established in FY 2009.

Budget Policy: The FY 2011 budget estimate for Countermeasures against Nuclear/Radiological Threats and Chemical Countermeasures Research is \$99.825 million, a \$3.114 million or 3.2 percent increase from the FY 2010 estimate. The program plans for FY 2011, along with expected accomplishments are as follows: The research program for Countermeasures against Nuclear/Radiological Threats will

support basic and applied research to develop new products for measuring radiation exposure, protecting against exposure and minimizing and treating the effects of exposure to a wide range of radioactive compounds. Examples of specific activities include expanding research to accelerate the development of medical countermeasures to reduce the gastrointestinal toxicity of acute radiation and to enhance the excretion of radionuclides from persons with internal radiological contamination. In addition, NIH will initiate research to identify and characterize biomarkers that are predictive of organ and tissue damage due to acute radiation exposure. Within the Chemical Countermeasures research program, special attention will be directed at promising drugs and antidotes for nerve agents, poisons such as cyanide, toxic industrial chemicals capable of causing pulmonary edema, and vesicating (blistering) agents, such as mustard gas which blisters the skin and mucous membranes on contact. NIH will continue clinical safety and efficacy trials for specific products including midazolam, a promising anticonvulsant drug currently in advanced development. Elements of the research effort include basic research addressing critical gaps in knowledge important to product development, evaluation of mechanisms of injury and host response, along with the enhancement of the repair process, and the evaluation and development of promising countermeasures.

Program Description and Accomplishments

Foundation for the National Institutes of Health: The mission of the Foundation for NIH is to foster public health through scientific discovery, translational research, and the dissemination of research results through specially-configured, high-impact public-private partnerships consistent with the priorities of NIH. The Foundation for NIH helps to underwrite biomedical initiatives that might not be attractive for private funding alone, or are not appropriate for exclusively public funding. With the goals of NIH as its guide, the Foundation serves both the public and private sectors, helping them achieve significant breakthroughs in human health in areas of interest that overlap with those of NIH. In FY 2008, the FNIH entered into an agreement with several pharmaceutical manufacturers to supply free medicine for patient's general care and clinical studies at the NIH's Clinical Center. In FY 2009, the FNIH received donations valued at \$1.3 million that were shipped to the Clinical Center. In addition, Dell Computers donated 23 laptops, valued at \$28,378, through the FNIH for use by the students in the NIH/Oxford/Cambridge scholars program.

Budget Policy: The FY 2011 budget estimate for the Foundation for NIH is \$.500 million, the same as the FY 2010 estimate. The Foundation for NIH will continue serving both the public and private sectors in those areas of interest that overlap with those of NIH.

Program Description and Accomplishments

OD Operations: OD Operations is comprised of several OD offices that provide advice to the NIH Director, policy direction 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, Financial Management, Disease Prevention, Human Resources, Executive Office, and NIH Chief Information Officer. Within the Office of

Science Policy, the Office of Biotechnology Activities coordinates the functions of the Recombinant DNA and Gene Transfer Advisory Committee; the Secretary's Committee on Genetics, Health, and Society; and the National Science Advisory Board for Biosecurity.

Budget Policy: The FY 2011 budget estimate for OD Operations is \$158.420 million, a \$7.384 million or 4.8 percent increase from the FY 2010 estimate. The program plans for FY 2011, along with expected accomplishments are as follows: payroll growth to support the annual pay raise and increased resources to accommodate the NIH Reform Act's provision for activities associated with the Scientific Management Review Board. Funding will also be used to support requirements that would lessen agency vulnerabilities and provide for staff to accommodate new and expanded initiatives such as the expansion of the Office of Extramural Research's grants compliance oversight activities and continuing educational efforts to improve and enhance compliance requirements. There will be increased support for the Office of Intramural Research's human subject's research initiatives to accommodate required NIH-wide policy development, educational activities, oversight and coordination of the NIH Human Research Protection Program. The Office of Management Assessment's will enhance its risk management program operations; fund staffing growth to support increased workload requirements in the area of program integrity audit support; and expand compliance and training activities within the NIH Privacy Program. Funds will support the restoration and replacement of the OD's IT hosting and networking infrastructure to prevent the potential of increasing network outages both in frequency and duration that could adversely impact OD-wide staff productivity.

In FY 2011, the OD will provide support to expand the Therapeutics for Rare and Neglected Diseases (TRND) program to encourage and speed the development of new drugs for rare and neglected diseases for \$.990 million. The OD also will fund the NSLS-II for \$.163 million, a new DOE synchrotron facility that will replace NSLS at Brookhaven National Laboratory.

The Office of Science Policy will continue to manage the initiative on bioethics established in FY 2010 for \$5.000 million. This initiative will be funded in coordination with NIH ICs. The OD will fund various strategic management and oversight activities. Bioethics research and training is necessary to maintain and enhance public trust and confidence as we explore new frontiers in science, bioinformatics, and biomedical and behavioral medicine.

OD Operations will also continue to fund the NIH Director's Challenge Fund established in FY 2008 for \$1.500 million. 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. Some funds may be set aside for one-time only use (i.e., instrumentation). Subsequently, the host ICs would be expected to fully support projects. Specific criteria for a successful project remain to be determined, but

priority will be given to novel, high-risk approaches that include interdisciplinary and trans-NIH components.

Program Description and Accomplishments

The National Children's Study (NCS): The NCS is a multi-year research study that examines the effects of environmental influences on the health and development of a large, nationally representative sample of children across the United States, following them from birth to adulthood. Scientists are examining the effects of the physical, chemical, biological, and psychosocial environment on such outcomes as premature birth, birth defects, autism, learning disorders, asthma, obesity, and diabetes. The pilot phase of the Study includes seven Vanguard Centers that commenced enrollment in FY 2009.

Budget Policy: The FY 2011 budget estimate for NCS is \$194.400 million, a \$.520 million or .3 percent increase from the FY 2010 estimate. In FY 2011, the OD will support continuation of the NCS pilot or feasibility phase, termed the Vanguard Study. The Vanguard Study began in January 2009 with two centers, and expanded in April 2009 with five additional centers. The Vanguard Study will run in parallel with the Main Study, but always by a time interval ahead of the Main Study. The experience of the Vanguard Study will allow the NCS to develop and refine the operational approach and assessments for the Main Study. The NCS Vanguard Study is testing the feasibility, acceptability and costs of each study activity and determines the appropriate level of support for an activity, thus collecting scientific as well as cost information for more informed budget estimates. The NCS program staff reviews the budgetary requirements of the study on a regular basis and provides budget estimates based on the empirical evidence available at the time of the request, such as study costs per site, economic indicators and constant dollar projections. The major NIH components involved in this activity (NIH/OD, NICHD and NCS program staff) regularly meet to review the budget status and address budgetary concerns. The FY 2011 budget request will allow the NCS to continue data acquisition, evaluate the methods used in the Vanguard Study and make data-driven recommendations for the methodology of the Main Study. The Main Study protocol will be designed with assurance that the approaches tested are feasible and effective, and can be accommodated within the budget. The protocol will be peer reviewed by an expert panel convened by the Director, NIH, before field implementation of the Main Study. Analysis of the early data from the current Vanguard Study locations necessitated investigating new recruitment strategies in additional locations which will, in turn, inform a refined budget model. The NCS intends to use FY 2011 funds to enhance community outreach and communications and to assess these alternative recruitment strategies. This will allow the Vanguard Study recruitment experience to inform the design of the Main Study with greater confidence in performance and cost estimates. In addition, having data on several alternatives will allow greater flexibility to select the most effective recruitment strategies for each city, town or local area. The administrative components of the NCS include a data coordinating center, an information management system, logistics, and communication support for the Vanguard Study Centers.

The NCS FY 2011 budget request will also continue to support bio-specimen and environmental collections. The NCS is collaborating with other partners to optimize the logistical components of the study for greater efficiency and cost effectiveness. The NCS has established a process to ensure reconciliation of successive budget iterations. The NICHD recognizes that long-term multi-year estimates are subject to influences outside the study, and thus are not feasible until each phase of the Vanguard Study is reviewed, and the Main Study design has been completed.

Recovery Act Implementation

Recovery Act Funding: \$1,336.837 billion

In FY 2009, OD received \$1,336.837 billion under the Recovery Act. Of this amount, \$699.551 million was obligated in FY 2009 and \$637.286 million will be obligated in FY 2010. In FY 2009, these funds supported signature initiatives including the Cancer Genome Atlas (TCGA) project focused on the discovery of the molecular alterations that occur in major types and subtypes of cancer and the DNA Sequencing project. The latter project greatly enhances the opportunity for researchers to discover specific genetic variants that map precisely with disease phenotypes by enabling them to scour thousands of DNA sequences in extremely fine detail. The OD Recovery Act funds also supported NIH Challenge Grants in Health and Science, the Grand Opportunities (GO) grant program and administrative supplements to provide summer research experiences for students and science educators.

In FY 2010, a major segment of the funds will support the initiatives reflected below:

The Director's Opportunity for Research in Five Thematic Areas to develop and implement critical research innovations in one or more of the following five thematic areas:

1. Applying Genomics and Other High Throughput Technologies
2. Translating Basic Science Discoveries into New and Better Treatments
3. Using Science to Enable Health Care Reform
4. Focusing on Global Health
5. Reinvigorating the Biomedical Research Community

The Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program aims to accelerate the transition of research innovations and technologies toward the development of products or services that will improve human health, help advance the mission of NIH and its Institutes and Centers (ICs), and create significant value and economic stimulus.

The Small Business Catalyst Award invites grant applications from small business concerns that propose to accelerate innovation through high risk, high reward research and development (R&D) that has commercial potential and is relevant to the mission of the NIH.

The Academic Research Enhancement Award (AREA) program is to stimulate research in educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support.

**NATIONAL INSTITUTES OF HEALTH
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Budget Authority by Object

	FT 2010 Estimate	FT 2011 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	642	671	29
Full-time equivalent of overtime & holiday hours	4	4	0
Average ES salary	\$171,650	\$175,124	\$3,434
Average GM/GS grade	12.6	12.6	0.0
Average GM/GS salary	\$105,347	\$108,508	\$3,161
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$111,867	\$115,223	\$3,356
Average salary of ungraded positions	\$116,752	\$120,255	\$3,503
OBJECT CLASSES	FT 2010 Estimate	FT 2011 PB	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	\$56,783,000	\$61,430,000	\$4,647,000
11.3 Other than Full-Time Permanent	7,115,000	7,622,000	507,000
11.5 Other Personnel Compensation	2,948,000	3,154,000	206,000
11.7 Military Personnel	1,005,000	1,075,000	70,000
11.8 Special Personnel Services Payments	1,448,000	1,536,000	88,000
Total, Personnel Compensation	69,299,000	74,817,000	5,518,000
12.0 Personnel Benefits	20,819,000	22,476,000	1,657,000
12.2 Military Personnel Benefits	399,000	427,000	28,000
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	90,517,000	97,720,000	7,203,000
21.0 Travel & Transportation of Persons	1,725,000	1,811,000	86,000
22.0 Transportation of Things	125,000	131,000	6,000
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	180,000	189,000	9,000
23.3 Communications, Utilities & Miscellaneous Charges	1,659,000	1,742,000	83,000
24.0 Printing & Reproduction	1,260,000	1,323,000	63,000
25.1 Consulting Services	950,000	997,000	47,000
25.2 Other Services	67,677,000	68,784,000	1,107,000
25.3 Purchase of Goods & Services from Government Accounts	124,674,000	127,181,000	2,507,000
25.4 Operation & Maintenance of Facilities	1,185,000	1,244,000	59,000
25.5 Research & Development Contracts	219,002,000	210,224,000	(8,778,000)
25.6 Medical Care	15,000	16,000	1,000
25.7 Operation & Maintenance of Equipment	1,584,000	1,663,000	79,000
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	415,087,000	410,109,000	(4,978,000)
26.0 Supplies & Materials	2,235,000	2,347,000	112,000
31.0 Equipment	7,300,000	7,665,000	365,000
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	656,932,000	697,441,000	40,509,000
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	1,086,503,000	1,122,558,000	36,255,000
Total Budget Authority by Object	1,002,000,000	1,220,478,000	218,478,000

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

**NATIONAL INSTITUTES OF HEALTH
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Salaries and Expenses

OBJECT CLASSES	FY 2010 Estimate	FY 2011 PB	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-Time Permanent (11.1)	\$56,783,000	\$61,430,000	\$4,647,000	8.2
Other Than Full-Time Permanent (11.3)	7,115,000	7,622,000	507,000	
Other Personnel Compensation (11.5)	2,948,000	3,154,000	206,000	7.0
Military Personnel (11.7)	1,005,000	1,075,000	70,000	7.0
Special Personnel Services Payments (11.8)	1,448,000	1,536,000	88,000	6.1
Total Personnel Compensation (11.2)	69,299,000	74,815,000	5,516,000	8.0
Civilian Personnel Benefits (12.1)	20,819,000	22,476,000	1,657,000	8.0
Military Personnel Benefits (12.2)	399,000	427,000		
Benefits to Former Personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	90,517,000	97,718,000	7,201,000	8.0
Travel (21.0)	1,725,000	1,811,000	86,000	5.0
Transportation of Things (22.0)	125,000	131,000	6,000	4.8
Rental Payments to Others (23.2)	180,000	189,000	9,000	5.0
Communications, Utilities and Miscellaneous Charges (23.3)	1,659,000	1,742,000	83,000	5.0
Printing and Reproduction (24.0)	1,260,000	1,323,000	63,000	5.0
Other Contractual Services:				
Advisory and Assistance Services (25.1)	950,000	997,000	47,000	4.9
Other Services (25.2)	67,677,000	68,784,000	1,107,000	1.6
Purchases from Govt. Accounts (25.3)	124,674,000	127,181,000	2,507,000	2.0
Operation & Maintenance of Facilities (25.4)	1,185,000	1,244,000	59,000	5.0
Operation & Maintenance of Equipment (25.7)	1,584,000	1,663,000	79,000	5.0
Subsistence & Support of Persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	196,076,000	199,869,000	3,793,000	1.9
Supplies and Materials (26.0)	2,235,000	2,347,000	112,000	5.0
Subtotal, Non-Pay Costs	203,254,000	207,412,000	4,158,000	2.0
Total, Administrative Costs	293,771,000	305,132,000	11,361,000	3.9

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

Authorizing Legislation

	PHSAct/ Other Citation	U.S. Code Citation	2009 Amount Authorized	FY 2010 Estimate	2010 Amount Authorized	FY 2011 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
	Section 402(a)	42§281	Indefinite	\$1,177,020,000	Indefinite	\$1,220,478,000
Office of the Director						
Total, Budget Authority				1,177,020,000		1,1,220,478,000

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

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2002	232,098,000 <u>2/</u>	232,098,000	236,408,000	235,540,000
Rescission				(140,000)
2003	253,859,000	0	257,974,000	267,974,000
Rescission				(1,742,000)
2004	317,983,000	317,568,000	323,068,000	329,707,000
Rescission				(2,203,000)
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 ^{3/}
Rescission				0
2008 ^{4/}	517,062,000	1,114,422,000	1,145,790,000	1,109,099,000
Rescission				(19,720,000)
Supplemental				2,636,000
2009 ^{4/}	1,056,797,000	0	1,275,281,000	1,246,864,000
Rescission				0
2010 ^{4/}	1,182,777,000	1,168,704,000	1,182,777,000	1,177,020,000
Rescission				0
2011 ^{4/}	1,220,478,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

3/ Annualized current rate.

4/ Includes funds for the Common Fund

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
Office of the Director	629	642	671
Total	629	642	671
Includes FTEs which are reimbursed from the NTH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2007	12.2		
2008	12.2		
2009	12.6		
2009	12.6		
2011	12.6		

NATIONAL INSTITUTES OF HEALTH
Office of the Director

Detail of Positions

GRADE	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
Total, ES Positions	16	16	16
Total, ES Salary	2,739,261	2,805,551	2,889,718
GM/GS-15	112	116	116
GM/GS-14	135	139	141
GM/GS-13	142	147	151
GS-12	84	87	108
GS-11	43	44	44
GS-10	6	6	6
GS-9	33	34	35
GS-8	15	16	16
GS-7	14	14	14
GS-6	5	5	5
GS-5	2	2	2
GS-4	0	0	0
GS-3	1	1	1
GS-2	0	0	0
GS-1	1	1	1
Subtotal	593	612	640
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	9	9	9
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	9	9	9
Ungraded	62	62	63
Total permanent positions	575	594	623
Total positions, end of year	680	699	728
Total full-time equivalent (ETE) employment, end of year	629	642	671
Average ES salary	171,204	171,690	175,124
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	102,858	105,347	108,508

Includes FTEs which are reimbursed from the NTH Roadmap for Medical Research.

NATIONAL INSTITUTES OF HEALTH
Office of the Director

New Positions Requested

	FY 2011		
	Grade	Number	Annual Salary
Health Scientist	AD-0/0	1	\$118,315
Health Science Administrator	GS-14	2	128,084
Auditor	GS-13	1	105,694
Program Analyst	GS-13	3	105,694
Health Scientist	GS-12	17	83,111
Auditor	GS-12	4	83,111
Program Assistant	GS-9	1	61,288
Total Requested		29	