

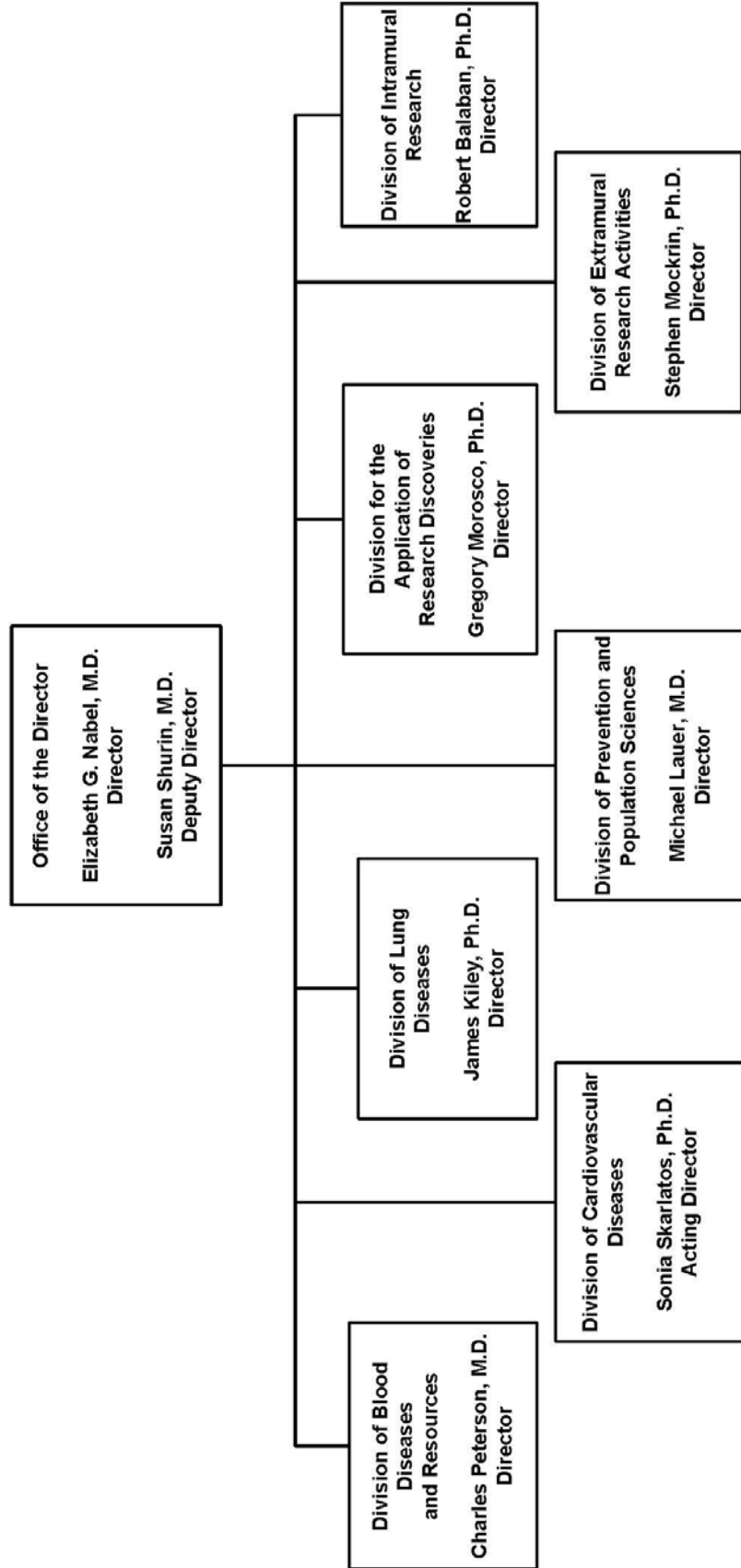
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

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NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute



NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

For carrying out section 301 and title IV of the Public Health Services Act with respect to cardiovascular, lung, and blood diseases and blood products [~~\$2,974,900,000~~]

\$2,924,942,000. (Department of Health and Human Services Appropriation Act, 2008)

**National Institutes of Health
National Heart, Lung, and Blood Institute**

Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$2,921,757,000	\$2,974,900,000	\$2,924,942,000
Pay cost add-on	1,172,000	0	0
Rescission	0	-51,972,000	0
Subtotal, adjusted appropriation	2,922,929,000	2,922,928,000	2,924,942,000
Real transfer under Director's one-percent transfer authority (GEI)	-538,000	0	0
Comparative transfer to NIBIB	-82,000	0	0
Comparative transfer to OD	-37,000	0	0
Comparative transfer to NCRR	-2,827,000	0	0
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-3,000	0	0
Comparative transfer to NIDDK	-800,000	-816,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	538,000	0	0
Subtotal, adjusted budget authority	2,919,180,000	2,922,112,000	2,924,942,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	2,919,180,000	2,922,112,000	2,924,942,000
Unobligated balance lapsing	-68,000	0	0
Total obligations	2,919,112,000	2,922,112,000	2,924,942,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2007 - \$13,593,000 FY 2008 - \$20,000,000 FY 2009 - \$20,000,000
Excludes \$1,400,000 in FY 2008 and \$1,400,000 in FY 2009 for royalties.

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute
(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects:								
Noncompeting	2,843	\$1,433,098	2,801	\$1,435,676	2,903	\$1,460,069	102	\$24,393
Administrative supplements	(112)	13,092	(114)	13,000	(112)	13,092	(-2)	92
Competing:								
Renewal	306	147,613	287	142,900	269	134,423	(18)	-8,477
New	631	315,136	609	303,905	573	285,649	(36)	-18,256
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	937	462,749	896	446,805	842	420,072	(54)	-26,733
Subtotal, RPGs	3,780	1,908,939	3,697	1,895,481	3,745	1,893,233	48	-2,248
SBIR/STTR	174	73,515	169	71,250	170	71,500	1	250
Subtotal, RPGs	3,954	1,982,454	3,866	1,966,731	3,915	1,964,733	49	-1,998
Research Centers:								
Specialized/comprehensive	55	140,664	48	128,750	48	128,750	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	420	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	55	141,084	48	128,750	48	128,750	0	0
Other Research:								
Research careers	534	72,127	556	74,834	556	74,834	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	48	36,622	42	32,800	42	32,800	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	4	2,475	4	2,500	4	2,500	0	0
Other	99	21,233	67	21,500	67	21,500	0	0
Subtotal, Other Research	685	132,457	669	131,634	669	131,634	0	0
Total Research Grants	4,694	2,255,995	4,583	2,227,115	4,632	2,225,117	49	-1,998
Research Training:								
Individual awards	174	8,193	176	8,250	176	8,310	0	60
Institutional awards	1,789	85,123	1,789	85,123	1,789	85,600	0	477
Total, Training	1,963	93,316	1,965	93,373	1,965	93,910	0	537
Research & development contracts (SBIR/STTR)	204 (5)	300,753 (1,274)	207 (2)	324,500 (1,000)	207 (2)	324,500 (1,000)	0 (0)	0 (0)
Intramural research	413	168,678	414	175,134	414	177,845	0	2,711
Research management and support	401	100,438	401	101,990	407	103,570	6	1,580
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHLBI	814	2,919,180	815	2,922,112	821	2,924,942	6	2,830

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

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute
BA by Program
(Dollars in thousands)

<u>Extramural Research</u>	<u>FY 2005 Actual</u>		<u>FY 2006 Actual</u>		<u>FY 2007 Actual</u>		<u>FY 2007 Comparable</u>		<u>FY 2008 Enacted</u>		<u>FY 2009 Estimate</u>		<u>Change</u>	
	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>
<u>Detail:</u>														
Heart and Vascular Diseases	1,607,188	1,632,680	1,633,337	1,632,011	1,628,885	1,627,986								
Lung Diseases	631,725	600,892	601,134	600,646	599,496	599,164								
Blood Diseases and Resources	442,082	417,578	417,746	417,407	416,607	416,377								
Subtotal, Extramural	2,680,995	2,651,150	2,652,217	2,650,064	2,644,988	2,643,527								
Intramural research	405	170,200	413	168,678	414	177,845	413	168,678	414	175,134	414	177,845	0	2,711
Res. management & support	391	90,006	401	100,614	401	101,990	401	100,438	401	101,990	407	103,570	6	1,580
TOTAL	796	2,941,201	814	2,922,391	814	2,922,112	814	2,919,180	815	2,922,112	821	2,924,942	6	2,830

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

Major Changes in the Fiscal Year 2009 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 2009 budget request for NHLBI, which is +\$2.830 million more than the FY 2008 Enacted, for a total of \$2,924.942 million.

Research Project Grants (-\$1.998 million; total \$1,964.733 million): The NIH Budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs. NHLBI noncompeting grants will increase by \$24.393 million in FY 2009. Some of the increased number of grants in the noncompeting mechanism (\$6 million) are a result of the Pathways to Independence (K99/R00) program, which will be converted to R00s in FY 2009. NHLBI competing RPGs will decrease by \$26.733 million from FY 2008. This decrease will result in the institute funding 54 fewer competing awards. Intramural Research and Research Management Support receive modest increases to help offset the cost of pay and other increases. NHLBI will continue to support new investigators and to maintain an adequate number of competing RPGs.

Research Careers (+/- \$0; total \$74.834 million): NHLBI will continue to support the Pathway to Independence Program by funding an additional 22 awards in FY 2009. Funds are available as the first round of K99s convert to the R00 mechanism.

Systolic Blood Pressure Intervention Trial (SPRINT) (+\$3.070 million): This initiative will support a multicenter randomized trial to determine whether treating systolic blood pressure to a lower goal than is currently recommended can reduce cardiovascular disease.

Medical Education for K-12 Teachers and Students (MKITS II) (+\$3.025 million): NHLBI will develop a program, under a contract, that enables experienced PIs to help NHLBI disseminate and evaluate K-12 science education curricula, materials, and educational activities that incorporate best practices learned from previous such programs. These objectives remain unchanged from NHLBI's original program released in FY 2003.

Integrated Analytical Methods for Large-Scale Multi-dimensional Biomarker, Phenotype, and Genotype Data from the Framingham Biomarkers Project (+\$4.0 million): This new project will build upon the Framingham Biomarkers Project by supporting the design of new data integration and analysis methods for extensive heterogeneous biological data and their application to large population studies. Such innovative analytical approaches would seek to model biological mechanisms and disease development processes relevant to the NHLBI mission.

Translating Discoveries in the Behavioral Sciences to Reduce Obesity and Promote Cardiovascular Health (+\$5.0 million): This research program would seek to translate findings from basic research on human behavior into effective clinical, community, and population interventions to reduce obesity and promote cardiovascular health. NHLBI anticipates funding 7 awards starting in FY 2009.

NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute
Summary of Changes

FY 2008 Enacted		\$2,922,112,000		
FY 2009 estimated budget authority		2,924,942,000		
Net change		2,830,000		
CHANGES	2008 Enacted		Change from Base	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2008 pay increase				
		\$64,071,000		\$719,000
b. January FY 2009 pay increase				
		64,071,000		1,394,000
c. One less day of pay				
		64,071,000		(245,000)
d. Payment for centrally furnished services				
		28,853,000		433,000
e. Increased cost of laboratory supplies, materials, and other expenses				
		82,210,000		1,489,000
Subtotal				3,790,000
2. Research management and support:				
a. Annualization of January 2008 pay increase				
		\$52,421,000		\$588,000
b. January FY 2009 pay increase				
		52,421,000		1,140,000
c. One less day of pay				
		52,421,000		(200,000)
d. Payment for centrally furnished services				
		18,095,000		271,000
e. Increased cost of laboratory supplies, materials, and other expenses				
		31,474,000		562,000
Subtotal				2,361,000
Subtotal, Built-in				6,151,000

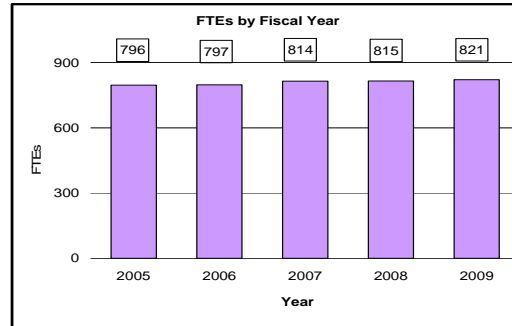
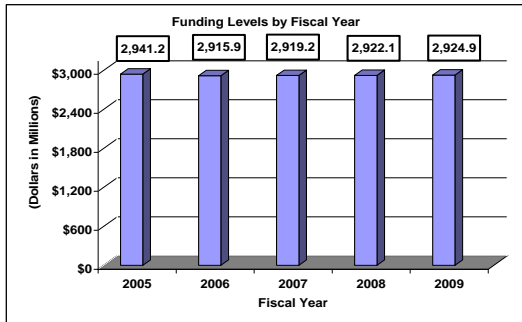
**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Summary of Changes--continued

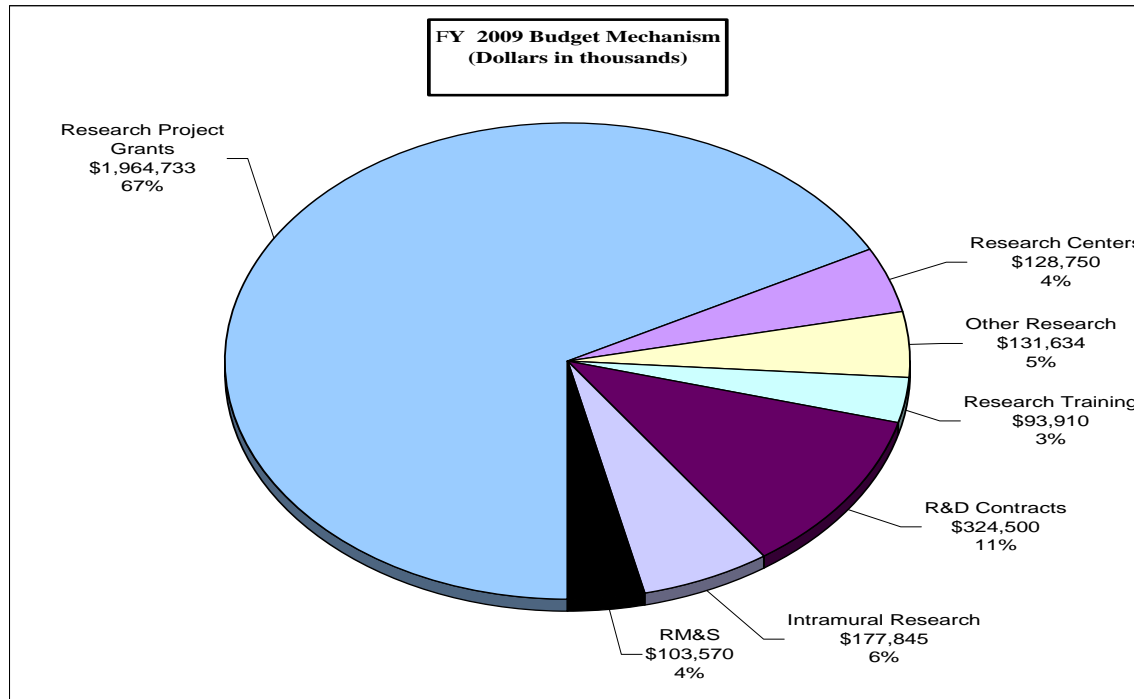
CHANGES	2008 Enacted Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	2,801	\$1,448,676,000	102	\$24,485,000
b. Competing	896	446,805,000	(54)	(26,733,000)
c. SBIR/STTR	169	71,250,000	1	250,000
Total	3,866	1,966,731,000	49	(1,998,000)
2. Research centers	48	128,750,000	0	0
3. Other research	669	131,634,000	0	0
4. Research training	1,965	93,373,000	0	537,000
5. Research and development contracts	207	324,500,000	0	0
Subtotal, extramural				(1,461,000)
6. Intramural research	414	175,134,000	0	(1,079,000)
7. Research management and support	401	101,990,000	6	(781,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		2,922,112,000		(3,321,000)
Total changes	815		6	2,830,000

Fiscal Year 2009 Budget Graphs

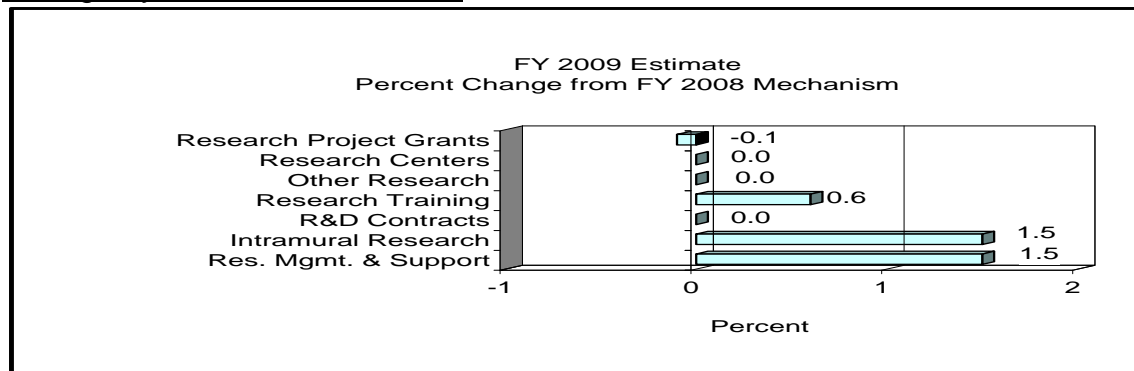
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



Justification of Budget Request

National Heart, Lung, and Blood Institute

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority:

FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Increase or Decrease	
<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>
814	\$2,919,180,000	815	\$2,922,112,000	821	\$2,924,942,000	6	\$2,830,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Heart, Lung, and Blood Institute (NHLBI), including HIV/AIDS activities. Details of the FY 2009 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 NHLBI provides global leadership for a research and education program to promote **prevention** and treatment of heart, lung, and blood diseases. The vision is to enhance the health of all individuals and thereby enable them to lead longer and happier lives.

To achieve this vision, NHLBI supports and guides research on the **prevention**, causes, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases. The NHLBI supports individuals in private and public sectors working in fields related to its mission area, and the education of investigators working across the spectrum of scientific discovery. The NHLBI creates and supports a robust, collaborative research infrastructure in partnership with private and public organizations, including academic institutions, industry, and government agencies, to address the scientific and educational needs of the nation. The NHLBI collaborates with individuals, families, communities, physicians, scientists, health care professionals, professional societies, patient advocacy groups, and the media to ensure wide dissemination and maximal use of knowledge to reduce human suffering and benefit individual and public health.

The pursuit of this vision and mission occurs in a spirit of service that exemplifies excellence, innovation, integrity, respect, and compassion.

The NHLBI Strategic Plan

With the extensive involvement of the communities it serves, the NHLBI's recently completed development of a scientific working plan to guide its activities and initiatives in the near future. *Shaping the Future of Research: A Strategic Plan for the National Heart, Lung, and Blood Institute* is on the NHLBI Web site at <http://apps.nhlbi.nih.gov/strategicplan/>.

The plan is structured around three goals that reflect the successive movement of scientific discovery—from “form to function,” “function to causes,” and “causes to cures”—and inform and complement one another. This crosscutting, versus disease-specific, approach highlights areas where the NHLBI is well positioned to make major contributions through investigator-initiated research and through programs that enable and complement investigator-initiated activities.

The plan identifies a number of basic research areas of focus with the intent of delineating normal and pathological biological mechanisms and exploiting the emerging understanding of these mechanisms to identify biomarkers of disease. Such biomarkers—broadly defined as measurable indicators of genotype, biological or pathological processes, or responses to therapeutic intervention—will facilitate identification of disease subtypes and point the way toward new molecular targets for **preempting** and **preventing** disease, as well as for diagnosis and treatment.

The plan's clinical and translational research goal emphasizes transmission of knowledge between basic and clinical research so that findings in one arena rapidly inform and stimulate research in the other. More precise methods of risk-stratification and diagnosis are expected to arise from application of new approaches (e.g., noninvasive imaging, biomarkers) from basic science laboratories. A critical challenge will be to develop **personalized preventive** and therapeutic regimens based on genetic makeup in combination with developmental and environmental exposures. Insights are already emerging, but robust and efficient means of validating both individualized and population-based treatments will be needed to establish an evidence base to guide medical practice.

The plan acknowledges the need to enhance understanding of the processes involved in translating research into practice and to use that understanding to enable improvements in public health and stimulate further scientific discovery. It places particular emphasis on conducting research in primary **prevention** and identifying interventions that work in the practice communities that will ultimately constitute the targets for translation and education. As well, continued development and evaluation of new approaches to communicate research advances to the public is an important priority for ensuring full and informed **participation** of individuals in their health care.

The plan is intended to provide the NHLBI with a guide for its research and training programs over the next 5 to 10 years. It presents broad strategies that the NHLBI will employ to facilitate the conduct of research; enhance interdisciplinary work; speed

early-stage translation of basic discoveries; ensure cross-fertilization of basic, clinical, and epidemiologic discoveries, and maximize the resultant public health benefit of the information created. Specific measures to implement the plan will now be developed in consultation with the National Heart, Lung, and Blood Advisory Council and the scientific community. Investigator-initiated research has long constituted the largest share of the NHLBI research portfolio, and we fully expect that much of the plan will be realized through continued support of such research. Institute-initiated investments guided by the plan will be directed largely toward programs that either enable or complement investigator-initiated activities.

As the challenges identified in the plan are met and as new ones emerge, the NHLBI will identify and embrace new strategies. The Institute also will continue to look to its Advisory Council and to the larger research community for guidance to ensure that these strategies are updated as needed to reflect the rapidly changing environments of research and public health issues.

FY 2009 JUSTIFICATION BY PROGRAM DETAIL

Program Descriptions and Accomplishments

Overall Budget Policy: Investigator-initiated research projects and new investigator research and career development remain the Institute's highest priorities. The NHLBI carefully evaluates investigator-initiated requests to submit grants applications for all large programs. A scientific review is conducted, and the results are presented to the NHLBI Advisory Council to determine level of recommended support, if any. The level of support provided for Institute-initiated projects (e.g. RFAs) is also evaluated. The Institute maintains a balance between solicitations issued to the extramural community in areas that need stimulation and funding made available to support investigator-initiated projects.

Extramural Research

Heart and Vascular Diseases: This program seeks to increase knowledge of the causes of heart and vascular diseases and develop effective strategies to diagnose, treat, and **prevent** them. Diseases and conditions of interest include coronary heart disease, arrhythmias and sudden cardiac death, congenital heart disease, heart failure, hypertension, and peripheral vascular disease.

In fiscal year 2007, the NHLBI initiated a 5-year program to develop and support a Cardiovascular Disease Research Network. Its purpose is to increase scientific knowledge of cardiovascular diseases—including epidemiology, risk and risk factors, prevention, detection and diagnosis, treatment, and prognosis—in the context of **participatory**, community-based health-care delivery. The Institute awarded 8 cooperative agreements to establish a network for cardiothoracic surgical interventions in cardiovascular medicine. Panels of experts in the fields of lipids and hypertension were convened to assess the needs and opportunities for new clinical trials of

cholesterol and blood pressure lowering to **prevent** cardiovascular disease. The Institute held working groups to identify future research opportunities in two large-scale epidemiological studies—the Multi-ethnic Study of Atherosclerosis and the Coronary Artery Risk Development in Young Adults Study.

Budget Policy: The FY 2009 budget estimate for the Heart and Vascular Diseases program is \$1,627,986,000, a decrease of \$899,000 or .055% less than the FY 2008 estimate. During the FY 2009 NHLBI plans to continue to support research on the biology of the development of the heart and vascular system and the relationship between cardiovascular physiology and the function of other organs, particularly the lungs, brains, and kidneys. The NHLBI will continue to fund research that uses systems biology approaches and thereby enhances interactions with programs supported by other NIH components. NHLBI also will continue to support work on improving understanding of the characteristics of stem cells in multiple systems and will emphasize translation of fundamental knowledge of stem cell biology into approaches to repair and regenerate damaged tissues and organs.

Population and community-based studies will be supported to improve the outcomes of resuscitation after myocardial infarction, to enhance the management of acute coronary syndromes, and to develop better biomarkers and imaging approaches for identifying pre-clinical cardiovascular disease and implementing **preventive, preemptive** interventions. Research ranging from basic investigations to clinical studies that address management of heart failure and understanding of cardiac energetics will be supported.

Portrait of a Program: Framingham Heart Study

FY 2008 Level:	\$10,800,000
FY 2009 Level:	<u>\$10,867,000</u>
Change	\$ 67,000

The Framingham Heart Study (FHS) is a prospective, community-based, family study that began in 1948 among residents of Framingham, Massachusetts. The original group of participants included 5,209 adults between the ages of 30 and 62 at enrollment who visited the research center every two years for medical histories, physical exams, and laboratory tests. In 1971, 5,124 of the original group's adult children and their spouses were added. A third-generation cohort – 4,095 grandchildren of the original participants – was enrolled in 2002. Over the years, the study has provided a wealth of information regarding the contributions of hypertension, high cholesterol, cigarette smoking, and other risk factors to the development of cardiovascular diseases. Funds budgeted for FY 2009 provide support for part of a 7-year extension of the study that will reexamine the living participants from each of the three cohorts and gather genetic, laboratory, and clinical data for analysis.

The Framingham SNP-Health Association Resource (SHARe) is a comprehensive new effort to pinpoint genes underlying cardiovascular and other chronic diseases. The program builds on the FHS and on other NIH-funded research demonstrating that common but minute variations in human DNA, called single nucleotide polymorphisms (SNPs), can be used to identify genetic contributors to common diseases. It includes data on more than 9,300 FHS participants who had their DNA tested for 550,000 SNPs. In addition, the participants' clinical information gathered during the study, such as blood pressure or weight, is included. SHARe will enable researchers to relate study participants' genetic variations with their clinical and laboratory test results and their health outcomes. This represents a milestone in moving toward an era of **personalized** medicine in which diagnostic, therapeutic, and **preventive** approaches are tailored to the individual. The FHS SHARe resides in a new NIH database that will make the combined genotypic and phenotypic data available to researchers around the world. The database will help researchers integrate the wealth of information collected over the years in the FHS and other large cohort studies with new genetic data, resulting in an increased understanding of genetic influences on disease risk, manifestation, and progression. Because of its uniqueness in including three generations of subjects with comparable data obtained from each generation at the same age, the FHS is the first study to be included in the SHARe initiative. The NHLBI is currently considering expansion of SHARe to include other large longitudinal studies such as the Jackson Heart Study and the new Hispanic Community Health Study.

Lung Diseases: This program seeks to understand the causes and progression of lung diseases and sleep disorders and thereby improve their diagnosis, treatment, and **prevention**. Research areas include asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunology and fibrosis, lung cell and vascular biology, and pulmonary complications of AIDS and tuberculosis. The National Center on Sleep Disorders Research is administered as part of the Lung Diseases program.

In fiscal year 2007, the NHLBI initiated a program to foster research on lung stem cell biology and cell-based therapy for lung diseases. It will support collaborations between basic scientists and clinical investigators to advance these promising areas of investigation. In concert with the National Cancer Institute, the NHLBI convened the workshop "Lung Cancer and COPD, Different Outcomes of a Common Etiopathogenetic Pathway?" to identify areas for joint research efforts. Workshops were also held to discuss the future structure and direction of lung diseases clinical research networks, to explore newly identified cellular components of the lung, and to assess the role of circadian timing in the function of cells that make up heart, lung, and blood tissues.

Budget Policy: The FY 2009 budget estimate for the Lung Diseases program is \$599,164,000 a decrease of \$332,000 or .055% less than the FY 2008 estimate. Plans for FY 2009 continue to emphasize research on lung development, inflammation, injury

and repair. Research topics to be investigated include gene therapy for cystic fibrosis, prenatal origins of asthma, and the early indicators of COPD, as detected by biomarkers and imaging. The ultimate goals are to **preempt** the development of acquired lung diseases and to enhance early detection and thereby **prevent** or limit disease progression.

The FY 2009 budget estimate for the National Center for Sleep Disorders Research is \$50,560,000 the same level as the FY 2008 estimate. The plan for FY 2009 is to continue to support the area of sleep disorders research.

Portrait of a Program: Asthma Therapy Research Networks

FY 2008 Level:	\$
FY 2009 Level:	<u>\$5,800,000</u>
Change	\$5,800,000

For about 2 decades, NHLBI-supported clinical research networks in asthma have been highly effective in providing a flexible and efficient structure for the rapid development and conduct of clinical trials on important clinical management questions. Each network consists of several clinical centers and a data coordinating center, and is governed by a steering committee with responsibility for identifying important research questions; selecting topics for investigation; designing, developing, overseeing, and monitoring protocols; and participating in data analysis and interpretation and reporting of results. Funds budgeted for FY 2009 provide support for the first of the seven years.

The Asthma Clinical Research Network (ACRN), initiated in fiscal year 1993, is a group of interactive asthma clinical research sites established to facilitate rapid assessment of new treatment methods. The ACRN ensures that findings on optimal management of adult asthmatic patients are rapidly disseminated to practitioners and health-care professionals.

The Childhood Asthma Research and Education (CARE) Network, initiated in fiscal year 1999, has been evaluating current and novel therapies and management strategies for children with asthma. The emphasis is on clinical trials to help identify optimal, more **personalized** therapy for children with different asthma phenotypes, genotypes, and ethnic backgrounds and children at different developmental stages.

The current funding period is drawing to a close so NHLBI convened a workshop in May 2007 to obtain advice on network structures that would sustain past successes while meeting future clinical research needs. Participants from the research community strongly endorsed the concept of networks and emphasized the need to increase flexibility, facilitate scientific exchange, enhance efficiency, encourage shared use of resources, and promote training. In FY 2009, to preserve the best of past networks while incorporating these recommendations, the Institute will establish the Asthma Therapy Research Network (ATRN), a single entity to replace the ACRN and the CARE. Its focus will remain on important clinical management questions, but will also have the flexibility to conduct ancillary and proof-of-concept studies on topics important to clinical care across the age span. The cooperative development of protocols and standardization of data collections will enable researchers to address questions on the similarities, differences, and relationships between adult and pediatric asthma. Funds previously used to support CARE and ACRN will support the new network.

Blood Diseases and Resources: This program supports research on the causes, **prevention**, and treatment of nonmalignant blood diseases, including anemias, sickle cell disease, and thalassemia; premalignant processes such as myelodysplasia and myeloproliferative disorders; abnormalities of hemostasis and thrombosis such as hemophilia; and immune dysfunction. A major program responsibility is to conduct research to ensure the adequacy and safety of the nation's blood supply.

In fiscal year 2007, the NHLBI initiated a program of Pediatric Transfusion Medicine Academic Career Awards. Its goal is to develop curricula designed to attract new investigators into the field of pediatric transfusion medicine. A working group titled "The Interface Between Thrombosis and Inflammation" was convened to achieve a better understanding of how acute and chronic inflammation leads to thrombosis (blood coagulation) and, conversely, how coagulation affects inflammatory activity.

Budget Policy: The FY 2009 budget estimate for the Blood Diseases and Resources program is \$416,377,000 a decrease of \$230,000 or .055% less than the FY 2008 estimate. During FY 2009, the program plans to continue its support for studies of bone marrow failure, thrombosis, and coagulation disorders, and intrinsic disorders of red cells, white cells, and platelets. Priorities include development of better hematopoietic stem cell therapies and a clearer understanding of the nature of the stem cells that participate in the development of the hematopoietic and immunologic systems. Considerable new knowledge about the interaction between the vascular wall and the coagulation system has expanded the blood program into study of organ damage that arises from thrombosis. Networks for research on hemoglobinopathies (sickle cell disease and the thalassemias) continue to explore approaches for **personalizing** assessments of disease severity and prognosis and **preventing** organ damage related to disordered blood flow and iron overload.

The NHLBI will continue to support work to enhance blood safety and ensure the adequacy of the nation's blood supply, including studies of improved component therapies, better procurement and testing, and alternatives to transfusion. Supportive care with cellular therapies is also a component of this program. A transfusion medicine network continues innovative work on approaches to improving the global blood supply, emphasizing enhanced access, lower costs, and more effective therapies.

Portrait of a Program: Blood and Marrow Clinical Trial Network

FY 2008 Level:	\$6,800,000
FY 2009 Level:	<u>\$6,900,000</u>
Change	\$ 100,000

The Blood and Marrow Transplant Clinical Trials Network, established in FY 2001, conducts scientifically meritorious multicenter clinical trials to improve outcomes of blood and marrow transplants. It develops and carries out high-quality studies to evaluate promising therapies in an effort to obtain definitive answers to significant problems in hematopoietic stem cell transplantation. The Network is cosponsored by the National Cancer Institute (NCI). It comprises 16 core clinical centers, some of which are consortia of two or more centers, and a data coordinating center formed by collaboration between the Center for International Blood and Marrow Transplant research, the National Marrow Donor Program, and the EMMES Corporation. Over 50 non-core centers are approved to participate in Network clinical trials. In addition, to enhance accrual of patient participants, collaborations with four NCI-funded Cancer Cooperative Groups are being developed.

The Network has a number of protocols, including studies of patients undergoing treatment for multiple myeloma, non-Hodgkin's lymphoma, leukemia, and aplastic anemia. The program was renewed for a 5-year period in fiscal year 2006. Expanded activities in the second phase include the conduct of phase II trials that provide a basis for phase III studies on transplantation methodologies to improve long-term outcome following transplantation; the conduct of phase II/III clinical trials addressing the needs of pediatric patients and those with rare diseases; and the development of procedures for protocol development, conduct, and data management that will enable collaboration with other NIH-funded cooperative research programs and increase the efficiency of conducting trials in blood and marrow transplant. Recognizing the wealth of expertise in allogeneic transplantation represented by the Network, the National Institute of Allergy and Infectious Diseases has recently provided support for a phase II trial in scleroderma and associated ancillary studies.

Intramural Research

The Intramural Research program conducts laboratory and clinical research in heart, vascular, lung, blood, and kidney diseases and develops technology related to cardiovascular and pulmonary diseases. The program comprises four centers (Biochemistry and Biophysics, Cell Biology and Physiology, Genetics and Developmental Biology, and Immunology), four branches (Cardiovascular, Hematology, Pulmonary Critical Care Medicine, and Vascular Medicine), and the Cardiothoracic Surgery Research Program.

Budget Policy: The FY 2009 budget estimate for the Intramural Research program is \$177,845,000, an increase of \$2,711,000 or 1.5% from the FY 2008 estimate. The program plans for FY 2009, along with expected outputs, are as follows. Increases for salaries and related costs are covered in the budget request. The budget provides support for new programs, which include (a) expansion of the newly formed Pulmonary and Vascular Medicine Branch to include two new tenure track scientists, one working on sickle cell disease, the other in lipid metabolism therapeutics, (b) recruitment of one tenure track scientists in the basic sciences in physical biology, (c) recruitment of one tenure track scientist in the general clinical sciences, (d) using technology developed within the DIR to establish a epigenetic screening center for the human genome, (e) initiation of a state of the art computer tomography system for the study of heart disease, (f) continued expansion of the post-translational modification detection capabilities in the proteomic core, (g) establish a state of the heart cardiovascular phenotyping center for the mouse, (h) further develop systems biology platforms for the analysis of proteomic and genomic data, (i) further develop the in vivo optical microscopy program using adaptive optics, motion compensation and novel detection systems to reach sub-micron resolution in intact animal models, (j) expand the robotic and catheter fabrication capabilities within the DIR to support MRI guided therapeutic approaches applications in man.

Research Management and Support

This activity provides administrative management and scientific direction in the review, award, and monitoring of research grants, training awards and research and development contracts and in the overall planning, coordination, and evaluation of the Institute's programs.

In fiscal year 2008, the Division of Extramural Research Activities administered the review, processing, award, and scientific performance appraisal of approximately 5,000 research grants, 750 training awards, and 600 contracts. The Division for the Application of Research Discoveries continued its public and professional education activities in cardiovascular diseases and asthma and developed a new educational campaign, "COPD: Learn More, Breathe Better."

Budget Policy: The FY 2009 budget estimate for Research Management and Support is \$103,570,000, an increase of \$1,580,000 or 1.5% over the FY 2008 estimate. The program plans for FY 2009, along with expected outputs, are as follows. Increases for salaries and related costs are covered in the budget request, but decreases are planned for operating expenses such as maintenance contracts and information technology costs. The NHLBI Division for the Application of Research Discoveries will continue with the planning and implementation of knowledge networks to support rapid sharing of knowledge and experience between researchers and practitioners. Establishment of the initial Cardiovascular Knowledge Network will be followed closely by the establishment of the Pulmonary Knowledge Network to address asthma and COPD.

In regard to its lifespan approach to addressing **prevention** and treatment of cardiovascular disease, the Division will conduct activities to follow the issuance of the first-ever integrated guidelines for reduction of cardiovascular risk factors in children ages 2 to 22. FY 09 activities will include implementation of educational efforts directed at health care professionals as well as a consumer-oriented education and outreach campaign to facilitate and enhance **participatory** medicine.

In the asthma area, the Division will design and implement similar efforts based on the asthma management and treatment guidelines issued in late 2007. Education activities will be developed for children, adolescents, and adults as well as for health care professionals in the two related campaigns.

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Budget Authority by Object

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	815	821	6
Full-time equivalent of overtime and holiday hours	2	2	0
Average ES salary	\$173,560	\$178,767	\$5,207
Average GM/GS grade	12.2	12.2	0.0
Average GM/GS salary	\$93,549	\$96,355	\$2,806
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$99,177	\$102,153	\$2,976
Average salary of ungraded positions	112,145	115,509	3,364
OBJECT CLASSES	FY 2008 Estimate	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$66,869,000	\$70,544,000	\$3,675,000
11.3 Other than full-time permanent	13,758,000	14,391,000	633,000
11.5 Other personnel compensation	3,068,000	3,209,000	141,000
11.7 Military personnel	1,301,000	1,360,000	59,000
11.8 Special personnel services payments	9,038,000	9,462,000	424,000
Total, Personnel Compensation	94,034,000	98,966,000	4,932,000
12.0 Personnel benefits	21,603,000	22,797,000	1,194,000
12.2 Military personnel benefits	856,000	896,000	40,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	116,493,000	122,659,000	6,166,000
21.0 Travel and transportation of persons	3,197,000	3,070,000	(127,000)
22.0 Transportation of things	295,000	280,000	(15,000)
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	210,000	200,000	(10,000)
23.3 Communications, utilities and miscellaneous charges	1,413,000	1,375,000	(38,000)
24.0 Printing and reproduction	687,000	660,000	(27,000)
25.1 Consulting services	5,229,000	5,000,000	(229,000)
25.2 Other services	14,832,000	14,200,000	(632,000)
25.3 Purchase of goods and services from government accounts	210,694,000	211,796,000	1,102,000
25.4 Operation and maintenance of facilities	3,550,000	3,400,000	(150,000)
25.5 Research and development contracts	208,000,000	208,000,000	0
25.6 Medical care	1,055,000	1,010,000	(45,000)
25.7 Operation and maintenance of equipment	6,960,000	6,650,000	(310,000)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	450,320,000	450,056,000	(264,000)
26.0 Supplies and materials	16,271,000	15,600,000	(671,000)
31.0 Equipment	12,723,000	12,000,000	(723,000)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	2,320,488,000	2,319,027,000	(1,461,000)
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	15,000	15,000	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	2,805,619,000	2,802,283,000	(3,336,000)
Total Budget Authority by Object	2,922,112,000	2,924,942,000	2,830,000

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

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Salaries and Expenses

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$66,869,000	\$70,544,000	\$3,675,000
Other than full-time permanent (11.3)	13,758,000	14,391,000	633,000
Other personnel compensation (11.5)	3,068,000	3,209,000	141,000
Military personnel (11.7)	1,301,000	1,360,000	59,000
Special personnel services payments (11.8)	9,038,000	9,462,000	424,000
Total Personnel Compensation (11.9)	94,034,000	98,966,000	4,932,000
Civilian personnel benefits (12.1)	21,603,000	22,797,000	1,194,000
Military personnel benefits (12.2)	856,000	896,000	40,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	116,493,000	122,659,000	6,166,000
Travel (21.0)	3,197,000	3,070,000	(127,000)
Transportation of things (22.0)	295,000	280,000	(15,000)
Rental payments to others (23.2)	210,000	200,000	(10,000)
Communications, utilities and miscellaneous charges (23.3)	1,413,000	1,375,000	(38,000)
Printing and reproduction (24.0)	687,000	660,000	(27,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	1,779,000	1,550,000	(229,000)
Other services (25.2)	14,832,000	14,200,000	(632,000)
Purchases from government accounts (25.3)	22,060,000	14,908,000	(7,152,000)
Operation and maintenance of facilities (25.4)	3,550,000	3,400,000	(150,000)
Operation and maintenance of equipment (25.7)	6,960,000	6,650,000	(310,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	49,181,000	40,708,000	(8,473,000)
Supplies and materials (26.0)	16,206,000	15,560,000	(646,000)
Subtotal, Non-Pay Costs	71,189,000	61,853,000	(9,336,000)
Total, Administrative Costs	187,682,000	184,512,000	(3,170,000)

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2008 Enacted	2008 Amount Authorized	FY 2009 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				\$2,922,112,000		\$2,924,942,000
National Heart, Lung, and Blood Institute	Section 402(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				2,922,112,000		2,924,942,000

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation ^{1/}
2000	1,759,806,000 ^{2/}	1,937,404,000	2,001,185,000	2,040,291,000
Rescission				(10,867,000)
2001	2,069,582,000 ^{2/}	2,321,320,000	2,328,102,000	2,299,100,000
Rescission				(875,000)
2002	2,567,429,000	2,547,675,000	2,618,966,000	2,576,125,000
Rescission				(3,063,000)
2003	2,778,728,000	2,791,411,000	2,820,011,000	2,812,011,000
Rescission				(18,278,000)
2004	2,867,995,000	2,867,995,000	2,897,595,000	2,897,145,000
Rescission				(18,454,000)
2005	2,963,953,000	2,963,953,000	2,985,900,000	2,965,453,000
Rescission				(24,252,000)
2006	2,951,270,000	2,951,270,000	3,023,381,000	2,951,270,000
Rescission				(29,513,000)
2007	2,918,808,000	2,901,012,000	2,924,299,000	2,918,808,000
2008	2,894,341,000	2,965,775,000	2,992,197,000	2,974,900,000
Rescission				(51,972,000)
2009	2,924,942,000			

^{1/} Reflects enacted supplementals, rescissions, and reappropriations.

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

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	15	15	15
Office of Biostatistics Research	12	12	12
Office of Science and Technology	18	18	18
Office of Administrative Management	69	69	69
Office of Research Training and Minority Health	4	4	4
Office of Clinical Research	5	5	5
Division of Cardiovascular Diseases	57	57	59
Division of Prevention and Population Sciences	43	43	46
Center for Population Studies	4	4	4
Center for Biomedical Informatics	17	17	18
Division of Lung Diseases	22	22	22
Division of Blood Diseases and Resources	23	23	23
Division of Intramural Research	386	386	386
Division of Extramural Research Activities	104	105	105
Division Application Research Discoveries	35	35	35
Total	814	815	821
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FISCAL YEAR	Average GM/GS Grade		
2005	12.2		
2006	13.0		
2007	12.1		
2008	12.2		
2009	12.2		

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

Detail of Positions

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	1	1	1
Total, ES Salary	166,102	173,560	178,767
GM/GS-15	97	97	97
GM/GS-14	113	113	113
GM/GS-13	138	139	141
GS-12	94	96	97
GS-11	34	35	36
GS-10	2	2	2
GS-9	55	56	57
GS-8	32	33	33
GS-7	17	17	18
GS-6	11	11	11
GS-5	7	7	7
GS-4	5	5	5
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	606	612	618
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	7	7	7
Senior Grade	2	2	2
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	11	11	11
Ungraded	252	255	258
Total permanent positions	720	727	734
Total positions, end of year	870	879	888
Total full-time equivalent (FTE) employment, end of year	814	815	821
Average ES salary	166,102	173,560	178,767
Average GM/GS grade	12.1	12.2	12.2
Average GM/GS salary	89,529	93,549	96,355

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

**NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute**

New Positions Requested

	FY 2009		
	Grade	Number	Annual Salary
Health Scientist Administrator	13	2	\$94,000
Project Manager	13	1	\$94,000
Procurement Analyst	14	1	\$111,000
Clinical Trial Specialist	13	2	\$94,000
Total Requested		6	