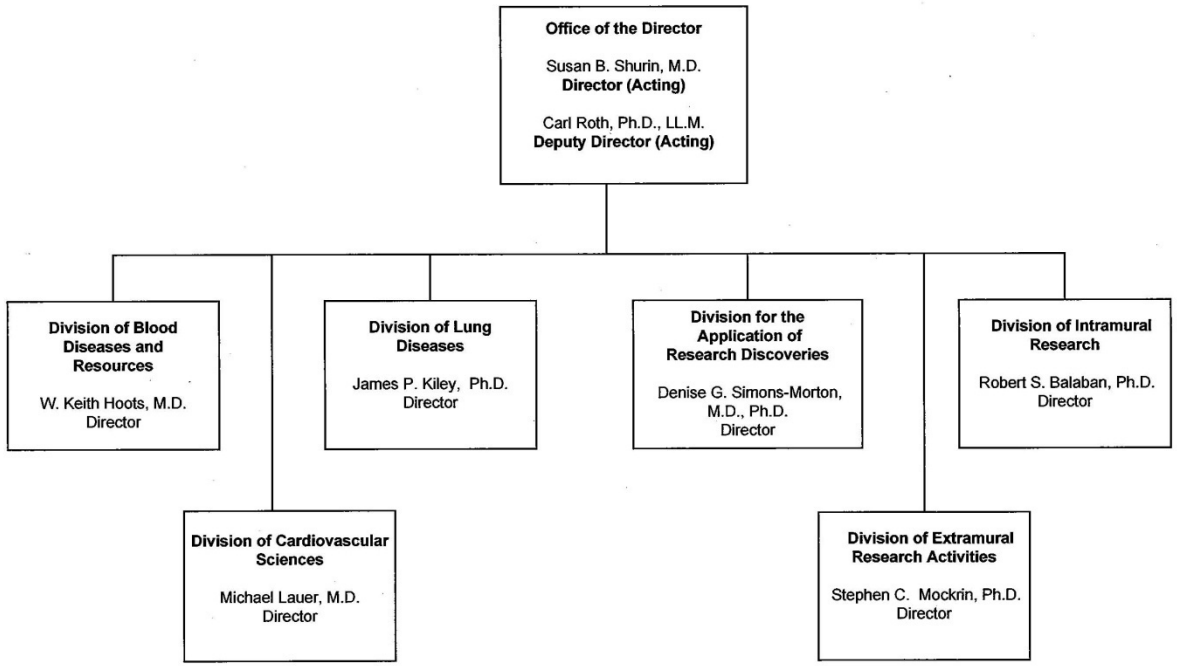
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute (NHLBI)

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 [$3,095,812,000] *$3,187,516,000.* (Public Law 111-117, Consolidated Appropriations Act, 2010)

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

Amounts Available for Obligation 1/

Source of Funding	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Appropriation	$3,015,689,000	$3,096,916,000	$3,187,516,000
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	3,015,689,000	3,096,916,000	3,187,516,000
Real transfer under Director's one-percent transfer authority (GEI)	-1,060,000	0	0
Real transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	0	0	0
Comparative transfer to NLM for NCBI	-475,000	-736,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	1,060,000	0	0
Comparative transfer to NLM for Public Access	-341,000	-368,000	0
Comparative transfer from DHHS for Autism	0	0	0
Subtotal, adjusted budget authority	3,014,873,000	3,095,812,000	3,187,516,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	3,014,873,000	3,095,812,000	3,187,516,000
Unobligated balance lapsing	-77,000	0	0
Total obligations	3,014,796,000	3,095,812,000	3,187,516,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2009 - $15,472,000 FY 2010 - $20,000,000 FY 2011 - $20,000,000
Excludes $1,173,169 in FY 2009 and $1,196,632 in FY 2010 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung and Blood Institute

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2009 Actual		FY 2009 Recovery Act Actual		FY 2010 Recovery Act Estimated		FY 2010 Enacted		FY 2011 PB		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:												
Noncompeting	2,921	$1,474,182	$0	$0	506	$293,658	2,975	$1,554,173	2,963	$1,608,267	(12)	$54,094
Administrative supplements	(114)	7,583	519	91,362		0	(95)	7,500	(94)	7,600	(1)	$100
Competing:												
Renewal	270	153,869	100	48,780	0	0	259	150,265	251	150,533	(8)	$268
New	697	323,838	409	251,818	6	8,000	667	316,148	660	317,511	(7)	$1,363
Supplements	1	266	0	0	0	0	1	250	1	250	0	0
Subtotal, competing	968	477,973	509	300,598	6	8,000	927	466,663	912	468,294	(15)	1,631
Subtotal, RPGs	3,889	1,959,738	509	391,960	512	301,658	3,902	2,028,336	3,875	2,084,161	(27)	55,825
SBIR/STTR	172	76,400	0	24	5	1,000	159	75,000	161	76,200	2	1,200
Subtotal, RPGs	4,061	2,036,138	509	391,984	517	302,658	4,061	2,103,336	4,036	2,160,361	(25)	57,025
Research Centers:												
Specialized/comprehensive	43	89,698	35	20,578	35	19,910	49	90,650	48	92,010	(1)	1,360
Clinical research	0	0	0	0	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0	0	0	0	0
Comparative medicine	0	455	0	0	0	0	0	855	0	881	0	26
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, Centers	43	90,153	35	20,578	35	19,910	49	91,505	48	92,891	(1)	1,386
Other Research:												
Research careers	572	84,647	0	257	0	0	569	85,201	571	86,053	2	852
Cancer education	0	0	0	0	0	0	0	0	0	0	0	0
Cooperative clinical research	23	18,775	0	0	0	0	22	19,500	25	25,500	3	6,000
Biomedical research support	0	0	0	0	0	0	0	0	0	0	0	0
Minority biomedical research support	10	2,167	0	0	0	0	12	2,200	12	2,266	0	66
Other	111	25,412	0	0	0	0	115	26,000	114	26,000	(1)	0
Subtotal, Other Research	716	131,001	0	257	0	0	718	132,901	722	139,819	4	6,918
Total Research Grants	4,820	2,257,292	544	412,819	552	322,568	4,828	2,327,742	4,806	2,393,071	(22)	65,329
Research Training:	FTTPs		FTTPs		FTTPs		FTTPs		FTTPs			
Individual awards	242	10,330	0	0	0	0	240	10,433	240	11,059	0	626
Institutional awards	1,747	86,249	0	0	0	0	1,747	86,711	1,747	91,793	0	5,082
Total, Training	1,989	96,579	0	0	0	0	1,987	97,144	1,987	102,852	0	5,708
Research & development contracts	216	366,010	0	0	5	8,000	218	371,500	221	380,500	3	9,000
(SBIR/STTR)	(8)	(2,402)	(0)	(0)	(0)	(0)	(6)	(3,500)	(6)	(3,500)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs		FTEs		FTEs	
Intramural research	448	181,091	0	51	0	3,759	438	183,543	455	189,416	17	5,873
Research management and support	408	113,901	0	962	0	14,425	434	115,883	456	121,677	22	5,794
Construction		0						0		0		0
Buildings and Facilities		0						0		0		0
Total, NHLBI	856	3,014,873	0	413,832	0	348,752	872	3,095,812	911	3,187,516	39	91,704

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

Extramural Research	FY 2007 Actual FTEs	FY 2007 Actual Amount	FY 2008 Actual FTEs	FY 2008 Actual Amount	FY 2009 Actual FTEs	FY 2009 Actual Amount	FY 2009 Comparable FTEs	FY 2009 Comparable Amount	FY 2010 Enacted FTEs	FY 2010 Enacted Amount	FY 2011 PB FTEs	FY 2011 PB Amount	Change FTEs	Change Amount
Detail:														
Heart and Vascular Diseases		$1,633,337		$1,650,199		$1,659,109		$1,659,836		$1,706,524		$1,755,367		48,843
Lung Diseases		$601,134		$574,222		$627,848		$628,123		$645,791		$664,275		18,484
Blood Diseases and Resources		$417,746		$426,252		$431,733		$431,922		$444,071		$456,781		12,710
Subtotal, Extramural		2,652,217		2,650,673		2,718,690		2,719,881		2,796,386		2,876,423		80,037
Intramural research	413	169,560	442	177,490	448	181,734	448	181,091	438	183,543	455	189,416	17	5,873
Res. management & support	401	100,614	404	109,215	408	114,128	408	113,901	434	115,883	456	121,677	22	5,794
TOTAL	814	2,922,391	846	2,937,378	856	3,014,552	856	3,014,873	872	3,095,812	911	3,187,516	39	91,704

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 2011 budget request for NHLBI, which is $91.704 million more than the FY 2010 Estimate, for a total of $3,187.516 million.

Research Project Grants (RPGs; +$57.025 million; total $2,160.361million): NHLBI will continue to fund of competing RPGs—912 awards in FY 2011, a decrease of 15 from FY 2010. About 2,963 noncompeting RPG awards, totaling $1,608.267 million will be made in FY 2011.

Blood and Marrow Transplant Clinical Trials Network (+$8.000 million): The objective of this competitive solicitation is to continue the operation of a network and data coordinating center for a third 5-year period to accelerate research on the management of hematopoietic stem cell transplantation, standardize and compare the effectiveness and toxicities of existing treatments, and evaluate new therapies. This network is supported by both NHLBI as the primary Institute, and by the NCI.

Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases (CADET) (+$15.000 million):
The objective of this RFA is to identify potential biomarkers, surrogate markers, and drug targets, in concert with early disease detection, population stratification, and prognostic indicators, and to validate in humans their effects on target pathways that may be shared by multiple lung diseases. The first of two phases (CADET I) will involve up to 30 2-year awards and will allow wide exploration and validation of new targets for therapeutic or diagnostic development. The second phase, CADET II, beginning in FY 2013 and lasting 5 years, will support seven clinical research centers and one data coordinating center to develop new therapeutics or diagnostics based on the most promising previously identified targets. The goal is to advance biomarkers and new therapies into early clinical trials by the end of the program.

Common Pathogenetic Mechanisms of Lung Cancer and COPD (+$3.000 million): The objective of this new RFA is to identify the fundamental etiologic, pathologic, and genetic commonalities between lung cancer and chronic obstructive pulmonary disease (COPD) in order to characterize the determinants of individual susceptibility and the shared biochemical and immunological pathways involved in the origin and progression of the two diseases, which have common pathogenesis and etiologic factors expressed differently in the same organ system. This initiative requires dual principal investigators per award: one each from the pulmonary and cancer communities. This RFA is supported by both NHLBI and NCI.

Cross Organ Mechanism-Associated Phenotypes for Genetic Analyses of Heart, Lung, Blood, and Sleep Diseases (MAPGen for HLBS) (+$6.000 million): The objective of this RFA is to define mechanism-associated traits that cross organ systems based upon

evolving knowledge of biological and molecular networks. The initiative will establish a cooperative network of research teams, each of which will propose its own research of discovery or validation of one or more mechanisms common to a heart, lung, blood, or sleep disorder and to other disorders from different organ systems.

Heart Failure Clinical Research Network (+$9.000 million): This program will fund the network of nine regional clinical centers and a data coordinating center for an additional 7 years to conduct multiple collaborative, concurrent clinical protocols to evaluate strategies for advancing the diagnosis and management of acute and chronic heart failure.

Pediatric Heart Network (+$13.000 million): This RFA will support a network of interactive pediatric clinical research centers and a data coordinating center for a third 5-year period to promote the efficient evaluation of new treatment methods and management strategies designed to benefit children with structural congenital heart disease, inflammatory heart disease, heart muscle disease, and arrhythmias.

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

FY 2010 estimate				$3,095,812,000
FY 2011 estimated budget authority				3,187,516,000
Net change				91,704,000
	2010 Current Estimate Base		Change from Base	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2010 pay increase		$67,944,000		$411,000
b. January FY 2011 pay increase		67,944,000		713,000
c. Zero less days of pay (n/a for 2011)		67,944,000		0
d. Payment for centrally furnished services		28,344,000		567,000
e. Increased cost of laboratory supplies, materials, and other expenses		87,255,000		1,453,000
Subtotal				3,144,000
2. Research management and support:				
a. Annualization of January 2010 pay increase		$61,944,000		$375,000
b. January FY 2011 pay increase		61,944,000		650,000
c. Zero less days of pay (n/a for 2011)		61,944,000		0
d. Payment for centrally furnished services		19,036,000		381,000
e. Increased cost of laboratory supplies, materials, and other expenses		34,903,000		576,000
Subtotal				1,982,000
Subtotal, Built-in				5,126,000

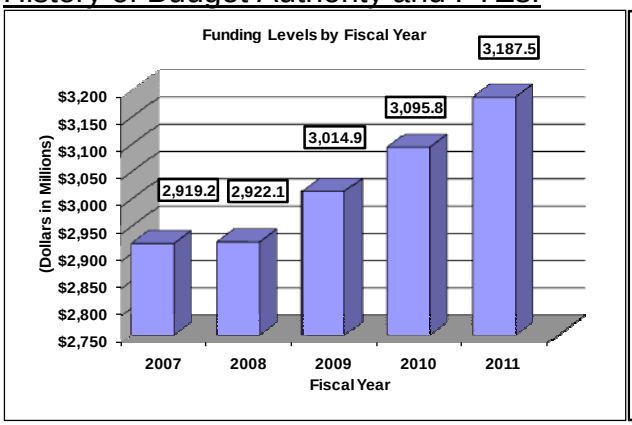
NATIONAL INSTITUTES OF HEALTH
National Heart, Lung, and Blood Institute

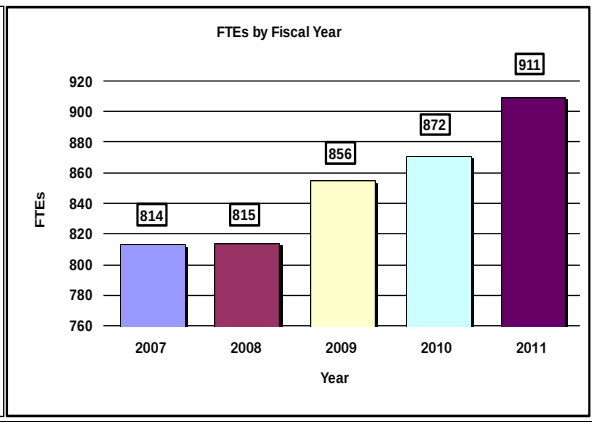
Summary of Changes--continued

CHANGES	2010 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	2,975	$1,561,673,000	(12)	$54,194,000
b. Competing	927	466,663,000	(927)	831,000
c. SBIR/STTR	159	75,000,000	(159)	2,000,000
Total	4,061	2,103,336,000	(1,098)	57,025,000
2. Research centers	49	91,505,000	(49)	1,386,000
3. Other research	708	132,901,000	(708)	6,918,000
4. Research training	1,987	97,144,000	0	5,708,000
5. Research and development contracts	218	371,500,000	(218)	9,000,000
Subtotal, extramural				80,037,000
	FTEs		FTEs	
6. Intramural research	438	183,543,000	17	2,729,000
7. Research management and support	434	115,883,000	22	3,812,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		3,095,812,000		86,578,000
Total changes	872		39	91,704,000

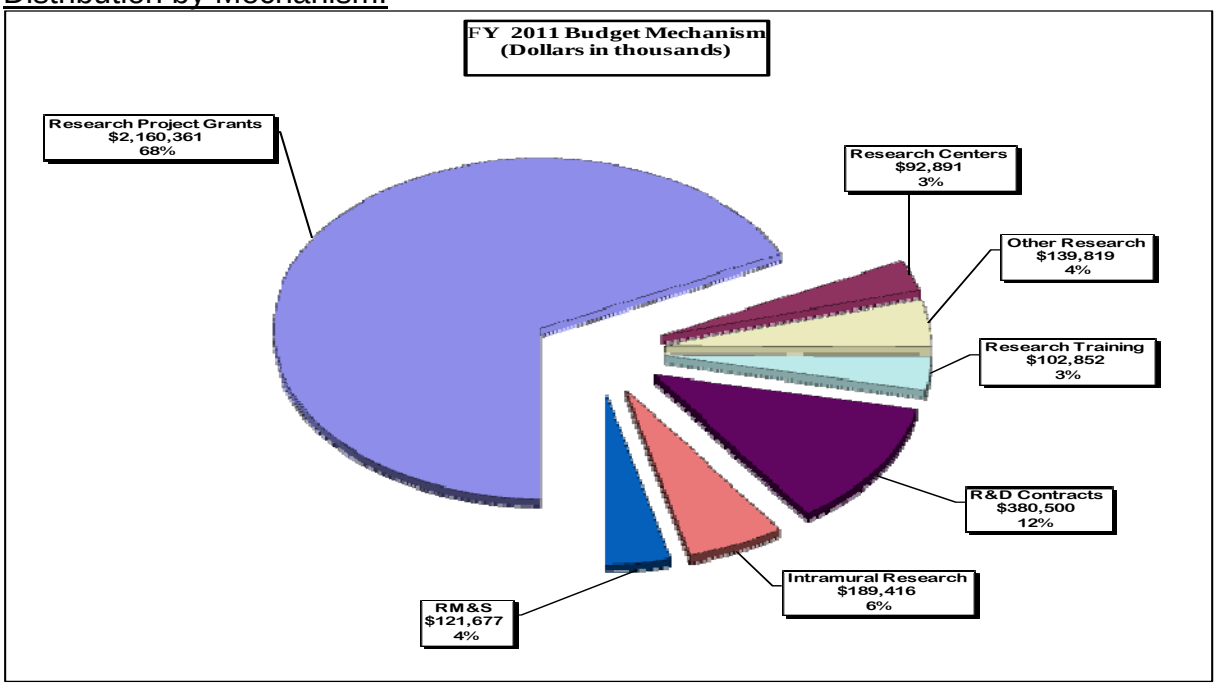
Fiscal Year 2011 Budget Graphs

History of Budget Authority and FTEs:

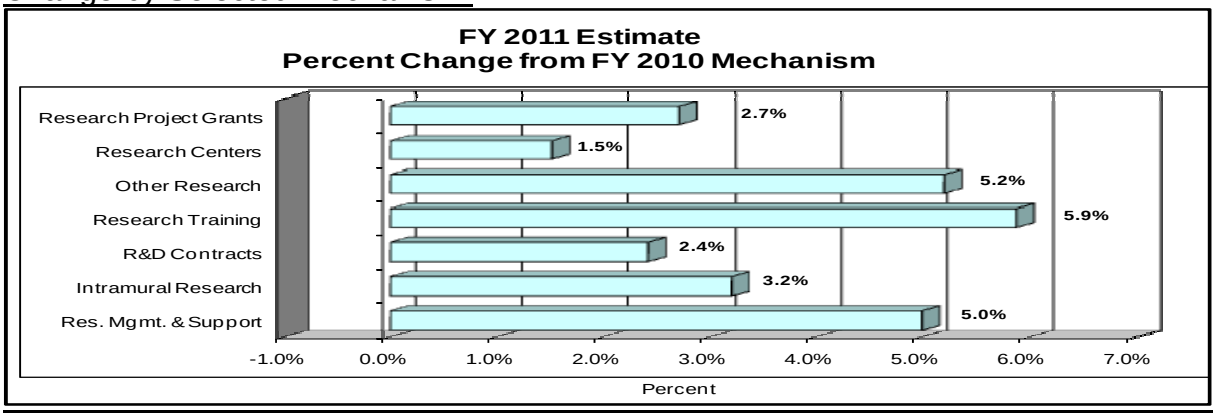




Distribution by Mechanism:



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 2009 Omnibus	FY 2010 Appropriation	FY 2011 President's Budget	FY 2011 +/- 2010 Appropriation
BA	$3,014,873,000	$3,095,812,000	$3,187,516,000	+91,704,000
FTE	856	872	911	39

This document provides justification for the Fiscal Year (FY) 2011 activities of the National Heart, Lung, and Blood Institute (NHLBI), 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 NHLBI provides global leadership for a research and education program to promote prevention and treatment of heart, blood vessel, lung, and blood diseases. Guided by *Shaping the Future of Research: A Strategic Plan*, the NHLBI supports a robust, collaborative research enterprise, in partnership with private and public organizations, to address the scientific and educational needs of the nation. Illustrative activities that align with the NIH Director's Themes are described below.

The Institute is making a substantial investment in use of cutting-edge approaches to assess the importance of genetic influences in heart, lung, and blood diseases. In recent years detailed knowledge about the human genome made it possible to look at markers spaced across all of the chromosomes and identify small regions containing potential or candidate genes associated with disease. Tremendous technological advances in DNA sequencing and computing now allow for vastly greater amounts of sequencing to be performed relatively cheaply. Instead of using markers to identify regions, we can sequence all of the important areas of the genome involved in the production of proteins that are key to the functioning of cells and tissues. By selecting only the more important regions, the relevant information about an individual can be obtained at a much lower cost than would be entailed in sequencing a person's entire genome. The genomic data can then be coupled with the wealth of information in

NHLBI population studies—Framingham and other cohorts designed to capture the ethnic diversity and diseases prevalent in the U.S. population—to determine the genetic basis or causes for heart, lung, and blood diseases. The new knowledge will bring us much closer to a time when personal genomic information can be used to tailor prevention, management, or treatment of a disease to the individual.

Translation of basic science findings into new and better treatments is an area of strong emphasis for NHLBI. For instance, we have launched a novel pediatric cardiovascular translational initiative, the Bench to Bassinet (B2B) program that will create a critical mass of collaborative research across three interacting consortia. The *Cardiovascular Development Consortium* will probe the details of the transcriptional regulatory networks that govern cardiac development, using complementary animal models. The *Pediatric Cardiac Genomics Consortium* will recruit children into a common protocol to speed discovery of causative genes and evaluate the effects of genetic variation on short- and long-term outcomes in patients with congenital heart disease. These two Consortia will align with the third component of B2B, the ongoing Pediatric Heart Network, a multi-center clinical research enterprise funded by NHLBI in 2001. B2B is designed to accelerate the pace of fundamental discovery while simultaneously establishing a new paradigm for conducting translational research.

NHLBI has also developed a range of new programs to foster translation of basic research discoveries to clinical application for the diagnosis and treatment of lung and sleep diseases. The Translational Program Project Grant in Lung Diseases initiative supports interrelated projects designed to become progressively more clinical during the grant period. The Phase II Clinical Trials of Novel Therapies for Lung Diseases will conduct proof-of-concept testing of interventions that have the potential to revolutionize clinical management of a lung disease or sleep disorder. In addition, two ambitious programs for translational research will be launched in 2011. Cross Organ Mechanism-Associated Phenotypes for Genetic Analyses of Heart, Lung, Blood, and Sleep Diseases will help to re-define diseases at the level of pathogenetic mechanisms. Furthermore, it will enable the development of strategies for prevention, diagnosis, and treatment that can account for the individual patient's unique genetic makeup and environmental background. The Centers for Advancing Lung Diagnostics and Therapeutics will support exploratory and validation research in humans that relates to promising diagnostic or therapeutic targets.

The NHLBI supports an extensive portfolio of comparative effectiveness research. For example, two recent clinical trials evaluated strategies to reduce cardiovascular complications in patients with type 2 diabetes. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial found no preventive benefit from aggressive blood sugar control; on the contrary, there was actually an increased risk of death. The Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI2D) determined that medical therapy worked as well as stents or bypass surgery for most diabetic patients who already had heart disease. In the area of global health, NHLBI has joined the UnitedHealth Chronic Disease Initiative in establishing a network of 11 Collaborating Centers of Excellence in low- and middle-income countries to build sustainable

programs for combating chronic cardiovascular and lung diseases. The Centers are located in Argentina, Bangladesh, China, Guatemala, India (2 centers), Kenya, Peru, South Africa, Tunisia and at the U.S.–Mexico Border. Each includes a research institution in a developing country paired with at least one partner academic institution in a developed country, nine of which are in the United States. The program is expected to stimulate research in clinical medicine, epidemiology, health services and outcomes, health policy, translation, and behavioral sciences. Also NHLBI has played a major role with the World Health Organization in continuing to implement the global alliance for respiratory disease program, and the Institute is building global consortia to identify major genes and their function in the etiology of asthma and COPD. In addition, the Institute supports international studies in Asia and South America to prevent the transmission of HIV/AIDS and other known and emerging infectious agents through blood transfusion. Other research on mosquito-borne viruses such as West Nile virus and Dengue virus will guide U.S. and international donor screening policies for these infectious agents and provide unique insights into the factors that influence the acquisition and severity of these diseases.

The Institute continues to place strong emphasis on fostering talent and diversity in the biomedical research community. The Institutional Training Program in Vascular Medicine, for instance is preparing clinicians for academic and scientific leadership roles by providing comprehensive training in research methodology, risk assessment, diagnosis, treatment, and prevention of arterial, venous, and lymphatic vascular diseases. A new scientific training initiative for clinical research conducted in emergency settings is being planned for FY 2010.

Overall Budget Policy: The FY 2011 request for NHLBI is $3,187.516 million, an increase of $91.704 million or +3.0 percent over the FY 2010 enacted level. The NHLBI will continue to support early stage investigators and competing RPGs. In FY 2011, NHLBI will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. The NHLBI is providing a 2 percent inflationary increase for non-competing and competing grants. In addition, the NHLBI is providing increases of 6 percent for research training stipends and approximately 3 percent for other non-RPG extramural mechanisms. The Institute also seeks to maintain a balance between solicitations issued to the extramural community and funding made available to support investigator-initiated projects. Intramural Research and Research Management and Support will receive an increase to help cover the cost of pay and other increases. 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 PROGRAM DETAIL

Program Descriptions and Accomplishments

Heart and Vascular Diseases: This program supports research on the causes, diagnosis, treatment, and prevention of heart and vascular diseases. Research areas include atherothrombosis, coronary artery disease, myocardial infarction and ischemia, heart failure, arrhythmia, sudden cardiac death, adult and pediatric congenital heart disease, cardiovascular complications of diabetes and obesity, and hypertension. The program's efforts encompass basic, translational, clinical, epidemiological, behavioral, nutritional, comparative-effectiveness, international, and health services research disciplines. In fiscal year 2009, the NHLBI funded nine Global Health Centers in Bangladesh, China, Guatemala, India (Bangalore and New Delhi), South Africa, Argentina, Kenya, and Peru. In fiscal year 2010, the Institute will fund a combined renewal of its Proteomic Centers and its Clinical Proteomic Program. The ultimate goal is to bring greater precision, reliability, and sensitivity to detection, diagnosis, treatment, and prevention strategies for the individual patient. The initiative will integrate expertise from the disciplines of proteomics, physiology, clinical medicine, molecular biology, genomics, chemistry, physics, engineering, computational biology, bioinformatics, and biostatistics. Each of seven centers will focus on proteomic technology development and molecular mechanistic and functional studies related to a specific clinical need, problem, or disease.

Budget Policy: The FY 2011 budget estimate for the Heart and Vascular Diseases program is $1,755.367 million, an increase of $48.843 million or 2.86% over the FY 2010 estimate. During FY 2011 NHLBI plans to continue two major initiatives. The first will evaluate strategies for advancing the diagnosis and management of acute and chronic heart failure. The second will evaluate new treatment methods and management strategies designed to benefit children with structural congenital heart disease, inflammatory heart disease, heart muscle disease, and arrhythmias. NHLBI also plans to support an initiative that will develop multidisciplinary clinical research training programs to prepare clinician-scientists for academic leadership roles and independent research careers in emergency-setting diagnosis and treatment of patients who have sustained severe trauma or have acute manifestations of cardiovascular, pulmonary, or hematologic diseases.

Portrait of a Program: Atherosclerosis Risk in Communities (ARIC)

FY2010 Level: $7.390 million
FY2011 Level: $6.020 million

Change: $-1.370 million

The ARIC study began in 1985 with two components—a community-wide surveillance and a prospective cohort. The community surveillance has been following trends in hospitalized myocardial infarction, fatal coronary heart disease (CHD), and heart failure, according to race and gender, in four U.S. communities. Its findings have enabled the NHLBI to monitor the outcomes of efforts to reduce the burden of heart disease in the population. The cohort component has been investigating the etiology of CHD in 15,792 white or African American adults from the same four communities who were 45-64 years of age when they enrolled in the study. The participants received four examinations over 9 years (1987-89, 1990-92, 1993-95, and 1996-98), providing a rich set of data on physical, behavioral, genetic, and psychosocial factors. The study has produced many unique contributions to understanding the etiology of atherosclerosis and clinical cardiovascular disease that have been used to develop evidence-based clinical practice guidelines for CHD, diabetes, stroke, and chronic kidney disease. Beginning in 2011, ARIC will re-examine approximately 9,100 participants with a focus on heart failure, a major epidemic in our rapidly aging population. This work will provide critical insights about the development, progression, and treatment of heart failure and other cardiovascular diseases in aging adults.

Lung Diseases: This program supports research on the causes, diagnosis, treatment, and prevention of lung diseases and sleep disorders. 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 within the Lung Diseases program.

In fiscal year 2009, the NHLBI initiated a study to identify subtypes of COPD based on disease mechanism and identify and validate intermediate outcome measures; translational research to improve prevention, diagnosis, and treatment of lung diseases and sleep disorders; support for proof-of-concept phase II clinical trials of novel interventions for lung diseases or sleep-associated cardiopulmonary disorders; and a new asthma clinical research network. In FY 2010, the NHLBI will initiate programs to develop early molecular markers of chronic respiratory disease risk in premature newborns; to identify the biological and structural components that create airflow limitation in congenital or acquired disorders of the upper airway of infants, children, and adolescents; and to evaluate how treatment of sleep apnea modifies the appearance and progression of cardiovascular disease in high-risk individuals.

Budget Policy: The FY 2011 budget estimate for the Lung Diseases program is $664.275 million an increase of $18.484 million or 2.86% over the FY 2010 estimate. The program plans for FY 2011 include support for an initiative to identify potential biomarkers, surrogate markers, and drug targets, in concert with early disease detection, population stratification, and prognostic indicators, and to validate in humans their effects on target pathways that may be shared by multiple lung diseases. Another

new initiative will seek to identify the fundamental etiologic, pathologic, and genetic commonalities between lung cancer and chronic obstructive pulmonary disease in order to characterize the determinants of individual susceptibility and the shared biochemical and immunological pathways involved in the origin and progression of the two diseases.

Portrait of a Program: Pediatric Lung Disease

FY2010 Level: $83.466 million
FY2011 Level: $83.466 million

Change: 0

The NHLBI Pediatric Lung Disease program seeks to understand, prevent, and treat diseases of newborns and children and to explore the pediatric origins of adult lung disorders that may begin in utero. Efforts in lung development include identifying specific molecules and processes responsible for healthy lung growth and function, differences that may signal abnormal development, and changes in response to harmful inhaled substances. Also supported are studies on how the lung repairs itself after injury. Knowledge of these processes and deviations early in life will help us understand the development of lung diseases in children and adults such as asthma, bronchopulmonary dysplasia, cystic fibrosis, pulmonary hypertension, and apnea. Research is under way to elucidate fundamental mechanisms of lung surfactant regulation and lung stability. Investigations of gene–gene and gene–environment interactions regulating lung surfactant functions and endogenous nitric oxide are providing a solid foundation for understanding the genes associated with increased susceptibility to respiratory distress syndrome and bronchopulmonary dysplasia. This work holds promise for advancing new strategies to reduce morbidity and mortality in premature infants. The ongoing Developmental Origins of Altered Lung Physiology and Immune Function initiative is stimulating the discovery of key molecules and the investigation of potential therapeutic targets. Understanding the genetic components of lung development in both health and disease will be critical to development of targeted therapeutics for infants and children at risk of lung disease. Applied studies to develop innovative methods of diagnosing causes of early childhood respiratory difficulties and predicting which infants will be at risk for future illness include the Prematurity and Respiratory Outcomes Program (PROP) and Functional Modeling of the Pediatric Upper Airway. Investigator-initiated studies of promising therapies for the prevention of early childhood breathing problems include the Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in Extremely Low Birth Weight Infants, Maternal Vitamin D to Prevent Asthma, the Childhood Adenotonsillectomy Trial (CHAT), the Infant Study of Inhaled Saline (ISIS) for young children with cystic fibrosis, and the Trial Of Late SURFactant (TOLSURF) to prevent bronchopulmonary dysplasia in premature newborns. In addition, the NHLBI plans to support the development of new pulmonary devices designed specifically for use in newborns who require intensive care. A new project will determine the efficacy of antenatal late-preterm steroid treatment to prevent respiratory distress in newborn infants. Emerging areas of basic research include identifying and characterizing lung progenitor and stem cells and investigating their roles in regulating lung development, regeneration, and repair.

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. Another program responsibility is to support research and research training on the use , safety, efficacy, and availability of blood and blood components for transfusion and cellular therapeutics. In fiscal year 2009, the NHLBI initiated research to identify the molecular and cellular changes that occur during red blood cell unit preparation and storage and their effects on transfusion recipients.

The Institute also supported a program to increase understanding of the pathogenesis of pain syndromes in sickle cell disease. In FY 2010 the NHLBI will begin an initiative to develop clinical research capacity in hemoglobinopathies. The NHLBI will also renew funding for the Production Assistance for Cellular Therapies (PACT) program to support up to six geographically dispersed U.S. facilities with the capacity to provide consulting, manufacturing, and regulatory expertise essential for the development of clinical-grade cellular products for evaluation as therapies for heart, lung, and blood disorders.

Budget Policy: The FY 2011 budget estimate for the Blood Diseases and Resources program is $456.781 million, an increase of $12.710 million or 2.86% over the FY 2010 estimate. The program plans for FY 2011 include support to accelerate research on the management of hematopoietic stem cell transplantation, standardize and compare the effectiveness and toxicities of existing treatments, and evaluate new therapies. Another initiative will seek to translate emerging discoveries in glycosciences (the study of complex carbohydrates and their roles in metabolism) into new diagnostics and clinical applications as well as to build research capacity by training 30-35 postdoctoral trainees over seven years.

Portrait of a Program: Transcranial Doppler With Transfusions Changing to Hydroxyurea (TWiTCH)

FY 2010 Level: $ 4.962 million
FY 2011 Level: $ 4.480 million
Change: $-.482 million

Sickle cell disease (SCD) is the most common cause of stroke in children and may lead to devastating short-and long-term neurologic sequelae. In the 1990s the NHLBI funded a series of landmark clinical trials demonstrating that a group of children at particularly high risk for stroke could be identified and treated successfully, resulting in a much lower stroke risk. The at-risk children were identified through use of transcranial Doppler (TCD), a non-invasive test that allows the detection of high-velocity blood flow in the large arteries of the brain. When red blood cell transfusions were given on a regular basis to such high-risk children, their risk of a subsequent stroke was greatly diminished. As a result of these studies, currently many children and adolescents with SCD receive chronic red cell transfusion therapy for stroke prevention. While effective in stroke prevention, this therapy results in the accumulation of harmful amounts of iron in the body, which may lead to life-threatening liver and cardiac disease. It would be very useful if an alternative therapy, such as an oral medication, were available that conferred the same degree of protection against stroke as transfusion therapy but had a lower risk of side effects and greater convenience.

The TWiTCH study is a Phase III clinical trial in which such high-risk children who are already on chronic transfusion regimen are randomly assigned to receive either hydroxyurea (an oral drug with proven effectiveness in SCD) or continued transfusion therapy. The study will demonstrate whether children who receive hydroxyurea have a reduction in the velocity of their blood flow in the large arteries of the brain, as measured by TCD. If hydroxyurea were proven to have an equivalent effect to transfusions, many children with SCD would be able to avoid receiving blood transfusions on a monthly basis for life, as is currently the case.

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), three branches (Hematology, Pulmonary and Vascular Medicine, and Translational Medicine), and the Cardiothoracic Surgery Research Program. In fiscal year 2009, Intramural Research program contributed to establishing the Center for Human Immunology as a trans-NIH initiative administratively within the NHLBI. The program continued its support for the Imaging Probe Development Center, another trans-NIH initiative, which brings together synthetic chemists to make imaging probes available for both basic and clinical studies. In fiscal year 2010 the tenure-track search system will be expanded to include the entire NIH with the initiation of the Earl Stadtman Investigator program. A new Clinical Pulmonary Research Program will be started in collaboration with regional hospitals to improve the impact of the Intramural clinical program in the surrounding community and also seek specific opportunities for working on innovative research and therapeutic approaches for clinical pulmonary conditions in the Clinical Center. A program on Pediatric Imaging using MRI will be initiated at the Children's National Medical Center with the goals of minimizing ionizing radiation exposure, applying real-time MRI approaches to simple diagnostic procedures that avoid general anesthetics, and providing visual guides for minimally invasive surgery in pediatric cases.

Budget Policy: The FY 2011 budget estimate for the Intramural Research program is $189.416 million, an increase of $5.873 million or 3.2% from the FY 2010 estimate. Increases for salaries and related costs are covered in the budget request. A new Intramural-based computational biology program will support systems medicine and biology. It will require a state-of-the-art computational facility and recruitment of investigators with specialized expertise in computer and simulation sciences as well as biomedicine. Specific plans for 2011 are to double the computational capacity and the number of junior faculty associated with this program. The Intramural Research Program will also begin planning for a new clinical cardiology research program.

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 2009, the Division of Extramural Research Activities administered the review, processing, award, and scientific performance appraisal of approximately 5,500 research grants, 750 training awards, and 600 contracts. The Division for the Application of Research Discoveries (DARD) continued its public and professional education activities in cardiovascular diseases and asthma and developed an initiative to increase the implementation of asthma evidence-based guidelines recommendations. The DARD also secured new partners such as SUBWAY Restaurants and the Cherokee Nation to continue the ***We Can!*** education program to address the growing overweight and obesity problem in children ages 8 through 13 years. In all, more than 1,100 community sites and 40 partners have committed to implementing ***We Can!*** In fiscal year 2010, the

DARD will complete the development of the pediatric integrated cardiovascular disease (CVD) guidelines and initiate relevant implementation activities, as well as complete sickle cell disease guidelines. Work will continue on the initiatives started in FY 2009 in the areas of asthma, health disparities, and obesity.

Budget Policy: The FY 2011 budget estimate for Research Management and Support is $121.677 million, an increase of $5.794 million or 5.0% over the FY 2010 estimate. Increases for salaries and related costs are covered in the budget request.

Recovery Act Implementation
Recovery Act Funding: $763.000 million

In FY 2009, the National Heart, Lung, and Blood Institute (NHLBI) received $763.0 million under the Recovery Act. Of this amount, $413.8 million was obligated in FY 2009 and $348.8 million will be obligated in FY 2010. These funds support rigorously peer-reviewed research on the prevention and treatment of heart, lung, and blood diseases and are based on the NHLBI's scientific priorities: DNA sequencing, stem cells and regenerative medicine, and translational research. Signature initiatives include the landmark $64 million NHLBI Large-Scale DNA Sequencing Project, which will mine genetic data gathered from decades of NHLBI-funded population studies; studies of stem and progenitor cells; and the translation of basic research findings into clinical treatments.

The NHLBI's Recovery Act grants are preserving and creating jobs across the nation, not only for established principal investigators but also for early-career researchers, summer interns, science teachers, and technical staff. One $2.6 million Grand Opportunity award to the American College of Cardiology supports 35 researchers from five organizations, including several new hires, as they conduct a comparative effectiveness study of coronary artery bypass surgery and angioplasty. Many grants support minorities and stimulate historically underserved areas. American industry is indirectly supported as labs are able to purchase new scientific equipment.

Several NHLBI Recovery Act grants have allowed promising studies to continue operating. A $566,000 grant rescued Vanderbilt University researchers whose 11 years of work, including the development and testing of an innovative cardiac imaging system, would have been left incomplete. A growing collection of stories is featured on an NHLBI Web site developed to show how Recovery Act funds are stimulating the economy and advancing science and public health.

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National Heart, Lung, and Blood Institute

Budget Authority by Object

	FY 2010 Enacted	FY 2011 PB	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	872	911	39	4.5
Full-time equivalent of overtime and holiday hours	2	2	0	0.0
Average ES salary	$172,200	$174,611	$2,411	1.4
Average GM/GS grade	12.4	12.4	0.0	0.0
Average GM/GS salary	$102,558	$103,994	$1,436	1.4
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$92,312	$93,604	$1,292	1.4
Average salary of ungraded positions	$123,162	124,886	1,724	1.4

OBJECT CLASSES	FY 2010 Estimate	FY 2011 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	$60,573,000	$65,021,000	$4,448,000	7.3
11.3 Other than full-time permanent	31,159,000	33,630,000	2,471,000	7.9
11.5 Other personnel compensation	3,809,000	4,091,000	282,000	7.4
11.7 Military personnel	919,000	990,000	71,000	7.7
11.8 Special personnel services payments	8,106,000	8,769,000	663,000	8.2
Total, Personnel Compensation	104,566,000	112,501,000	7,935,000	7.6
12.0 Personnel benefits	24,785,000	26,666,000	1,881,000	7.6
12.2 Military personnel benefits	537,000	580,000	43,000	8.0
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	**129,888,000**	**139,747,000**	**9,859,000**	**7.6**
21.0 Travel and transportation of persons	3,123,000	3,134,000	11,000	0.4
22.0 Transportation of things	199,000	201,000	2,000	1.0
23.1 Rental payments to GSA	0	0	0	0.0
23.2 Rental payments to others	85,000	84,000	(1,000)	-1.2
23.3 Communications, utilities and miscellaneous charges	2,093,000	2,119,000	26,000	1.2
24.0 Printing and reproduction	386,000	398,000	12,000	3.1
25.1 Consulting services	1,160,000	1,188,000	28,000	2.4
25.2 Other services	40,981,000	42,014,000	1,033,000	2.5
25.3 Purchase of goods and services from government accounts	207,510,000	213,598,000	6,088,000	2.9
25.4 Operation and maintenance of facilities	4,114,000	4,103,000	(11,000)	-0.3
25.5 Research and development contracts	248,304,000	256,962,000	8,658,000	3.5
25.6 Medical care	1,741,000	1,728,000	(13,000)	-0.7
25.7 Operation and maintenance of equipment	5,845,000	5,904,000	59,000	1.0
25.8 Subsistence and support of persons	2,000	2,000	0	0.0
25.0 Subtotal, Other Contractual Services	**509,657,000**	**525,499,000**	**15,842,000**	**3.1**
26.0 Supplies and materials	15,222,000	15,120,000	(102,000)	-0.7
31.0 Equipment	10,269,000	10,287,000	18,000	0.2
32.0 Land and structures	0	0	0	0.0
33.0 Investments and loans	0	0	0	0.0
41.0 Grants, subsidies and contributions	2,424,886,000	2,490,923,000	66,037,000	2.7
42.0 Insurance claims and indemnities	0	0	0	0.0
43.0 Interest and dividends	4,000	4,000	0	0.0
44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	**2,965,924,000**	**3,047,769,000**	**81,845,000**	**2.8**
Total Budget Authority by Object	**3,095,812,000**	**3,187,516,000**	**91,704,000**	**3.0**

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

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Salaries and Expenses

OBJECT CLASSES	FY 2010 Enacted	FY 2011 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	$60,573,000	$65,021,000	$4,448,000
Other than full-time permanent (11.3)	31,159,000	33,630,000	2,471,000
Other personnel compensation (11.5)	3,809,000	4,091,000	282,000
Military personnel (11.7)	919,000	990,000	71,000
Special personnel services payments (11.8)	8,106,000	8,769,000	663,000
Total Personnel Compensation (11.9)	**104,566,000**	**112,501,000**	**7,935,000**
Civilian personnel benefits (12.1)	24,785,000	26,666,000	1,881,000
Military personnel benefits (12.2)	537,000	580,000	43,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	**129,888,000**	**139,747,000**	**9,859,000**
Travel (21.0)	3,123,000	3,134,000	11,000
Transportation of things (22.0)	199,000	201,000	2,000
Rental payments to others (23.2)	85,000	84,000	(1,000)
Communications, utilities and miscellaneous charges (23.3)	2,093,000	2,119,000	26,000
Printing and reproduction (24.0)	386,000	398,000	12,000
Other Contractual Services:			
Advisory and assistance services (25.1)	1,160,000	1,188,000	28,000
Other services (25.2)	40,981,000	42,014,000	1,033,000
Purchases from government accounts (25.3)	113,567,000	115,416,000	1,849,000
Operation and maintenance of facilities (25.4)	4,114,000	4,103,000	(11,000)
Operation and maintenance of equipment (25.7)	5,845,000	5,904,000	59,000
Subsistence and support of persons (25.8)	2,000	2,000	0
Subtotal Other Contractual Services	**165,669,000**	**168,627,000**	**2,958,000**
Supplies and materials (26.0)	15,077,000	14,976,000	(101,000)
Subtotal, Non-Pay Costs	186,632,000	189,539,000	2,907,000
Total, Administrative Costs	**316,520,000**	**329,286,000**	**12,766,000**

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National Heart, Lung, and Blood Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2010 Amount Authorized	FY 2010 Estimate	2011 Amount Authorized	FY 2011 PB
Research and Investigation	Section 301	42§241	Indefinite	$3,095,812,000	Indefinite	$3,187,516,000
	Section 402(a)	42§281	Indefinite		Indefinite	
National Heart, Lung, and Blood Institute						
Total, Budget Authority				3,095,812,000		3,187,516,000

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

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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
Rescission				0
2008	2,894,341,000	2,965,775,000	2,992,197,000	2,974,900,000
Rescission				(51,972,000)
Supplemental				15,542,000
2009	2,924,942,000	3,025,500,000	3,006,344,000	3,015,689,000
Rescission				0
2010	3,050,356,000	3,123,403,000	3,066,827,000	3,096,916,000
Rescission				0
2011	3,187,516,000			

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 2009 Actual	FY 2010 Enacted	FY 2011 PB
Office of the Director	103	147	125
Division of Blood Diseases and Resources	21	24	25
Division of Lung Diseases	26	21	27
Division for the Application of Research Discoveries	25	28	27
Division of Intramural Research	442	422	455
Division of Cardiovascular Sciences	121	111	128
Division of Extramural Research Activities	118	119	124
Total	856	872	911
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)

FISCAL YEAR	Average GM/GS Grade
2007	12.1
2008	12.2
2009	12.4
2010	12.4
2011	12.4

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Detail of Positions

GRADE	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Total, ES Positions	0	1	1
Total, ES Salary	0	172,200	174,611
GM/GS-15	98	111	105
GM/GS-14	124	124	131
GM/GS-13	166	155	170
GS-12	85	100	95
GS-11	54	44	54
GS-10	1	2	2
GS-9	50	50	55
GS-8	28	31	31
GS-7	11	12	12
GS-6	2	5	5
GS-5	2	3	3
GS-4	3	3	3
GS-3	1	2	2
GS-2	0	0	0
GS-1	0	0	0
Subtotal	625	642	668
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	5	5	5
Senior Grade	1	2	2
Full Grade	1	1	1
Senior Assistant Grade	1	0	0
Assistant Grade	0	0	0
Subtotal	9	9	9
Ungraded	262	258	279
Total permanent positions	633	652	676
Total positions, end of year	896	910	957
Total full-time equivalent (FTE) employment, end of year	856	872	911
Average ES salary	0	172,200	174,611
Average GM/GS grade	12.4	12.4	12.4
Average GM/GS salary	100,942	102,558	103,994

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

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New Positions Requested

	FY 2011		
	Grade	Number	Annual Salary
Staff Scientist	AD/401/0	6	$112,908
Investigator	AD/401/0	4	120,144
Medical Officer	GS-14	8	120,907
Health Science Administrator	GS-13	10	102,317
Program Analyst	GS-9	2	59,330
Biologist	GS-9	5	59,330
Grants Management Specialist	GS-9	2	59,330
Research Fellow	AD/401/0	2	59,330
Total Requested		39	