

DEPARTMENT OF HEALTH AND HUMAN SERVICES

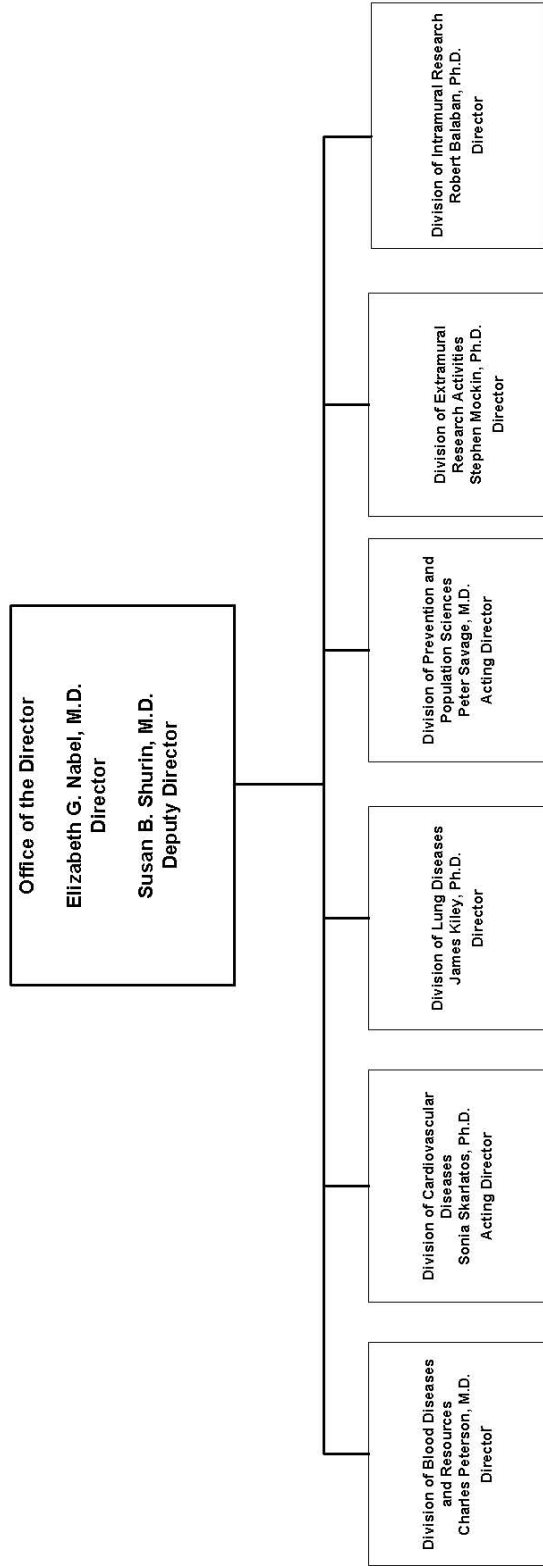
NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

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# NATIONAL INSTITUTE OF HEALTH

## National Heart, Lung, and Blood Institute



**FY 2008 Proposed Appropriation Language**

**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, \$2,925,413,000.*

**Supplemental Exhibit**

**Comparison of Proposed FY 2008 Appropriation Language to  
Most Recently Enacted Full-Year Appropriations**

**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 [~~\$2,951,270,000~~] **\$2,925,413,000.**

(Department of Health and Human Services Appropriation Act, 2006)

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

**Amounts Available for Obligation 1/**

Source of Funding	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Appropriation	\$2,951,270,000	\$2,921,757,000	\$2,925,413,000
Enacted Rescissions	-29,513,000	0	0
Subtotal, Adjusted Appropriation	2,921,757,000	2,921,757,000	2,925,413,000
Real Transfer under Roadmap Authority	-26,109,000		
Real Transfer under Secretary's One-percent transfer authority	-2,007,000		
Comparative transfer from OD for NIH Roadmap	26,109,000		
Comparative Transfer to NIBIB	-80,000	-82,000	
Comparative transfer to OD	-36,000	-37,000	
Comparative Transfer to NCRR	-3,708,000	-2,827,000	
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	-3,000	
Subtotal, adjusted budget authority	2,915,923,000	2,918,808,000	2,925,413,000
Unobligated Balance, start of year	0	0	0
Unobligated Balance, end of year	0	0	0
Subtotal, adjusted budget authority	2,915,923,000	2,918,808,000	2,925,413,000
Unobligated balance lapsing	-114,000	0	0
Total obligations	2,915,809,000	2,918,808,000	2,925,413,000

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

FY 2006 - \$10,675,000 FY 2007 - \$20,000,000 FY 2008 - \$20,000,000

Excludes \$1,400,000 in FY 2007 and \$1,400,000 in FY 2008 for royalties.

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

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2006		FY 2007		FY 2008		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<b>Research Grants:</b>								
<u>Research Projects:</u>								
Noncompeting	3,029	\$1,512,273	2,869	\$1,445,189	2,782	\$1,400,681	-87	-\$44,508
Administrative supplements	(125)	14,720	(81)	7,750	(87)	9,900	(6)	2,150
<u>Competing:</u>								
Renewal	316	168,264	331	178,000	364	195,900	33	17,900
New	553	242,913	587	256,148	645	281,306	58	25,158
Supplements	2	419	2	500	3	600	1	100
Subtotal, competing	871	411,596	920	434,648	1,012	477,806	92	43,158
Subtotal, RPGs	3,900	1,938,589	3,789	1,887,587	3,794	1,888,387	5	800
<b>SBIR/STTR</b>	181	72,460	178	71,000	175	70,500	-3	-500
Subtotal, RPGs	4,081	2,011,049	3,967	1,958,587	3,969	1,958,887	2	300
<u>Research Centers:</u>								
Specialized/comprehensive	57	140,401	54	141,400	48	140,500	-6	-900
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	1	765	0	293	0	0	0	-293
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	58	141,166	54	141,693	48	140,500	-6	-1,193
<u>Other Research:</u>								
Research careers	512	66,657	560	74,611	582	76,591	22	1,980
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	47	33,684	46	36,665	42	36,500	-4	-165
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	1	2,403	0	2,475	0	2,500	0	25
Other	82	17,350	67	19,520	65	19,500	-2	-20
Subtotal, Other Research	642	120,094	673	133,271	689	135,091	16	1,820
<b>Total Research Grants</b>	<b>4,781</b>	<b>2,272,309</b>	<b>4,694</b>	<b>2,233,551</b>	<b>4,706</b>	<b>2,234,478</b>	<b>12</b>	<b>927</b>
<u>Research Training:</u>								
Individual awards	205	10,045	215	10,545	215	10,545	0	0
Institutional awards	1,742	79,134	1,757	79,771	1,757	79,771	0	0
<b>Total, Training</b>	<b>1,947</b>	<b>89,179</b>	<b>1,972</b>	<b>90,316</b>	<b>1,972</b>	<b>90,316</b>	<b>0</b>	<b>0</b>
Research & development contracts (SBIR/STTR)	181 (1)	262,851 (477)	205 (3)	291,308 (750)	210 (3)	293,600 (750)	5 (0)	2,292 (0)
Intramural research	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
	401	168,283	401	168,954	405	167,855	4	-1,099
Research management and support	394	97,192	399	99,660	406	100,700	7	1,040
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
NIH Roadmap for Medical Research	2	26,109	6	35,019	6	38,464	0	3,445
<b>Total, NHLBI</b>	<b>797</b>	<b>2,915,923</b>	<b>806</b>	<b>2,918,808</b>	<b>817</b>	<b>2,925,413</b>	<b>11</b>	<b>6,605</b>

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

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

	FY 2004		FY 2005		FY 2006		FY 2006		FY 2007		FY 2008		Change	
	Actual	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<b>Extramural Research</b>														
Detail:														
Heart and Vascular Diseases	1,604,705			1,597,762		1,618,452		1,583,001		1,586,966		1,587,367		401
Lung Diseases	595,988			628,020		595,656		606,400		604,787		606,492		1,705
Blood Diseases and Resources	429,219			439,489		413,939		434,938		423,422		424,535		1,113
<b>Subtotal, Extramural</b>	<b>2,629,912</b>			<b>2,665,271</b>		<b>2,628,047</b>		<b>2,624,339</b>		<b>2,615,175</b>		<b>2,618,394</b>		<b>3,219</b>
<b>Intramural research</b>	<b>426</b>	<b>164,260</b>	<b>404</b>	<b>168,274</b>	<b>401</b>	<b>168,363</b>	<b>401</b>	<b>168,283</b>	<b>401</b>	<b>168,954</b>	<b>405</b>	<b>167,855</b>	<b>4</b>	<b>-1,099</b>
<b>Res. management &amp; support</b>	<b>434</b>	<b>88,543</b>	<b>391</b>	<b>89,062</b>	<b>394</b>	<b>97,231</b>	<b>394</b>	<b>97,192</b>	<b>399</b>	<b>99,660</b>	<b>406</b>	<b>100,700</b>	<b>7</b>	<b>1,040</b>
<b>NIH Roadmap for Medical Research</b>	<b>1</b>	<b>9,887</b>	<b>1</b>	<b>18,594</b>	<b>2</b>	<b>26,109</b>	<b>2</b>	<b>26,109</b>	<b>6</b>	<b>35,019</b>	<b>6</b>	<b>38,464</b>	<b>0</b>	<b>3,445</b>
<b>TOTAL</b>	<b>861</b>	<b>2,892,602</b>	<b>796</b>	<b>2,941,201</b>	<b>797</b>	<b>2,919,750</b>	<b>797</b>	<b>2,915,923</b>	<b>806</b>	<b>2,918,808</b>	<b>817</b>	<b>2,925,413</b>	<b>11</b>	<b>6,605</b>

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

## **Major Changes in the Fiscal Year 2008 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 2008 budget request for NHLBI which is +\$6.605 million more than the FY 2007 Continuing Resolution, for a total of \$2,925.413 million.

Research Project Grants (+\$.3 million, total \$1,958.887 million). NHLBI will support a total of 3,969 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPGs will decrease by 87 awards and decrease by \$44.508 million. Competing RPGs will increase by 92 awards and increase by \$43.158 million.

Research Centers (-\$1.193 million; total \$140.500 million): NHLBI will begin implementation of its new strategic plan resulting in a more targeted and focused Centers program in FY 2008.

Research Careers (+\$1.980 million; total \$76.591 million). NHLBI will support the Pathway to Independence program by funding an additional 22 awards in FY 2008. Total support for the Pathway program in FY 2008 is 45 awards and \$4.0 million.

Research and Development contracts (+2.292 million; total \$293.600 million): NHLBI will support additional Program Evaluation requirements in FY 2008.

NIH Roadmap for Biomedical Research (+\$3.445 million; total \$38.464 million): NHLBI will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

Ancillary Studies in Clinical Trials (+4.200 million; total \$7.000 million): NHLBI will use the patient cohorts, data, and biological materials of ongoing Phase II and Phase III clinical trials associated with heart, lung, blood, and sleep disorders to carry out ancillary studies related to disease mechanisms, genetics, proteomics, therapeutic response, quality of life, behavioral lifestyle issues, treatment adherence, and/or health economic questions. This is a renewal of an RFA conducted in 2001 and 2002 that funded 28 applications, of which 9 were from new investigators. FY 2008 will be the second of three years where NHLBI anticipates funding between three and twelve four-year awards per year.

Cardiothoracic Surgical Investigations in Cardiovascular Medicine (+\$2.000 million; total \$7.000 million): NHLBI will evaluate new surgical techniques, technologies, devices, and bioengineered products related to cardiovascular medicine through rigorous Phase I and II clinical trials. A cardiothoracic surgical network would help overcome some of the challenges of clinical research by providing standard measures or methods for investigations and outcomes, coordinating multidisciplinary teams, and providing resources for collection and interpretation of data. The network would be designed to allow research teams led by cardiac surgeons to evaluate, in small randomized trials, newer therapies and techniques as they move from laboratory science or small case series, and might inform the development of larger Phase III clinical trials through separate funding. NHLBI anticipates funding 7 awards starting in FY 2007.

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

FY 2007 Continuing Resolution		\$2,918,808,000		
FY 2008 Estimated Budget Authority		2,925,413,000		
Net change		6,605,000		
CHANGES	FY 2007		Change from Base	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2007 pay increase				
		\$59,214,000		\$591,000
		59,214,000		2,011,000
		59,214,000		455,000
		28,017,000		280,000
		81,805,000		1,864,000
Subtotal				5,201,000
2. Research Management and Support:				
a. Annualization of January 2007 pay increase				
		\$50,441,000		\$533,000
		50,441,000		1,682,000
		50,441,000		388,000
		15,537,000		155,000
		33,722,000		623,000
Subtotal				3,381,000
Subtotal, Built-in				8,582,000



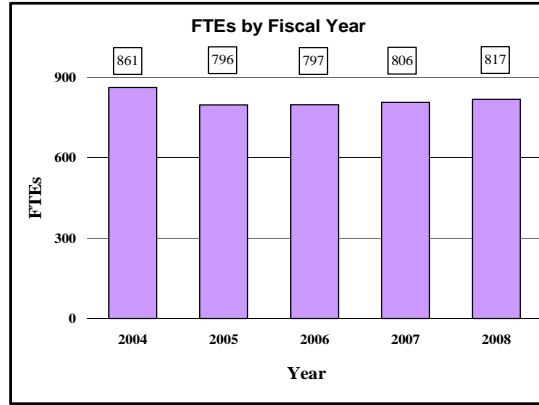
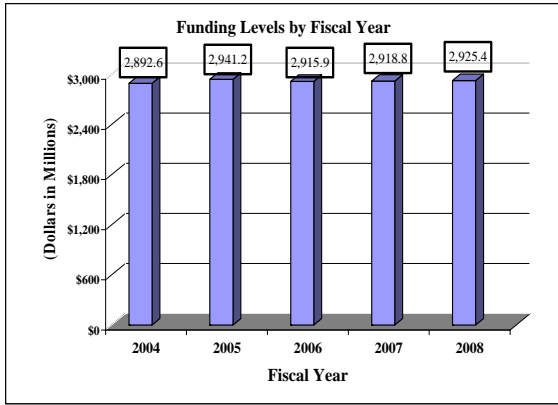
**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Summary of Changes--continued**

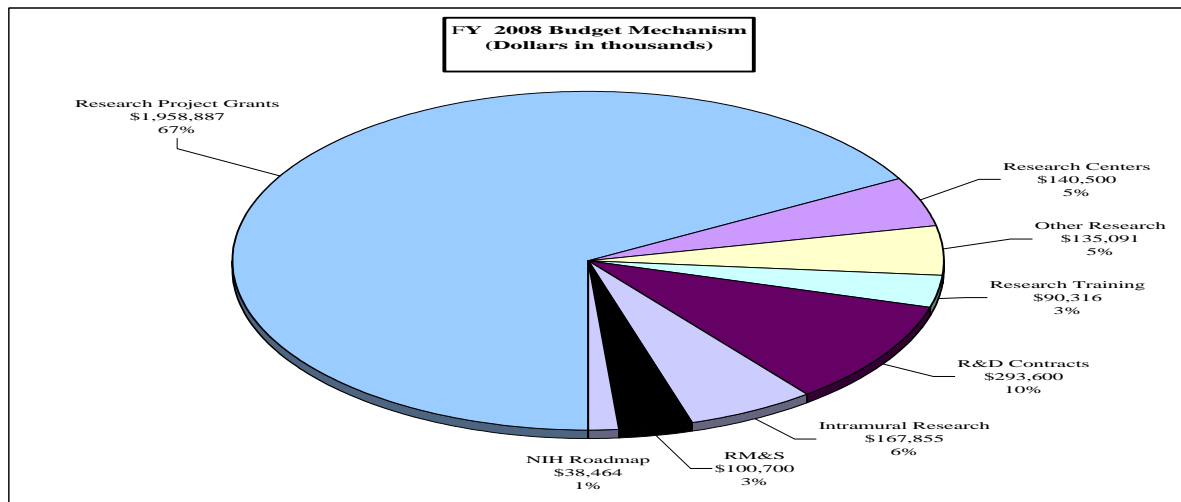
CHANGES	2007			
	Cont. Resol.		Change from Base	
	No.	Amount	No.	Amount
<b>B. Program:</b>				
1. Research project grants:				
a. Noncompeting	2,869	\$1,452,939,000	-87	-42,358,000
b. Competing	920	434,648,000	92	43,158,000
c. SBIR/STTR	178	71,000,000	-3	-500,000
<b>Total</b>	<b>3,967</b>	<b>1,958,587,000</b>	<b>2</b>	<b>300,000</b>
2. Research centers	54	141,693,000	-6	-1,193,000
3. Other research	673	133,271,000	16	1,820,000
4. Research training	1,972	90,316,000	0	0
5. Research and development contracts	205	291,308,000	5	2,292,000
Subtotal, extramural				3,219,000
6. Intramural research	<u>FTEs</u> 401	168,954,000	<u>FTEs</u> 4	-6,300,000
7. Research management and support	399	99,660,000	7	-2,341,000
8. Cancer control and prevention	0	0	0	0
9. Construction		0		0
10. Buildings and Facilities		0		0
11. NIH Roadmap for Medical Research	0	35,019,000	0	3,445,000
Subtotal, program		2,918,808,000		-1,977,000
<b>Total changes</b>	<b>800</b>		<b>11</b>	<b>6,605,000</b>

## Fiscal Year 2008 Budget Graphs

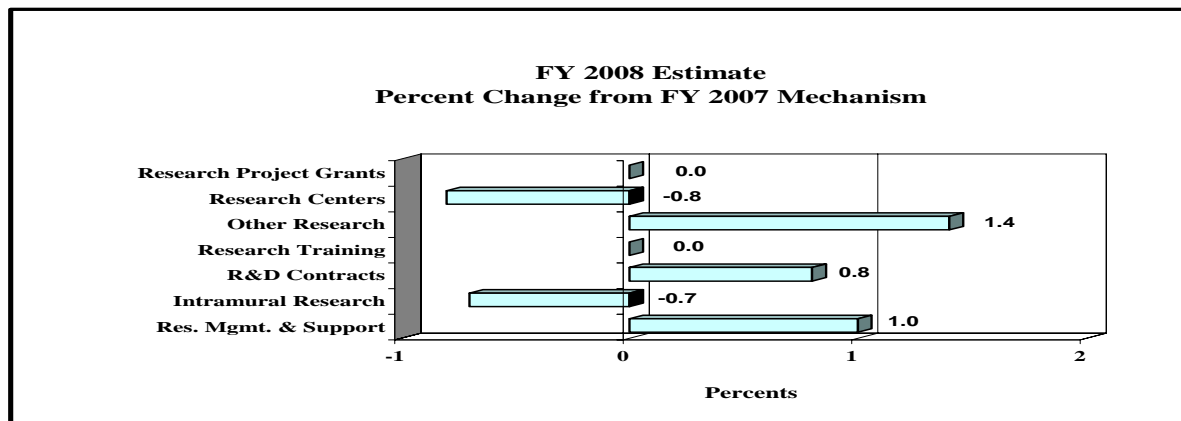
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanisms:



## 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 2006		FY 2007		FY 2008		Increase or	
Actual		Cont. Resol.		Estimate		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>
797	\$2,915,923,000	806	\$2,918,808,000	817	\$2,925,413,000	11	\$6,605,000

This document provides justification for the Fiscal Year (FY) 2008 activities of the National Heart, Lung, and Blood Institute (NHLBI), including NIH/AIDS activities. Details of the FY 2008 HIV/AIDS activities are in the “Office of AIDS Research (OAR)” Section of the Overview. Details on the Roadmap/Common Fund are located in the Overview, Volume One.

#### **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 goal 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 achievement of this vision and mission occurs in a spirit of service that exemplifies excellence, innovation, integrity, respect, and compassion.

## Strategic Planning

Under the direction of its new leadership, NHLBI embarked in 2005 upon an intensive, community-based effort to develop a scientific working plan for the next 10 years. The new strategic plan is expected to be published in the spring of 2007.

The first step (Level I) of the new strategic planning process comprised 23 thematic meetings held April through August of 2006. The meetings incorporated input from approximately 500 investigators, who were asked to identify scientific areas for which NHLBI is well positioned to make major contributions and to recommend operational policies to facilitate conduct of high-priority scientific research.

In October 2006, a Level II meeting brought together members of the National Heart, Lung, and Blood Advisory Council, chairpersons of the Level I meetings, and other leaders from the research community. Their task was to review the reports of the Level I meetings, synthesize and prioritize objectives and strategies, determine methods for measuring progress toward achieving objectives, and recommend approaches for fostering development of the research workforce. Participants were asked to give particular consideration to efficient and cost-effective strategies to achieve the objectives that were identified.

Level III, scheduled for completion in February 2007, has entailed development of a draft plan to reflect the vision of the research community. The plan includes specific implementation steps, focusing on areas where NHLBI can be most effective in driving and/or facilitating research that addresses high-priority goals. Comments on the draft plan have been solicited from patient advocacy groups, professional societies, and other members of the scientific and lay communities. Thus, the final version will reflect the collective vision and wisdom of the Institute's diverse stakeholders.

## Capitalizing on Previous Successful Investments

The nation has realized extraordinary public health benefits from the longstanding NHLBI investment in epidemiological research. Longitudinal studies supported by the Institute have not only identified the major risk factors for cardiovascular disease (CVD) but also originated the very concept of risk factors for a chronic disease. With the development of new genomic resources (e.g., the international HapMap project) and new genomic technologies (e.g., high-density gene chips), it is now possible to increase substantially the scientific returns from the investment in epidemiological studies. The Institute is moving rapidly to exploit that opportunity.

The NHLBI is investing substantial resources in activities to develop genotypic data on the participants in its epidemiological studies that can then be married with the wealth of already-available data about participant characteristics and health indicators to refine our understanding of the genetic influences on disease risk and on disease manifestations and progression. And to ensure that the public obtains the greatest possible scientific benefit from the Institute's investment in large-scale genotyping, NHLBI is working to provide access to the available data for all qualified investigators. It is developing, in cooperation with the National Center for

Biotechnology Information of the National Library of Medicine, a data repository—the SNP-Health Association Resource (SHARe)—that will include both the newly developed genotypic data along with the extensive body of phenotypic data. Because of its uniqueness in including three generations of participants with comparable data obtained from each generation at the same age, the Framingham Heart Study is the first of the Institute’s studies to be included in the SHARe. Other likely candidates include the Institute’s Jackson Heart Study and its newly initiated Hispanic Cohort Study.

In addition to the genotyping of study cohorts established by NHLBI, the Institute has funded research studies for innovative strategies to conduct genome-wide association studies in existing study populations and new approaches to designing and conducting genome-wide association studies. The latter activity represents the NHLBI contribution to the NIH-wide ENDGAME (Enhancing Development of Genome-wide Association Methods) consortium to enhance the utility of genome-wide association studies.

Finally, the Institute has begun to explore potential public–private partnership opportunities to use the resources of the Framingham Heart Study and the SHARe to identify biomarkers for CVD that can be used not only for early detection of CVD but also for the design and development of new approaches to its prevention and treatment.

## **FY 2008 JUSTIFICATION BY PROGRAM DETAIL**

Overall Budget Policy: Investigator-initiated research projects and new investigator research and career development are the Institute’s highest priorities. The NHLBI carefully evaluates investigator-initiated requests to submit grant applications for all large programs. A scientific review is conducted, and the results are presented to the NHLBI Advisory Council to determine the 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:** The mission of the Heart and Vascular Diseases program is to increase knowledge and understanding of the causes of heart and vascular diseases and develop effective strategies for their prevention, diagnosis, and treatment. Fundamental biomedical research, including cutting-edge approaches such as genomics, proteomics, nanotechnology, cell-based therapeutics, and gene therapy, is emphasized. Multidisciplinary programs are supported to advance basic knowledge of disease and generate the most effective methods of clinical management and prevention. The program also encompasses a broad array of epidemiological studies, clinical trials of interventions to prevent and treat disease, demonstration and education research, basic and applied behavioral studies, and the NIH Women’s Health Initiative. Diseases and conditions of interest include coronary heart disease, arrhythmias and sudden cardiac death, congenital heart disease, heart failure, hypertension, and peripheral vascular disease.

**Budget Policy:** The FY 2008 budget estimate for the Heart and Vascular Diseases program is \$1,587,367,000, an increase of \$401,000 or .025% over the FY 2007 Continuing Resolution. During the FY 2008 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. NHBLI 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: Pediatric Heart Network**

FY 2007 Level:	\$6,722,000
FY 2008 Level:	<u>\$6,732,000</u>
Change	\$ 10,000

The Pediatric Heart Network was established in FY 2001 to accelerate research on the diagnosis and management of congenital and acquired pediatric heart disease. Since its inception, the emphasis has been on clinical studies to identify optimal diagnostic and therapeutic methods involving investigational drugs or existing drugs of unproven value, devices, interventional procedures, and surgical techniques. Such clinical research has been impeded by the small numbers of children at any one location with a particular malformation or condition, a lack of uniformity in treatment approaches, and the absence of centralized databases and resources—all of which were addressed by formation of the Network. The Network also provides a platform for training junior investigators and a vehicle for rapid and widespread dissemination of findings. During FY 2006 the program was re-competed; eight clinical centers and one data coordinating center were awarded for a 5-year project period.

To date, the Network has undertaken seven studies, including the first-ever randomized clinical trial of a surgical procedure for congenital heart disease. Its newest study has tremendous importance for patients with Marfan syndrome, a rare multi-system disease that typically leads to enlargement and potentially fatal weakening of the aorta. This randomized clinical trial involving 600 children and young adults is evaluating the effectiveness of a commonly used blood pressure medicine, losartan, in preventing or reversing aortic damage. The trial follows on the heels of a breakthrough discovery, published in April 2006, that demonstrated the drug's efficacy in a mouse model of Marfan syndrome—the culmination of 15 years of basic research on the underlying mechanisms causing this disease. The ability to organize and initiate a clinical trial within months of such a discovery is testimony to the value of the Network in providing the infrastructure and expertise to capitalize on new findings as they emerge.

In FY 2008, the Network will examine scientific priorities presented in the NHLBI Strategic Plan to help guide future directions. Areas of emphasis include a greater understanding of the biological mechanisms that result in developmental heart abnormalities, including genetic contributions and gene-environment interactions. The Network will continue its support of clinical research, especially in the areas of surgical correction of congenital heart disease and treatment of Marfan syndrome. Efforts will also focus on health promotion among adult survivors of congenital heart disease.

**Lung Diseases:** The Lung Diseases program seeks to understand the causes and progression of lung diseases and sleep disorders in order to improve their diagnosis, treatment, and prevention. Areas of emphasis include the biology and function of the respiratory system, fundamental mechanisms associated with specific pulmonary and sleep disorders, the interplay between genetic and environmental factors in lung health and disease, and innovative approaches to therapy. The program encompasses research on a wide range of topics, including asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, neurobiology and sleep, 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.

**Budget Policy:** The FY 2008 budget estimate for the Lung Diseases program is \$606,492,000 an increase of \$1,705,000 or .28% over the FY 2007 Continuing Resolution. Plans for FY 2008 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 prevent the development of acquired lung diseases and to enhance early detection and thereby prevent or limit disease progression.

The FY 2008 budget estimate for the National Center for Sleep Disorders Research is \$53,812,000 an increase of \$118,000 or .2% from the FY 2007 Continuing Resolution.

#### **Portrait of a Program: COPD**

FY 2007 Level:	\$50,483,000
FY 2008 Level:	<u>\$50,594,000</u>
Change	\$ + 111,000

The NHLBI COPD program seeks to understand the pathogenic mechanisms of disease development and progression and to improve disease management. Investigators are exploring mechanisms of injury and repair in the lung, pathways involved in the regulation of airway mucous secretion, and genetic and environmental determinants of COPD, with a recent focus on the causes of COPD in lifelong nonsmokers. Applied studies are developing new methods of lung imaging by computed x-ray tomography or magnetic resonance imaging and testing their ability to provide a better characterization of changes that occur in disease. The NHLBI supports this research through investigator-initiated projects and special initiatives, including the following:

- Specialized Centers of Clinically Oriented Research in COPD — initiated in FY 2007 to foster multidisciplinary basic and clinical research related to COPD and speed progress in diagnosis, prevention, and treatment; funding will continue through FY 2011.
- COPD Clinical Research Network — initiated in FY 2003 to provide an infrastructure for conducting multiple, collaborative trials of disease-management approaches; funding will continue through FY 2009.
- Long-Term Oxygen Treatment Trial — initiated in FY 2007 to test the efficacy of long-term oxygen therapy in COPD patients with less-than-severe hypoxemia; funding will continue through FY 2011.
- Lung Tissue Research Consortium — initiated in FY 2004 to collect lung tissues and prepare and distribute them for research; funding will continue through FY 2009.

During 2007, the NHLBI launched the public-education component of its new COPD awareness and education program. The “Learn More, Breathe Better” campaign seeks to increase awareness of COPD as a serious, but treatable, disease and to encourage people at risk to have their breathing tested and talk with their doctors about treatment options.

In FY 2008, the NHLBI will continue its growing support of research and education programs in COPD, highlighting COPD’s importance as the fourth most common cause of death and disability in this country. Important clinical research into the causes and treatment of COPD will be in full swing through the Specialized Centers of Clinically Oriented Research, the COPD Clinical Research Network, and the Long-Term Oxygen Treatment Trial. Emerging opportunities in identification of new biomarkers for COPD diagnosis and treatment will be pursued through the Lung Tissue Research Consortium. The NHLBI plans active collaborations with public and private partners in implementation of the COPD awareness and education campaign.

**Blood Diseases and Resources:** The Blood Diseases and Resources 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. The program encompasses a broad spectrum of research ranging from basic biology to medical management of blood diseases. The program also has a major responsibility for research to assure the adequacy and safety of the nation’s blood supply, and for applying scientific advances in transfusion medicine and stem cell biology to the development of new cell-based therapies to repair and regenerate human tissues and organs.

Budget Policy: The FY 2008 budget estimate for the Blood Diseases and Resources program is \$424,535,000 an increase of \$1,113,000 or .26% over the FY 2007 Continuing Resolution. During FY 2008, 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 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: Sickle Cell Disease (SCD)**

FY 2007 Level: \$67,854,000

FY 2008 Level: \$68,003,000

Change: \$ + 149,000

Since the establishment of the National Sickle Cell Disease Program in 1972, the NHLBI has committed more than \$1 billion to research on SCD. The Institute supports an extensive research program to improve understanding of the pathophysiology of SCD and to identify effective approaches for its management and treatment and for prevention of complications. Areas of current interest include genetic influences on disease manifestations, regulation of hemoglobin synthesis, discovery of drugs to increase fetal hemoglobin production, transplantation of blood-forming stem cells, gene therapy, and development of animal models for preclinical studies. The NHLBI supports this research through investigator-initiated projects and special initiatives, including the following:

- Comprehensive Sickle Cell Centers — established in 1972, in response to a Presidential initiative and a Congressional mandate, to support multidisciplinary research to expedite development and application of new knowledge for improved diagnosis and treatment of SCD; 10 centers are funded through FY 2007 and the program will be renewed in FY 2008.
- Pediatric Hydroxyurea Phase II Clinical Trial (BABY HUG) — initiated in FY 2000 to assess the effectiveness of hydroxyurea in preventing chronic organ damage in young children with SCD; funding will continue through FY 2009.
- Sickle Cell Disease Clinical Research Network — established in FY 2006 to facilitate translation of results from basic studies and phase I/II clinical trials into phase III trials in patients with SCD; funding will continue through FY 2010.
- Phase II/III Trial of Sildenafil for Sickle Cell Disease-Associated Pulmonary Hypertension — initiated in FY 2006 as a complement and extension an NHLBI intramural trial to test the effects of sildenafil therapy on exercise endurance and pulmonary artery pressure in SCD patients who have pulmonary hypertension; funding will continue through FY 2009.

In FY 2008, the NHLBI will examine opportunities to enhance research efforts in SCD in two areas. New technologies in genomics will facilitate research into genetic modifiers and gene-environment interactions that promote development and progression of SCD. Furthermore, clinical research evidence now supports the concept that pulmonary hypertension is a major clinical risk factor for significant morbidity and mortality in SCD. This greater understanding of SCD pathophysiology affords the opportunity to evaluate treatments for pulmonary hypertension in individuals with sickle cell disease, raising the possibility of hope for relief of symptoms and an improvement in quality of life.

### **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. Areas of interest include the biology of experimental and clinical arteriosclerosis and its manifestations; pathophysiology of hypertensive vascular disease; functions of the lung; clinical and experimental studies on physiologic and pharmacologic aspects of heart, lung, and blood diseases; and a broad program of other basic research and technological development related to them. 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 a new Cardiothoracic Surgery Research Program.

Budget Policy: The FY 2008 budget estimate for the Intramural Research program is \$167,855,000, a decrease of \$1,099,000 or .7% from the FY 2007 Continuing Resolution. The program plans for FY 2008, along with expected outputs, are as follows. The budget provides support for new programs, which include (a) expansion of the Vascular Medicine Branch to include a clinical Pulmonary Hypertension Research Program in conjunction with area hospitals, (b) recruitment of a new Chief of the Cardiology Clinical Research Branch, (c) initiation of a monochromatic x-ray imaging and fluorescence program, (d) establishment of a new tenure-track position in the Cell Biology and Cell Physiology Center, (e) creation of a new Translational Medicine Center combining the translational research groups within the pulmonary and cardiology research programs, (f) expansion of the post-translational modification detection capabilities and mass-spectroscopy imaging in the proteomic core, (g) expansion of the ability of the histology core to perform 3D cryo-sectioning of biological samples, (h) initiation of a genomics evaluation of the environmental radiation-sensitive genes associated with human heart development, (i) initiation of a systems biology program on the mitochondria and stem cell biology, and (j) creation of a 5-year junior faculty position for outstanding new clinical investigators with a potential to transition to the extramural program with continuing NHLBI support.

### **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. The Division of Extramural Research is funded under this activity and administers the review, processing, award and scientific performance appraisal of approximately 5,000 research grants, 750 training awards and 600 contracts in heart and vascular, lung and blood diseases and blood resources program areas. The NHLBI Center for the Application of Research Discoveries, which is responsible for disease prevention, education, and control programs, is funded through this activity.

Budget Policy: The FY 2008 budget estimate for Research Management and Support is \$100,700,000, an increase of \$1,040,000 or 1% over the FY 2007 Continuing Resolution. The program plans for FY 2008, 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 Center for Application of Research Discoveries will continue with the planned transition and implementation of the Cardiovascular Knowledge Network that will support rapid sharing of knowledge and experience between researchers and practitioners.

Support will also be provided to the integrated National Cardiovascular Education Program, which will address cardiovascular disease in all settings, life stages, and priority populations. The program will coordinate the application of the latest advances in the prevention and treatment of cardiovascular disease to achieve the best possible outcomes for specific populations and individual patients. As well, it will provide feedback for generating new knowledge and more effective interventions at the community level.

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**Budget Authority by Object**

	FY 2007 Cont. Resol.	FY 2008 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	806	817	11
Full-time equivalent of overtime & holiday hours	2	2	0
Average ES salary	\$165,225	\$170,181	\$4,956
Average GM/GS grade	12.2	12.2	0.0
Average GM/GS salary	\$90,303	\$93,012	\$2,709
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$93,746	\$96,559	\$2,813
Average salary of ungraded positions	113,030	116,421	3,391
<b>OBJECT CLASSES</b>	FY 2007 Cont. Resol.	FY 2008 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	\$63,000,000	\$66,000,000	\$3,000,000
11.3 Other than Full-Time Permanent	13,000,000	13,000,000	0
11.5 Other Personnel Compensation	2,519,000	2,550,000	31,000
11.7 Military Personnel	1,768,000	1,795,000	27,000
11.8 Special Personnel Services Payments	8,494,000	8,500,000	6,000
<b>Total, Personnel Compensation</b>	<b>88,781,000</b>	<b>91,845,000</b>	<b>3,064,000</b>
12.0 Personnel Benefits	19,848,000	21,000,000	1,152,000
12.2 Military Personnel Benefits	1,026,000	1,040,000	14,000
13.0 Benefits for Former Personnel	0	0	0
<b>Subtotal, Pay Costs</b>	<b>109,655,000</b>	<b>113,885,000</b>	<b>4,230,000</b>
21.0 Travel & Transportation of Persons	3,400,000	3,400,000	0
22.0 Transportation of Things	335,000	335,000	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	185,000	185,000	0
23.3 Communications, Utilities & Miscellaneous Charges	1,775,000	1,780,000	5,000
24.0 Printing & Reproduction	1,035,000	1,030,000	-5,000
25.1 Consulting Services	2,775,000	2,700,000	-75,000
25.2 Other Services	15,600,000	15,000,000	-600,000
25.3 Purchase of Goods & Services from Government Accounts	166,915,000	166,448,000	-467,000
25.4 Operation & Maintenance of Facilities	4,500,000	4,500,000	0
25.5 Research & Development Contracts	217,133,000	218,683,000	1,550,000
25.6 Medical Care	2,130,000	2,100,000	-30,000
25.7 Operation & Maintenance of Equipment	6,175,000	6,100,000	-75,000
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>415,228,000</b>	<b>415,531,000</b>	<b>303,000</b>
26.0 Supplies & Materials	16,200,000	16,000,000	-200,000
31.0 Equipment	12,100,000	10,000,000	-2,100,000
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	2,323,867,000	2,324,794,000	927,000
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	9,000	9,000	0
44.0 Refunds	0	0	0
<b>Subtotal, Non-Pay Costs</b>	<b>2,774,134,000</b>	<b>2,773,064,000</b>	<b>-1,070,000</b>
<b>NIH Roadmap for Medical Research</b>	<b>35,019,000</b>	<b>38,464,000</b>	<b>3,445,000</b>
<b>Total Budget Authority by Object</b>	<b>2,918,808,000</b>	<b>2,925,413,000</b>	<b>6,605,000</b>

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

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**Salaries and Expenses**

OBJECT CLASSES	FY 2007 Cont. Resol.	FY 2008 Estimate	Increase or Decrease
<b>Personnel Compensation:</b>			
Full-Time Permanent (11.1)	\$63,000,000	\$66,000,000	\$3,000,000
Other Than Full-Time Permanent (11.3)	13,000,000	13,000,000	0
Other Personnel Compensation (11.5)	2,519,000	2,550,000	31,000
Military Personnel (11.7)	1,768,000	1,795,000	27,000
Special Personnel Services Payments (11.8)	8,494,000	8,500,000	6,000
<b>Total Personnel Compensation (11.9)</b>	<b>88,781,000</b>	<b>91,845,000</b>	<b>3,064,000</b>
Civilian Personnel Benefits (12.1)	19,848,000	21,000,000	1,152,000
Military Personnel Benefits (12.2)	1,026,000	1,040,000	
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal, Pay Costs</b>	<b>109,655,000</b>	<b>113,885,000</b>	<b>4,230,000</b>
Travel (21.0)	3,400,000	3,400,000	0
Transportation of Things (22.0)	335,000	335,000	0
Rental Payments to Others (23.2)	185,000	185,000	0
Communications, Utilities and Miscellaneous Charges (23.3)	1,775,000	1,780,000	5,000
Printing and Reproduction (24.0)	1,035,000	1,030,000	-5,000
<b>Other Contractual Services:</b>			
Advisory and Assistance Services (25.1)	2,775,000	2,700,000	-75,000
Other Services (25.2)	15,600,000	15,000,000	-600,000
Purchases from Govt. Accounts (25.3)	74,240,000	72,846,000	-1,394,000
Operation & Maintenance of Facilities (25.4)	4,500,000	4,500,000	0
Operation & Maintenance of Equipment (25.7)	6,175,000	6,100,000	-75,000
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>103,290,000</b>	<b>101,146,000</b>	<b>-2,144,000</b>
Supplies and Materials (26.0)	16,152,000	15,952,000	-200,000
<b>Subtotal, Non-Pay Costs</b>	<b>126,172,000</b>	<b>123,828,000</b>	<b>-2,344,000</b>
<b>Total, Administrative Costs</b>	<b>235,827,000</b>	<b>237,713,000</b>	<b>1,886,000</b>

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**Authorizing Legislation**

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2007 Cont. Resol.	2008 Amount Authorized	FY 2008 Budget Estimate	
Research and Investigation	Section 301	42§241	Indefinite		Indefinite		
National Heart, Lung, and Blood Institute	Section 402(a)	P.L.-109-482	Indefinite	\$2,918,808,000	Indefinite	\$2,925,413,000	
<b>Total, Budget Authority</b>						<b>\$ 2,918,808,000</b>	<b>\$ 2,925,413,000</b>

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**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
1999	1,641,524,000 <u>2/ 3/</u>	1,720,344,000	1,793,697,000	1,793,697,000
Rescission				-1,188,000
2000	1,759,806,000 <u>2/</u>	1,937,404,000	2,001,185,000	2,040,291,000
Rescission				-10,867,000
2001	2,069,582,000 <u>2/</u>	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	2,901,012,000	2,901,012,000	2,924,299,000	2,921,757,000 <u>4/</u>
2008	2,925,413,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

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

3/ Reflects a decrease of \$5,161,000 for the budget amendment for Bioterrorism

4/ Annualized current rate

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**Detail of Full-Time Equivalent Employment (FTEs)**

OFFICE/DIVISION	FY 2006 Actual	FY 2007 Cont. Resol.	FY 2008 Estimate
Office of the Director	13	11	9
Office of Biostatistics Research	13	13	13
Office of Science and Technology	19	19	19
Office of Prevention, Education, and Control	38	39	40
Office of Administrative Management	68	69	70
Office of Minority Health Affairs	4	4	4
Division of Cardiovascular Diseases	57	58	59
Division of Prevention and Population Sciences	45	45	45
Center for Population Studies	4	4	5
Division of Lung Diseases	21	22	23
Division of Blood Diseases and Resources	23	24	25
Division of Intramural Research	376	378	380
Division of Extramural Research Activities	100	102	105
Center for Research Informatics and Information Technology	16	18	20
<b>Total</b>	<b>797</b>	<b>806</b>	<b>817</b>
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FISCAL YEAR	Average GM/GS Grade		
2004	11.7		
2005	12.2		
2006	12.3		
2007	12.2		
2008	12.2		

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**Detail of Positions**

GRADE	FY 2006 Actual	FY 2007 Cont. Resol.	FY 2008 Estimate
Total, ES Positions	2	1	1
Total, ES Salary	\$160,950	\$165,225	\$170,181
GM/GS-15	94	94	94
GM/GS-14	102	102	102
GM/GS-13	131	131	137
GS-12	94	95	96
GS-11	40	40	40
GS-10	4	4	4
GS-9	34	38	40
GS-8	43	43	43
GS-7	12	14	14
GS-6	8	8	8
GS-5	3	3	3
GS-4	1	1	1
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	567	574	583
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	10	10	10
Senior Grade	4	4	4
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	14	14	14
Ungraded	234	237	240
Total permanent positions	752	760	771
Total positions, end of year	817	826	838
Total full-time equivalent (FTE) employment, end of year	797	806	817
Average ES salary	\$160,950	\$165,225	\$170,181
Average GM/GS grade	12.3	12.2	12.2
Average GM/GS salary	\$87,980	\$90,303	\$93,012

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



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**New Positions Requested**

	FY 2008		
	Grade	Number	Annual Salary
Technical Writer Editor	13	2	\$90,000
Health Scientist Administrator	13	2	\$90,000
Administrative Technician	9	2	\$50,000
Management Analyst	12	1	\$73,000
IT Specialist	13	2	\$90,000
Medical Officer	AD	3	\$180,000
<b>Total Requested</b>		<b>12</b>	