DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute (NHLBI)

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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 [\$3,015,689,000] \$3,050,356,000. (Department of Health and Human Services Appropriations Act, 2009)

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

Amounts Available for Obligation 1/

	FY 2008	FY 2009	FY 2010
Source of Funding	Actual	Estimate	Estimate
Appropriation	\$2,974,900,000	\$3,015,689,000	\$3,050,356,000
Rescission	-51,972,000	0	0
Supplemental	15,542,000	0	0
Subtotal, adjusted appropriation	2,938,470,000	3,015,689,000	3,050,356,000
Real transfer under Director's one-percent transfer			
authority (GEI)	-1,092,000	0	0
Comparative transfer to NIDDK	-816,000	0	0
Comparative transfer under Director's one-percent			
transfer authority (GEI)	1,092,000	0	0
Subtotal, adjusted budget authority	2,937,654,000	3,015,689,000	3,050,356,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	2,937,654,000	3,015,689,000	3,050,356,000
Unobligated balance lapsing	-45,000	0	0
Total obligations	2,937,609,000	3,015,689,000	3,050,356,000

<u>1</u>/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2008 - \$14,671,000 FY 2009 - \$20,000,000 FY 2010 - \$20,000,000 Excludes \$1,153,671 in FY 2008; \$1,354,667 in FY 2009 and \$1,381,760 in FY 2010 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

(Dollars in Thousands)

Budget Mechanism - Total

		idget Mecha Y 2008		Y 2009	_	Y 2010	ı	
MECHANISM		1 2006 Actual		stimate		stimate	C.	ange
Research Grants:	No.		No.		No.			Amount
	NO.	Amount	INO.	Amount	INO.	Amount	INO.	Amount
Research Projects:	0.770	#4 400 074	0.000	Φ4 407 47F	0.005	#4 500 005	70	#40.000
Noncompeting		\$1,420,071			2,985	\$1,500,805	79	\$13,330
Administrative supplements	(129)	13,988	(110)	8,700	(88)	6,000	((22))	(2,700)
Competing: Renewal	24.4	400 000	200	100.004	204	107 100	4	2 720
New	314 682	166,286	300	163,694	301	167,430	1	3,736
Supplements	1	301,527 179	653 0	296,828 0	655 0	303,603	2 0	6,775
Subtotal, competing	997	467,992	953	460,522	956	471,033	3	10,511
Subtotal, RPGs	3,773	1,902,051	3,859		3,941	1,977,838	82	21,141
SBIR/STTR	173		<u> </u>	75,500		74,010	-4	-1,490
		77,914	163		159		-	
Subtotal, RPGs Research Centers:	3,946	1,979,965	4,022	2,032,197	4,100	2,051,848	78	19,651
Specialized/comprehensive	48	106,958	42	109,418	45	111,059	3	1,641
Clinical research	0	00,930	0	09,410	0	0	0	1,041
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	435	0	435	0	435	0	0
Research Centers in Minority Institutions	0	433	0	433	0	433	0	0
Subtotal, Centers	48	107,393	42	109,853	45	111,494	3	1,641
Other Research:	10	107,000	72	100,000	10	111,404	Ŭ	1,041
Research careers	549	78,715	560	81,715	564	82,941	4	1,226
Cancer education	0	0	0	01,710	0	02,041	0	1,220
Cooperative clinical research	29	23,514	22	24,055	22	24,415	ő	360
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	7	1,572	7	1,572	7	1,588	0	16
Other	93	22,186	85	24,500	85	24,868	0	368
Subtotal, Other Research	678	125,987	674	131,842	678	133,812	4	1,970
Total Research Grants	4,672	2,213,345	4,738	2,273,892	4,823	2,297,154	85	23,262
Research Training:	FTTPs		FTTPs	<u>3</u>	FTTPs	<u>3</u>		
Individual awards	202	9,075	204	9,166	205	9,303	1	137
Institutional awards	1,684	85,798	1,689	86,313	1,691	87,608	2	1,295
Total, Training	1,886	94,873	1,893	95,479	1,896	96,911	3	1,432
Research & development contracts	207	343,699	209	354,010	211	359,320	2	5,310
(SBIR/STTR)	3	471	(6)	(2,000)		(2,500)		(500)
(OBINGOTTIN)	_	77.1	1	(2,000)		(2,000)		(000)
Intromural receases	FTEs	170.074	FTEs	100 707	FTEs	100 440	<u>FTEs</u>	0.744
Intramural research	442	176,674	429	180,737	438	183,448	9	2,711
Research management and support	404	109,063	426	111,571	434	113,523	8	1,952
Construction		0		0		0		0
Buildings and Facilities	0.46	0	055	0 045 000	076	0 050 050	4-	0 1 007
Total, NHLBI	846	2,937,654	855	3,015,689	872	3,050,356	17	34,667

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

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

	F	FY 2006	FΥ	FY 2007	FΥ	FY 2008	Ē	FY 2008	E	FY 2009	Ē	FY 2010		
	A	Actual	Ā	Actual	ď	Actual	COL	Comparable	Es	Estimate	ES	Estimate	ភ	Change
Extramural Research	FTES	Amount	FTES	Amount										
Detail:												3		
Diseases		1 632 680		\$1 633.337		\$1 650 199		\$1 650 957		\$1 695 446		\$1 714 125		18 679
Lung Diseases		600.892		601.134		574,222		574.501		589,983		596,483		6.500
Blood Diseases and						Name Attack						coccontratories.		
Resources		417,578		417,746		426,252		426,459		437,952		442,777		4.825
Subtotal, Extramural		2,651,150		2,652,217		2,650,673		2,651,917		2,723,381		2,753,385		30.004
Intramural research	402	170,736	413	169,560	442	177,490	442	176,674	429	180,737	438	183,448	0	2.711
Res. Mgt. & support	395	97,864	401	100,614	404	109,215	404	109,063	426	111,571	434	113,523	8	1,952
TOTAL	797	797 2,919.750		814 2,922,391		846 2,937,378	846	846 2,937,654		855 3,015,689		872 3,050,356	17	34,667

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

Major Changes in the Fiscal Year 2010 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2010 budget request for NHLBI, which is \$34.667 million more than the FY 2009 Estimate, for a total of \$3,050.356 million.

Research Project Grants (+\$19.651 million; total \$2,051.848 million): NHLBI noncompeting grants will increase by \$13.330 million in FY 2010. The NIH Budget policy for RPGs in FY 2010 is to provide 2% inflationary increases in noncompeting awards and 2% increase in average cost for competing RPGs. Some of the increased number of noncompeting grants (\$6.200 million) are a result of the Pathways to Independence (K99/R00) program, which will be converted to R00s in FY 2010. NHLBI competing RPGs will increase by \$10.511 million from FY 2009. Intramural Research and Research Management Support will receive an increase to help cover the cost of pay and other increases. NHLBI will continue to support new investigators and to maintain an adequate number of competing RPGs.

Research Centers (+\$1.640 million; total \$111.494 million): The Cardiac Translational Research Implementation Program will accelerate the translation of recent, exciting, and promising fundamental research discoveries for the treatment and prevention of heart failure and arrhythmias into well designed clinical trials that demonstrate the efficacy and safety of new therapeutic interventions.

Phase II Clinical Trials for Evaluation of Novel Therapies for Lung Diseases and Sleep Disorders (+\$3.600 million): Conduct phase II clinical treatment trials of innovative and novel agents for lung diseases and sleep disorders. Through the study of isolated lung cells, transgenic animals, biomarker analysis, and candidate genes, there is a better understanding of pathways (e.g., apoptosis, immune stimulation) and cellular interactions, giving rise to many new ideas for novel treatment targets. There remains, however, an important gap in research support between these basic research discoveries and the evaluation of new agents in large clinical trials. Phase II trials will be proof of concept, interventional studies that use physiologic or biochemical, rather than clinical, endpoints. In addition, support will be available for one or more ancillary mechanistic studies linked to the clinical questions.

NHLBI Cardiovascular Outcomes Research Centers (+\$4.950 million): This initiative will fund observational and quasi-experimental cardiovascular research which focuses on the end results, or outcomes, of healthcare and the determinants of these outcomes.

Childhood Obesity Prevention and Treatment Research Consortium (+\$4.000 million): This initiative will support multiple outstanding controlled trials to test the efficacy of innovative interventions that address issues immediately germane to the childhood obesity epidemic. The ultimate goal is prevention of future obesity-related morbidity and mortality.

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

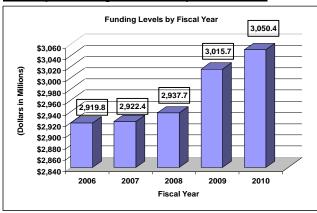
FY 2009 estimate				\$3,015,689,000
FY 2010 estimated budget authority				3,050,356,000
Net change				34,667,000
	20	09 Current		
	Esti	imate Base	Change	e from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
Intramural research:				
a. Annualization of January				
2009 pay increase		\$68,603,000		\$816,000
b. January FY 2010 pay increase		68,603,000		1,029,000
c. Payment for centrally furnished services		27,596,000		552,000
d. Increased cost of laboratory supplies,				
materials, and other expenses		84,538,000		1,353,000
Subtotal				3,750,000
Research management and support:				
a. Annualization of January				
2009 pay increase		\$54,695,000		\$799,000
b. January FY 2010 pay increase		54,695,000		820,000
c. Payment for centrally furnished services		19,227,000		385,000
d. Increased cost of laboratory supplies,				
materials, and other expenses		37,649,000		602,000
Subtotal				2,606,000
Subtotal, Built-in				6,356,000

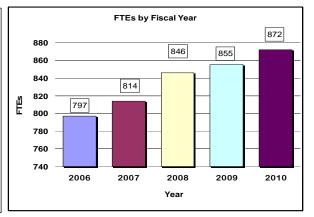
Summary of Changes--continued

	2	009 Current		
	Es	stimate Base		e from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research project grants:				
a. Noncompeting	2,906	\$1,496,175,000	79	\$10,630,000
b. Competing	953	460,522,000	3	10,511,000
c. SBIR/STTR	163	75,500,000	(4)	(1,490,000)
Total	4,022	2,032,197,000	78	19,651,000
2. Research centers	42	109,853,000	3	1,641,000
3. Other research	674	131,842,000	4	1,970,000
4. Research training	1,893	95,479,000	3	1,432,000
5. Research and development contracts	209	354,010,000	2	5,310,000
Subtotal, extramural				30,004,000
	FTEs		FTEs	
6. Intramural research	429	180,737,000	9	(1,039,000)
7. Research management and support	426	111,571,000	8	(654,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		3,015,689,000		28,311,000
Total changes	855		17	34,667,000

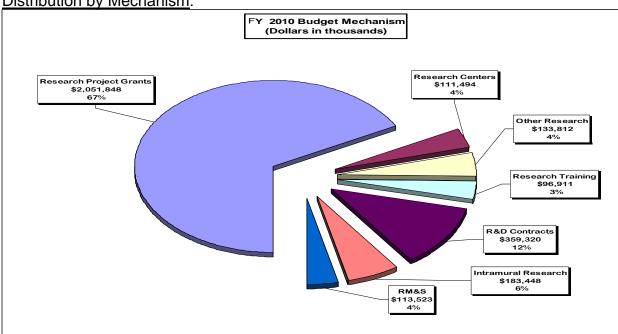
Fiscal Year 2010 Budget Graphs

History of Budget Authority and FTEs:

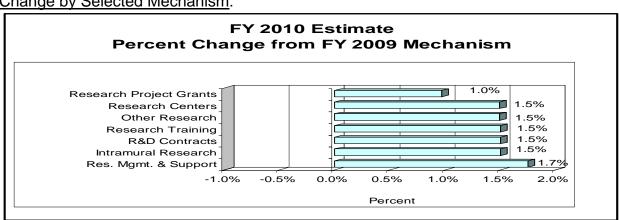




Distribution by Mechanism:



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	FY 2010	FY 2010 +/-
	FY 2008	FY 2009	Recovery	President's	2009
	Appropriation	Omnibus	Act	Budget	Omnibus
BA	\$2,937,654,000	\$3,015,689,000	\$766,734,000	\$3,050,356,000	\$+34,667,000
FTE	846	855	0	872	+17

This document provides justification for the Fiscal Year (FY) 2010 activities of the National Heart, Lung, and Blood Institute (NHLBI), including HIV/AIDS activities. Details of the FY 2010 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. In FY 2009, a total of \$766,734,000 American Recovery and Reinvestment Act (ARRA) funds were transferred from the Office of the Director. These funds will be used to support scientific research opportunities that help support the goals of the ARRA. The ARRA allows NIH to execute these funds via any NIH funding mechanism. Funds are available until September 30, 2010. These funds are not included in the FY 2009 Omnibus amounts reflected in this document.

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 Institute supports individuals in private and public sectors working in fields related to its mission, 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.

While NHLBI activities are focused on diseases and conditions that fall specifically within its mandate, research efforts are highly relevant to other health issues as well. For example, the Institute supports considerable basic research on fundamental mechanisms that influence such diverse phenomena as arrhythmias, autism, and night blindness. The NHLBI has a large investment in cancer-related research. Representative topics include angiogenesis (the development of new blood vessels, a key process in tumor growth) and the pathogenesis of smoking-related airways diseases such as COPD and lung cancer. The Institute's portfolio of research into bone marrow failure diseases includes studies of aplastic anemia, which can result from chemotherapy or radiation therapy, and other myelodysplastic syndromes and myeloproliferative disorders that are involved in certain leukemias. NHLBI-funded research on Diamond-Blackfan anemia is expected to provide new insights into cancer predisposition and recovery from chemotherapy.

The Institute has made considerable progress toward implementing the NHLBI Strategic Plan, which was completed and published more than a year ago. *Shaping the Future of Research: A Strategic Plan for the National Heart, Lung, and Blood Institute* is available on the NHLBI Web site at http://apps.nhlbi.nih.gov/strategicplan/.

As described previously, the plan is structured around three complementary goals that reflect the successive movement of scientific discovery from basic research through clinical applications. This crosscutting approach highlights areas where the NHLBI is well positioned to make major contributions through investigator-initiated research and through programs that enable and extend investigator-initiated activities. The plan recommends a number of broad strategies that the NHLBI will employ to facilitate the conduct of research; enhance interdisciplinary work; speed early-stage translation of basic discoveries; ensure cross-fertilization of basic, clinical, and epidemiologic discoveries, and maximize the resultant public health benefit of the information created. In consultation with the National Heart, Lung, and Blood Advisory Council and the scientific community, the Institute has already invested in a number of initiatives that address the plan's goals.

Goal 1 is to improve understanding of the molecular and physiological basis of health and disease and to use that understanding to develop improved approaches to disease diagnosis, treatment, and prevention. The NHLBI has put forth a number of initiatives to further this goal, including an investigation of the role played by airway smooth muscle in the development of asthma, with the objective of uncovering new targets for therapy; research to identify the molecular and cellular changes that occur during the preparation and storage of red blood cells for transfusion and to characterize the body's response to them; and a consortium of multidisciplinary projects on progenitor ("stem") cell biology. During FY 2010, the Institute plans to support a detailed investigation of the role played by heart muscle cell components known as cardiomyocyte mitochondria in the development of heart disease, and we will continue and expand the operation of facilities that provide production assistance for the development of novel cellular therapies for heart, lung, and blood diseases.

Goal 2 is to improve understanding of the clinical mechanisms of disease and thereby enable better prevention, diagnosis, and treatment. Initiatives in support of this goal include a new program called PumpKIN ("Pumps for Kids, Infants, and Neonates") that seeks to develop for infants and young children with congenital and acquired cardiovascular disease a family of viable mechanical circulatory support devices that would bridge these patients to heart transplantation or recovery. The Institute has also renewed a solicitation that encourages use of patient cohorts, data, and biological materials of ongoing clinical trials to carry out ancillary studies associated with heart, lung, blood, and sleep disorders. During FY 2010, we plan to renew our highly successful program in clinical proteomics, which is evaluating protein markers that may be appropriate for routine use in the diagnosis and management of heart, lung, blood, or sleep disorders; to begin a program supporting phase II clinical trials for evaluation of innovative therapies for lung diseases and sleep disorders; and to launch the Cardiac Translational Research Implementation Program to speed translation of promising new fundamental research discoveries for the treatment and prevention of heart failure and arrhythmias.

Goal 3 is to generate an improved understanding of the processes involved in translating research into practice and use that understanding to enable improvements in public health and to stimulate further scientific discovery. In this area, the Institute has solicited projects to develop, refine, and test innovative behavioral and/or environmental approaches for weight control in young adults at high risk for weight gain. A related initiative is establishing research centers to translate findings from basic research on human behavior into more effective clinical, community, and population interventions to reduce obesity and promote cardiovascular health. A major new clinical trial of hypertension control is being undertaken, as described in the Program Portrait, below.

The NHLBI will continue to look to its Advisory Council and to the larger research community for guidance to ensure optimal use of its resources and steady progress toward the goals articulated in its strategic plan.

FY 2010 JUSTIFICATION BY PROGRAM DETAIL

Program Descriptions and Accomplishments

Overall Budget Policy: The NHLBI will continue to support early stage investigators and to maintain an adequate number of competing RPGs. The NHLBI is providing a 2 percent inflationary increase for non-competing and competing grants. In addition, the NHLBI has targeted a portion of the funds available for competing research project grants to support high priority projects outside of the payline, including awards to early stage investigators. The Institute also seeks to maintain a balance between solicitations issued to the extramural community in areas that need stimulation 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.

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.

In fiscal year 2008, the NHLBI extended the Framingham Study for seven years. The extension will include re-examination of each of the three Framingham cohorts (Original, Offspring, and Generation III) for measurement of complex phenotypes; rapid distribution of DNA for extensive and focused genotyping; rapid distribution of genetic and phenotypic measurements for use by investigators internal and external to the Framingham Study; and analyses of the contribution of genes, new and established risk factors, and innovative biomarkers to the development and progression of subclinical and clinical disease.

In fiscal year 2009, the NHLBI will establish eight Global Health Centers of Excellence in developing countries to combat non-communicable chronic cardiovascular and pulmonary diseases. The Centers will develop clinical research infrastructure, conduct doctoral and post-doctoral research training, and carry out research on new or improved approaches, programs, measures, and treatments to prevent, reduce, or treat chronic cardiovascular and pulmonary diseases.

<u>Budget Policy</u>: The FY 2010 budget estimate for the Heart and Vascular Diseases program is \$1,714.125 million, an increase of \$18.679 million or 1.1% over the FY 2009 estimate. During FY 2010 NHLBI plans to follow its strategic plan; which contains three sets of goals: 1) enabling technologies and methodologies, 2) clinical problems or disease states, and 3) research training and career development. One initiative the NHLBI will renew is it's Programs of Excellence in Nanotechnology (PEN's) with an increased emphasis on translation to pre-clinical/clinical studies and commercialization.

Portrait of a Program: Systolic Blood Pressure Intervention Trial (SPRINT)

FY 2009 Level: \$ 3.070 million FY 2010 Level: \$13.987 million

Change: \$10.917 million

Current hypertension control guidelines set a systolic blood pressure (SBP) goal of less than 140 mm Hg for most people. However, ample evidence from observational studies suggests that an even lower level may be optimal. SPRINT is a multi-center clinical trial that will test the effectiveness of intensively lowering SBP in preventing cardiovascular disease (CVD). Approximately 7,500 volunteers will be randomly assigned either to have their SPB treated according to the current guidelines or to receive a more intensive treatment that strives to reach an SPB goal of less than 120 mm Hg. Participants will be 55 years or older with SPB of at least 130 mm Hg. All will be "high risk" by virtue of having clinical CVD other than stroke, having stage 3 chronic kidney disease (CKD), or having other CVD risk factors such as low levels of HDL cholesterol.

Two high-risk groups will be excluded because they are the subjects of other ongoing NHLBI and NINDS trials that are testing a lower BP goal—patients with diabetes and those who have had a stroke. The trial will compare the two blood-pressure—lowering approaches in terms of their effects on CVD mortality and non-fatal myocardial infarction, stroke, and heart failure. Several secondary outcomes will also be examined, including renal function in non-CKD participants, quality of life, and cost-effectiveness.

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 2008, the NHLBI began a project to re-define major categories of lung diseases using molecular phenotypes, a critical step toward the development of personalized and pre-emptive approaches to pulmonary medicine. Molecular phenotype is defined here as any molecular entity with complex and quantitative traits that is shaped by multiple and possibly interacting genetic and environmental factors. A central repository of findings will provide a full spectrum of molecular signatures from normal lungs and across many respiratory diseases.

In fiscal year 2009, the NHLBI will establish an Asthma Network. The Network will develop and conduct multiple clinical trials that address the most important management and new treatment questions in asthma leveraging resources across the age and disease severity spectrum.

<u>Budget Policy</u>: The FY 2010 budget estimate for the Lung Diseases program is \$596.483 million an increase of \$6.500 million or 1.1% over the FY 2009 estimate. The program plans for FY 2010 include support for the new initiative and on-going programs as described below, as well as meritorious new investigator-initiated research grants, and research training related to its mission. The NHLBI will conduct phase II clinical treatment trials of innovative and novel agents for lung diseases and sleep disorders.

Portrait of a Program: COPD

FY 2009 Level: \$ 63.047 million FY 2010 Level: \$ 63.740 million Change \$.693 million

The NHLBI COPD program seeks to shed new light on the pathways by which the disease develops and progresses and to uncover effective approaches for COPD management and prevention. Investigators are exploring mechanisms of injury and repair in the lung and environmental and genetic determinants of COPD, including alpha-1 antitrypsin deficiency. Applied studies, including the SPIROMICS program mentioned in the Budget Policy above, are developing new methods of lung imaging and using them to characterize various subtypes of COPD and measure disease progression and outcomes.

The NHLBI supports this research through investigator-initiated projects and special initiatives. Ongoing programs include the Long-Term Oxygen Treatment Trial (LOTT), a collaborative effort with the Centers for Medicare & Medicaid Services. LOTT is testing the hypothesis that long-term home oxygen therapy can reduce disability and perhaps even prolong life in COPD patients who have less-than-severe hypoxemia. A major investigator-initiated project, Genetic Epidemiology of COPD, is establishing a large, racially diverse cohort of healthy smokers and patients with a range of COPD severity for genome-wide association studies. A new area of research interest is the commonalities between lung cancer and COPD, both major causes of mortality in the United States and worldwide. An initiative is under development to bring together investigators from the cancer and pulmonary communities for in-depth exploration of pathogenetic factors shared by these two diseases.

The NHLBI **Learn More, Breathe Better** campaign seeks to increase awareness that COPD is a serious, but treatable, lung disease and to encourage people at risk to have their breathing tested and talk to their doctors about treatment options. The campaign directs its messages primarily toward men and women over age 45, especially those who smoke or have smoked and those who are at risk of developing COPD by virtue of their genetic background or other environmental exposures.

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 conduct research to ensure the adequacy and safety of the nation's blood supply.

In fiscal year 2008, the NHLBI began a project to support local and collaborative basic and clinical research on venous thrombotic diseases with an emphasis on the sharing of resources to improve diagnosis, therapy, and prevention. The NHLBI also supported a project to collect and analyze outcome data from recipients of hematopoietic stem cell transplants (HSCT).

In fiscal year 2009, the NHLBI will begin an initiative to improve red blood cell transfusion therapies. Basic and translational research will be supported to identify the molecular and cellular changes that occur during red blood cell unit preparation and storage.

<u>Budget Policy</u>: The FY 2010 budget estimate for the Blood Diseases and Resources program is \$442.777 million, an increase of \$4.825 million or 1.1% over the FY 2009 estimate. The program plans for FY 2010 include support for the new initiative and ongoing programs as described below, as well as meritorious new investigator-initiated research grants, and research training related to its mission. The NHLBI will renew the Production Assistance for Cellular Therapies (PACT) program. Additional services of the program will include providing support to proof-of-principle animal and early translational research and diversifying the cell therapy expertise within the program.

Portrait of a Program: A Randomized Trial of Genotype-Guided Dosing of Warfarin Therapy

FY 2009 Level: \$ 3.530 million FY 2010 Level: \$ 2.279 million

Change: \$-1.251 million

The potential use of pharmacogenomics—an understanding of how genetics explains individual differences in response to drugs—to guide prescribing decisions is a topic of tremendous interest and opportunity. A case in point is the use of the anticoagulant warfarin. Warfarin is highly efficacious at preventing thromboembolism, however, it must be dosed properly to achieve the desired effect yet avoid life-threatening complications from overdosing. The dose requirement can vary widely from one patient to another, and current practice relies primarily on a trial-and-error approach to arrive at the optimal dosage for an individual patient. Research has identified two specific genetic variations that appear to account for much of the inter-individual variation in sensitivity to warfarin. Building on this discovery, the NHLBI has launched a clinical trial to evaluate the clinical efficacy of a genotype-guided prescribing strategy for warfarin therapy and to determine whether the increment in efficacy and safety warrants the cost of genetic testing. Approximately 2,000 patients will be recruited at 12 North American clinical sites.

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.

<u>Budget Policy</u>: The FY 2010 budget estimate for the Intramural Research program is \$183.448 million, an increase of \$2.711 million or 1.5% from the FY 2009 estimate. The program plans for FY 2010, along with expected outputs, are as follows. Increases for salaries and related costs are covered in the budget request.

The budget provides support for new programs, which include: a) pediatric radiology and interventional cardiology to translate real time MRI approaches; b) Pulmonary Clinical research concentrating on pulmonary hypertension, pulmonary fibrosis and asthma; c) bench top monochromatic "soft" x-ray systems; followed by use of "hard" mono-chromatic x-rays; d) Clinical Human Immunology Center in collaboration with several other IC's to provide the basic tools to evaluate the role of the human immune system in a variety of disease states including atherosclerosis, heart failure and diabetes; e) epigenetic modification of gene expression in the human genome.

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 a new educational campaign, "COPD: Learn More, Breathe Better."

<u>Budget Policy</u>: The FY 2010 budget estimate for Research Management and Support is \$113.523 million, an increase of \$1.952 million or 1.75% over the FY 2009 estimate. The program plans for FY 2009, along with expected outputs, are as follows. Increases for salaries and related costs are covered in the budget request, but decreases are planned for operating expenses such as maintenance contracts and information technology costs.

The budget provides support for health disparities issues through the expansion of community-based efforts to promote healthy lifestyle behaviors. In addition, development of clinical guidelines on Sickle Cell Disease, adult hypertension, high blood cholesterol, and overweight and obesity, are underway.

Budget Authority by Object

		FY 2009	FY 2010	Increase or
		Estimate	Estimate	Decrease
Total c	ompensable workyears:			
	Full-time employment	855	872	17
	Full-time equivalent of overtime and holiday hours	3	5	2
	Average ES salary	\$172,200	\$172,200	\$0
	Average GM/GS grade	12.4	12.4	0.0
	Average GM/GS salary	\$100,235	\$102,558	\$2,323
	Average salary, grade established by act of	\$100,233	Ψ102,330	Ψ2,323
	July 1, 1944 (42 U.S.C. 207)	\$98,759	\$100,734	\$1,975
	• • •	' '		
	Average salary of ungraded positions	\$119,846	\$122,243	\$2,397
		EV 0000	E)/0040	
	OD 1507 OL 40050	FY 2009	FY 2010	Increase or
	OBJECT CLASSES	Estimate	Estimate	Decrease
11 1	Personnel Compensation:	\$57.604.000	¢60.456.000	¢2 025 000
11.1 11.3	Full-time permanent	\$57,631,000	\$60,456,000	\$2,825,000
	Other than full-time permanent	28,175,000	29,555,000	1,380,000
11.5	Other personnel compensation	3,383,000	3,548,000	165,000
11.7	Military personnel	1,178,000	1,236,000	58,000
11.8	Special personnel services payments	8,923,000	9,360,000	437,000
	Total, Personnel Compensation	99,290,000	104,155,000	4,865,000
12.0	Personnel benefits	23,299,000	24,441,000	1,142,000
12.2	Military personnel benefits	709,000	744,000	35,000
13.0	Benefits for former personnel	0	0	0
	Subtotal, Pay Costs	123,298,000	129,340,000	6,042,000
21.0	Travel and transportation of persons	3,324,000	3,340,000	16,000
22.0	Transportation of things	237,000	232,000	(5,000)
23.1	Rental payments to GSA	0	0	0
23.2	Rental payments to others	9,000	9,000	0
23.3				
	miscellaneous charges	1,645,000	1,604,000	(41,000)
24.0	Printing and reproduction	560,000	543,000	(17,000)
25.1	Consulting services	996,000	975,000	(21,000)
25.2	Other services	25,440,000	25,168,000	(272,000)
25.3	Purchase of goods and services from			
	government accounts	207,089,000	208,553,000	1,464,000
25.4	Operation and maintenance of facilities	2,087,000	2,053,000	(34,000)
25.5	Research and development contracts	241,939,000	245,495,000	3,556,000
25.6	Medical care	2,084,000	2,053,000	(31,000)
25.7	Operation and maintenance of equipment	8,563,000	8,354,000	(209,000)
25.8	Subsistence and support of persons	0	0	0
25.0	Subtotal, Other Contractual Services	488,198,000	492,651,000	4,453,000
26.0	Supplies and materials	16,559,000	16,308,000	(251,000)
31.0	Equipment	12,487,000	12,263,000	(224,000)
32.0	Land and structures	0	0	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	2,369,371,000	2,394,065,000	24,694,000
42.0	Insurance claims and indemnities	0	0	0
43.0	Interest and dividends	1,000	1,000	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	2,892,391,000	2,921,016,000	28,625,000
	Total Budget Authority by Object	3,015,689,000	3,050,356,000	34,667,000

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

Salaries and Expenses

	ilia Expelises		
	FY 2009	FY 2010	Increase or
OBJECT CLASSES	Estimate	Estimate	Decrease
Personnel Compensation:	LStilliate	LStilliate	Decrease
-	¢EZ CO4 000	#60 456 000	¢o ooe ooo
Full-time permanent (11.1)	\$57,631,000	\$60,456,000	\$2,825,000
Other than full-time permanent (11.3)	28,175,000	29,555,000	1,380,000
Other personnel compensation (11.5)	3,383,000	3,548,000	165,000
Military personnel (11.7)	1,178,000	1,236,000	58,000
Special personnel services payments (11.8)	8,923,000	9,360,000	437,000
Total Personnel Compensation (11.9)	99,290,000	104,155,000	4,865,000
Civilian personnel benefits (12.1)	23,299,000	24,441,000	1,142,000
Military personnel benefits (12.2)	709,000	744,000	35,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	123,298,000	129,340,000	6,042,000
Travel (21.0)	3,324,000	3,340,000	16,000
Transportation of things (22.0)	237,000	232,000	(5,000)
Rental payments to others (23.2)	9,000	9,000	0
Communications, utilities and			
miscellaneous charges (23.3)	1,645,000	1,604,000	(41,000)
Printing and reproduction (24.0)	560,000	543,000	(17,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	996,000	975,000	(21,000)
Other services (25.2)	25,440,000	25,168,000	(272,000)
Purchases from government accounts (25.3)	100,881,000	100,752,000	(129,000)
Operation and maintenance of facilities (25.4)	2,087,000	2,053,000	(34,000)
Operation and maintenance of equipment (25.7)	8,563,000	8,354,000	(209,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	137,967,000	137,302,000	(665,000)
Supplies and materials (26.0)	16,509,000	16,259,000	(250,000)
Subtotal, Non-Pay Costs	160,251,000	159,289,000	(962,000)
Total, Administrative Costs	283,549,000	288,629,000	5,080,000

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

		Authorizir	Authorizing Legislation			
	PHS Act/ Other Citation	U.S. Code Citation	2009 Amount Authorized	FY 2009 Estimate	2010 Amount Authorized	FY 2010 PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
	Section 402(a)	42§281	Indefinite	\$3,015,689,000	Indefinite	\$3,050,356,000
National Heart, Lung, and Blood Institute						
Total, Budget Authority				3,015,689,000		3,050,356,000

Appropriations History

Fiscal	Budget Estimate	House	Senate	
Year	to Congress	Allowance	Allowance	Appropriation 1/
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	2,918,808,000	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			

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

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

Details of Full-Time Equivalent Employment (FTEs)

Details of Full-Time Equivalent Emp		,	
	E)/0000	EV/2000	E)/0040
	FY 2008	FY 2009	FY 2010
OFFICE/DIVISION	Actual	Estimate	Estimate
Office of the Director (OD)	146	147	147
Division of Blood Diseases and Resources (DBDR)	22	24	24
Division of Lung Diseases (DLD)	21	21	21
Division for the Application of Research Discoveries (DARD		28	28
Division of Intramural Research (DIR)	413	413	422
Division of Cardiovascular Diseases (DCVD)	60	62	68
Division of Prevention and Population Sciences (DPPS)	41	43	43
Division of Extramural Research Activities (DERA)	115	117	119
Total	846	855	872
Includes FTEs which are reimbursed from the NIH Roadmap			5.2
The state of the s	.554.64.1	.55541011	
FTEs supported by funds from Cooperative Research and			
Development Agreements	(0)	(0)	(0)
,	()		()
FISCAL YEAR	Avera	age GM/GS (Grade
2022		40.0	
2006		13.0	
2007		12.1	
2008		12.4	
2009		12.4	
2010		12.4	

Detail of Positions

	E)/0000	E\/.0000	E)/0040
00405	FY 2008	FY 2009	FY 2010
GRADE	Actual	Estimate	Estimate
Total, ES Positions	172 200	172 200	172 200
Total, ES Salary	172,200	172,200	172,200
GM/GS-15	98	102	111
GM/GS-14 GM/GS-13	124	124	124
	150	152	155
GS-12	92	95	100
GS-11 GS-10	44	44	44
GS-10 GS-9	2	2	2
GS-8	50 31	50 31	50 31
GS-7	12	12	12
GS-6	5	5	5
GS-5	3	3	3
GS-4	3	3	3
GS-3	2	2	2
GS-2	0	0	0
GS-1	Ö	0	0
Subtotal	616	625	642
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	2	2	2
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	9	9	9
Ungraded	258	258	258
Total permanent positions	626	635	652
Total positions, end of year	884	893	910
Total full-time equivalent (FTE)			
employment, end of year	846	855	872
Average ES salary	172,200	172,200	172,200
Average GM/GS grade	12.4	12.4	12.4
Average GM/GS salary	95,521	100,235	102,558

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

New Positions Requested

	FY 2010		
	Grade	Number	Annual Salary
Medical Officer Health Science Administrator Nurse Practicioner Nurse Practicioner Program Analyst	15 13 12 13 12	2 1 1	\$139,680 \$100,488 \$84,502 \$100,488 \$84,502
Total Requested		17	