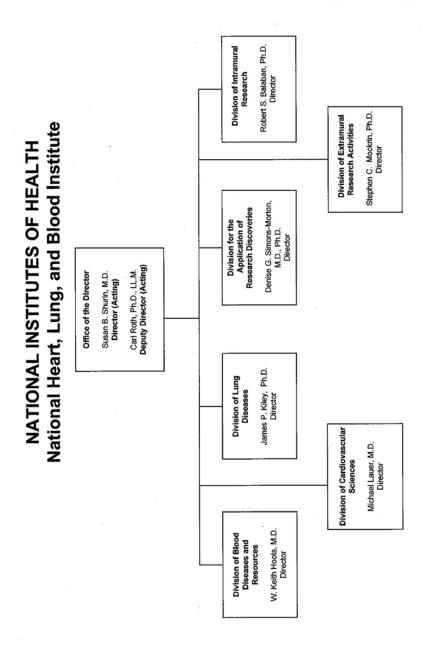
## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 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 PHS Act with respect to cardiovascular, lung, and blood diseases and blood products, [\$3,084,851,000] \$3,076,067,000. (Department of Health and Human Services Appropriations Act, 2012.)

# Amounts Available for Obligation <sup>1</sup>

Source of Funding	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Appropriation	3,096,916	3,084,851	3,076,067
Type 1 Diabetes	0	0	0
Rescission	(27,193)	(5,830)	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	3,069,723	3,079,021	3,076,067
Real transfer under Secretary's transfer authority	0	(877)	0
Comparative Transfers for NCATS reorganization	692	0	0
Comparative Transfers to NCATS for Therapeutics and Rare and Neglected Diseases (TRND)	(2,527)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(2,634)	(2,786)	0
Subtotal, adjusted budget authority	3,065,254	3,075,358	3,076,067
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	3,065,254	3,075,358	3,076,067
Unobligated balance lapsing	0	0	0
Total obligations	3,065,254	3,075,358	3,076,067

<sup>&</sup>lt;sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2011 - \$22,900 FY 2012 - \$24,999 FY 2013 - \$24,998

## Budget Mechanism - Total 1/

		2011		2012	FY 2013			
MECHANISM		ctual		acted		PB	Change v	s. FY 2012
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects								
Noncompeting	2,903	\$1,542,086	2,814	\$1,622,536	2,632	\$1,556,209	(182)	(\$66,327)
Administrative Supplements	118	16,925	100	6,000	100	5,500	0	(500)
Competing:								
Renewal	182	113,286	156	98,465	180	110,250	24	11,785
New	674	332,689	588	289,131	676	330,750	88	41,619
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	856	\$445,975	744	\$387,596	856	\$441,000	112	\$53,404
Subtotal, RPGs	3,759	\$2,004,986	3,558	\$2,016,132	3,488	\$2,002,709	(70)	(\$13,423)
SBIR/STTR	163	\$74,934	174	\$78,040	185	\$81,225	11	\$3,185
Research Project Grants	3,922	\$2,079,920	3,732	\$2,094,172	3,673	\$2,083,934	(59)	(\$10,238)
Research Centers								
Specialized/Comprehensive	60	\$55,175	45	\$60,000	34	\$64,000	(11)	\$4,000
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	1,448	0	1,449	0	1,000	0	(449)
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	60	\$56,623	45	\$61,449	34	\$65,000	(11)	\$3,551
Other Research								
Research Careers	570	\$79,090	575	\$80,000	582	\$81,000	7	\$1,000
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	50	44,705	69	49,500	60	49,500	(9)	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	13	2,883	13	2,900	13	2,900	0	0
Other	115	26,095	115	23,500	100	20,000	(15)	(3,500)
Other Research	748	\$152,773	772	\$155,900	755	\$153,400	(17)	(\$2,500)
Total Research Grants	4,730	\$2,289,316	4,549	\$2,311,521	4,462	\$2,302,334	(87)	(\$9,187)
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Research Training	FTTPs		FTTPs		FTTPs			
Individual Awards	246	\$10,627	238	\$10,500	232	\$10,500	(6)	\$0
Institutional Awards	1,780	87,371	1,737	86,000	1,703	86,000	(34)	0
Total Research Training	2,026	\$97,998	1,975	\$96,500	1,935	\$96,500	(40)	\$0
				-		·		
Research & Development Contracts	177	\$363,130	169	\$353,637	165	\$363,033	(4)	\$9,396
SBIR/STTR	5	\$2,498	6	\$4,500	5	\$3,500	(1)	\$1,000
	<u>FTEs</u>		FTEs		<u>FTEs</u>		<u>FTEs</u>	
Intramural Research	478	\$192,083	478	\$191,840	473	\$192,590	(5)	\$750
Research Management and Support	439	122,727	439	121,860	435	121,610	(4)	(250)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHLBI	917	\$3,065,254	917	\$3,075,358	908	\$3,076,067	(9)	\$709

 $<sup>1/\,\</sup>mbox{All}$  items in italics are "non-adds"; items in parenthesis are subtractions.

#### Major Changes in the Fiscal Year 2013 President's 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 2013 budget request for NHLBI, which is \$709 thousand more than the FY 2012 level, for a total of \$3,076.067 million.

Research Project Grants (RPGs; -\$10.238 million; total \$2,083.934 million): NHLBI will continue to fund competing RPGs-856 awards in FY 2013, an increase of 112 from FY 2012. The average cost is a 1.0 percent decrease from FY 2012. About 2,632 noncompeting RPG awards, totaling to \$1,556.209 million, will be made in FY 2013. NIH budget policy for RPGs in FY 2013 discontinues inflationary allowances and reduces the average cost of noncompeting and competing RPGs by one percent below the FY 2012 level. New investigators are supported at success rates equal to those of established investigators submitting R01s.

<u>Research Training (\$0 change; total \$96.500 million)</u>: Stipends are provided a 2.0 percent increase. The number of FTTPs are reduced by 40 from the FY 2012 level of 1,975.

Recipient Epidemiology and Donor Evaluation Study-III (REDS-III, +\$59.268 million): The objective of this program is to assure safe and effective blood banking and transfusion medicine practices through basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks. This research is not only important to public health in the U.S., but also to countries struggling with the HIV epidemic where blood safety and availability are major concerns. The global focus will be on donors with new infections while the U.S. focus will be on recipients.

<u>CoronaryArtery Risk Development in Young Adults (CARDIA, +\$4.322 million)</u>: This is a renewal of the original study that examined the evolution of cardiovascular disease risk factors and early clinical events in a cohort of black and white young adults, aged 18-30 years.

Trial of Aldosterone Antagonists Therapy in Adults With Preserved Ejection Fraction

Congestive Heart Failure (TOPCAT, +\$2.765 million): The purpose of this international,
randomized trial is to evaluate the effectiveness of spironolactone, a generic and inexpensive
drug, to reduce cardiovascular mortality and heart failure in patients who have heart failure with
preserved systolic function.

Maximizing the Scientific Value of the NHLBI Biologic Specimen Repository (+\$1.250 million): The objective of this new initiative is to provide investigators with the resources (i.e. funding, biospecimens and associated data), to conduct exploratory research in heart, lung, and blood diseases, and blood resources.

<u>Long-Term Oxygen Treatment Trial (LOTT, +\$1.053 million)</u>: The purpose of this program is to determine the effectiveness and safety of long-term oxygen therapy in patients with Chronic Obstructive Pulmonary Disease.

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

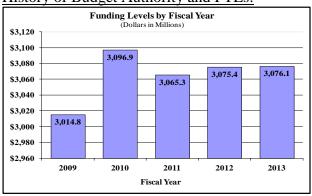
FY 2012 Enacted				\$3,075,358
FY 2013 President's Budget				\$3,076,067
Net change				\$709
	2	2013		
	Preside	nt's Budget	Change fro	om FY 2012
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January				
2012 pay increase & benefits		\$72,956		\$2
b. January FY 2013 pay increase & benefits		72,956		221
c. One more day of pay		72,956		281
d. Annualization of PY net hires		72,956		0
e. Payment for centrally furnished services		30,829		0
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		88,805		0
Subtotal				\$504
2. Research Management and Support:				
a. Annualization of January				
2012 pay increase & benefits		\$63,721		\$1
b. January FY 2013 pay increase & benefits		63,721		192
c. One more day of pay		63,721		245
d. Annualization of PY net hires		63,721		0
e. Payment for centrally furnished services		17,196		0
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		40,693		0
Subtotal				\$438
Subtotal, Built-in				\$942

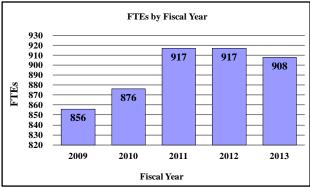
## **Summary of Changes--continued**

		2013		
	Presi	dent's Budget	Change	from FY 2012
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	2,632	\$1,561,709	(182)	(\$66,827)
b. Competing	856	441,000	112	53,404
c. SBIR/STTR	185	81,225	11	3,185
Total	3,673	\$2,083,934	(59)	(\$10,238)
2. Research Centers	34	\$65,000	(11)	\$3,551
3. Other Research	755	153,400	(17)	(2,500)
4. Research Training	1,935	96,500	(40)	0
5. Research and development contracts	165	363,033	(4)	9,396
Subtotal, Extramural		\$2,761,867		\$209
	<u>FTEs</u>		FTEs	
6. Intramural Research	473	\$192,590	(5)	\$246
7. Research Management and Support	435	121,610	(4)	(688)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	908	\$3,076,067	(9)	(\$233)
Total changes				\$709

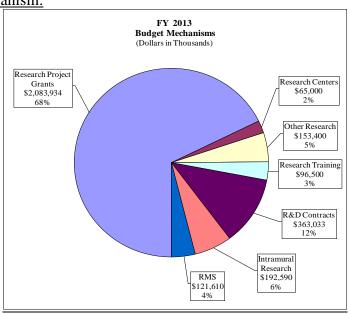
## Fiscal Year 2013 Budget Graphs

History of Budget Authority and FTEs:

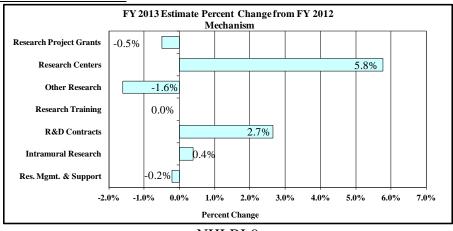




Distribution by Mechanism:



Change by Selected Mechanism:



NHLBI-9

### NATIONAL INSTITUTES OF HEALTH

#### National Heart, Lung, and Blood Institute Budget Authority by Activity

Extramural Research Detail	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Heart and Vascular Diseases		\$1.733,477		\$1,740,474		\$1,740,606		132
Lung Diseases		634,418		637,049		637,097		48
Blood Diseases and Resources		382,549	384,135			384,164		29
Subtotal, Extramural		\$2,750,444		\$2,761,568		\$2,761,867		\$209
Intramural Research	478	\$192,083	478	\$191,840	473	\$192,590	(5)	\$750
Research Management & Support	439	\$122,727	439	\$121,860	435	\$121,610	(4)	(\$250)
TOTAL:	917	\$3,065,254	917	\$3,075,358	908	\$3,076,067	(9)	\$709

<sup>1.</sup> Includes FTEs which are reimbursed from the NIH Common Fund.

<sup>2.</sup> Includes Real Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

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

Authorizing Legislation

	PHS Act U.S. Code 2012 Amount Other Citation Citation Authorized	U.S. Code Citation	U.S. Code 2012 Amount Citation Authorized	FY 2012 Enacted	2013 Amount Authorized	FY 2013 PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Heart, Lung, and Blood Institute	Section 401(a)	42§281	Indefinite	<b>\$3,075,358,000</b>	Indefinite	- \$3,076,067,000
Total Budget Authority				\$3.075.358.000		83 076 067 000

## **Appropriations History**

Fiscal	Budget Estimate to			
Year	Congress	House Allowance	Senate Allowance	Appropriation
2004	\$2,867,995,000	\$2,867,995,000	\$2,897,595,000	\$2,897,145,000
Rescission				(\$18,454,000)
2005	Φ2 0 < 2 0 52 000	Φ2 0 < 2 0 52 000	Φ2 007 000 000	Φ2 0.65 452 000
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
2000	Ф2 004 241 000	Φ2.0 <i>CE</i> 775.000	Ф2 002 107 000	Ф2 074 000 000
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
Resension				ΨΟ
2010	\$3,050,356,000	\$3,123,403,000	\$3,066,827,000	\$3,096,916,000
Rescission				\$0
2011	\$3,187,516,000		\$3,182,524,000	\$3,096,916,000
Rescission				(\$27,192,768)
2012	\$3,147,992,000	\$3,147,992,000	\$3,036,189,000	\$3,084,851,000
Rescission	\$5,117,55 <b>2</b> ,000	φυ,117,22 <u>2,000</u>	\$5,050,105,000	(\$5,830,368)
Rescission				(\$3,630,308)
2013	\$3,076,067,000			

#### **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 2013		
	FY 2011	FY 2012	President's	FY 2013 +/	
	Actual	Enacted	Budget	- FY 2012	
BA	\$3,065,254,000	\$3,075,358,000	\$3,076,067,000	+\$709,000	
FTE	917	917	908	- 9	

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 <u>Shaping</u> <u>the Future of Research: A Strategic Plan</u>, the NHLBI supports a robust, collaborative research enterprise, in partnership with private and public organizations, that includes training and career development of new investigators.

The following material describes three areas of extraordinary opportunity, enhanced efforts to engage small businesses in the research enterprise, and clinical trials.

#### Areas of Opportunity

**Functional Genomics.** For the past several years, the Institute has supported large genome-wide studies of over 100,000 participants in multiple well-phenotyped cohorts such as the Framingham Heart Study and the Jackson Heart Study. This research has yielded unprecedented data not only about the relationship of genetic variations to disease outcomes and responses to treatment, but also about the effects of particular genetic variants on processes occurring at the molecular level. The logical and vitally important next step is to understand how the molecular concomitants of a particular genetic variant are related to health and disease in patients.

**Induced Pluripotent Stem Cells.** As a result of past investments in understanding stem cell biology, scientists are now able to create stem cells by reprogramming mature adult cells from various tissues. Because these so-called induced pluripotent stem cells can be used to generate a wide range of mature cells types from a specific individual and can be produced in large quantities, they represent a powerful new tool for basic and translational research. They are expected to prove particularly useful for research on genetic disorders, for patient-specific research, and for high-throughput screens to identify drugs that are safe and effective in a particular cell type.

Emerging Technologies. Although NIH-supported investigators continue to generate extraordinary new insights into health and disease, all too often promising discoveries are not effectively translated into therapies that benefit patients. New approaches are needed to identify emerging drugs, devices, and diagnostics in addition to facilitating their evolution in a manner consistent with business case development and regulatory requirements toward the ultimate commercialization of products that improve patient care and advance public health. The Institute plays a vital role in moving promising NHLBI-funded technologies closer to marketability by supporting feasibility, prototype-development, and proof-of-concept studies, and providing researchers with access to expertise in areas required for early-stage technology development.

#### **Small-Business Activities**

The new emphasis on early-stage development of emerging technologies complements intensified efforts already under way to make the most of the NHLBI investment in the Small Business Innovation Research (SBIR) program, which constitutes 2.5 percent of the extramural budget. Plans are being developed to direct SBIR investments to specific discoveries and technologies that not only promise to address a health need but also have an identifiable potential market. One of the targeted approaches that NHLBI will use is an SBIR technology transfer model, pioneered by the National Institute of Standards and Technology that would enable small businesses to leverage the expertise of the Institute's intramural research program. For example, the Institute is currently soliciting contract proposals from small businesses to develop a catheter-delivered treatment of mitral valve dysfunction based on an invention by an intramural investigator. The Institute is also initiating a program to bridge the funding gap that often exists between the end of an SBIR Phase II award and the next round of financing needed to advance a promising technology toward commercialization.

#### Clinical Trials

While basic and translational research efforts are essential for development of new therapeutic approaches, the Institute has never lost sight of the importance of the final step in the process—rigorous trials to evaluate an intervention's actual value to patients. NHLBI continues to make a substantial investment in clinical trials—the gold standard for evidence on which to base treatment decisions. Whenever the Institute undertakes a clinical trial of a drug or procedure, it does so to test the hypothesis that the new approach may be better (more effective or less toxic) than the current standard of practice or that value of the current standard will be validated. Trials that demonstrate the lack of benefit of promising therapies are of great value to the public, physicians, and payers because they provide evidence which spares patients from undergoing treatments that may be ineffective, harmful, inconvenient, uncomfortable, and costly. A recent example is a large trial that tested the effects of high-dose niacin—a treatment to raise HDL ("good") cholesterol—on cardiovascular disease risk. Despite what was considered to be compelling evidence that raising HDL cholesterol with high dose niacin would reduce risk of heart attacks, strokes, and other cardiovascular events, the trial showed no benefit to patients whose LDL (bad) cholesterol was already in the optimal range.

#### **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 FY 2011, the NHLBI funded a renewal of the Pediatric Heart Network, a follow-up study of the Action to Control Cardiovascular Risk in Diabetes (ACCORD) clinical trial, and a program to develop new strategies for growing three-dimensional tissues. In FY 2012, the Institute plans a new initiative titled Basic Research on Calcific Aortic Valve Disease, a renewal of the Cardiovascular Cell Therapy Research Network, and the second phase of its Cardiac Translational Research Implementation Program (C-TRIP).

<u>Budget Policy</u>: The FY 2013 President's Budget request for the Heart and Vascular Diseases program is \$1,740.606 million, an increase of \$0.132 million or 0.01 percent over the FY 2012 Enacted level. During FY 2013 the program plans to support an initiative with the long-term goal of fostering sustainable interventions and scientific research that will lead to reduced CVD morbidity and mortality in high-risk rural populations. In addition, the program will continue support of the *Hispanic Community Health Study – Study of Latinos* to further investigate the apparent paradox of high socioeconomic adversity, substantial cardiovascular and pulmonary disease (CVPD) risk, and low CVPD prevalence and mortality in Hispanics.

#### **Program Portrait: Cardiothoracic Surgical Trials Network**

FY 2012 Level: \$ 0 million FY 2013 Level: \$12.144 million Difference: \$12.144 million

Cardiothoracic surgery is an important therapeutic tool in addressing many of the most prevalent cardiovascular conditions, including coronary heart disease, congestive heart failure, and valvular disease. Over the years, coronary artery bypass grafting, cardiac valve repairs, ventricular assist devices, and arrhythmia surgery have extended survival and improved the quality of life for many patients. Today, however, the acceleration of innovation in surgical practice—including the use of new technologies and the extension of surgical approaches to older, sicker patients—has outpaced the development of an evidence base to establish improved outcomes. In 2007 NHLBI, in collaboration with NINDS and the Canadian Institute for Health Research, launched the Cardiothoracic Surgical Trials Network to facilitate rigorous scientific evaluation of newer surgical techniques, devices, and pharmaceutical and bioengineered products for cardiovascular disease. The goal is to provide a strong evidence base to inform surgical practice and thereby ensure that the public has access to the most effective procedures determined by careful assessment. Since its inception, the Network has addressed a variety of clinical issues including mitral valve regurgitation, atrial fibrillation, and post-surgical infections. In light of current successes and continuing needs, NHLBI plans to renew the Network for a seven-year period beginning in FY 2012.

Lung Diseases: The Lung Diseases 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 FY 2011, the NHLBI funded research to explore common pathogenetic mechanisms of lung cancer and COPD, renewed the Severe Asthma Research Program, and launched the first stage of Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases (CADET). In FY 2012, the Institute plans to establish the Integrative Genomics Resource Consortium for Lung Diseases and the Genomic Research in Alpha-1 Antitrypsin Deficiency and Sarcoidosis (GRADS) program.

<u>Budget Policy</u>: The FY 2013 President's Budget request for the Lung Diseases program is \$637.097 million, an increase of \$.048 million or 0.01 percent from the FY 2012 Enacted level. The program plans for FY 2013 include support for an initiative to integrative genomics studies for discovery of molecular determinants and biomarkers that will improve diagnosis and treatment of lung diseases. Pulmonary research has been hampered by the complexity of the lung pathobiology.

Program Portrait: Consortium of Lung Repair and Regeneration: Building the Foundation

FY 2012 Level: \$5.000 million FY 2013 Level: \$5.000 million Difference: \$0 million

Exposure of the lung to potentially injurious insults can often lead to irreversible remodeling and dysfunction. Mechanisms by which the lung could repair or regenerate itself after such exposures are being explored in a variety of models, but this area of research continues to be complex and challenging. Moreover, while the search for regenerative strategies applicable to other organ-system disorders (e.g., neurodegenerative, cardiac, and hematologic diseases; trauma to skin and bones) has progressed, the resultant knowledge has not been leveraged to expand understanding of lung regeneration. A new initiative in FY 2012—Consortium of Lung Repair and Regeneration—will seek to apply innovative technologies that are being used to investigate regeneration and repair in organ systems outside of the lung to advance lung regenerative medicine. Concurrently, it will build on knowledge derived from research in lung molecular embryology and developmental biology, acute and chronic lung injury, pathobiology of pulmonary fibrosis and other lung diseases, and lung progenitor-cell biology. The intent is to create partnerships among investigators from each of these research domains with scientists studying regeneration of other organs and bioengineers. It is hoped that this initiative will catalyze development of a highly interactive and synergistic consortium of investigators who will share ideas, data, and resources to move the field of lung regeneration forward toward the development of new therapies for human diseases. Plans are to support up to six research centers and an administrative coordinating center responsible for generating, validating, and sharing reagents, protocols, technologies, and other resources that would be beyond the scope of any single center's research effort.

**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 FY 2011, the NHLBI renewed the Blood and Marrow Transplant Clinical Trials Network, funded new planning grants for pivotal clinical trials in hemoglobinopathies, and established Programs of Excellence in Glycosciences. In FY 2012, the Institute plans to fund Translational Research Centers in Thrombotic and Hemostatic Disorders and Clinical Trials Planning Studies for Rare Thrombotic and Hemostatic Disorders, and to establish a Clinical Trials Development Resource for Hematologic Disorders.

<u>Budget Policy</u>: The FY 2013 President's Budget request for the Blood Diseases and Resources program is \$384.164 million, an increase of \$0.029 million or 0.01 percent from the FY 2012 Enacted level. The program plans for FY 2013 include continued support of the collection of research-grade clinical outcomes data from patients receiving hematopoietic stem cell transplants (HCT); providing investigators access to a contemporary outcomes database; and promoting research within the mission of NHLBI using these data.

#### Program Portrait: Excellence in Hemoglobinopathy Research Awards (EHRA)

FY 2012 Level: \$ 0 million FY 2013 Level: \$14.000 million Difference: \$14.000 million

Hemoglobinopathies—sickle cell disease and the thalassemias—constitute significant public health problems worldwide and have been a longstanding focus of NHLBI-supported research. In 2008, the Institute embarked on a major realignment of its portfolio in sickle cell disease and other hemoglobinopathies with the goal of identifying and using more effective approaches to address high-priority areas of basic, translational, and clinical research. The Excellence in Hemoglobinopathy Research Award, to be launched in FY 2013, is the next major phase of this ongoing process. The initiative is designed to accelerate multidisciplinary basic and translational research in hemoglobinopathies and facilitate collaboration among basic and translational scientists and clinical hematologists. Specifically, the hope is to create new scientific partnerships among scientists outside of the traditional areas of hematology and to engage clinician-investigators in hypothesisdirected basic and early translational studies that may lead to future interventional strategies. High-priority areas for translational and clinical research include pain pathophysiology and management, fetal hemoglobin induction, major interventional trials of promising alternatives to hydroxyurea, antioxidant and anti-adhesion therapies, curative therapies, and prediction, prevention, and management of severe disease manifestations and end-organ damage. The initiative is expected to support 10 research centers, and will encourage formation of "virtual centers" comprising components that may be in different locations, thereby facilitating collaborations unconstrained by geographic boundaries.

**Intramural Research**: The Intramural Research program conducts basic, translational, and clinical research in heart, vascular, lung, blood, and kidney diseases. It is committed to developing novel approaches and advanced biomedical technologies related to cardiovascular, pulmonary, and blood diseases. Studies in the intramural program range from the fundamental biology examining the structures and interactions of proteins and motility/energetics of cells to the clinical diagnosis and treatment of a wide range of diseases. The intramural program has established many interdisciplinary collaborative efforts to tackle difficult scientific questions that

are not easily addressed by a single researcher in order to stimulate innovation and advance research progress. The program comprises six centers (Biochemistry and Biophysics, Cell Biology and Physiology, Genetics and Developmental Biology, Systems Biology, Molecular Medicine, and Immunology), two branches (Hematology, Cardiovascular-Pulmonary Branch), the Cardiothoracic Surgery Research Program, as well as two trans-NIH programs (the Center for Human Immunology and the Imaging Probe Development Center), which are administered and staffed by NHBLI for the benefit of the entire NIH campus. They provide unique systems medicine approaches to clinical immunology and infrastructure and expertise to develop novel imaging probes, respectively. An adult interventional heart program at Suburban Hospital is now in its sixth year. A Pediatric Imaging MRI program has been launched in partnership with the Children's National Medical Center in Washington D.C. In FY 2012 a major intramural initiative will be to reengineer the clinical research program.

<u>Budget Policy</u>: The FY 2013 President's Budget request for the Intramural Research program is \$192.590 million, an increase of \$0.750 million or 0.39 percent from the FY 2012 Enacted level. Increases for salaries and related costs are covered in the budget request.

Research Management and Support: In FY 2011, the Office of Communications updated NHLBI Web-based health topics and used a variety of media to communicate health information to the public and other audiences. The Division for the Application of Research Discoveries supported development of guidelines on cardiovascular risk reduction for adults and for children and adolescents. Plans for FY 2012 are to establish a National Program to Reduce Cardiovascular Risk, release guidelines for sickle cell disease and implement them via a National Blood Disorders Program, and launch a health education initiative for sickle cell disease patients and families. NHLBI continues its public health campaigns on childhood obesity (We Can!), heart disease in women (The Heart Truth), and chronic obstructive pulmonary disease (Learn More, Breathe Better).

<u>Budget Policy</u>: The FY 2013 President's Budget request for Research Management and Support is \$121.610 million, a decrease of \$0.250 million or 0.21 percent from the FY 2012 Enacted level. Increases for salaries and related costs are covered in the budget request.

# Budget Authority by Object (Dollars in Thousands)

	FY 2012	FY 2013	Increase or
	Enacted	PB	Decrease
Total compensable workyears:			
Full-time employment	917	908	(9)
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary (in dollars)	\$165,382	\$165,382	\$0
Average GM/GS grade	12.5	12.5	0.0
Average GM/GS salary (in dollars)	\$102,464	\$102,464	\$0
Average salary, grade established by act of			
July 1, 1944 (42 U.S.C. 207) (in dollars)	\$99,221	\$99,221	\$0
Average salary of ungraded positions (in dollars)	120,995	120,995	0
	EN/ 2012	ES/ 2012	T
OBJECT CLASSES	FY 2012 Enacted	FY 2013 PB	Increase or
Personnel Compensation:	Ellacteu	FD	Decrease
11.1 Full-time permanent	\$61,612	\$61,650	\$38
11.3 Other than full-time permanent	34,125	34,122	(3)
11.5 Other personnel compensation	3,827	3,829	2
11.7 Military personnel	711	722	11
11.8 Special personnel services payments	7,868	7,865	(3)
Total, Personnel Compensation	\$108,143	\$108,188	\$45
12.0 Personnel benefits	\$28,553	\$28,456	(\$97)
12.2 Military personnel benefits	450	449	(1)
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$137,146	\$137,093	(\$53)
21.0 Travel and transportation of persons	\$3,456	\$2,765	(\$691)
22.0 Transportation of things	269	269	0
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	0	0	0
23.3 Communications, utilities and			
miscellaneous charges	1,090	1,090	0
24.0 Printing and reproduction	195	156	(39)
25.1 Consulting services	678	682	4
25.2 Other services	53,485	54,152	667
25.3 Purchase of goods and services from			
government accounts	306,523	324,795	18,272
25.4 Operation and maintenance of facilities	810	810	0
25.5 Research and development contracts	133,125	125,577	(7,548)
25.6 Medical care	2,044	2,024	(20)
25.7 Operation and maintenance of equipment 25.8 Subsistence and support of persons	4,595 0	4,549 0	(46) 0
25.8 Subsistence and support of persons 25.0 Subtotal, Other Contractual Services	\$501,260	\$512,589	\$11,329
26.0 Supplies and materials	\$14,651	\$14,151	(\$500)
31.0 Equipment	9,270	9,120	(150)
32.0 Land and structures	9,270	9,120	(130)
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	2,408,021	2,398,834	(9,187)
42.0 Insurance claims and indemnities	0	0	0,107)
43.0 Interest and dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	\$2,938,212	\$2,938,974	\$762
Total Budget Authority by Object	\$3,075,358	\$3,076,067	\$709

Includes FTEs which are reimbursed from the NIH Common Fund.

# Salaries and Expenses (Dollars in Thousands)

	FY 2012	FY 2013	Increase or
OBJECT CLASSES	Enacted	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$61,612	\$61,650	\$38
Other than full-time permanent (11.3)	34,125	34,122	(3)
Other personnel compensation (11.5)	3,827	3,829	2
Military personnel (11.7)	711	722	11
Special personnel services payments (11.8)	7,868	7,865	(3)
<b>Total Personnel Compensation (11.9)</b>	\$108,143	\$108,188	\$45
Civilian personnel benefits (12.1)	\$28,553	\$28,456	(\$97)
Military personnel benefits (12.2)	450	449	(1)
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$137,146	\$137,093	(\$53)
Travel (21.0)	\$3,456	\$2,765	(\$691)
Transportation of things (22.0)	269	269	0
Rental payments to others (23.2)	0	0	0
Communications, utilities and			
miscellaneous charges (23.3)	1,090	1,090	0
Printing and reproduction (24.0)	195	156	(39)
Other Contractual Services:			
Advisory and assistance services (25.1)	678	682	4
Other services (25.2)	53,485	54,152	667
Purchases from government accounts (25.3)	231,049	228,188	(2,861)
Operation and maintenance of facilities (25.4)	810	810	0
Operation and maintenance of equipment (25.7)	4,595	4,549	(46)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$290,617	\$288,381	(\$2,236)
Supplies and materials (26.0)	\$14,522	\$14,022	(\$500)
Subtotal, Non-Pay Costs	\$310,149	\$306,683	(\$3,466)
Total, Administrative Costs	\$447,295	\$443,776	(\$3,519)

#### Details of Full-Time Equivalent Employment (FTEs)

		FY 2011		]	FY 2012			FY 2013	
		Actual			Enacted			PB	
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	128	1	129	128	1	129	128	1	129
Reimbursable:	120	0	0	0	0	0	0	0	0
Total:	128	1	129	128	1	129	128	1	129
Division of Blood and Resources									
Direct:	26	0	26	26	0	26	26	0	26
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	26	0	26	26	0	26	26	0	26
Division of Lung Diseases									
Direct:	28	0	28	28	0	28	28	0	28
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	28	0	28	28	0	28	28	0	28
Division for the Application of Research Discoveries									
Direct:	21	0	21	21	0	21	21	0	21
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	21	0	21	21	0	21	21	0	21
Division of Intramural Research									
Direct:	438	5	443	438	5	443	433	5	438
Reimbursable:	20	1	21	20	1	21	20	1	21
Total:	458	6	464	458	6	464	453	6	459
Division of Cardiovascular Sciences									
Direct:	124	1	125	124	1	125	122	1	123
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	124	1	125	124	1	125	122	1	123
Division of Extramural Research Activities									
Direct:	124	0	124	124	0	124	122	0	122
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	124	0	124	124	0	124	122	0	122
Total	909	8	917	909	8	917	900	8	908
Includes FTEs which are reimbursed from the NIH Common Fund.								· · · · · · · · · · · · · · · · · · ·	
FTEs supported by funds from Cooperative Research and									
Development Agreements	0	0	0	0	0	0	0	0	0
FISCAL YEAR				Ave	rage GS (	Grade			
2009					12.4				
2010					12.4				
2011					12.5				
2011					12.5				
2012					12.5				
2013	ı				14.5				

#### **Detail of Positions**

	FY 2011	FY 2012	FY 2013
GRADE	Actual	Enacted	PB
Total, ES Positions	1	1	1
Total, ES Salary	165,382	165,382	165,382
GM/GS-15	98	98	98
GM/GS-14	137	137	137
GM/GS-13	165	165	165
GS-12	90	90	86
GS-11	62	62	58
GS-10	2	2	2
GS-9	39	39	38
GS-8	22	22	22
GS-7	14	14	14
GS-6	9	9	9
GS-5	2	2	2
GS-4	2	2	2
GS-3	1	1	1
GS-2	0	0	0
GS-1	0		0
Subtotal	643	643	634
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	5	5	5
Director Grade	0	0	0
Senior Grade	0	0	0
Full Grade	2	2	2
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	8	8	8
Ungraded	0	0	0
Total permanent positions	651	651	642
Total positions, end of year	945	945	936
Total full-time equivalent (FTE)			
employment, end of year	917	917	908
Average ES salary	165,382	165,382	165,382
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	102,464	102,464	102,464

Includes FTEs which are reimbursed from the NIH Common Fund.