

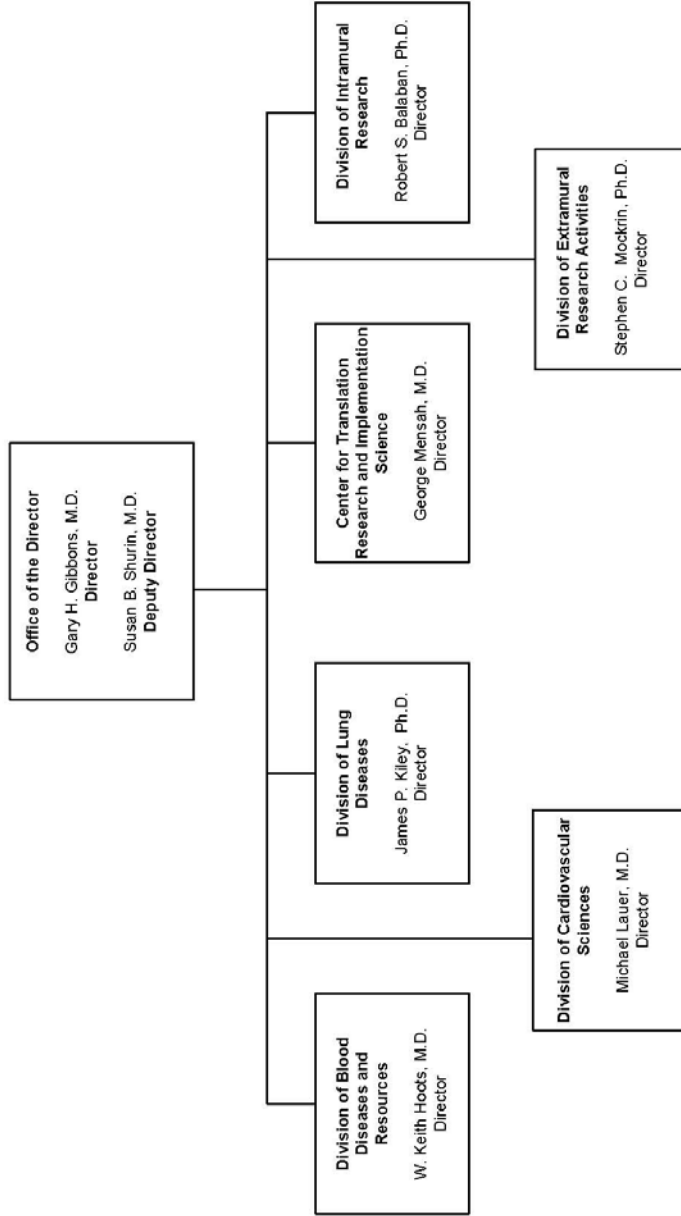
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**



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 and blood products,[\$2,988,605,000] \$2,987,685,000.

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

**Amounts Available for Obligation<sup>1</sup>**  
(Dollars in Thousands)

<b>Source of Funding</b>	<b>FY 2013 Actual</b>	<b>FY 2014 Enacted</b>	<b>FY 2015 President's Budget</b>
Appropriation	\$3,079,021	\$2,988,605	\$2,987,685
Type 1 Diabetes	0	0	0
Rescission	-6,158	0	0
Sequestration	-154,546	0	0
Subtotal, adjusted appropriation	\$2,918,317	\$2,988,605	\$2,987,685
FY 2013 Secretary's Transfer	-17,024	0	0
OAR HIV/AIDS Transfers	0	-1,756	0
Comparative transfers to NLM for NCBI and Public Access	-3,447	-4,112	0
National Children's Study Transfers	2,475	0	0
Subtotal, adjusted budget authority	\$2,900,321	\$2,982,737	\$2,987,685
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$2,900,321	\$2,982,737	\$2,987,685
Unobligated balance lapsing	0	0	0
Total obligations	\$2,900,321	\$2,982,737	\$2,987,685

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2013 - \$29,457    FY 2014 - \$30,112    FY 2015 - \$30,112

**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**  
**Budget Mechanism - Total<sup>1</sup>**

(Dollars in Thousands)

MECHANISM	FY 2013 Actual		FY 2014 Enacted <sup>2</sup>		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<b>Research Projects:</b>								
Noncompeting	2,663	\$1,477,673	2,586	\$1,435,494	2,601	\$1,453,164	15	\$17,670
Administrative Supplements	(87)	12,378	(70)	10,000	(70)	10,000	(0)	0
<b>Competing:</b>								
Renewal	176	106,375	221	129,159	214	126,694	-7	-2,465
New	558	287,309	651	349,118	611	339,083	-40	-10,035
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	734	\$393,684	872	\$478,277	825	\$465,777	-47	-\$12,500
Subtotal, RPGs	3,397	\$1,883,735	3,458	\$1,923,771	3,426	\$1,928,941	-32	\$5,170
SBIR/STTR	142	76,535	155	83,365	155	83,365	0	0
Research Project Grants	3,539	\$1,960,270	3,613	\$2,007,136	3,581	\$2,012,306	-32	\$5,170
<b>Research Centers:</b>								
Specialized/Comprehensive	26	\$54,638	26	\$57,139	26	\$57,139	0	\$0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	1	2,312	1	2,312	1	2,312	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	27	\$56,950	27	\$59,451	27	\$59,451	0	\$0
<b>Other Research:</b>								
Research Careers	522	\$77,064	534	\$79,068	534	\$79,068	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	68	51,140	70	52,799	70	52,799	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	8	2,960	11	3,037	11	3,037	0	0
Other	110	33,233	113	34,097	113	34,097	0	0
Other Research	708	\$164,397	728	\$169,001	728	\$169,001	0	\$0
Total Research Grants	4,274	\$2,181,617	4,368	\$2,235,588	4,336	\$2,240,758	-32	\$5,170
<b>Ruth L. Kirchstein Training Awards:</b>								
Individual Awards	209	\$9,508	212	\$9,822	212	\$10,018	0	\$196
Institutional Awards	1,543	80,957	1,563	83,605	1,563	85,277	0	1,672
Total Research Training	1,752	\$90,465	1,775	\$93,427	1,775	\$95,295	0	\$1,868
Research & Develop. Contracts (SBIR/STTR) (non-add)	207	\$323,907	213	\$333,063	213	\$337,175	0	\$4,112
	(9)	(3,682)	(12)	(10,416)	(12)	(10,416)	(0)	(0)
Intramural Research	469	184,909	469	190,271	469	191,571	0	1,300
Res. Management & Support	473	119,423	473	122,886	473	122,886	0	0
Res. Management & Support (SBIR Admin) (non-add)	(0)	(1,392)	(0)	(1,447)	(0)	(1,447)	(0)	(0)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHLBI	942	\$2,900,321	942	\$2,982,737	942	\$2,987,685	0	\$4,948

<sup>1</sup> All items in italics and brackets are non-add entries. FY 2013 and FY 2014 levels are shown on a comparable basis to FY 2015.

<sup>2</sup> The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

## **Major Changes in the Fiscal Year 2015 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 mechanisms and activity detail and these highlights will not sum to the total change for the FY 2015 budget request for NHLBI, which is \$4.9 million more than the FY 2014 Enacted level, for a total of \$2,987.7 million.

### NHLBI has recently established the Center for Translational Research and Implementation Science (CTRIS):

This realignment is to enhance our focus on implementation science and further bend the curve on health inequities that result from disproportionate burden of heart, lung, blood, and sleep diseases in specific communities.

### Research Project Grants (RPGs) (+\$5.170 million; total \$2,012.306 million):

NHLBI will fund 825 competing RPGs and approximately 2,601 noncompeting RPG awards totaling to \$1,928.941 million, in FY 2015.

### Research Training (+\$1.868 million; total \$95.295 million):

The Ruth L. Kirschstein NRSA budget reflects a stipend increase for entry level postdoctoral trainees and fellows at 2 percent over FY 2014 Enacted levels.

### Intramural Research (+\$1.300 million; total \$191.571 million):

NHLBI will support the research of our cardiovascular portfolio related to coronary vasculature and blood flow through the Intramural Program, which reflects an increase of 0.7 percent over FY 2014 Enacted levels.

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

**Summary of Changes<sup>1</sup>**

(Dollars in Thousands)

<b>FY 2014 Enacted</b>					\$2,982,737
<b>FY 2015 President's Budget</b>					\$2,987,685
<b>Net change</b>					\$4,948
	<b>FY 2015 President's Budget</b>		<b>Change from FY 2014</b>		
<b>CHANGES</b>	<b>FTEs</b>	<b>Budget Authority</b>	<b>FTEs</b>	<b>Budget Authority</b>	
A. Built-in:					
1. Intramural Research:					
a. Annualization of January 2014 pay increase & benefits		\$77,395		\$191	
b. January FY 2015 pay increase & benefits		77,395		269	
c. Zero more days of pay (n/a for 2015)		77,395		0	
d. Differences attributable to change in FTE		77,395		0	
e. Payment for centrally furnished services		30,027		502	
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		80,818		0	
Subtotal					\$962
2. Research Management and Support:					
a. Annualization of January 2014 pay increase & benefits		\$69,225		\$173	
b. January FY 2015 pay increase & benefits		69,225		246	
c. Zero more days of pay (n/a for 2015)		69,225		0	
d. Differences attributable to change in FTE		69,225		0	
e. Payment for centrally furnished services		3,272		55	
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		49,545		0	
Subtotal					\$473
Subtotal, Built-in					\$1,435

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

**Summary of Changes - Continued<sup>1</sup>**

(Dollars in Thousands)

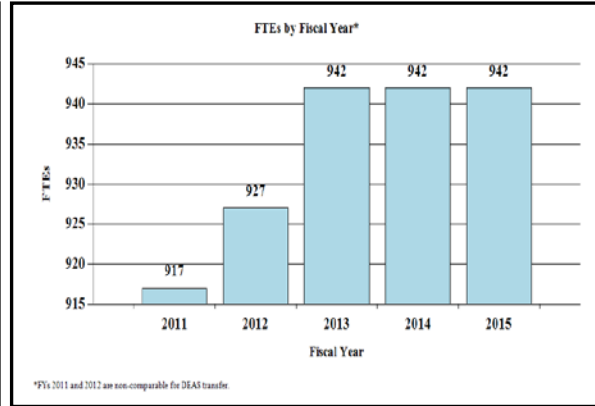
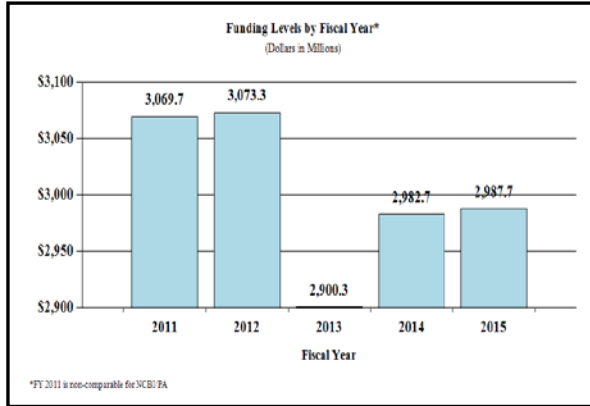
CHANGES	FY 2015 President's Budget		Change from FY 2014	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	2,601	\$1,463,164	15	\$17,670
b. Competing	825	465,777	-47	-12,500
c. SBIR/STTR	155	83,365	0	0
Subtotal, RPGs	3,581	\$2,012,306	-32	\$5,170
2. Research Centers	27	\$59,451	0	\$0
3. Other Research	728	169,001	0	0
4. Research Training	1,775	95,295	0	1,868
5. Research and development contracts	213	337,175	0	4,112
Subtotal, Extramural		\$2,673,228		\$11,150
6. Intramural Research	<u>FTEs</u> 469	\$191,571	<u>FTEs</u> 0	\$338
7. Research Management and Support	473	122,886	0	-473
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	942	\$2,987,685	0	\$11,015
Total changes				\$4,948

<sup>1</sup> The amounts in the Change from FY 2014 column take into account funding reallocations and, therefore, may not add to the net change reflected herein.

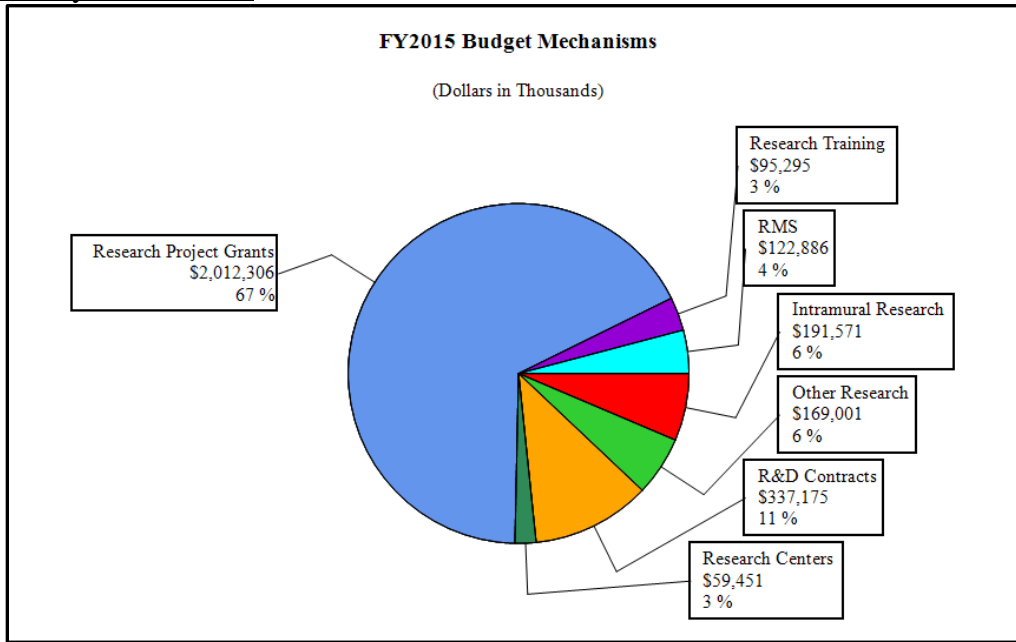


## Fiscal Year 2015 Budget Graphs

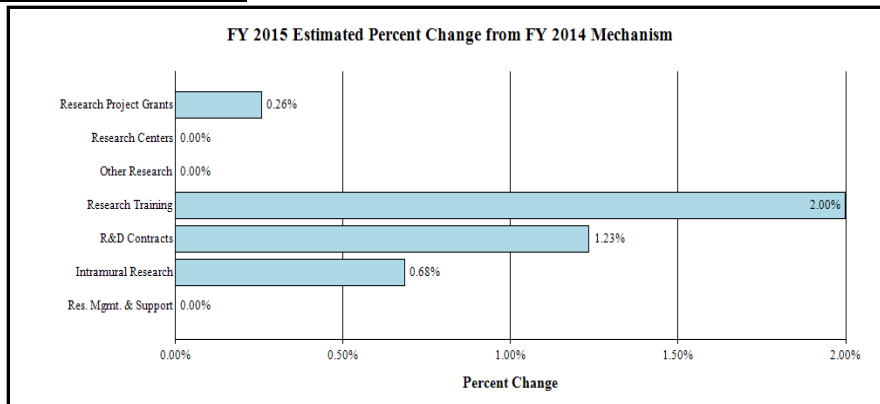
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



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

**Budget Authority by Activity<sup>1</sup>  
(Dollars in Thousands)**

	FY 2013 Actual		FY 2014 Enacted <sup>2</sup>		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<b><u>Extramural Research</u></b>								
<u>Detail</u>								
Heart and Vascular Diseases	0	1,604,246	0	1,645,820	0	1,654,728	0	8,908
Lung Diseases	0	596,297	0	610,744	0	612,169	0	1,425
Blood Diseases and Resources	0	395,446	0	405,514	0	406,331	0	817
<b>Subtotal, Extramural</b>		<b>\$2,595,989</b>		<b>\$2,662,078</b>		<b>\$2,673,228</b>		<b>\$11,150</b>
<b>Intramural Research</b>	<b>469</b>	<b>\$184,909</b>	<b>469</b>	<b>\$190,271</b>	<b>469</b>	<b>\$191,571</b>	<b>0</b>	<b>\$1,300</b>
<b>Research Management &amp; Support</b>	<b>473</b>	<b>\$119,423</b>	<b>473</b>	<b>\$122,886</b>	<b>473</b>	<b>\$122,886</b>	<b>0</b>	<b>\$0</b>
<b>TOTAL</b>	<b>942</b>	<b>\$2,900,321</b>	<b>942</b>	<b>\$2,982,737</b>	<b>942</b>	<b>\$2,987,685</b>	<b>0</b>	<b>\$4,948</b>

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

<sup>2</sup> The amounts in the FY 2014 column take into account funding reallocations and, therefore, may not add to the total budget authority reflected herein.

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

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2014 Amount Authorized</b>	<b>FY 2014 Enacted</b>	<b>2015 Amount Authorized</b>	<b>FY 2015 President's Budget</b>
Research and Investigation	Section 301	42§241	Indefinite	\$2,982,737,000	Indefinite	\$2,987,685,000
National Heart, Lung, and Blood Institute	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$2,982,737,000</b>		<b>\$2,987,685,000</b>

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

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2005 Rescission	\$2,963,953,000	\$2,963,953,000	\$2,985,900,000	\$2,965,453,000 (\$24,252,000)
2006 Rescission	\$2,951,270,000	\$2,951,270,000	\$3,023,381,000	\$2,951,270,000 (\$29,513,000)
2007 Rescission	\$2,918,808,000	\$2,901,012,000	\$2,924,299,000	\$2,918,808,000 \$0
2008 Rescission Supplemental	\$2,894,341,000	\$2,965,775,000	\$2,992,197,000	\$2,974,900,000 (\$51,972,000) \$15,542,000
2009 Rescission	\$2,924,942,000	\$3,025,500,000	\$3,006,344,000	\$3,015,689,000 \$0
2010 Rescission	\$3,050,356,000	\$3,123,403,000	\$3,066,827,000	\$3,096,916,000 \$0
2011 Rescission	\$3,187,516,000		\$3,182,524,000	\$3,096,916,000 (\$27,192,768)
2012 Rescission	\$3,147,992,000	\$3,147,992,000	\$3,036,189,000	\$3,084,851,000 (\$5,830,368)
2013 Rescission Sequestration	\$3,076,067,000		\$3,085,390,000	\$3,079,020,632 (\$6,158,041) (\$154,545,663)
2014 Rescission	\$3,098,508,000		\$3,077,916,000	\$2,988,605,000 \$0
2015	\$2,987,685,000			

## 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 (BA):

	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
BA	\$2,900,320,856	\$2,982,737,000	\$2,987,685,000	+\$4,948,000
FTE	942	942	942	+0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

### Director's Overview

#### Introduction

Over the past 50 years, research supported by the National Heart, Lung, and Blood Institute (NHLBI) has contributed to dramatic improvements in the longevity and quality of life for the citizens of this Nation. NHLBI's research portfolio addresses the most common, costly, and consequential diseases that affect both the health and wealth of the United States and the world. NHLBI supports a robust, collaborative research enterprise, in partnership with private and public organizations, to address scientific and educational needs nationally and globally. NHLBI's Fiscal Year (FY) 2015 budget will leverage the tremendous scientific breakthroughs and discoveries to conduct research that bends the curve on disease outcomes by translating discoveries into life-changing improvements in the prevention and treatment of heart, lung, blood, and sleep (HLBS) disorders. NHLBI's strategic approach focuses on four overarching themes: *Theme 1: Today's Basic Science for Tomorrow's Breakthroughs*; *Theme 2: Preventing and Pre-empting Chronic HLBS Disorders*; *Theme 3: Precision Medicine for Public Health Impact*; and *Theme 4: Turning Discovery into Health—Nurturing Talent and Innovation*.

#### **Theme 1: Today's Basic Science for Tomorrow's Breakthroughs**

*Diet, Gut Microbes, and Cardiovascular Disease.* NHLBI-funded studies have established a clear linkage between the dietary intake of certain foods (such as fruits and vegetables) and a lower risk of coronary heart disease (CHD). Recent studies by NHLBI-funded investigators indicate that the diet-CHD connection may be mediated by microbes that co-exist within our digestive tracts. This type of discovery is opening new opportunities to develop novel biological markers that link diet to CHD, as well as new therapeutic approaches involving dietary and/or novel drug interventions that have the potential to preempt the earliest stages of CHD.

*New Frontiers in Sickle Cell Disease (SCD) Research.* Recently, NHLBI-funded investigators have gained important new insights into the molecular switches that turn on the gamma-globin gene, a gene that inhibits the sickle cell shape change of red blood cells and ameliorates the clinical course of SCD. These exciting basic research findings open a new pathway for developing the next generation of therapeutic agents capable of preventing clinical complications

and enhancing the quality of life for patients with SCD. The NHLBI-funded Excellence in Hemoglobinopathies research program will serve as a platform for catalyzing translational science that continues to advance our knowledge about SCD to promote better patient outcomes.

### **Theme 2: Preventing and Pre-empting Chronic HLBS Disorders**

*Predictive Biomarkers to Prevent Chronic Disorders.* The NHLBI population-based cohort studies such as the Framingham Heart Study and the Women’s Health Initiative serve as discovery platforms for research to pre-empt chronic disease. Recently, the Chronic Kidney Disease Prognosis Consortium (CKD-PC) conducted a meta-analysis of 93,000 patients from different cohort studies and found that cystatin C, a biomarker of kidney function, led to better risk classification of chronic kidney disease than creatinine, a laboratory test routinely used by clinicians. The development of more refined prognostic tests combined with clinical trials of intervention strategies, such as the NHLBI-supported Systolic Blood Pressure Intervention Trial ([SPRINT](#)), hold promise for providing better care and better outcomes for patients in association with lower healthcare expenditures.

*Regenerative Medicine: Preventing Heart Failure.* A major healthcare challenge is to halt the symptomatic burden and disability of progressive heart failure, a leading cause of hospitalization and healthcare costs. NHLBI-supported investigators are exploring new ways to prevent the progression of heart failure by gaining insights into the intrinsic capacity of the heart to repair itself. The 2012 Nobel Laureate, Shinya Yamanaka, is part of a large inter-institutional team of NHLBI-funded investigators who are further characterizing how adult stem cells contribute to the repair and regeneration of the heart, lung and blood systems. Similarly, the Institute is supporting the Cardiovascular Cell Therapy Research Network that is systematically testing the safety and efficacy of adult stem cell-based therapies as a new strategy to prevent heart failure.

### **Theme 3: Precision Medicine for Public Health Impact**

*Precision Medicine for Lung Disease.* Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States. The clinical course of the disease is highly variable among patients, and the current clinical strategy of awaiting the onset of symptoms before the initiation of treatment may result in irreversible, debilitating lung pathology. The NHLBI-supported COPD Gene Study is using leading-edge imaging and biomarker technologies and genomic analyses to define the molecular underpinnings of COPD in a cohort of 10,000 subjects. These investigators have recently demonstrated that high-resolution computed tomography (CT) of the lung can facilitate the identification of certain lung pathologies well before the onset of symptoms and irreversible damage has occurred. Programs like these will lead to more accurate prognoses for patients and enable the development of more precisely targeted, personalized, and effective therapies to preempt chronic disease.

### **Theme 4: Turning Discovery into Health – Nurturing Talent and Innovation**

*Nurturing a Diverse, New Generation of Scientific Leaders.* Advancing innovation requires a continued investment in training a diverse next generation of researchers across various disciplines. The Institute’s Programs to Increase Diversity among Individuals Engaged in Health-Related Research (PRIDE) supports early-career development and independent research awards for early-stage investigators of diverse backgrounds who might not have considered research careers.

*Accelerating Innovation: From the Laboratory to the Marketplace of Patient Care.* A critical need exists for the NIH to serve the public interest by bridging the gap between discoveries generated by NIH-funded investigators and the effective transformation of these inventions into commercially viable products in the patient care marketplace. In FY 2015, NHLBI will launch three NIH Centers for Accelerated Innovations (NCAI) that are designed to facilitate public-private partnerships that catalyze the commercialization of innovative ideas by creating a collaborative knowledge-exchange environment composed of entrepreneurs, venture capitalists, and academic scientists.

### **Principles and Strategy**

NHLBI's enduring principles and strategic priorities include the following: valuing investigator-initiated fundamental discovery science; maintaining a balanced, cross-disciplinary portfolio in basic, translational, clinical, and population science; supporting implementation science and research that promotes the integration of research findings into clinical care and public health practice by training a diverse biomedical workforce; engaging the public and patient communities to establish research priorities; and developing an evidence-based research agenda to eliminate health inequities. In addressing current fiscal realities, NHLBI is focusing on aligning its strategic priorities with resource allocation, exploring different funding strategies to maximize efficiency and effectiveness, and reviewing past investments while planning for the future.

### **Summary**

NHLBI's FY 2015 budget request reflects two important fundamental principles: first, our commitment to our enduring principles promotes strategic research priorities that capitalize on scientific opportunities while advancing the richness of experimental ideas and the talent of investigators; and second, our commitment to good stewardship of the public's trust by focusing our efforts on aligning our strategic priorities with resource allocation, program effectiveness and prudent planning to address important public health challenges.

## **Program Descriptions and Accomplishments**

**Cardiovascular Diseases:** This program supports research on the causes, diagnosis, treatment, and prevention of heart and vascular diseases, including atherothrombosis, coronary artery disease, myocardial infarction and ischemia, heart failure, arrhythmia, sudden cardiac death, congenital heart disease in adults and children, cardiovascular disease (CVD) 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. Additionally, NHLBI continues to support a number of large clinical trials, many of which directly address questions of great concern to patients, practitioners, and policy makers.

These investments have led to important discoveries. In FY 2013, NHLBI's Pediatric Cardiac Genomics Consortium published findings that patients with mutations of genes expressed early in cardiac development were 7.5 times more likely to develop congenital heart disease. Many of these genes modify the protein bound to DNA, thereby expanding our understanding of the basic biology of the normal development of the heart and the underpinnings of congenital heart

disease. NHLBI-supported researchers at the Cleveland Clinic published findings suggesting that metabolism of L-carnitine—a substance found in red meat—by gut bacteria may contribute to the development of heart disease. Results from this study will improve our understanding of how diet interacts with other environmental factors to affect the risk of individuals and populations for development of heart disease. The results of the Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease ([FREEDOM](#)) trial—a randomized trial comparing surgery to percutaneous coronary intervention with drug-eluting stents in patients with diabetes and multi-vessel coronary artery disease who were also receiving intensive medical therapy—found that patients who had surgery showed better outcomes after four years of follow-up. This finding has major implications to improve patient outcomes as well as health care delivery and financing.

#### Budget Policy:

The FY 2015 budget estimate for the Heart and Vascular Diseases program is \$1,654.728 million, an increase of \$8.908 million or 0.5 percent over the FY 2014 Enacted level. In FY 2015, NHLBI will continue to support three high-profile trials:

- 1) PROspective Multicenter Imaging Study for Evaluation of Chest Pain ([PROMISE](#)), a trial comparing computerized tomography angiography to standard stress testing for improving outcomes in patients with suspected coronary disease;
- 2) VITamin D and OmegaA-3 Trial ([VITAL](#)), a trial testing the ability of high-dose Vitamin D and/or omega-3 fatty acids for prevention of CVD and cancer; and the
- 3) Systolic Blood Pressure Intervention Trial ([SPRINT](#)), which compares standard versus lower blood pressure treatment targets in patients with systolic hypertension.

Results from all three trials will provide evidence to guide patients, doctors, and policy makers in optimal disease prevention and management.

The ‘digital age’ in biomedicine combined with advances in genomics, imaging technologies, and computational biology promises to revolutionize population-based epidemiology research and ultimately patient care. Seizing new opportunities in ‘big data’, NHLBI has supported research in networks and health systems such as Kaiser-Permanente that recently demonstrated the utility of leveraging electronic medical record-based clinical decision support and systems-level intervention to dramatically improve the control of CVD risk factors such as hypertension. In FY 2015, NHLBI will support the use of established data and health system networks to enable low-cost pragmatic trials that will answer questions important to patients and health care providers.



**Program Portrait: Progenitor Cell Biology Consortium (PCBC)****FY 2014 Level:** \$20.2 million**FY 2015 Level:** \$20.2 million**Change:** \$ 0.0 million

Progenitor cells are critical to tissue and organ development. They have great potential for use in the repair of damaged organs, but as yet have limited clinical use. The Progenitor Cell Biology Consortium (PCBC) supports an interactive consortium carrying out research to identify and characterize progenitor cell lineages, direct the differentiation of stem and progenitor cells to desired cell fates, and develop new strategies to address the unique challenges presented by the transplantation of these cells. Progenitor cells are similar to stem cells, but are limited in the cell types they can produce, and cannot divide or reproduce indefinitely. Both stem and progenitor cells have great therapeutic potential. The PCBC seeks to harness advances in stem cell and progenitor cell biology to improve the understanding and treatment of cardiovascular, lung, and blood diseases. The interactive consortium PCBC is working to make the data, tools, and technologies it produces available to the research community. To this end, the PCBC has established several key bioinformatics collaborations to accelerate knowledge discovery in the progenitor and stem cell biology fields. The PCBC is collaborating with SAGE Bionetwork and with the Harvard Stem Cell Institute's Center for Stem Cell Bioinformatics to support open, collaborative data sharing and analysis. These activities are expected to increase innovation and speed progress in understanding progenitor and stem cells, how their differentiation is regulated, and how they can be usefully reprogrammed for therapeutic purposes.

**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 FY 2013, key findings from NHLBI-supported research efforts provided new insights into the pathogenesis of challenging diseases such as idiopathic pulmonary fibrosis (IPF) and pulmonary hypertension (PH). Two large genome-wide studies have confirmed the association between a gene variation of genes, MUC5B and IPF, and have identified additional immune response and cell-cell adhesion genes that are associated with this disease. The gene variation associated with IPF greatly increases the risk of pulmonary fibrosis in the general population, providing valuable clues not only to IPF but also to the fibrosis that occurs as an end result of many lung diseases. Pulmonary fibrosis can lead to pulmonary hypertension, another key area of investment in our portfolio. Basic science research and translational studies in PH have advanced our understanding of how lung vascular disease occurs, and have identified novel targets for potential therapeutics. For example, the first genome-wide association study (GWAS) of idiopathic and familial PH identified an allele associated with twofold greater risk of the disease in families who do not have the BMP2 gene mutation previously known to be associated with the disease, thereby expanding our understanding of the pathogenesis of PH.

In FY 2014, NHLBI began four major activities: 1) the Centers for Advanced Diagnostics and Experimental Therapeutics Stage II (CADET II) to further develop promising therapeutics agents for lung diseases such as pulmonary fibrosis and scleroderma based on pathobiologic mechanisms; 2) the Pulmonary Trials Cooperative (PTC), a new pilot network structure to

evaluate treatment strategies for acute, serious lung conditions, such as exacerbations of chronic obstructive pulmonary disease; 3) the Redefining Pulmonary Hypertension Through Pulmonary Vascular Disease Phenomics initiative; and 4) the Clinical Trials Network for the Prevention and Early Treatment of Acute Lung Injury (PETAL). NHLBI will continue its support for the AsthmaNet and the Premature and Respiratory Outcomes Program (PROP).

**Budget Policy:**

The FY 2015 budget estimate for the Lung Diseases program is \$612.169 million, an increase of \$1.425 million or 0.2 percent over the FY 2014 Enacted level. In FY 2015, efforts will focus on evaluating novel cell therapy treatment strategies for individuals with lung disease.

**Program Portrait: Asthma Empowerment Partnerships to Reduce Childhood Asthma Disparities**

**FY 2014 Level:** \$ 0.0 million

**FY 2015 Level:** \$43.0 million

**Change:** +\$43.0 million (of which \$25.0 million is NHLBI)

Minority and economically disadvantaged children who have asthma have significantly worse outcomes than white and more prosperous children. African American children are twice as likely to be hospitalized and four times as likely to die due to asthma, and African American and Latino children are less likely to have been prescribed or taken recommended treatments. A Federal Coordinated Action Plan to Reduce Racial and Ethnic Asthma Disparities, part of the President's Task Force on Children's Environmental Risks and Safety Risks to Children, concluded that multiple risk factors contribute to this disparity. They include clinicians not providing evidence-based care, patient non-adherence, patient-provider communication barriers, low health literacy or asthma management skills, increased exposure to allergens, environmental tobacco smoke, pollutants, and genetic and biological factors. Interventions aimed at a single modifiable risk factor have not been sufficient to substantially reduce disparities. Significant progress requires system-wide approaches that integrate and foster synergies among all key sectors that affect the multiple risk factors.

Through this program, three or more centers will form a collective that will build and test several different models for integrating asthma programs at the community level. These centers will link broad sectors that impact asthma management: medical care, individual/family systems (e.g., asthma self-management behaviors and the social context of family and cultural perceptions of disease and health care seeking), home (e.g., exposures in the home and neighborhood environments); and community (e.g., school and day care environments and programs and policies that support asthma self-management).

The scientific gains expected from this program are urgently needed models for integrated approaches at the community level to improve asthma outcomes among children experiencing the highest burden of disease, and to improve adoption and sustainability of the programs to guide wider dissemination and implementation. The public health gains will close the disparity gap among minority children who have asthma and reduce the cost of uncontrolled asthma and inequities to society.

**Blood Diseases and Resources:** This program supports research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, such as 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 research and research training on the use, safety, efficacy, and availability of blood and blood components for transfusion and cellular therapeutics. In FY 2013, NHLBI funded eight Excellence in Hemoglobinopathies research awards to accelerate high-impact multi-disciplinary research in sickle cell disease and the thalassemias, and to facilitate collaborations among basic and translational scientists and clinical hematologists to elucidate the complications of these diseases and assist in developing new and effective therapies. Follow-up of young sickle cell disease patients who participated in the Pediatric Hydroxyurea Phase II Clinical Trial (BABY HUG) has been extended. NHLBI has joined the next stage of a multi-component collaborative research program of trauma-induced coagulopathy that builds upon clinical studies conducted by the Department of Defense to support basic research on the fundamental processes in trauma and sepsis, which contribute to high mortality. NHLBI studies of hematopoietic stem cell (HSC) transplantation compared to chemotherapy for several diseases will be provided to the Centers for Medicare and Medicaid Services to inform decisions on Medicare coverage of HSC transplantation in patients over 65 years.

In FY 2014, NHLBI continued support for a collaborative initiative with the National Cancer Institute (NCI), Building a National Resource to Study Myelodysplastic Syndromes (MDS), to create a standardized clinical dataset linked to genetically and phenotypically characterized biospecimens from thousands of individuals with MDS that will aid in understanding MDS disease progression. NHLBI will begin an initiative in collaboration with the National Institute of General Medical Sciences (NIGMS) aimed at fostering a multi-disciplinary approach to the discovery of cellular and molecular mechanisms, underlying the development of the severe endothelial dysfunction that contributes to sepsis-related coagulopathy and vascular collapse.

Budget Policy:

The FY 2015 budget estimate for the Blood Diseases and Resources program is \$406.331 million, an increase of \$0.817 million or 0.2 percent over the FY 2014 Enacted level. The program plans for FY 2015 include supporting initiatives that will address the effectiveness and toxicities of red blood cell transfusion; supporting Translational Research Centers that will address disorders of bleeding and thrombosis, including deep vein thrombosis; and supporting a program that will elucidate the late-stage differentiation processes in red blood cells, important in the development of new transfusion products and relevant to understanding how induced pluripotent stem cells (iPS cells) can be used to create new tissues and organs.

**Program Portrait: Hematopoietic Cell Transplantation and HIV Cure**

**FY 2014 Level:** \$ 0.0 million

**FY 2015 Level:** \$11.0 million

**Change:** +\$11.0 million (of which \$5.5 million is NHLBI)

Building on the national and international epidemiologic studies of HIV through the Recipient Epidemiology and Donor Evaluation Study (REDS) program, as well as NHLBI funded investigator-initiated research in cell-based therapies for HIV, this program addresses use of hematopoietic cell transplantation in combination with other anti-HIV therapies as potential cures for HIV infection. Highly active anti-retroviral therapy (HAART) and combination anti-retroviral therapy (cART) drastically reduce HIV viral load in infected persons, but seldom eradicate the virus, which persists in reservoirs including the hematopoietic system. HIV cure requires elimination of virus from hematopoietic cells. Hematopoietic stem cell (HSC) transplantation may play a critical role in an HIV cure through replacement with HIV-uninfected hematopoietic cells. Long-term control of HIV infection without HAART has been achieved following an HSC transplant. Much more research is needed to achieve cures and make them available to HIV-infected patients.

To accelerate research on innovative approaches to cure HIV and to encourage multidisciplinary efforts, NHLBI, in collaboration with NIAID, is developing a joint Request for Applications (RFA): Beyond HAART: Innovative Approaches to Cure HIV-1 for funding in FY 2015. Research topics of interest are: cell therapies, including those based on hematopoietic stem cells; novel gene therapy approaches; and non-traditional antiviral strategies (e.g., miRNAs, siRNAs, and gene-editing enzymes) and their delivery. Applications are expected to include basic science, preclinical research, and translational studies in animal models or humans. A key component of this initiative is the formation of partnerships between academia and the private sector.

NHLBI expertise in HSCs and cell therapy addresses the critical need for HIV cures that build upon known instances of cure of HIV with HSC transplantation.

FY 2015 Level: \$5.5 million from NHLBI and \$5.5 million from NIAID

**Intramural Research:** The Division of Intramural Research (DIR) program conducts basic, translational, clinical, and population research in heart, vascular, lung, blood, sleep, and kidney diseases. This program has made numerous high-impact fundamental discoveries that lay the foundation for many of tomorrow's medical breakthroughs.

Some recent examples include the discovery of a new mechanism to explain how vertebrate cells divide; the determination of key players in the immune response to pneumonia infection; and the elucidation of a role for the Myc oncogene in regulating gene transcription. A new technology, transcatheter aortic valve replacement (TAVR), has been developed for non-surgical treatment of aortic stenosis—an approach that can be used in many older patients for whom surgery may be unacceptably risky. The Framingham Heart Study, now in its seventh decade of epidemiological cardiovascular research, continues to contribute through broad sharing of genomic and phenotypic data. Other “big data” initiatives include a state-of-the-art DNA sequencing facility in DIR that provides next-generation sequencing for investigator-initiated projects, and a newly implemented clinical data management system poised to integrate clinical data collected in the NIH Clinical Center and local partner hospitals (e.g., Suburban/Johns Hopkins and Children's National Medical Center) across clinical trial protocols. Stunning progress has been made in the field of pediatric cardiology, an area of clinical study that is typically underrepresented but

occupies a significant burden on children born with congenital heart defects and on their families. These advances include the development of a next-generation scanner that provides improved images of the heart and other tissues without irradiation exposure to the children, and groundbreaking work on fetal imaging and minimally invasive intervention techniques. Additional strengths of the DIR program include cross-disciplinary research in the areas of stem cell biology, hematopoietic transplantation, mitochondria energetics, biological membrane structure, and a growing program in sickle cell disease.

Budget Policy:

The FY 2015 President's Budget estimate for the Intramural Research program is \$191.571 million, an increase of \$1.300 million, or 0.7 percent above the FY 2014 Enacted level.

**Research Management and Support (RMS):** RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. RMS activities include strategic planning, coordination, and evaluation of the Institute's programs, as well as regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

Budget Policy:

The FY 2015 President's Budget estimate for Research Management and Support is \$122.886 million, the same as the FY 2014 Enacted level.

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**Budget Authority by Object Class<sup>1</sup>**  
(Dollars in Thousands)

	<b>FY 2014 Enacted</b>	<b>FY 2015 President's Budget</b>	<b>FY 2015 +/- FY 2014</b>
Total compensable workyears:			
Full-time employment	942	942	0
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary	\$165	\$165	\$0
Average GM/GS grade	12.3	12.3	0.0
Average GM/GS salary	\$103	\$104	\$0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$101	\$102	\$0
Average salary of ungraded positions	\$360	\$364	\$0
<b>OBJECT CLASSES</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2015</b>
Personnel Compensation			
11.1 Full-Time Permanent	\$69,912	\$70,611	\$699
11.3 Other Than Full-Time Permanent	32,285	32,608	323
11.5 Other Personnel Compensation	2,935	2,965	29
11.7 Military Personnel	908	917	9
11.8 Special Personnel Services Payments	7,928	8,007	79
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$113,968</b>	<b>\$115,108</b>	<b>\$1,140</b>
12.1 Civilian Personnel Benefits	\$29,811	\$30,854	\$1,043
12.2 Military Personnel Benefits	650	657	7
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$144,430</b>	<b>\$146,619</b>	<b>\$2,190</b>
21.0 Travel & Transportation of Persons	\$2,335	\$2,375	\$40
22.0 Transportation of Things	246	251	4
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	1,269	1,291	22
24.0 Printing & Reproduction	36	36	1
25.1 Consulting Services	\$576	\$576	\$0
25.2 Other Services	25,213	21,870	-3,343
25.3 Purchase of goods and services from government accounts	\$214,526	\$214,514	-\$12
25.4 Operation & Maintenance of Facilities	\$2,415	\$2,456	\$41
25.5 R&D Contracts	227,859	226,252	-1,607
25.6 Medical Care	1,240	1,286	46
25.7 Operation & Maintenance of Equipment	9,149	9,294	145
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$480,978</b>	<b>\$476,248</b>	<b>-\$4,730</b>
26.0 Supplies & Materials	\$15,341	\$15,600	\$259
31.0 Equipment	9,085	9,211	125
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	2,329,015	2,336,053	7,038
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	1	1	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$2,838,307</b>	<b>\$2,841,066</b>	<b>\$2,758</b>
<b>Total Budget Authority by Object Class</b>	<b>\$2,982,737</b>	<b>\$2,987,685</b>	<b>\$4,948</b>

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

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**Salaries and Expenses**  
(Dollars in Thousands)

OBJECT CLASSES	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$69,912	\$70,611	\$699
Other Than Full-Time Permanent (11.3)	32,285	32,608	323
Other Personnel Compensation (11.5)	2,935	2,965	29
Military Personnel (11.7)	908	917	9
Special Personnel Services Payments (11.8)	7,928	8,007	79
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$113,968</b>	<b>\$115,108</b>	<b>\$1,140</b>
Civilian Personnel Benefits (12.1)	\$29,811	\$30,854	\$1,043
Military Personnel Benefits (12.2)	650	657	7
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$144,430</b>	<b>\$146,619</b>	<b>\$2,190</b>
Travel & Transportation of Persons (21.0)	\$2,335	\$2,375	\$40
Transportation of Things (22.0)	246	251	4
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	1,269	1,291	22
Printing & Reproduction (24.0)	36	36	1
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	15	15	0
Other Services (25.2)	25,213	21,870	-3,343
Purchases from government accounts (25.3)	127,505	126,188	-1,317
Operation & Maintenance of Facilities (25.4)	2,415	2,456	41
Operation & Maintenance of Equipment (25.7)	9,149	9,294	145
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$164,297</b>	<b>\$159,823</b>	<b>-\$4,474</b>
Supplies & Materials (26.0)	\$15,341	\$15,600	\$259
<b>Subtotal Non-Pay Costs</b>	<b>\$183,525</b>	<b>\$179,376</b>	<b>-\$4,149</b>
<b>Total Administrative Costs</b>	<b>\$327,954</b>	<b>\$325,995</b>	<b>-\$1,959</b>

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**Detail of Full-Time Equivalent Employment (FTE)<sup>1</sup>**

OFFICE/DIVISION	FY 2013 Actual			FY 2014 Est.			FY 2015 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	126	3	129	127	2	129	117	2	119
Reimbursable:	18		18	18		18	18		18
Total:	144	3	147	145	2	147	135	2	137
Division of Blood and Resources									
Direct:	30		30	30		30	30		30
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	30		30	30		30	30		30
Division of Lung Diseases									
Direct:	31		31	31		31	31		31
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	31		31	31		31	31		31
Division for the Application of Research Discoveries									
Direct:	15		15	15		15	-		-
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	15		15	15		15	-		-
Center for Translation Research and Implementation Science									
Direct:			-			-	25		25
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:			-			-	25		25
Division of Intramural Research									
Direct:	430	6	436	430	6	436	430	6	436
Reimbursable:	21	-	21	21	-	21	21	-	21
Total:	451	6	457	451	6	457	451	6	457
Division of Cardiovascular Sciences									
Direct:	135	1	136	135	1	136	135	1	136
Reimbursable:	1		1	1		1	1		1
Total:	136	1	137	136	1	137	136	1	137
Division of Extramural Research Activities									
Direct:	124	-	124	124		124	124		124
Reimbursable:	1		1	1		1	1		1
Total:	125	-	125	125		125	125		125
<b>Total</b>	<b>932</b>	<b>10</b>	<b>942</b>	<b>933</b>	<b>9</b>	<b>942</b>	<b>933</b>	<b>9</b>	<b>942</b>
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2011	12.4								
2012	12.5								
2013	12.3								
2014	12.3								
2015	12.3								

<sup>1</sup> FTE changes shown for FY 2015 reflect realignment of programs into newly established Center for Translational Research and Implementation Science



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**Detail of Positions**

GRADE	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	165,382	165,382	165,382
GM/GS-15	95	95	95
GM/GS-14	150	150	150
GM/GS-13	190	190	190
GS-12	87	87	87
GS-11	51	51	51
GS-10	0	0	0
GS-9	35	35	35
GS-8	30	30	30
GS-7	24	24	24
GS-6	11	11	11
GS-5	2	2	2
GS-4	2	2	2
GS-3	3	3	3
GS-2	0	0	0
GS-1	0	0	0
<b>Subtotal</b>	<b>680</b>	<b>680</b>	<b>680</b>
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	1	1	1
Director Grade	4	4	4
Senior Grade	1	1	1
Full Grade	3	3	3
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
<b>Subtotal</b>	<b>10</b>	<b>10</b>	<b>10</b>
Ungraded	275	275	275
Total permanent positions	692	692	692
Total positions, end of year	966	966	966
Total full-time equivalent (FTE) employment, end of year	942	942	942
Average ES salary	165,382	165,382	165,382
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	101,952	102,717	103,744

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.