

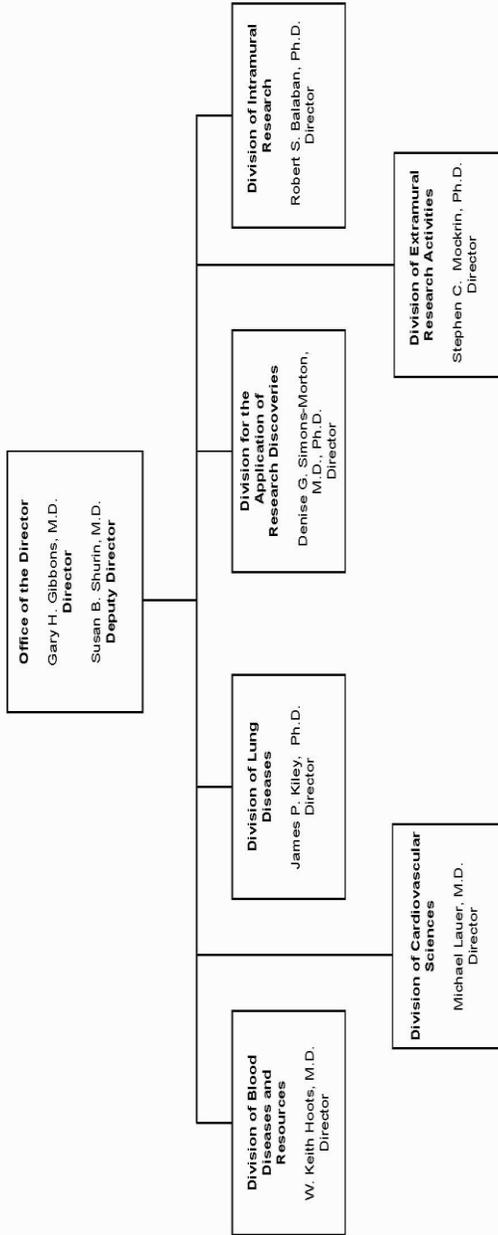
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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, \$3,098,508,000.*

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

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

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	3,084,851	3,097,864	3,098,508
Rescission	(5,830)	0	0
Subtotal, adjusted appropriation	3,079,021	3,097,864	3,098,508
Secretary's Transfer for Alzheimer's disease (AD)	(2,029)	0	0
Secretary's Transfer for AIDS authorized by P.L. 112-74, Section 206	(877)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(2,813)	(3,644)	0
Subtotal, adjusted budget authority	3,073,302	3,094,220	3,098,508
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	3,073,302	3,094,220	3,098,508
Unobligated balance lapsing	0	0	0
Total obligations	3,073,302	3,094,220	3,098,508

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2012 - \$15,197    FY 2013 - \$20,001    FY 2014 - \$20,001

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

MECHANISM	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	2,885	\$1,620,244	2,636	\$1,577,166	2,403	\$1,472,612	-482	-\$147,632
Administrative Supplements	<i>(113)</i>	14,826	<i>(100)</i>	6,000	<i>(100)</i>	6,000	<i>-(13)</i>	-8,826
Competing:								
Renewal	153	90,356	167	101,475	205	124,860	52	34,504
New	614	290,901	673	326,904	828	402,240	214	111,339
Supplements	1	182	0	0	0	0	-1	-182
Subtotal, Competing	768	\$381,439	840	\$428,379	1,033	\$527,100	265	\$145,661
Subtotal, RPGs	3,653	\$2,016,509	3,476	\$2,011,545	3,436	\$2,005,712	-217	-\$10,797
SBIR/STTR	167	75,973	182	82,727	194	88,300	27	12,327
Research Project Grants	3,820	\$2,092,482	3,658	\$2,094,272	3,630	\$2,094,012	-190	\$1,530
<u>Research Centers</u>								
Specialized/Comprehensive	46	62,400	49	64,949	55	68,267	9	5,867
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	1	2,343	1	1,906	1	2,500	0	157
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	47	\$64,743	50	\$66,855	56	\$70,767	9	\$6,024
<u>Other Research</u>								
Research Careers	562	80,177	587	81,575	587	81,575	25	1,398
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	59	46,075	65	46,800	73	48,058	14	1,983
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	10	2,199	13	2,900	13	2,900	3	701
Other	110	27,908	120	24,530	148	28,889	38	981
Other Research	741	\$156,359	785	\$155,805	821	\$161,422	80	\$5,063
Total Research Grants	4,608	\$2,313,584	4,493	\$2,316,932	4,507	\$2,326,201	-101	\$12,617
<u>Ruth L. Kirschstein Training Awards</u>	<u>FTIPs</u>		<u>FTIPs</u>		<u>FTIPs</u>		<u>FTIPs</u>	
Individual	220	9,827	233	10,270	220	10,023	0	196
Institutional	1,648	84,190	1,691	83,725	1,608	84,190	-40	0
Total Research Training	1,868	\$94,017	1,924	\$93,995	1,828	\$94,213	-40	\$196
Research & Development Contracts	183	351,581	176	369,593	176	364,394	-7	12,813
<i>SBIR/STTR (non-add)</i>	<i>(11)</i>	<i>(9,683)</i>	<i>(10)</i>	<i>(7,296)</i>	<i>(2)</i>	<i>(2,942)</i>	<i>-(9)</i>	<i>-(6,741)</i>
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural Research	473	191,840	473	191,840	473	191,840	0	0
Research Management and Support	454	122,280	504	121,860	504	121,860	50	-420
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHLBI	927	\$3,073,302	977	\$3,094,220	977	\$3,098,508	50	\$25,206

<sup>1</sup> All items in italics and brackets are "non-adds."

## **Major Changes in the Fiscal Year 2014 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 2014 budget request for NHLBI, which is \$25.2 million more than the FY 2012 level, for a total of \$3,098.5 million.

Research Project Grants (RPGs; +\$1.530 million; total \$2,094.012 million): NHLBI will fund 1,033 competing RPGs in FY 2014, an increase of +265 from FY 2012. About 2,403 noncompeting RPG awards, totaling to \$1,472.612 million, will be made in FY 2014. NIH budget policy for RPGs in FY 2014, continues FY 2012 policy of eliminating inflationary increases for future year commitments. However adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.

Research Training (+\$0.196 million; total \$94.213 million): The Ruth L. Kirschstein NRSA budget reflects a stipend increase to \$42,000 for entry level postdoctoral trainees and fellows along with 4 percent increases for each subsequent level of experience. The number of FTFPs are reduced by 40 from the FY 2012 level of 1,868.

Pragmatic Patient-Centered Randomized Controlled Trials (+\$0.0 million; total \$3.375 million): Developing more cost-efficient strategies to conduct clinical trials will continue to promote innovation and enhance research efficiency. This new initiative promotes low cost, high-impact randomized controlled trials that are integrated into existing clinical practice settings and/or leverage existing data resources (such as registries and electronic health data) to enhance the evidence base for care of individual patients.

Centers for Advance Diagnostics and Experimental Therapeutics in Lung Diseases (CADET) (+\$24.800 million; total \$24.800 million): To ensure that important discoveries are developed into products that improve public health, CADET offers support for academic investigators to carry out additional translational research that clarifies the potential of their findings to yield marketable products.

Technologies To Assess Sleep Health in Populations (+\$0.0 million; total \$0.550 million): NHLBI is partnering with the Department of Transportation to understand how work schedules such as shift work impact sleep health and how poor sleep health may predispose to public health safety risks such as individual or commercial transportation accidents. This new initiative supports small businesses to develop and validate tests to efficiently assess and categorize individual "sleep health status" in relation to both physical and mental functioning. These tests will facilitate the management of potentially unsafe conditions through the prediction of operator vulnerability to work and sleep schedule variations (e.g. shift work).

**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**  
**Summary of Changes**  
(Dollars in Thousands)

<b>FY 2012 Actual</b>				<b>\$3,073,302</b>
<b>FY 2014 President's Budget</b>				<b>\$3,098,508</b>
<b>Net change</b>				<b>\$25,206</b>
<b>CHANGES</b>	<b>2014 President's Budget</b>		<b>Change from FY 2012</b>	
	<b>FTEs</b>	<b>Budget Authority</b>	<b>FTEs</b>	<b>Budget Authority</b>
A. Built-in:				
1. Intramural Research:				
a. Annualization of March				
		\$72,550		\$184
		72,550		536
		72,550		275
		72,550		0
		32,186		576
		87,104		282
Subtotal				\$1,853
2. Research Management and Support:				
a. Annualization of March				
		\$74,131		\$189
		74,131		548
		74,131		280
		74,131		0
		7,987		175
		39,742		1
Subtotal				\$1,194
Subtotal, Built-in				\$3,047

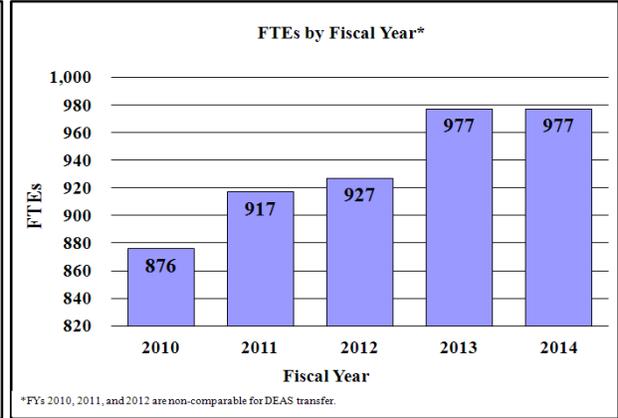
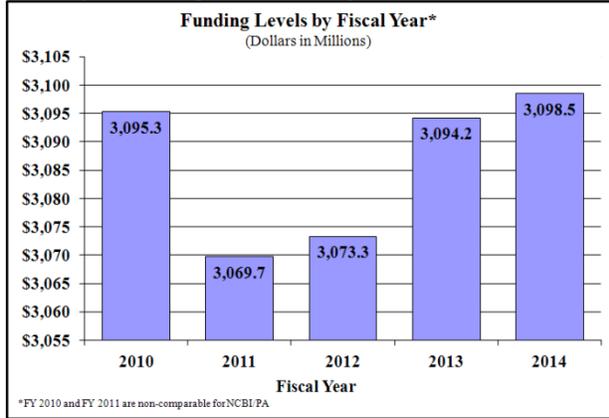
**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Summary of Changes--continued**

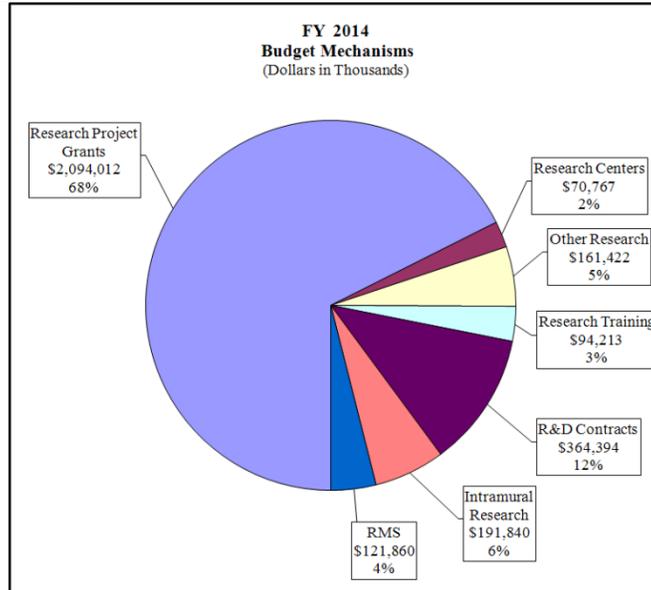
CHANGES	2014 President's Budget		Change from FY 2012	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	2,403	\$1,478,612	-482	-\$156,458
b. Competing	1,033	527,100	265	145,661
c. SBIR/STTR	194	88,300	27	12,327
Total	3,630	\$2,094,012	-190	\$1,530
2. Research Centers	56	\$70,767	9	\$6,024
3. Other Research	821	161,422	80	5,063
4. Research Training	1,828	94,213	-40	196
5. Research and development contracts	176	364,394	-7	12,813
Subtotal, Extramural		\$2,784,808		\$25,626
6. Intramural Research	<u>FTEs</u> 473	\$191,840	<u>FTEs</u> 0	-\$1,853
7. Research Management and Support	504	121,860	50	-1,614
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	977	\$3,098,508	50	\$22,159
Total changes				\$25,206

## Fiscal Year 2014 Budget Graphs

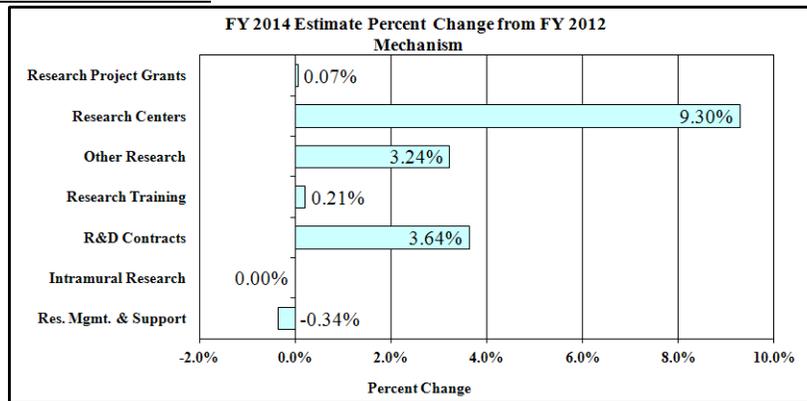
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**  
**Budget Authority by Activity**<sup>1,2</sup>  
(Dollars in Thousands)

	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>
<b><u>Extramural Research</u></b>								
Detail:								
Heart and Vascular Diseases		\$1,721,157		\$1,734,467		\$1,737,142		\$15,985
Lung Diseases		635,388		640,302		641,289		\$5,901
Blood Diseases and Resources		402,637		405,751		406,377		\$3,740
<b>Subtotal, Extramural</b>		\$2,759,182		\$2,780,520		\$2,784,808		\$25,626
<b>Intramural Research</b>	473	\$191,840	473	\$191,840	473	\$191,840	0	\$0
<b>Research Management &amp; Support</b>	454	\$122,280	504	\$121,860	504	\$121,860	50	(\$420)
<b>TOTAL</b>	927	\$3,073,302	977	\$3,094,220	977	\$3,098,508	50	\$25,206

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

2. Includes 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**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2013 Amount Authorized</b>	<b>FY 2013 CR</b>	<b>2014 Amount Authorized</b>	<b>FY 2014 PB</b>
Research and Investigation	Section 301	42§241	Indefinite	\$3,094,220,000	Indefinite	\$3,098,508,000
National Heart, Lung, and Blood Institute	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$3,094,220,000</b>		<b>\$3,098,508,000</b>

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

**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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				-
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				-
2010	\$3,050,356,000	\$3,123,403,000	\$3,066,827,000	\$3,096,916,000
Rescission				-
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				(\$5,830,368)
2013	\$3,076,067,000	-	\$3,085,390,000	-
Rescission				-
2014	\$3,098,508,000	-	-	-

## 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 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 +/- FY 2012
BA	\$3,073,302,000	\$3,094,220,000	\$3,098,508,000	+\$25,206,000
FTE	927	977	977	+50

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

### Director's Overview

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for research and education programs to prevent and treat heart, blood vessel, lung, and blood diseases. Guided by *Shaping the Future of Research: A Strategic Plan*,<sup>1</sup> NHLBI supports a robust, collaborative research enterprise, in partnership with private and public organizations, to address critical scientific and educational needs nationally and worldwide.

The following material describes three areas of extraordinary opportunity that will be the focus of expanded, strategic NHLBI investments in FY 2014 and beyond. The first supports NIH Director's Theme 1 (Today's Basic Science for Tomorrow's Breakthroughs); the second and third support Theme 2 (Translational Science). The success of these investments hinges upon the development and nurturing of a research workforce highly trained in many scientific disciplines and reflecting wide-ranging perspectives; NHLBI is, accordingly, strongly committed to addressing Theme 3 (Recruiting and Retaining Diverse Scientific Talent and Creativity) throughout its endeavors.

### Changing the Course of Chronic Diseases: National Networks and Mega-Cohort Studies

For many decades, NHLBI has designed and supported epidemiological studies that provide insights into potential environmental, biological, and behavioral causes of disease. More recently, the Institute has integrated new biomedical technologies (e.g., genomic research tools, electronic medical records) into its portfolio of epidemiological studies. For example, large genome-wide studies of participants in multiple well-characterized cohorts have been undertaken. As a result of these efforts, researchers worldwide now have access to a wealth of data that are yielding new insights into the genetic and other factors that influence chronic diseases among people from many different walks of life.

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<sup>1</sup> <http://www.nhlbi.nih.gov/about/strategicplan/index.htm?/>

Nevertheless, most of NHLBI's cohort studies have been relatively small, typically including thousands or tens of thousands of participants, and researchers are coming to recognize that increased sample sizes would likely lead to more robust findings. With the advent of new technologies for handling extremely large and complex datasets, it is now feasible to consider expanding the size of epidemiological studies to form "mega" epidemiological and clinical cohorts. In FY 2014, the Institute will consider approaches to combine data from various sources (e.g., existing NHLBI cohorts, integrated health care systems) to create a mega-cohort that would include not thousands but hundreds of thousands or even millions of individuals. The consortium of investigators involved in this groundbreaking effort would conduct not only observational studies but also large, low-cost clinical trials related to heart, lung, and blood diseases. Given the scope of the endeavor, NHLBI would seek to collaborate with other NIH Institutes and Centers to maximize use of resources by examining a range of other diseases and conditions within these same studies.

### **Translational Science: Linking Basic Discoveries to Advances in Therapeutics**

Over the past several years, NHLBI has invested heavily in programs to accelerate the translation of basic research findings into new diagnostics and therapeutics. These efforts have provided private and public sector communities with the support needed to move promising agents into clinical trials, address regulatory issues, and contribute to business case development necessary for commercialization of their discoveries. In FY 2014, the Institute will continue funding several ongoing efforts to support translational research in all three of its extramural program areas. These include programs to accelerate the translation of therapeutic interventions for diseases such as heart failure, arrhythmias, and pediatric cardiovascular disease (CVD); to conduct proof-of-concept testing of interventions for lung diseases such as pulmonary hypertension, chronic obstructive pulmonary disease (COPD), and pulmonary fibrosis; and to develop pilot studies that may lead to the design of full-scale clinical trials for sickle cell disease and thalassemias. The Institute will also continue programs that provide the research community with resources needed to test potential new biologics and small molecule therapeutics, follow Good Manufacturing Practices, and navigate regulatory issues related to early stage clinical trials. In addition, it will expand programs to provide access to expertise in scientific, regulatory, business, and legal issues.

In FY 2014, the Institute also will expand its translational research efforts to integrate "systems biology" approaches. Unlike many current approaches that focus on single molecules in linear pathways, systems biology considers multiple molecules and pathways and the interactions between them to improve understanding of the broader biological context that influences health and disease. For example, NHLBI will begin the second phase of its Centers for Advanced Diagnostics and Experimental Therapeutics (CADET) program, which seeks to incorporate systems approaches into translational research for lung diseases. The systems approach is expected to provide a wealth of information about the global effects of each promising therapeutic agent so that researchers have a complete understanding of how it affects the body. This approach can be expected to enable the design of drugs that are more effective, tailored to the individual, and free of significant side effects. Ultimately, the targeted investments in this new 'systems approach' hold promise for yielding breakthroughs that can change the course of chronic disease and thereby reduce the long-term burden of healthcare expenditures.

## **Regenerative Medicine**

For many years, the NHLBI has supported research on stem cells and their biology. One of the goals of such research is to identify and understand the biological factors that might enable regenerative medicine—the repair or even rebirth of damaged tissues and organs. Stem cell research has improved understanding of the biological processes and molecules that are involved in cellular repair and regeneration, but only to a limited extent. Until recently, many studies of stem cells and the mature cells that can be derived from them focused on observing single cell types grown in the 2-dimensional environment of a laboratory dish. In the body, cells and tissues exist in 3 dimensions and tissues contain many different types of cells that work together to enable tissues to function. As knowledge of stem cell biology has progressed, researchers have been increasingly successful at creating 3-dimensional models that more realistically represent the interactions among different kinds of cells and between cells and their environment. In FY 2014, the NHLBI will leverage a number of existing investments in stem cell biology, such as the Progenitor Cell Biology Consortium and a wealth of investigator-initiated research on induced pluripotent stem cells, to expand efforts to develop 3-dimensional, multi-cellular models of heart, lung, and blood tissues. The new models are expected to be more informative than single-cell 2-dimensional models and to move science closer to the goals of developing therapies to promote tissue regeneration or even engineered organs for transplantation.

Overall Budget Policy: The FY 2014 President’s Budget request is \$3,098.508 million, an increase of \$25.206 million, or 0.8 percent above the FY 2012 Actual level. Funds are included in R&D contracts to support trans-NIH initiatives, such as Basic Behavioral and Social Sciences Opportunity Network (OppNet). Support for NRSA training mechanism will remain constant reflecting a reduction in the number of trainees supported. The Ruth L. Kirschstein NRSA budget reflects a stipend increase to \$42,000 for the entry level postdoctoral trainees and fellows along with 4 percent increases for each subsequent level of experience. These increases are consistent with stipend increases recommended by the Advisory Committee to the NIH Director and the National Research Council. In addition, this increase is consistent with 42 USC 288(b)(5), which anticipates periodic adjustments in stipends “to reflect increases in the cost of living.”

### **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, 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. In FY 2012, the NHLBI continued its support for a number of large clinical trials including the Systolic Blood Pressure Intervention Trial (SPRINT) and the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA); funded renewals of the Heart Failure Research Network and the Cardiovascular Cell Therapy Research Network; and funded several new studies based on

existing family cohorts to identify genetic variants that contribute to the heritability of complex diseases. In FY 2013, the Institute plans to renew support for the Cardiovascular Research Network focused on cardiovascular disease intervention and comparative-effectiveness studies in community settings and the Cardiothoracic Surgical Trials Network; renew two landmark epidemiological programs in minority populations—the Jackson Heart Study and the Hispanic Community Health Study—and ongoing surveillance of participants in the Strong Heart Study of American Indians; award the second phase of its Research Centers at Minority-Serving Institutions; launch a new research program to explore CVD risk-reduction strategies in underserved rural populations; and award contracts for the new Vascular Intervention/Innovations and Therapeutic Advances (VITA) program.

**Budget Policy:** The FY 2014 President’s Budget estimate for the Heart and Vascular Diseases program is \$1,737.142 million, an increase of \$15.985 million, or 0.9 percent above the FY 2012 Actual level. During FY 2014, the NHLBI plans to continue its support for the Childhood Obesity Prevention and Treatment Research Consortium and the Resuscitation Outcomes Consortium; the Pediatric Heart Network, the Heart Failure Clinical Research Network, and the Cardiovascular Cell Therapy Research Network; and the initiative Basic Research in Calcific Aortic Valve Disease.

**Program Portrait: Cardiovascular Inflammation Reduction Trial (CIRT)**

**FY 2012 Level:** \$ 9.607 million

**FY 2014 Level:** \$16.503 million

**Change:** +\$ 6.896 million

CVD affects millions of people in the United States, causing considerable illness and death despite the availability of contemporary therapeutic regimens. Although inflammation is well appreciated as a major risk factor for CVD, the potential of targeted anti-inflammatory therapy to improve CVD outcomes is unknown. In FY 2012 the NHLBI funded CIRT to address this important public health question. CIRT will determine whether treatment with low-dose methotrexate (LDM)—an inexpensive, generic anti-inflammatory drug—reduces recurrent heart attacks, strokes, or deaths from CVD among patients with CVD who also have type 2 diabetes or metabolic syndrome. The trial will enroll 7,000 patients at 350–400 sites in the United States and Canada and follow them for 2–4 years. In addition to assessing the effects of LDM treatment on heart attacks, strokes, and deaths from CVD, the trial will evaluate all-cause mortality, deep vein thrombosis, pulmonary embolism, atrial fibrillation, hospitalization for chest pain, hospitalization for congestive heart failure, rates of percutaneous coronary intervention or coronary artery bypass surgery, and newly diagnosed diabetes. Quality of life and overall health status will also be studied. A blood and DNA bank will be established to measure a series of inflammatory biomarkers.

This study addresses a question of great scientific and public health importance. Rigorous evidence of benefits to be realized from targeted anti-inflammatory therapy would have huge global impact, potentially changing treatment paradigms for millions of individuals with CVD, diabetes, and metabolic syndrome.

**Lung Diseases:** This program supports research on the causes, diagnosis, treatment, and prevention of lung diseases and sleep disorders. Research areas include asthma, 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 2012, the NHLBI launched a new program to conduct

proof-of-concept clinical trials of interventions for lung diseases and sleep-related cardiopulmonary disorders, funded the Genomic Research in Alpha-1 Antitrypsin and Sarcoidosis (GRADS) study, established the Consortium of Lung Repair and Regeneration, awarded new grants to study lung disease in infants and children with cystic fibrosis, and provided funding for molecular imaging studies of the lung. In FY 2013, NHLBI will continue its support for the AsthmaNet, which conducts trials of asthma treatment approaches for adults and children, and the Trial of Late Surfactant to Prevent Bronchopulmonary Dysplasia (TOLSURF); solicit applications for integrated “omics” data analysis to understand complex interactions among genes and gene products in the context of pulmonary disease; and, redesign the chronic obstructive pulmonary disease (COPD) Network, NHLBI’s Engine for Fast Execution of Clinical Trials (EFFECT), which is a 7-year program focused on serious lung diseases.

Budget Policy: The FY 2014 President’s Budget estimate for the Lung Diseases program is \$641.289 million, an increase of \$5.901 million, or 0.9 percent above the FY 2012 Actual Level. Program plans for FY 2014 include; support for the second phase of the Centers for Advanced Diagnostic and Experimental Therapeutics in Lung Diseases (CADET), establishment of phase II Clinical Trials Network for the Prevention and Treatment of Acute Lung Injury, funding of innovative efforts to build a molecular atlas of late-stage lung development to enable discovery of critical events shaping lung anatomy, and support for career development of investigators in “omics” research.

**Program Portrait: Centers for Advanced Diagnostics and Experimental Therapeutics (CADET)**

**FY 2012 Level:** \$00.000 million

**FY 2014 Level:** \$24.800 million

**Change:** +\$24.800 million

Advances in understanding the biology of pulmonary diseases and sleep disordered breathing have enormous potential to improve patient care through the development of new diagnostic and therapeutic products, but translation of discovery to application is slow. NHLBI developed the CADET program specifically to reduce the latency period between discovery of new scientific knowledge and its application to the development of clinically meaningful new diagnostic tests or therapeutic products for the management of lung diseases and sleep disordered breathing. The first phase of CADET encouraged investigators to begin identifying molecular targets that could be modulated by a therapeutic agent with the goal of modifying disease.

The next phase of CADET, to be launched in FY 2014, will support a more ambitious effort to develop therapeutic agents based on complex fundamental pathobiologic processes. Its goal is to improve the quality and specificity of targets and agents and render the resultant products attractive to biotech/pharmaceutical companies who could then carry them into further clinical development. Diagnostic tests will be used to refine target populations to maximize benefit and minimize risk to individuals who are most susceptible to toxicity or least likely to have a meaningful response. CADET will encourage investigators to integrate data, using systems approaches to explore more fully the biological networks associated with potential targets, off-target effects of agents, and subpopulations of patients who may differ in their response to therapeutic agents. The broad approach to therapeutic development in CADET, including robust assessments of the appropriate population and therapeutic safety and efficacy, will integrate the expertise of multiple collaborators from scientists to clinicians.

Traditional treatments for respiratory diseases rely on broad-spectrum therapeutics without specifically targeting the underlying pathobiology or relevant patient subgroups. Broad-spectrum treatments may not reflect the underlying pathobiology and their efficacy varies greatly in different patient subgroups. CADET will encourage researchers to translate recent understandings of biology and disease heterogeneity to mechanism-based interventions that provide innovative, more effective approaches to treating patients with lung diseases and sleep disordered breathing.

**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 2012, the NHLBI awarded five Translational Research Centers in Thrombotic and Hemostatic Disorders, renewed the Clinical Hematology and Transfusion Medicine Research Career Development Program, funded new grants for studies using existing biospecimens stored in the NHLBI Biologic Specimen Repository, extended follow-up of young sickle cell disease patients who participated in the Pediatric Hydroxyurea Phase II Clinical Trial (BABY HUG), and renewed support for the Cardiovascular Cell Therapy Research Network. In FY 2013, NHLBI will launch phase II of the combined Department of Defense (DoD) and NHLBI group of studies defining physiology of coagulopathy through the Excellence in Hemoglobinopathies Research Award; establish the Trans Agency Research Consortium for Trauma-Induced Coagulopathy (TACTIC), a collaboration with the DoD; support NIH Centers for Accelerated Innovations to facilitate translation of promising emerging technologies to commercialized products that

advance patient care and improve health; and, continue collaborative funding with the National Cancer Institute of the Blood and Marrow Transplant Clinical Trials Network.

**Budget Policy:** The FY 2014 President's Budget estimate for the Blood Diseases and Resources program is \$406.377 million, an increase of \$3.740 million, or 0.9 percent above the FY 2012 Actual Level. Program plans for FY 2014 include; continued support for the Clinical Hematology and Transfusion Medicine Research Career Development Program and an initiative titled Understanding Mechanisms of Terminal Erythroid Maturation.

**Program Portrait: Building a National Resource to Study Myelodysplastic Syndromes (MDS)**

**FY 2012 Level:** \$0.000 million

**FY 2014 Level:** \$1.702 million

**Change:** +\$1.702 million

MDS are a heterogeneous group of chronic blood disorders posing significant health problems for the elderly. They frequently cause lethal infections and life-threatening bleeding and, in some patients, progress to chemotherapy-resistant acute myelogenous leukemia. Available therapies for MDS offer only limited efficacy, and many individuals die of either the primary illness or the associated leukemia.

Studies to date suggest that MDS are a result of genetic changes in bone marrow cells and that some genetic alterations may predict particularly poor outcomes. Such findings are based on the examination of a relatively small number of blood and bone marrow specimens obtained from MDS patients for whom only limited clinical information may be available.

A new initiative to be launched in 2014 in collaboration with the National Cancer Institute, *Building a National Resource to Study Myelodysplastic Syndromes*, will support a prospective study to create a standardized clinical dataset and well-annotated collection of biospecimens from thousands of individuals with MDS, steps that MDS experts agree are needed to advance understanding of these blood disorders. Biospecimens collected serially from study participants will be characterized genetically and phenotypically, and this information will be linked to the clinical data prospectively collected throughout the study period. The clinical and genetic datasets and linked biospecimen collection will be made widely available to the scientific community through the NHLBI Biological Specimen and Data Repository Information Coordinating Center (BioLINCC) program. Basic and preclinical research using these national resources will advance our understanding of the biology and genetics of MDS, provide valuable insights into causes and progression, and help improve the diagnosis and clinical management of individuals with MDS. The initiative is expected to support study coordination, enrollment of subjects and their longitudinal assessment, genetic studies, and a central laboratory for standardized processing and annotation of the biospecimens.

**Intramural Research:** The Intramural Research program conducts basic, translational, clinical, and population research in heart, vascular, lung, blood, and kidney diseases. It is committed to developing innovative approaches and advanced biomedical technologies related to cardiovascular, pulmonary, and blood diseases. Studies in the intramural program range from 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 solo researchers 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), the Cardiothoracic Surgery Research Program, and two trans-NIH programs (the Center for Human Immunology and the Imaging Probe Development Center) that 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 strategic initiative was begun to enhance the infrastructure supporting clinical research in the Intramural Research program, including the rollout of a multifaceted office of protocol support services to facilitate the design, implementation, maintenance, and regulatory oversight of cutting-edge investigator-initiated clinical trials. Moving forward on this initiative in FY 2013, the Institute will procure and use a new electronic data-capture system to support, in a manner that is compliant with good clinical practice regulations, the database needs of investigators conducting clinical research.

Budget Policy: The FY 2014 President's Budget estimate for the Intramural Research program is \$191.840 million, the same as the FY 2012 Actual Level.

**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. It also supports information-dissemination and outreach activities of the Institute. The Office of Communications (OC) implemented strategies for communicating with the public via social media platforms in FY 2012, and it expects to award a contract in FY 2013 for strategic and digital communications support. The OC continues to manage the NHLBI Health Information Center and public health campaigns on heart disease in women (The Heart Truth) and COPD (Learn More, Breathe Better) and will launch a health education initiative for sickle cell disease patients and families in FY 2013. In FY 2012, the Division for the Application of Research Discoveries (DARD) released an integrated guideline for cardiovascular health and risk reduction in children and adolescents and supported development of clinical practice guidelines on cardiovascular risk reduction for adults. The guideline reports were written by expert panels appointed by NHLBI. In FY 2012, DARD established a National Program to Reduce Cardiovascular Risk and a National Blood Disorders Program. Plans for FY 2013 include; release of guidelines for management of sickle cell disease and continuation of the National Asthma Education and Prevention Program, as well as national programs on childhood obesity (We Can!) and health-disparities reduction through community health workers.

Budget Policy: The FY 2014 President's Budget estimate for Research Management and Support is \$121.860 million, a decrease of \$0.420 million, or -0.3 percent below the FY 2012 Actual Level.

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**Budget Authority by Object Class**  
(Dollars in Thousands)

	<b>FY 2012 Actual</b>	<b>FY 2014 PB</b>	<b>Increase or Decrease</b>
Total compensable workyears:			
Full-time employment	927	977	50
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	12.4	(0.1)
Average GM/GS salary (in dollars)	\$102,886	\$99,067	(\$3,819)
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) (in dollars)	\$98,468	\$98,468	\$0
Average salary of ungraded positions (in dollars)	121,813	121,813	0
<b>OBJECT CLASSES</b>	<b>FY 2012 Actual</b>	<b>FY 2014 PB</b>	<b>Increase or Decrease</b>
Personnel Compensation:			
11.1 Full-time permanent	\$63,112	\$69,325	\$6,213
11.3 Other than full-time permanent	32,750	34,013	1,263
11.5 Other personnel compensation	3,427	3,746	319
11.7 Military personnel	784	843	59
11.8 Special personnel services payments	7,513	7,637	124
<b>Total, Personnel Compensation</b>	<b>\$107,586</b>	<b>\$115,564</b>	<b>\$7,978</b>
12.0 Personnel benefits	\$28,516	\$30,641	\$2,125
12.2 Military personnel benefits	455	477	22
13.0 Benefits for former personnel	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$136,557</b>	<b>\$146,682</b>	<b>\$10,125</b>
21.0 Travel and transportation of persons	\$3,234	\$2,734	(\$500)
22.0 Transportation of things	223	223	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	1,228	1,228	0
24.0 Printing and reproduction	103	102	(1)
25.1 Consulting services	1,141	809	(332)
25.2 Other services	34,433	31,754	(2,679)
25.3 Purchase of goods and services from government accounts	299,263	319,614	20,351
25.4 Operation and maintenance of facilities	2,225	2,224	(1)
25.5 Research and development contracts	155,112	145,081	(10,031)
25.6 Medical care	926	926	0
25.7 Operation and maintenance of equipment	3,569	3,569	0
25.8 Subsistence and support of persons	0	0	0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>\$496,668</b>	<b>\$503,977</b>	<b>\$7,309</b>
26.0 Supplies and materials	\$15,017	\$15,017	(\$0)
31.0 Equipment	12,671	8,130	(4,541)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	2,407,601	2,420,414	12,813
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	1	1	0
44.0 Refunds	0	0	0
<b>Subtotal, Non-Pay Costs</b>	<b>\$2,936,745</b>	<b>\$2,951,826</b>	<b>\$15,081</b>
<b>Total Budget Authority by Object Class</b>	<b>\$3,073,302</b>	<b>\$3,098,508</b>	<b>\$25,206</b>

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

**NATIONAL INSTITUTES OF HEALTH  
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**Salaries and Expenses**  
(Dollars in Thousands)

OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
<b>Personnel Compensation:</b>			
Full-time permanent (11.1)	\$63,112	\$69,325	\$6,213
Other than full-time permanent (11.3)	32,750	34,013	1,263
Other personnel compensation (11.5)	3,427	3,746	319
Military personnel (11.7)	784	843	59
Special personnel services payments (11.8)	7,513	7,637	124
<b>Total Personnel Compensation (11.9)</b>	<b>\$107,586</b>	<b>\$115,564</b>	<b>\$7,978</b>
Civilian personnel benefits (12.1)	\$28,516	\$30,641	\$2,125
Military personnel benefits (12.2)	455	477	22
Benefits to former personnel (13.0)	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$136,557</b>	<b>\$146,682</b>	<b>\$10,125</b>
Travel (21.0)	\$3,234	\$2,734	(\$500)
Transportation of things (22.0)	223	223	0
Rental payments to others (23.2)	0	0	0
Communications, utilities and miscellaneous charges (23.3)	1,228	1,228	0
Printing and reproduction (24.0)	103	102	(1)
<b>Other Contractual Services:</b>			
Advisory and assistance services (25.1)	1,141	809	(332)
Other services (25.2)	34,433	31,754	(2,679)
Purchases from government accounts (25.3)	132,704	134,613	1,909
Operation and maintenance of facilities (25.4)	2,225	2,224	(1)
Operation and maintenance of equipment (25.7)	3,569	3,569	0
Subsistence and support of persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$174,072</b>	<b>\$172,969</b>	<b>(\$1,103)</b>
Supplies and materials (26.0)	\$14,916	\$14,916	\$0
<b>Subtotal, Non-Pay Costs</b>	<b>\$193,776</b>	<b>\$192,172</b>	<b>(\$1,604)</b>
<b>Total, Administrative Costs</b>	<b>\$330,333</b>	<b>\$338,854</b>	<b>\$8,521</b>



**NATIONAL INSTITUTES OF HEALTH  
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**Detail of Positions**

<b>GRADE</b>	<b>FY 2012 Actual</b>	<b>FY 2013 CR</b>	<b>FY 2014 PB</b>
Total, ES Positions	1	1	1
Total, ES Salary	\$ 165,382	\$ 165,382	\$ 165,382
GM/GS-15	97	97	97
GM/GS-14	140	140	140
GM/GS-13	185	185	185
GS-12	95	98	98
GS-11	47	47	47
GS-10	1	1	1
GS-9	34	34	34
GS-8	27	52	52
GS-7	15	26	26
GS-6	3	8	8
GS-5	5	9	9
GS-4	2	2	2
GS-3	1	3	3
GS-2	2	2	2
GS-1	1	1	1
Subtotal	655	705	705
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	4	4	4
Senior Grade	1	1	1
Full Grade	1	1	1
Senior Assistant Grade	2	2	2
Assistant Grade	0	0	0
Subtotal	9	9	9
Ungraded	285	285	285
Total permanent positions	659	709	709
Total positions, end of year	950	1,000	1,000
Total full-time equiv (FTE) at YE	927	977	977
Average ES salary	\$165,382	\$165,382	\$165,382
Average GM/GS grade	12.5	12.4	12.4
Average GM/GS salary	\$102,886	\$99,067	\$99,067

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