

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

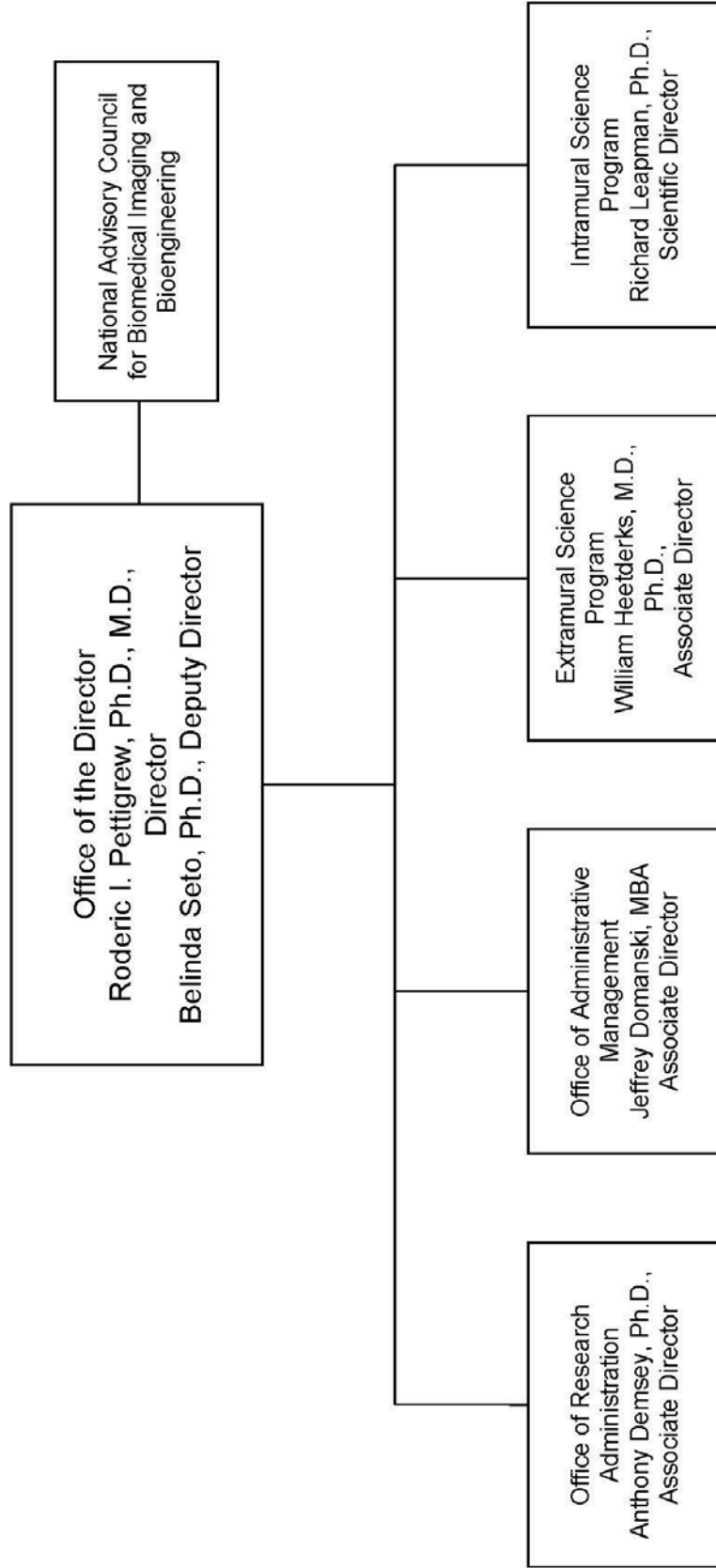
National Institute of Biomedical Imaging and Bioengineering (NIBIB)

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# NIBIB ORGANIZATIONAL CHART

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**NATIONAL INSTITUTES OF HEALTH**

National Institute of Biomedical Imaging and Bioengineering

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, [\$338,998,000] \$336,896,000. (*Department of Health and Human Services Appropriations Act, 2012.*)

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**

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

<b>Source of Funding</b>	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>
Appropriation	316,582	338,998	336,896
Rescission	(2,780)	(641)	0
Subtotal, adjusted appropriation	313,802	338,357	336,896
Real transfer under Secretary's transfer authority	0	(96)	0
Comparative Transfers for NCATS reorganization	31,900	0	0
Comparative Transfers to NCATS for Therapeutics and Rare and Neglected Diseases (TRND)	(258)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(269)	(307)	0
Subtotal, adjusted budget authority	345,175	337,954	336,896
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	345,175	337,954	336,896
Unobligated balance lapsing	(15)	0	0
Total obligations	345,160	337,954	336,896

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2011 - \$3,360    FY 2012 - \$3,360    FY 2013 - \$3,360

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**  
**Budget Mechanism - Total <sup>1/</sup>**  
(Dollars in Thousands)

MECHANISM	FY 2011 Actual		FY 2012 Enacted		FY 2013 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	379	\$161,756	387	\$163,543	353	\$150,785	(34)	(\$12,758)
Administrative Supplements	7	916	5	763	5	763	0	0
Competing:								
Renewal	31	16,471	28	14,649	37	18,989	9	4,340
New	128	44,360	112	39,319	145	50,316	33	10,997
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	159	\$60,831	140	\$53,968	182	\$69,305	42	\$15,337
Subtotal, RPGs	538	\$223,503	527	\$218,274	535	\$220,853	8	\$2,579
SBIR/STTR	45	\$14,311	34	\$9,032	35	\$9,287	1	\$255
Research Project Grants	583	\$237,814	561	\$227,306	570	\$230,140	9	\$2,834
<u>Research Centers</u>								
Specialized/Comprehensive	5	\$6,488	5	\$6,488	5	\$6,468	0	(\$20)
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	30	39,512	30	37,158	30	37,042	0	(116)
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	35	\$46,000	35	\$43,646	35	\$43,510	0	(\$136)
<u>Other Research</u>								
Research Careers	28	\$3,750	28	\$3,750	28	\$3,738	0	(\$12)
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	17	904	18	904	18	901	0	(3)
Other Research	45	\$4,654	46	\$4,654	46	\$4,639	0	(\$15)
Total Research Grants	663	\$288,468	642	\$275,606	651	\$278,289	9	\$2,683
<u>Research Training</u>								
Individual Awards	16	\$785	16	\$785	16	\$783	0	(\$2)
Institutional Awards	235	9,955	231	9,955	234	9,924	3	(31)
Total Research Training	251	\$10,740	247	\$10,740	250	\$10,707	3	(\$33)
Research & Development Contracts	9	\$14,794	12	\$20,612	12	\$16,904	0	(\$3,708)
<i>SBIR/STTR</i>	3	\$12	3	\$12	3	\$12	0	\$0
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural Research	32	\$12,158	32	\$12,158	32	\$12,158	0	\$0
Research Management and Support	66	19,015	66	18,838	65	18,838	(1)	0
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIBIB	98	\$345,175	98	\$337,954	97	\$336,896	(1)	(\$1,058)

1/ All items in italics are "non-adds"; items in parenthesis are subtractions.

## **Major Changes in the Fiscal Year 2013 President's Budget Request**

The FY 2013 budget request for NIBIB is \$1.058 million less than the FY 2012 level, for a total of \$336.896 million.

Research Project Grants (RPGs; +\$2.834 million; total \$230.140 million): NIBIB will continue to fund a substantial number of RPGs, 570 awards in FY 2013, an increase of 9 awards and \$2.834 million from FY 2012. This includes 182 competing RPGs (an increase of 42 awards and \$15.337 million from FY 2012) and 353 non-competing awards (a decrease of 34 awards and \$12.758 million from FY 2012). NIH budget policy for RPGs in FY 2013 discontinues inflationary allowances and reduces the average cost of noncompeting and competing RPGs by one percent below the FY 2012 level.

Training (-\$0.033 million; total \$10.707 million): NIH will provide an across-the-board increase in FY 2013 of two percent for stipends levels under the Ruth L. Kirschstein National Research Service Award training program. Training costs are also reflected in the FY 2013 Technological Competitiveness - Bridging the Sciences program total, as all NIBIB training activities are within that program.

Research & Development Contracts (-\$3.708 million; total \$16.904 million): The requested reduction for Research and Development Contracts as compared to the FY 2012 Enacted level is mostly due to a large one-time contract that required funding for a two-year increment in FY2012 that has no additional funding requirement in FY 2013.

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**  
**Summary of Changes**  
(Dollars in Thousands)

<b>FY 2012 Enacted</b>				<b>\$337,954</b>
<b>FY 2013 President's Budget</b>				<b>\$336,896</b>
<b>Net change</b>				<b>(\$1,058)</b>
<b>CHANGES</b>	<b>2013 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 January 2012 pay increase & benefits		\$3,683		\$0
b. January FY 2013 pay increase & benefits		3,683		11
c. One more day of pay		3,683		14
d. Annualization of PY net hires		3,683		0
e. Payment for centrally furnished services		1,601		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		6,874		0
Subtotal				\$25
2. Research Management and Support:				
a. Annualization of January 2012 pay increase & benefits		\$9,916		\$0
b. January FY 2013 pay increase & benefits		9,916		29
c. One more day of pay		9,916		38
d. Annualization of PY net hires		9,916		0
e. Payment for centrally furnished services		2,480		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		6,442		0
Subtotal				\$67
Subtotal, Built-in				\$92

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**

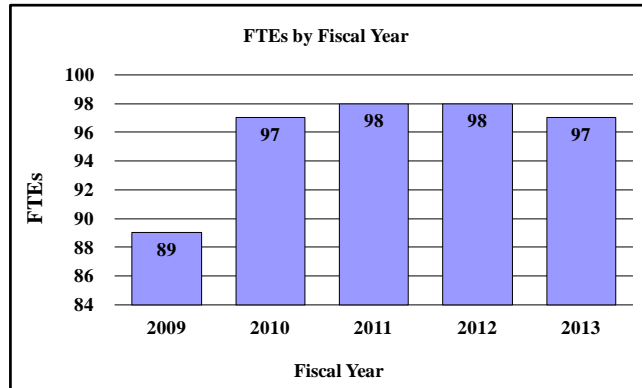
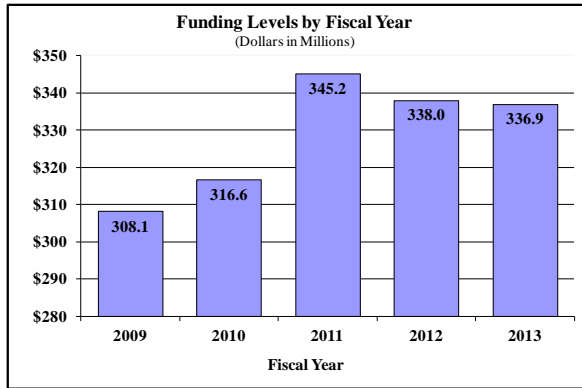
**Summary of Changes--continued**

CHANGES	2013 President's Budget		Change from FY 2012	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	353	\$151,548	(34)	(\$12,758)
b. Competing	182	69,305	42	15,337
c. SBIR/STTR	35	9,287	1	255
Total	570	\$230,140	9	\$2,834
2. Research Centers	35	\$43,510	0	(\$136)
3. Other Research	46	4,639	0	(15)
4. Research Training	250	10,707	3	(33)
5. Research and development contracts	12	16,904	0	(3,708)
Subtotal, Extramural		\$305,900		(\$1,058)
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	32	\$12,158	0	(\$25)
7. Research Management and Support	65	18,838	(1)	(67)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	97	\$336,896	(1)	(\$1,150)
Total changes				(\$1,058)

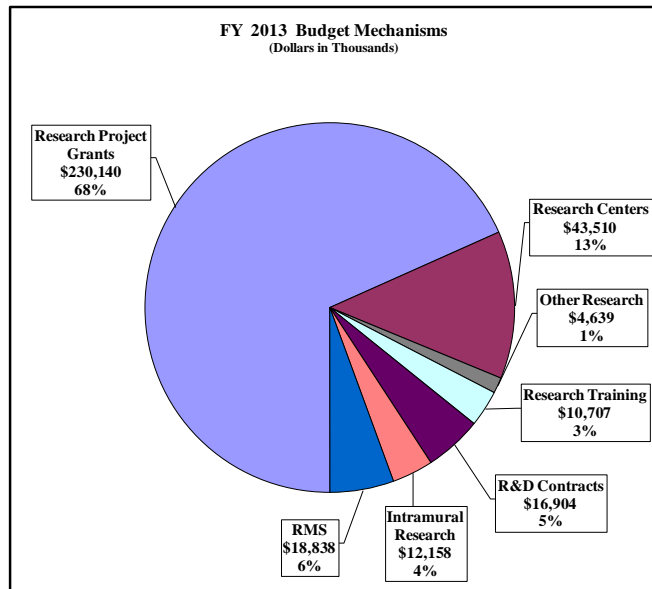


## Fiscal Year 2013 Budget Graphs

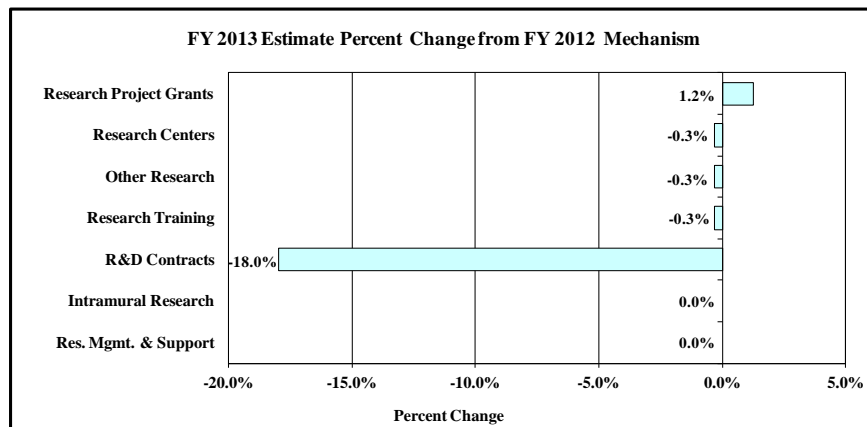
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanisms:



**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**  
**Budget Authority by Activity**  
(Dollars in Thousands)

	FY 2011 Actual		FY 2012 Enacted		FY 2013 PB		Change vs. FY 2012 Enacted	
	<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>								
<u>Detail:</u>								
Applied Science and Technology		\$176,005		\$174,177		\$173,545		(632)
Discovery Science and Technology		117,418		108,145		107,724		(421)
Technological Competitiveness - Bridging the Sciences		20,579		24,636		24,631		(5)
<b>Subtotal, Extramural</b>		\$314,002		\$306,958		\$305,900		(\$1,058)
<b>Intramural Research</b>	32	\$12,158	32	\$12,158	32	\$12,158	0	\$0
<b>Research Management &amp; Support</b>	66	\$19,015	66	\$18,838	65	\$18,838	(1)	\$0
<b>TOTAL</b>	98	\$345,175	98	\$337,954	97	\$336,896	(1)	(\$1,058)

1. Includes FTEs which are reimbursed from the NIH Common Fund.

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

**NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering**

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2012 Amount Authorized</b>	<b>FY 2012 Enacted</b>	<b>2013 Amount Authorized</b>	<b>FY 2013 PB</b>
Research and Investigation	Section 301	42§241	Indefinite	\$337,954,000	Indefinite	\$336,896,000
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$337,954,000</b>		<b>\$336,896,000</b>

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute of Biomedical Imaging and Bioengineering**

**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2004	\$282,109,000	\$282,109,000	\$289,300,000	\$288,900,000
Rescission				(\$1,771,000)
2005	\$297,647,000	\$297,647,000	\$300,800,000	\$300,647,000
Rescission				(\$2,438,000)
2006	\$299,808,000	\$299,808,000	\$309,091,000	\$299,808,000
Rescission				(\$2,998,000)
2007	\$296,810,000	\$294,850,000	\$297,606,000	\$296,887,000
Rescission				\$0
2008	\$300,463,000	\$303,318,000	\$304,319,000	\$303,955,000
Rescission				(\$5,310,000)
Supplemental				\$1,588,000
2009	\$300,254,000	\$310,513,000	\$307,254,000	\$308,208,000
Rescission				\$0
2010	\$312,687,000	\$319,217,000	\$313,496,000	\$316,582,000
Rescission				\$0
2011	\$325,925,000		\$325,415,000	\$316,582,000
Rescission				(\$2,779,778)
2012	\$322,106,000	\$322,106,000	\$333,671,000	\$338,998,000
Rescission				(\$640,706)
2013	\$336,896,000			

## Justification of Budget Request

### *National Institute of Biomedical Imaging and Bioengineering*

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority:

	FY 2011 Actual	FY 2012 Enacted	FY 2013 President's Budget	FY 2013 + / - FY 2012
BA	\$345,175,000	\$337,954,000	\$336,896,000	-1,058,000
FTE	98	98	97	-1

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

### Director's Overview

The mission of National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve human health by leading the development and accelerating the application of biomedical technologies. By focusing on improving health care through technology, NIBIB invests resources in scientific and technological opportunities and in the next generation of researchers. NIBIB is at the forefront of translating scientific advances into engineered medical solutions. Ultimately, NIBIB seeks to realize innovations that address health care challenges, reduce disease mortality and morbidity, and enhance quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate basic science into new and improved health care.

#### **Theme 1: Investing in Basic Research**

NIBIB supports research at the convergence of engineering, mathematics, and the physical and life sciences to advance fundamental discoveries and knowledge in basic biomedical research. Such convergence science approaches are leading to improved understanding of human physiology in both health and disease, and answering some of the biologic mysteries required for the design of improved diagnostics and therapies. For example one researcher, employing specialized nuclear magnetic resonance (NMR) spectroscopy techniques has begun to define the structure of the class of receptors that are most frequently the targets of drugs. In the future this may allow the chemical design of molecules as new therapeutics. Another group of investigators is defining the role of physical cues from the supportive matrix in concert with biochemical cues on the developmental fate of stem cells. In addition, our intramural scientists have begun to investigate the development of nascent nerve cells in living systems by using ultra-resolution photo-activatable microscopy. Finally, scientists are beginning to "peer" into single cells and examine the intracellular biological processes in vivo. Understanding and characterizing these processes should both advance knowledge of the heterogeneity of cells and the identification of the earliest indicators of abnormal function.

## **Theme 2: Accelerating Discovery through Technology**

The promise of exciting basic discoveries is limited by existing technological tools with adequate temporal-spatial resolution to examine biological processes across all physical scales. In FY 2013, NIBIB plans to pursue technology development that will enable such discoveries. For example, the development of imaging mass spectroscopy approaches provides tools that could be used to study complex functions of cells. Research on bioinformatics and computational tools to collect multi-parametric data in parallel and to analyze large volumes of data will complement the research on advanced discovery tools.

A specific example of a clinically important discovery enabled through technology advancement, is the work of one grantee to better understand and reduce the problem of cardiovascular device-induced blood clots. Over five million patients in the U.S. suffer annually from heart failure.<sup>1</sup> Many of these patients are treated with mechanical circulatory support (MCS) devices such as prosthetic valves, ventricular assist devices and total artificial hearts. A major problem with these devices is the development of a clot in the blood vessels (thromboembolism) and the risk for stroke. To facilitate the design of next generation MCS devices and to eliminate the potential for thromboembolism, Dr. Danny Bluestein and colleagues (State University of New York, Stony Brook) have developed a universal predictive computational model of thrombogenicity.<sup>2</sup> This method combines in silico simulations with in vitro measurements to correlate device hemodynamics with platelet activity. The combination then allows fine-tuning of the physical features of the prosthetic device to reduce thrombogenicity and the risk of blood clots. NIBIB also has an active Biomedical Technology Research Centers (BTRC) program, which fosters the development of cutting edge biomedical imaging and bioengineering technologies. In FY 2012, the NIBIB BTRC program will be expanded with the transfer of fourteen BTRC grants from the National Center for Research Resources (NCRR).

## **Theme 3: Advancing Translational Science**

A recent example of advancing translational science that could have a broad impact is the development of a hand-held integrated NMR, micro-fluidics, nanotechnology and smart phone device to detect and molecularly characterize cancer at the bedside. Early studies indicate this may be more accurate at the point-of-care than traditional biopsies that return results in days. This new technology is currently undergoing further clinical validation and is described in more detail in the first program portrait.

NIBIB also supports the development of imaging techniques for early disease detection, which can facilitate early treatment and potentially reduce costly chronic conditions. One such recent development is Magnetic Resonance Elastography (MRE) which can reduce the need for invasive biopsies. MRE is a process of imaging the response to acoustic shear waves aimed at organs deep inside the body to efficiently identify abnormal changes in the stiffness of tissues. Initial applications have been in the detection of liver fibrosis and cirrhosis due to infection with Hepatitis B and C as well as fatty liver disease-conditions. MRE detects pre-fibrotic changes in

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<sup>1</sup> <http://www.nlm.nih.gov/medlineplus/heartfailure.html>

<sup>2</sup> Alemu Y, Girdhar G, Xenos M, Sheriff J, Jesty J, Einav S, Bluestein D. 2010. Design optimization of a mechanical heart valve for reducing valve thrombogenicity-A case study with ATS valve. ASAIO J. Sep-Oct;56(5):389-96.

liver elasticity allowing for early treatment and reversal of fibrosis, potentially staving off chronic disease and the associated costs of life-long treatment. MRE is now being tested for early diagnosis of other diseases, including breast cancer and Alzheimer's disease (AD), where preliminary results indicate that the brain in AD patients loses significant stiffness compared with age-matched, cognitively normal subjects.

Many medical technologies have transformed health care in the U.S. However, they remain unavailable to many patients. In FY 2013, NIBIB plans to invest in research that will promote the development and translation of effective, low-cost medical technologies that are affordable and accessible by everyone. NIBIB has partnered with NIMHD to support small businesses in the development and deployment of medical technologies that can have a significant impact on health care access and outcomes for under-served populations. One current project is developing an inexpensive, portable blood analyzer for screening and monitoring blood disorders in children from low-resource settings. In collaboration with a Native American tribe, another project seeks to build a miniaturized, wireless cardiac monitor to better manage and treat heart disease in the Native American population. To address the disparities associated with tuberculosis (TB) infection, a low-cost point-of-care test for TB detection is being designed, enabling rapid diagnosis and ensuring that appropriate treatment is given to affected individuals. The translation of scientific discoveries into approaches delivered by mobile devices will improve the prevention, diagnosis and treatment of diseases in the under-served populations.

#### **Theme 4: Encouraging New Investigators and New Ideas**

NIBIB is an enthusiastic supporter of new investigators and has a longstanding policy that provides an additional 5 percentile point advantage to these individuals when selecting grants for funding. In FY 2011, the number of NIBIB-supported new investigators was equivalent to 45 percent of the new R01 awards. This policy encourages and nurtures the next generation of researchers who are likely to push the innovation boundaries. One example of the impact of this approach is a new investigator at Vanderbilt University who developed the first leg prosthesis with a powered knee and powered ankle joint to restore natural walking patterns in amputees. This technology has major practical utility. According to the National Limb Loss Information Center (NLLIC), 1.7 million people in the United States are living with an amputation, and approximately 300,000 of these are above-the-knee leg amputees.<sup>3</sup> Falling and fear of falling are significant problems in lower limb amputees. Current state-of-the-art prostheses are passive and severely compromise standing and walking in amputees. Unlike passive prostheses, a powered prosthetic has the capability to adapt to varying gait conditions and provide appropriate reactive behaviors in the presence of balance and walking perturbations. In April 2011, this technology was licensed to Freedom Innovations to make this product available to amputees around the world. This could tangibly improve the quality of life of a large population of lower extremity amputees and lower the rate of falls in this population.

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<sup>3</sup> Kathryn Ziegler-Graham, PhD, et al. "Estimating the Prevalence of Limb Loss in the United States - 2005 to 2050," Archives of Physical Medicine and Rehabilitation 89 (2008):422-429.

Overall Budget Policy: The FY 2013 request for NIBIB is \$336.896 million, a decrease of \$1.058 million or 0.31 percent, under the FY 2012 Enacted level. NIBIB funding policies give special consideration to applications that bridge and integrate the life and physical sciences, and also focus on enhancing support for new investigators. Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

### **Program Descriptions and Accomplishments**

**Applied Science and Technology (AST):** The AST program supports research, development and application of technologies for improving health and patient care. In addition to developing new technologies, AST also supports research that improves current clinical techniques. One example is the optimization of breast cancer diagnostics by developing dedicated breast CT scanners. Another example is the optimization of MRI exams using fast scanning approaches. New optical imaging techniques enable more precise biopsies for prostate cancer and uterine cancer. New MRI approaches are being developed that may allow more accurate screening for prostate cancer. Low-cost optical endoscopes have been developed to detect and ablate ovarian cancer. Focused ultrasound is being developed to enable delivery of potentially toxic cancer drugs exclusively at the target tissue. New electron paramagnetic resonance (EPR) imaging techniques are being developed that will allow better optimization of radiation dose for treatment of cancer. Upon development and validation, these technologies are integrated into specific clinical applications in collaboration with disease-specific NIH Institutes. In addition, research to deploy such technology around the world is a focus of global health research. The promise of these efforts is improved prevention, earlier diagnosis, better management of chronic diseases, and more effective treatment of acute disorders.

Budget Policy: The FY 2013 President's Budget request is \$173.545 million, a decrease of \$0.632 million or 0.36 percent, under the FY 2012 Enacted level. High priority is given to new and early-career investigators and to research that bridges the physical and life sciences. AST will place a high priority on molecular imaging and will continue to support research for image-guided interventions. High priority will also continue to be given to investigator-initiated research, including exploratory research grants and Bioengineering Research Partnerships.



**Program Portrait: Development of Low-Cost, Hand-Held, Point-of-Care Medical Devices**

FY 2012 Level: \$15.8 million

FY 2013 Level: \$15.7 million

Difference: -\$0.1 million

The NIBIB supports the development of hand-held medical devices that can be translated to low-cost, point-of-care situations. One example involves a hand-held ultrasound imaging device that was developed with funding from NIBIB and is now commercially available (General Electric “Vscan” system). This device is small, portable, does not involve radiation, and can acquire chest images in “real time”. A recent article in the *Annals of Internal Medicine* suggests that the hand-held ultrasound imaging device could become a high technology replacement for, and improvement on, the ubiquitous physician’s stethoscope.

The second example involves a hand-held micro nuclear magnetic resonance (micro NMR) device that combines nanotechnology with “smart phone” technology to diagnose cancer and perform “molecular profiling” of biopsy samples. Molecular profiling of tumors enables personalized medicine such that cancer patients are treated with the appropriate drugs based on the molecular characterization of their tumor cells. However, conventional molecular profiling approaches based on biopsy and histopathology studies in the hospital pathology lab are time-consuming, costly and require large biopsy samples. In order to circumvent these problems the NIBIB recently funded a grant to design and construct a novel micro NMR device that is portable, affordable, and gives rapid results with fine needle aspirate samples. Preliminary clinical results demonstrate that the new micro NMR device shows great potential for cost-effective “point-of-care” cancer diagnosis.

**Discovery Science and Technology (DST):** The DST program supports the acquisition of new knowledge about biomedical problems through the support of research on the development of bioengineering and biomedical imaging technologies and related research in the life and physical sciences. The DST program portfolio is broad in scope and includes innovative and revolutionary research focused on biomaterials; biomechanics; computational modeling, simulation, and analysis; drug and gene delivery systems; medical devices and implant science; nanotechnology; rehabilitation engineering; sensors and microsystems; surgical systems; and regenerative medicine including stem cell research. In addition, the DST program currently supports a Network for Point-of-Care Technology Development Centers that merge scientific and technological capabilities with clinical need in the areas of neuro-emergencies, sexually transmitted diseases, disaster readiness, and global health. A solicitation for applications for Phase II of the Network was recently released. The DST program continues to support an initiative on Predictive Multiscale Models of the Physiome in Health and Disease. The goal of this long-term effort is to develop mathematical and computational models that accurately describe complex medical responses at the cellular as well as clinical levels and that can be used to predict response to therapy. The Program also supports research on the development of multifunctional drug and gene delivery systems to target and release therapies at the target site in order to improve efficacy and reduce toxicity. This past year, the DST program released an initiative to develop technologies for independent living that will monitor health or deliver care in a real-time, accessible, effective, and minimally-obtrusive way. These technologies will integrate, process, analyze, communicate, and present data so that the individuals are engaged and empowered in their own health care. This personal empowerment has the potential to significantly improve the quality of life for people with disabilities, people aging with mild impairments, and individuals with chronic conditions.

**Budget Policy:** The FY 2013 President's Budget request is \$107.724 million, a decrease of \$0.421 million or 0.39 percent, under the FY 2012 Enacted level. DST will give high priority to supporting new and early-career investigators. Priority will be given to investigator-initiated research grants as this is the foundation on which future advances in new biomedical technologies and improved patient care will be developed. Large grants and Center programs will continue to receive support as will investment in other scientific opportunities and high priority areas. The research program in biomedical informatics will receive strong support.

**Program Portrait: Engineered Tissues as a Tool for Drug Development**

FY 2012 Level: \$1.5 million

FY 2013 Level: \$1.5 million

Difference: +\$0.0 million

Tissue Engineering is a field that integrates knowledge and technology from across the life and physical sciences to assemble tissues with organ-like function from cells, biomolecules, and materials. Typically, the goal is to generate constructs that can be transplanted to replace or restore organ function lost due to disease or trauma. However recently, there have been advances in using engineered tissues as a tool for drug development. An excellent example of this comes from an NIBIB-supported grant to Drs. Sangeeta Bhatia (Massachusetts Institute of Technology) and Christopher Chen (University of Pennsylvania), who have developed engineered human liver tissues capable of replicating human liver functions. The engineered human liver, when implanted in mice, makes human proteins and breaks down drugs as the human liver would. All experimental drugs must first be assessed in animals before they can be given to people. Mice are often used for such tests. However, liver enzymes in mice differ from those in humans and vary in how they metabolize drugs. As a result, experimental drugs that prove safe in mice may unexpectedly break down to create harmful metabolites in humans. This new technique of a human liver in a mouse could lead to more accurate testing of potential drugs. The idea that you could take a humanized mouse and identify these metabolites before going to clinical trials is potentially very valuable. With further research, the technique might be able to detect problematic drugs before they are tested in humans.

**Technological Competitiveness – Bridging the Sciences:** Basic research provides a foundation of new scientific discoveries on which to build improvements in health care. Building new treatments and diagnostics on this foundation requires engineering, clinical research, and basic sciences working together to construct practical solutions. Interdisciplinary approaches underpin technological advancement that will position the U.S. well in a highly competitive global environment. NIBIB has several interdisciplinary research programs that exemplify our investment toward technological competitiveness and the translation of science to treatments. The Quantum Grant program seeks to apply innovative biomedical technologies to critical national health care needs with the goal of reducing the burden of a major disease or public health problem. An example is the emerging development of a biodegradable microneedle patch for vaccinations that is painless and could be delivered by mail (Mark Prausnitz, Georgia Tech). Because it is quickly biodegradable, there is no concern about biohazardous waste for disposal. The Bioengineering Research Partnerships Program is another example of interdisciplinary translational research that supports a team that includes an engineer and a life scientist to solve a problem that neither could address alone. An NIBIB-led interagency program on bridging the sciences is identifying demonstration projects to explore new approaches to bridging the biological, computational, and physical science. In this endeavor, we are working cooperatively

with the National Science Foundation as well as with other NIH Institutes and Centers, and private organizations. In FY 2010, NIBIB and National Institute of Child Health and Human Development (NICHD) initiated a program for “Team-Based Design in Biomedical Engineering Education.” This program will support the enhancement of team-based design courses in undergraduate Biomedical Engineering and will serve to enhance the technological competitiveness of American industry by preparing a cadre of engineers who are trained to solve problems using a team-based, interdisciplinary approach. These efforts are closely aligned with the NIH Director’s key themes of “translating basic science to new and better treatments” and “reinvigorating the biomedical research community.”

Budget Policy: The FY 2013 President’s Budget request is \$24.631 million, a decrease of \$0.005 million or 0.02 percent, under the FY 2012 Enacted level. High priorities include increasing training stipends by 2 percent from the FY 2012 Enacted level. Other high priorities include developing interdisciplinary training programs and supporting the Quantum Grants Program, which establishes interdisciplinary research teams to address major healthcare problems.

**Program Portrait: NIBIB’s Undergraduate Training Initiative - Team-Based Design in Biomedical Engineering Education (R25) and DEsign by Biomedical Undergraduate Teams (DEBUT) Challenge**

FY 2012 Level: \$0.3 million  
FY 2013 Level: \$0.3 million  
Difference: +\$0.0 million

NIBIB has initiated a two-pronged program to support the training of the next generation of biomedical engineers to have not only the theoretical knowledge to address health problems but also the ability to translate new devices and technologies from the bench to the bedside.

The first part of NIBIB’s undergraduate training initiative includes the Team-Based Design in Biomedical Engineering Education (R25) program. This program provides support to Biomedical Engineering (BME) departments that establish new or enhance existing design courses that offer undergraduate students experience in working in teams, identifying unmet clinical needs, and designing, building and debugging solutions for open-ended problems.

The second part of the program involves the DEsign by Biomedical Undergraduate Teams (DEBUT) Challenge. Designed to complement the R25 program, the challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. The main goals of the challenge are 1) to provide undergraduate students experience in working in teams; 2) to generate novel, innovative tools to improve health care; and 3) to highlight and acknowledge the contributions and accomplishments of undergraduate students. One winning student team will be selected for each of three challenge categories: Diagnostic Devices/Methods; Therapeutic Devices/Methods; and Technology to Aid Underserved Populations and Individuals with Disabilities. Eligible team candidates must be full time undergraduate students (2011-2012) and U.S. citizens or permanent residents. Each winning team will receive a \$10,000 prize. Inaugural winners will be honored at the NIBIB DEBUT Award Ceremony during the 2012 Annual Meeting of the Biomedical Engineering Society (BMES) in Atlanta, GA.

**Intramural Research:** The Intramural Program supports NIBIB’s mission to integrate bioengineering with the life and physical sciences and to develop new technologies that allow scientific investigation at scales ranging from molecular and cellular to the whole organ. To aid in understanding diseases at the molecular level, innovative technology will be developed for high-resolution fluorescence imaging of specific proteins in living cells in “real-time” using lower, non-damaging, doses of light. Such an instrument has been developed and is based on rapidly scanning a thin sheet of light through a sample, to enable the first acquisition of a “four-dimensional” atlas (i.e., showing three dimensions varying with time) of thousands of genetically encoded proteins that are expressed during embryogenesis as they develop from a single cell to an intact organism. Previously, it has not been possible to obtain this type of high-resolution four-dimensional atlas due to light damage. This research, which is led by NIBIB’s recent intramural PECASE awardee, fundamentally changes how knowledge is obtained about embryogenesis; it uses animal models, and will be particularly important for understanding the regulation of specific genes during neural development. Effort will be expanded in the development of molecular imaging probes for improved disease diagnosis, as well as new nanomedicine platforms for therapies including drug and gene delivery. Clinical research will focus on development of patient-based methods for detecting and quantifying subclinical cardiovascular disease of the myocardium and blood vessels.

Budget Policy: The FY 2013 President’s Budget request is \$12.158 million, the same as the FY 2012 Enacted level. This includes funding for a molecular imaging and nanomedicine laboratory aimed at early diagnosis of disease, monitoring therapeutic response, and guiding drug discovery.

**Research Management and Support (RMS):** NIBIB 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 functions also encompass strategic planning, coordination, and evaluation of the Institute’s programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

Budget Policy: The FY 2013 President’s Budget request for is \$18.838 million, the same as the FY 2012 Enacted level. High priorities of RMS are the scientific support of NIBIB research programs and strategic planning.

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

	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>	<b>Increase or Decrease</b>
Total compensable workyears:			
Full-time employment	98	97	(1)
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary ( <i>in dollars</i> )	\$0	\$0	\$0
Average GM/GS grade	12.8	12.8	0.0
Average GM/GS salary ( <i>in dollars</i> )	\$109,273	\$109,819	\$546
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) ( <i>in dollars</i> )	\$0	\$0	\$0
Average salary of ungraded positions ( <i>in dollars</i> )	0	0	0
<b>OBJECT CLASSES</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 PB</b>	<b>Increase or Decrease</b>
Personnel Compensation:			
11.1 Full-time permanent	\$6,972	\$7,046	\$74
11.3 Other than full-time permanent	2,656	2,684	28
11.5 Other personnel compensation	264	267	3
11.7 Military personnel	0	0	0
11.8 Special personnel services payments	896	906	10
<b>Total, Personnel Compensation</b>	<b>\$10,788</b>	<b>\$10,903</b>	<b>\$115</b>
12.0 Personnel benefits	\$2,719	\$2,737	\$18
12.2 Military personnel benefits	0	0	0
13.0 Benefits for former personnel	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$13,507</b>	<b>\$13,640</b>	<b>\$133</b>
21.0 Travel and transportation of persons	\$400	\$369	(\$31)
22.0 Transportation of things	34	34	0
23.1 Rental payments to GSA	30	30	0
23.2 Rental payments to others	43	43	0
23.3 Communications, utilities and miscellaneous charges	196	196	0
24.0 Printing and reproduction	9	9	0
25.1 Consulting services	174	174	0
25.2 Other services	3,559	3,283	(276)
25.3 Purchase of goods and services from government accounts	23,699	25,433	1,734
25.4 Operation and maintenance of facilities	18	18	0
25.5 Research and development contracts	6,251	983	(5,268)
25.6 Medical care	3	3	0
25.7 Operation and maintenance of equipment	1,365	1,365	0
25.8 Subsistence and support of persons	0	0	0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>\$35,069</b>	<b>\$31,259</b>	<b>(\$3,810)</b>
26.0 Supplies and materials	\$752	\$752	\$0
31.0 Equipment	1,564	1,564	0
32.0 Land and structures	4	4	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	286,346	288,996	2,650
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	0	0	0
44.0 Refunds	0	0	0
<b>Subtotal, Non-Pay Costs</b>	<b>\$324,447</b>	<b>\$323,256</b>	<b>(\$1,191)</b>
<b>Total Budget Authority by Object</b>	<b>\$337,954</b>	<b>\$336,896</b>	<b>(\$1,058)</b>

Includes FTEs which are reimbursed from the NIH Common Fund.

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

OBJECT CLASSES	FY 2012 Enacted	FY 2013 PB	Increase or Decrease
<b>Personnel Compensation:</b>			
Full-time permanent (11.1)	\$6,972	\$7,046	\$74
Other than full-time permanent (11.3)	2,656	2,684	28
Other personnel compensation (11.5)	264	267	3
Military personnel (11.7)	0	0	0
Special personnel services payments (11.8)	896	906	10
<b>Total Personnel Compensation (11.9)</b>	<b>\$10,788</b>	<b>\$10,903</b>	<b>\$115</b>
Civilian personnel benefits (12.1)	\$2,719	\$2,737	\$18
Military personnel benefits (12.2)	0	0	0
Benefits to former personnel (13.0)	0	0	0
<b>Subtotal, Pay Costs</b>	<b>\$13,507</b>	<b>\$13,640</b>	<b>\$133</b>
Travel (21.0)	\$400	\$369	(\$31)
Transportation of things (22.0)	34	34	0
Rental payments to others (23.2)	43	43	0
Communications, utilities and miscellaneous charges (23.3)	196	196	0
Printing and reproduction (24.0)	9	9	0
<b>Other Contractual Services:</b>			
Advisory and assistance services (25.1)	174	174	0
Other services (25.2)	3,559	3,283	(276)
Purchases from government accounts (25.3)	12,909	12,764	(145)
Operation and maintenance of facilities (25.4)	18	18	0
Operation and maintenance of equipment (25.7)	1,365	1,365	0
Subsistence and support of persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$18,025</b>	<b>\$17,604</b>	<b>(\$421)</b>
Supplies and materials (26.0)	\$750	\$750	\$0
<b>Subtotal, Non-Pay Costs</b>	<b>\$19,457</b>	<b>\$19,005</b>	<b>(\$452)</b>
<b>Total, Administrative Costs</b>	<b>\$32,964</b>	<b>\$32,645</b>	<b>(\$319)</b>

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

OFFICE/DIVISION	FY 2011 Actual			FY 2012 Enacted			FY 2013 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	5	0	5	6	0	6	6	0	6
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	5	0	5	6	0	6	6	0	6
Extramural Science Program									
Direct:	23	0	23	22	0	22	21	0	21
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	23	0	23	22	0	22	21	0	21
Office of Research Administration									
Direct:	19	0	19	18	0	18	18	0	18
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	19	0	19	18	0	18	18	0	18
Office of Administrative Management									
Direct:	19	0	19	20	0	20	20	0	20
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	19	0	19	20	0	20	20	0	20
Intramural Science Program									
Direct:	20	0	20	20	0	20	20	0	20
Reimbursable:	12	0	12	12	0	12	12	0	12
Total:	32	0	32	32	0	32	32	0	32
<b>Total</b>	<b>98</b>	<b>0</b>	<b>98</b>	<b>98</b>	<b>0</b>	<b>98</b>	<b>97</b>	<b>0</b>	<b>97</b>
Includes FTEs which are reimbursed from the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements									
	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2009	12.5								
2010	12.9								
2011	12.8								
2012	12.8								
2013	12.8								

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**Detail of Positions**

GRADE	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	11	11	11
GM/GS-14	23	23	22
GM/GS-13	15	15	15
GS-12	11	11	11
GS-11	2	2	3
GS-10	1	1	1
GS-9	2	2	2
GS-8	1	1	1
GS-7	4	4	3
GS-6	1	1	1
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	71	71	70
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	0	0	0
Ungraded	26	26	26
Total permanent positions	66	69	68
Total positions, end of year	98	98	97
Total full-time equivalent (FTE) employment, end of year	98	98	97
Average ES salary	0	0	0
Average GM/GS grade	12.8	12.8	12.8
Average GM/GS salary	109,273	109,273	109,819

Includes FTEs which are reimbursed from the NIH Common Fund.