DEPARTMENT OF HEALTH AND HUMAN SERVICES

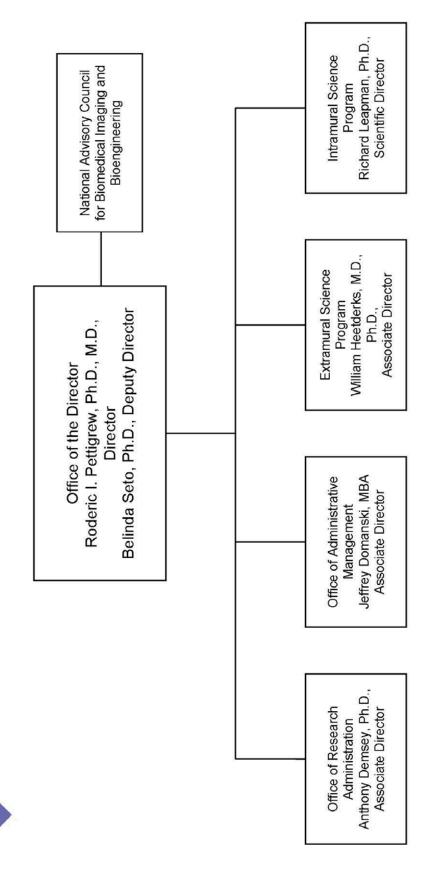
NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

FY 2014 Budget	Page No.
Organization Chart	2
Appropriation Language	3
Amounts Available for Obligation	4
Budget Mechanism Table	5
Major Changes in Budget Request	6
Summary of Changes	7
Budget Graphs	9
Budget Authority by Activity	10
Authorizing Legislation	11
Appropriations History	12
Justification of Budget Request	13
Budget Authority by Object Class	24
Salaries and Expenses	25
Detail of Full-Time Equivalent Employment (FTE)	26
Detail of Positions	27

NIBIB ORGANIZATIONAL CHART

m



For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and

bioengineering research \$338, 892, 000.

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	338,998	340,428	338,892
Rescission	(641)	0	0
Subtotal, adjusted appropriation	338,357	340,428	338,892
Secretary's Transfer for Alzheimer's disease (AD)	(223)	0	0
Secretary's Transfer	(96)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(310)	(401)	0
Subtotal, adjusted budget authority	337,728	340,027	338,892
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	337,728	340,027	338,892
Unobligated balance lapsing	(28)	0	0
Total obligations	337,700	340,027	338,892

Amounts Available for Obligation ¹ (Dollars in Thousands)

Excludes the following amounts for reimbursable activities carried out by this account: FY 2012 - \$2,995; FY 2013 - \$2,996; FY 2014 - \$2,995

Budget Mechanism - Total¹ (Dollars in Thousands)

MECHANISM		2012 ctual		2013 CR		2014 PB	Change vs	s. FY 2012
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants	1100	mount	1101	mount	1101	iniount	1101	moun
Research Projects								
Noncompeting	381	\$165,417	377	\$153,568	400	\$160,764	19	(\$4,653)
Administrative Supplements	5	284	5	284	5	283	0	(1
Competing:								
Renewal	27	12,809	36	17,081	28	13,385	1	570
New	134	39,953	179	53,277	141	42,010	7	2,057
Supplements	1	247	0	0	0	0	(1)	(247
Subtotal, Competing	162	\$53,009	215	\$70,358	169	\$55,395	7	\$2,386
Subtotal, RPGs	543	\$218,711	592	\$224,210	569	\$216,442	26	(\$2,269
SBIR/STTR	35	\$8,988	36	\$9,397	39	\$9,796	4	\$808
Research Project Grants	578	\$227,698	628	\$233,607	608	\$226,238	30	(\$1,460
Research Centers								
Specialized/Comprehensive	4	\$7,092	4	\$7,092	4	\$7,060	0	(\$32
Clinical Research	0	0	0	0	0	0	0	(
Biotechnology	30	38,094	30	38,094	30	37,923	0	(171
Comparative Medicine	0	0	0	0	0	0	0	(
Research Centers in Minority Institutions	0	0	0	0	0	0	0	(
Research Centers	34	\$45,187	34	\$45,186	34	\$44,983	0	(\$204
Other Research								
Research Careers	27	\$3,895	27	\$3,895	27	\$3,877	0	(\$18
Cancer Education	0	0	0	0	0	0	0	(
Cooperative Clinical Research	0	0	0	0	0	0	0	(
Biomedical Research Support	0	0	0	0	0	0	0	(
Minority Biomedical Research Support	0	0	0	0	0	0	0	(
Other	32	1,227	32	1,227	32	1,221	0	(6
Other Research	59	\$5,122	59	\$5,122	59	\$5,098	0	(\$24
Total Research Grants	671	\$278,007	721	\$283,915	701	\$276,319	30	(\$1,688
Ruth L. Kirschstein Training Awards	FTTPs		FTTPs		FTTPs		FTTPs	
Individual	20	\$950	20	\$950	19	\$946	(1)	(\$4
Institutional	219	9,375	219	9,375	210	9,333	(9)	(42
Total Research Training	239	\$10,326	239	\$10,325	229	\$10,279	(10)	(\$47
Research & Development Contracts	15	\$18,205	14	\$14,596	15	\$21,103	0	\$2,89
SBIR/STTR (non-add)	3	\$19	3	\$19	3	\$19	0	(\$0
	FTEs		FTEs		FTEs		FTEs	
Intramural Research	<u>FIES</u> 29	\$11,411	<u>FIES</u> 29	\$11,411	<u>F1Es</u> 29	\$11,411	<u>FIES</u> 0	\$
	29 68	\$11,411 19,780	29 76	\$11,411 19,780	29 76	\$11,411 19,780	8	D.
Research Management and Support	00	19,/00	/0	19,/00	/0	19,/00	0	(

¹ All items in italics are "non-adds."

Major Changes in the Fiscal Year 2014 President's Budget Request

The FY 2014 President's Budget request for NIBIB is \$1.2 million more than the FY 2012 level, for a total of \$338.9 million. 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 President's Budget.

<u>Research Project Grants (RPGs; -\$1.460 million; total \$226.238 million)</u>: NIBIB will continue to fund a substantial number of RPGs, 608 awards in FY 2014, an increase of 30 awards and -\$1.460 million from FY 2012. This includes 169 competing RPGs (an increase of 7 awards and \$2.386 million from FY 2012) and 400 non-competing awards (an increase of 19 awards and -\$4.653 million from FY 2012).

<u>Training (-\$0.047 million; total \$10.279 million)</u>: NIH will provide increases in FY 2014 for stipend levels under the Ruth L. Kirschstein National Research Service Award (NRSA) training program. Stipends for doctoral trainees are provided a 2 percent increase over FY 2012 levels. The 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. The number of trainees will be reduced in order to absorb the increased stipend levels.

<u>Research and Development Contracts (+\$2.898 million; total \$21.103 million)</u>: NIBIB will increase funding for R&D Contracts over the FY 2012 level. A large portion of this increase is due to the resumption in funding of the Quantitative Imaging Biomarkers Alliance contract in FY 2013 and FY 2014.

Summary of Changes (Dollars in Thousands)

FY 2012 Actual	\$337,728
FY 2014 President's Budget	\$338,892
Net change	\$1,164

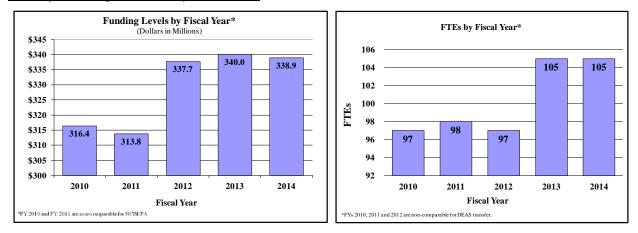
					2014 nt's Budget	Changes from FY 2012	
			CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A.	Bui	lt-in:					
	1.	Intr	amural Research:				
		a.	Annualization of March 2013 pay increase & benefits		\$4,387		\$11
		b.	January FY 2014 pay increase & benefits		4,387		33
		c.	One more day of pay		4,387		17
		d.	Differences attributable to change in FTE		4,387		0
		e.	Payment for centrally furnished services		457		8
		f.	Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		6,567		12
		Sub	total				\$80
	2.	Res	earch Management and Support:				
		a.	Annualization of March 2013 pay increase & benefits		\$10,171		\$25
		b.	January FY 2014 pay increase & benefits		10,171		75
		c.	One more day of pay		10,171		38
		d.	Differences attributable to change in FTE		10,171		0
		e.	Payment for centrally furnished services		2,278		41
		f.	Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		7,331		3
		Sub	total				\$182
		Sub	total, Built-in				\$263

Summary of Changes-continued

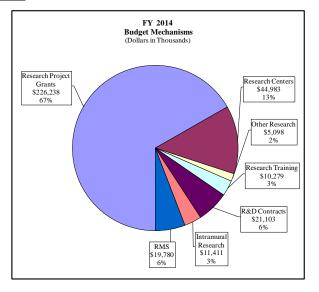
		2 Presider	2014 nt's Budget	Change from FY 2012	
	CHANGES	No.	Amount	No.	Amount
B.	Program:				
	1. Research Project Grants:	100	\$1 <1 0 45	10	(****
	a. Noncompeting	400	\$161,047	19	(\$4,654)
	b. Competing	169	55,395	7	2,386
	c. SBIR/STTR	39	9,796	4	808
	Total	608	\$226,238	30	(\$1,460)
	2. Research Centers	34	\$44,983	0	(\$204)
	3. Other Research	59	5,098	0	(24)
	4. Research Training	229	10,279	(10)	(47)
	5. Research and development contracts	15	21,103	0	2,898
	Subtotal, Extramural		\$307,701		\$1,163
		<u>FTEs</u>		<u>FTEs</u>	
	6. Intramural Research	29	\$11,411	0	(\$80)
	7. Research Management and Support	76	19,780	8	(182)
	8. Construction		0		0
	9. Buildings and Facilities		0		0
	Subtotal, Program	105	\$338,892	8	\$901
	Total changes				\$1,164

Fiscal Year 2014 Budget Graphs

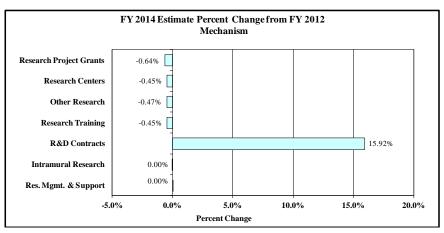
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Budget Authority by Activity ^{1,2} (Dollars in Thousands)

	FY201	2 Actual	FY 2	013 CR	FY 2	014 PB		nge vs. 2012
Extramural Research	FTEs	<u>Amount</u>	FTEs	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>
<u>Detail:</u>								
Applied Science and Technology		\$166,726		\$171,531		\$168,221		\$1,495
Discovery Science and Technology		87,032		88,666		86,938		(94)
Health Informatics Technology		32,456		27,935		32,241		(215)
Technological Competitiveness - Bridging the Sciences		20,323		20,704		20,301		(22)
Subtotal, Extramural		\$306,537		\$308,836		\$307,701		\$1,164
Intramural Research	29	\$11,411	29	\$11,411	29	\$11,411	0	(\$0)
Research Management & Support	68	\$19,780	76	\$19,780	76	\$19,780	8	\$0
TOTAL	97	\$337,728	105	\$340,027	105	\$338,892	8	\$1,164

^{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.

	PHS Act/ Other Citation	U.S. Code Citation	2013 Amount Authorized	FY 2013 CR	2014 Amount Authorized	FY 2014 PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite	\$340,027,000	Indefinite	\$338,892,000
Total, Budget Authority				\$340,027,000		\$338,892,000

Authorizing Legislation

NIBIB-11

NATIONAL INSTITUTES OF HEALTH National Institute of Biomedical Imaging and Bioengineering

	Budget Estimate to			
Fiscal Year	Congress	House Allowance	Senate Allowance	Appropriation
2005	\$297,647,000	\$297,647,000	\$300,800,000	\$300,647,000
Rescission				(\$2,438,000)
2005	*2 00,000,000	*2 00,000,000	*2 00 001 000	*****
2006 Rescission	\$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
2000	\$200.254.000	\$210,512,000	¢207.254.000	¢208 208 000
2009 Rescission	\$300,254,000	\$310,513,000	\$307,254,000	\$308,208,000 \$0
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		\$337,917,000	
Rescission				
2014	\$338,892,000			

Appropriations History

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 (BA):

	FY 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 +/- FY 2012
BA	\$337,728,000	\$340,027,000	\$338,892,000	\$1,164,000
FTE	97	105	105	+8

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

Director's Overview

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) works to improve human health by leading the development and accelerating the application of biomedical imaging and bioengineering technologies. The Institute is committed to integrating engineering and physical sciences with life sciences to advance basic research and medical care. As it enters its second decade, NIBIB will continue to build on that integration to transform 21st century medical practice with technology that improves outcomes, reduces costs, and establishes the patient as the center of the health care effort.

Current NIBIB funded research holds great promise for this transformation. We now have technologies that allow us to image with pinpoint accuracy. Research to develop precise, quantitative imaging to identify biomarkers of risk and early indications of diseases, such as stroke or cancer, can improve diagnosis and expand the window of opportunity for early treatment. "Time is brain" has been a slogan used by the stroke community to stress the importance of early treatment following the onset of a stroke; however, this strategy treats the stroke once it occurs. With these improved imaging technologies, it will be possible to detect one's risk of stroke, cancer, heart, and other diseases before they occur and do damage. Imaging is also being coupled with minimally-invasive therapeutic techniques, such as focused ultrasound, to remove tissue, destroy tumors, release drugs, or repair injured organs or blood vessels.

The convergence of physical and engineering sciences with medicine and life sciences will advance basic research and medical care in many ways. Already, improved targeting tools allow researchers to precisely deliver stem cells to specific tissues. Better chemistry allows vaccines to remain stable longer and without refrigeration. Application of advanced fluid dynamics to blood flow is providing a new understanding of the mechanics of blood clot formation. Advances in nanotechnology are providing new ways to deliver medications. High throughput engineering techniques are being applied to analysis of single cells, in hopes of revealing disease mechanisms at the cellular level. Engineering new approaches to image-sharing is redefining the way that medical images are shared between medical centers.

<u>Overall Budget Policy</u>: The FY 2014 request for NIBIB is \$338.892 million, an increase of \$1.164 million or 0.3 percent above the FY 2012 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).

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

NIBIB supports the entire continuum of technology development, from basic research to translation. Looking forward to FY 2014, NIBIB plans to support science devoted to developing next-generation bioengineering and imaging technologies. For example, researchers can observe at unprecedented resolution different points in the life cycle of cells using ultra-resolution microscopy. Such technology is developed by an NIBIB intramural lab that can capture the 14-hour cycle of embryo development in the C. elegans worm. We gain a better understanding of cell formation, structural organization, and motility by watching the development of neurons as the worm grows from a single cell to a fully-developed, mature organism. The ability to image living organisms at high resolution over the course of many hours without damaging the organism is the major breakthrough with this technology.

Theme 2: Translational Science

Translating bench research into practical solutions is a critical step toward improving health. NIBIB will continue to support translational efforts through various channels, including the development of point-of-care technologies that bring diagnostics and therapeutics to patients' bedsides, whether it be in the patient's home, a community clinic, a rural doctor's office, or in a village of a developing country. In one example, researchers have developed a battery-powered, portable, fiber optic microscope that non-invasively characterizes and diagnoses precancerous and malignant cells for cervical cancers. This easy-to-use technology is ideal for low-resource environments that may not even have electricity, much less the infrastructure or expertise to conduct and analyze Pap smears. This technology also provides immediate cancer diagnosis at the point of care. It has already been used for early detection of cervical pre-cancer in China and Botswana.

Another high priority focus across medical fields is helping wounded warriors and others who are disabled by accident or disease. In FY 2014, NIBIB plans to support the development of assistive technologies to help people live independently. For example, researchers at Case Western Reserve University are developing a modular functional electrical stimulation system to treat spinal cord injured individuals. This functional electrical stimulation system electrically stimulates paralyzed muscles in a coordinated fashion that enables a person to reach out with an arm, or grasp and release an object with a hand. This method can be custom tailored to the needs of each particular patient. A sustained commitment to innovation in these areas has made the impossible become a reality.

Theme 3: Recruiting and Retaining Diverse Scientific Talent and Creativity

NIBIB has a robust training program that supports graduate and postdoctoral training. Creating a diverse, interdisciplinary work force is part of the NIBIB mission. However, the 'leaky pipeline' for underrepresented students in the science, technology, engineering, and math (STEM) fields has been observed by many, and it points to the need for strong interactions with students early in their careers. To increase the number of underrepresented students in STEM fields, NIBIB will support an innovative project at the undergraduate level to test the effectiveness of a program that combines intensive recruitment and outreach efforts; strong faculty and peer-to-peer mentoring; exposure to academic and industrial research experiences; professional development counseling; and social networking. The results will inform future programs designed to further increase the STEM diversity pipeline and direct students in the pipeline to academic and industrial research careers.

Program Descriptions and Accomplishments

Applied Science and Technology

Applied Science and Technology promotes, fosters, and manages biomedical imaging research programs. Research programs in this area include: image-guided interventions; magnetic, biomagnetic, and bioelectric devices; magnetic resonance imaging (MRI) and spectroscopy; molecular imaging; nuclear medicine; ultrasound; and x-ray, electron, and ion beam modalities. The program also supports trans-NIH activities in single cell analysis and the Human Connectome Project, which is an effort that uses cutting edge imaging technologies to map the circuitry of the human brain.

In FY 2014, the program plans to support the development of an advanced diagnostic ultrasound imaging device for the breast that can provide clear images without the 'noise' that typically obscures ultrasound imaging, by using an array of 10,000 ultrasound transducers. This technological leap will enable 'low noise' ultrasound imaging at resolutions high enough to see individual cells, while also being compatible with functional imaging approaches.

Looking further to improve diagnostic procedures in the area of women's health, NIBIB continues to support the development and validation of a multifunction 3-D breast imaging system to improve diagnosis of breast abnormalities, guide biopsy, and improve removal of damaged or diseased tissue. The newest version will combine computerized tomography (CT) with positron emission tomography (PET) and will employ advanced computerized methods for tumor detection. A robotic needle positioning system that uses real time information from CT scans will be developed to enhance biopsy precision. This same system will be adapted to carry out image-guided, minimally-invasive techniques that use radiofrequency and x-rays to destroy tumors. These tools could reduce damage to healthy tissue while decreasing pain for patients.

NIBIB also supports research that harnesses the combined power of imaging and molecular biology, enabling us to probe disease mechanisms with molecular imaging techniques. Such research will advance knowledge of the heterogeneity of cancers and enable the development of targeted therapies for more precision medicine. For example, injecting hyperpolarized carbon 13 (C-13) compounds into prostate cancer patients can be used to measure the metabolic rate of a

tumor; this provides a more rapid and accurate picture of the tumor's aggressiveness. MRI imaging typically images hydrogen because it is so plentiful in all tissues. However, by 'hyperpolarizing' the isotope called carbon 13, investigators are able to increase its signal by about 10,000-fold, making this carbon signal readily detectable. The researchers developed a system for synthesizing, hyperpolarizing, and rapidly delivering carbon-13-labeled pyruvate, a natural human metabolite. The metabolic changes in the pyruvate serve as biomarkers for prostate cancer as the disease progresses. Monitoring these changes may improve risk prediction, a particularly critical issue in prostate cancer, where individuals often adopt a watch and wait strategy.

NIBIB's ongoing support of MRI scanner advances will also contribute to the success of the trans-NIH Human Connectome Project to map the circuitry of the human brain. This project has recently yielded a one-of-a-kind scanner that produces images of the brain at unprecedented resolution and at a much faster rate than previous methods, allowing researchers to examine how the connections in the brain relate to mood, personality, thought, and behavior.

Given the broad spectrum of imaging modalities and bioengineering approaches covered by NIBIB research, collaboration is essential. NIBIB is supporting a collaborative project between Lasker award-winning researchers and software developers to develop open source microscopy software that automatically captures digital microscopic images and can be used with many different types of microscopes, cameras, and instruments. The open source platform allows all members of the scientific community to write code for the program to make it compatible with any of the hardware in their labs. The grant supports general maintenance for the existing software as well as the development of new, advance microscopy techniques. Keeping the software user-friendly, while adding innovative imaging capabilities and the ability to share images, is a main focus of the grant.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the AST program is \$168.221 million, a \$1.495 million increase (0.9 percent) from the FY 2012 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 Non-Invasive Interventional Therapies by use of Ultrasound

FY 2012 Level:	\$ 6.3 million
FY 2014 Level:	\$ 6.2 million
Change:	- \$ 0.1 million

Ultrasound has traditionally been considered a diagnostic tool, but researchers are developing new therapeutic capabilities for ultrasound, including High-Intensity Focused Ultrasound and Ultrasound Thrombolysis. Researchers are developing high-intensity focused ultrasound technologies as MRI- image-guided, non-invasive therapies. One group has developed an ultrasound therapy system that can temporarily open the blood-brain barrier to enhance drug delivery for the treatment of brain tumors or other brain disorders. Also, the team is developing a method for breaking down blood clots in the brain (therapy for stroke). The unique, helmet-shaped ultrasound applicator developed by researchers at the University of Aberdeen and Brigham and Women's Hospital can also be used to non-invasively remove tumors in the brain. In addition, this technology has been licensed by a commercial company for use in the first clinical trials for the non-invasive treatment of essential tremor (a neurological disorder characterized by involuntary shaking movements). One of these trials was recently completed on 15 subjects with essential tremor and was highly successful. Recently, FDA approved clinical trials for the treatment of Parkinson's disease, which are now starting.

Researchers at the University of Nebraska have been developing thrombolytic ultrasound therapy technology for non-invasively re-opening blocked coronary arteries in the heart. This completely non-invasive technique achieves re-canalization of the coronaries, as well as re-opening the micro circulation of the heart muscle. The ultrasound applicator is a 2-dimensional ultrasound transducer array and can be used with presently existing diagnostic systems. The first-in-human clinical trials have been completed by an outside group, and these were successful. The goal of the next stage in the development of this project is to bring this technology into clinical use.

Discovery Science and Technology

Discovery Science and Technology (DST) supports research in a broad range of areas including biomaterials; drug and gene delivery systems and devices; mathematical modeling, simulation and analysis; medical devices and implant sciences; micro-biomechanics; nanotechnology; rehabilitation engineering; microsystems and devices for point-of-care technologies and high-throughput screening; surgical tools, techniques, and systems; and tissue engineering and regenerative medicine.

In FY 2014, DST plans to continue its strong support for a diverse collection of innovative Biotechnology Research and Development Centers. One such Center conducts research to develop a new silk-based stabilizer that, in the laboratory, has kept some vaccines and antibiotics stable even at very high temperatures. In an initial study, the measles, mumps, and rubella (MMR) vaccine was kept stable at up to 113 degrees Fahrenheit; and two antibiotics penicillin and tetracycline—maintained near optimal activity at temperatures up to 140 degrees Fahrenheit. This provides a new avenue to eliminate the need to keep vaccines and antibiotics continuously refrigerated, which could save billions of dollars every year and increase accessibility to low-income communities and third world populations.

In the area of robotics, NIBIB supports the development of a minimally invasive robot that can reach tumors deep within the brain. This project is a partnership between the medical and engineering schools at the University of Maryland to develop a minimally invasive neurosurgical intracranial robot that is compatible with MRI. Using information from continuous MRI, surgeons will be able to guide the robot to a tumor and then instruct it to destroy and eliminate cancerous tissue while preserving surrounding critical brain areas.

In another example, a team of NIBIB-funded investigators is developing a robotic microsurgery workstation to improve delicate eye surgeries. The workstation design addresses fundamental limitations in current microsurgical practice by eliminating physician hand tremors and fatigue while improving visual and tactile feedback of the target area for the ophthalmologist. In addition, the workstation integrates patients' preoperative imaging studies into the feedback display. Technologies of these types are designed to be less invasive, more effective, and/or result in fewer side effects.

DST also supports a Presidential Early Career Award for Scientists and Engineers grantee who has developed 3-D micro-fabricated patches infused with connective tissue cells that mimic the environment inside bone marrow, where blood cells are formed. Ongoing support will evaluate the implantation of these patches as a treatment for marrow failure, which can be caused by blood cancers. In addition, this research is aimed at creating a robust, reliable, and user-friendly platform to identify the mechanisms of blood formation and to screen compounds that could enhance that process.

In FY 2014, DST plans to support research on single cell analysis in order to understand what makes individual cells unique and to pave the way for medical treatments that are based on disease mechanisms at the cellular level. By profiling individual cells, researchers can identify rare cell types as well as alterations in the health or condition of specific cells that may relate to functional changes. Single cell profiling can also determine the influence of cellular organization and environment on specific cells and their states.

Research on biomaterials is also a priority. In one example, NIBIB-supported researchers developed a biodegradable cardiovascular stent. After insertion, this new stent is absorbed by the body, eliminating the complications caused by metal stents, which have to remain in the body for life. The new stent has all the properties of existing stents—strength, flexibility, biocompatibility, and the ability to deliver medication—but it is designed to be absorbed at a controlled rate and is radio-opaque, meaning it is easily visible using X-rays. The development of this stent, now in clinical trials, was made possible by ongoing NIBIB support of a larger program called Resource Integrated Technologies for Polymeric Biomaterials (RESBIO), which aims to meet the biomaterial needs of researchers. RESBIO investigators have created a library containing the properties of huge variety of biomaterials. When scientists submit a request for a specific type of biomaterial with certain qualities—such as a non-toxic composition or biodegradability—RESBIO investigators search the library of polymers and synthesize a material based on how it will be used and how it needs to perform. With this streamlined resource, the design of a biomaterial is greatly accelerated.

Commercialization is a long-term outcome goal for much of NIBIB research. For example, the effective treatment of sexually transmitted infections requires that disease diagnosis be completed during the patient's visit, so therapy can begin immediately. This capability can be provided by point-of-care devices if they can be both accurate and rapid in reporting test results. Researchers at the Center for STD Point-of-Care Tests at Johns Hopkins University have collaborated with Atlas Genetics to develop a molecular diagnostic platform for the electrochemical analysis of Chlamydial DNA in patient samples. This device has been shown to have laboratory-quality performance with a rapid result appropriate for use in the primary care office.

Regarding global health, infants and young children under five years of age suffer disproportionally from high morbidity and mortality due to infection, anemia, and poor nutrition, especially in low-resource settings. Obtaining the complete blood count is a commonly used test for diagnosis of these conditions, but it is unavailable in areas that need it most. Holomic, LLC is developing a compact, lightweight, and cost-effective point-of-care imaging device that can be operated by minimally trained personnel to provide immediate blood analysis results to health care practitioners in rural settings. The device relies on NIBIB-supported innovative, lens-free holographic imaging of cells, bacteria or other micro-scale particles on a low-cost cell phone camera chip and has the ability to rapidly process patient samples.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the DST program is \$86.938 million, a \$0.094 million decrease (0.1 percent) from the FY 2012 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.

Program Portrait: The NIBIB Program for Rehabilitation Engineering

 FY 2012 Level:
 \$18.6 million

 FY 2014 Level:
 \$18.4 million

 Change:
 -\$0.2 million

The NIBIB Program for Rehabilitation Engineering supports the development of next generation engineering systems that present a paradigm shift for neurotechnologies and rehabilitation medicine. This program supports rehabilitation engineering research that develops modeling, simulation, analysis, robotics, and systems engineering technology. These efforts are applied to early stage technology development of neuroprostheses, robotics rehabilitation, and biomechanics of human movement. Technologies include the development of intelligent hardware and software that allows patients to control mechanical arms with their thoughts, creates prosthetics that mimic natural movements, and uses robots to aid physical therapy. Many of the awards in this program support Bioengineering Research Partnerships that bring together engineers, physical and life scientists, and medical researchers to solve biomedical problems with a team approach.

For example, the Bioengineering Research Partnerships project focuses on spinal epidural electrode array to facilitate standing and stepping after Spinal Cord Injury. This project builds upon decades of basic neuroscience research on spinal cord injuries. Epidural spinal stimulation is a technique that applies very low level electrical stimulation to the surface of the spinal cord. This project recently demonstrated for the first time a successful therapeutic method to help spinal cord injured individuals regain various bodily functions. In combination with motor training, the spinal stimulation enabled an individual with paralysis to stand and voluntarily move some parts of his leg. The therapy also led to improved bowel, bladder, and sexual function, as well as enhanced thermoregulation (ability of the body to sweat or shiver), even in the absence of epidural stimulation. Follow-up work in other spinal cord injury patients shows equally promising results.

Technological Competitiveness–Bridging the Sciences

NIBIB supports interdisciplinary research in close collaboration with companies to improve technological competitiveness. In one example, a team of physicians and engineers are working with device manufacturers to improve the design of implants such as heart valves and circulatory assist devices that operate in contact with blood. These devices present a risk for the formation of blood clots, which can cause stroke and other complications. The risk and the elimination of the risk depend on the fine details of the implant's mechanical design, its impact on blood flow, and the materials used to make the implant. To assess this risk, NIBIB researchers have developed a computer model for blood flow, much like a flight simulator can be used to test the design of a plane, so that implants can be optimized before they are put in patients. These advances may lead to the elimination of difficult and costly anticoagulant drug therapy and pave the way for long-term use of these mechanical devices, ultimately saving countless lives and reducing healthcare costs.

Training is fundamental to advancing technology and maintaining competitiveness. NIBIB supports a broad range of training programs including disciplinary programs to support and bridge areas of NIBIB relevance, multidisciplinary programs to promote the clinical translation of emerging technology, and interdisciplinary programs to train a new cadre of researchers working at the intersection of the biological and physical sciences. NIBIB programs are designed to support researchers throughout the career continuum, increase the number of clinician-scientists, and enhance the participation of underrepresented populations in biomedical imaging and bioengineering research.

For example, in partnership with the Howard Hughes Medical Institute (HHMI), NIBIB is supporting projects that will help train the next generation of interdisciplinary researchers. HHMI is providing supplements to NIBIB training grant recipients to facilitate the dissemination of the interdisciplinary techniques being developed in these programs. The projects will respond to the growing need to share successful training strategies among biomedical research institutions that are developing graduate-level research training programs in emerging fields at the intersection of the life and physical sciences.

After establishing the Design by Undergraduate Teams Challenge last year, NIBIB recently announced the first winners and awarded each winning team a \$10,000 prize. In the first year of this challenge, 61 teams submitted entries from 39 different universities, involving a total of 284 undergraduate students. Teams included students from varying disciplines that came together to address sophisticated problems in the areas of diagnostic devices, therapeutic devices, and technologies to aid underserved populations and individuals with disabilities. Two teams have received provisional patents for their inventions.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the Technological Competitiveness – Bridging the Sciences program is \$20.301 million, a \$0.022 million decrease (0.1 percent) from the FY 2012 level. NIH will provide increases in FY 2014 for stipend levels under the Ruth L. Kirschstein National Research Service Award training program. The 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. 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: Increasing Diversity in Engineering and the Physical Sciences

FY 2012 Level: \$ 0.7 million **FY 2014 Level:** \$ 0.8 million **Chapter 1**

Change: +\$ 0.1 million

The Increasing Diversity in Engineering and the Physical Sciences project is a NIBIB initiative to increase the participation of underrepresented minorities in biomedical research by supporting cohorts of undergraduate diversity students in Science, Technology, Engineering and Mathematics (STEM) fields. This STEM initiative aims to increase the recruitment, retention, and graduation rates of students, enhance post-graduate educational and career choices for the students, and evaluate the relative effectiveness of program elements in accomplishing these objectives. Awards have been made to The University of Maryland, Baltimore County (UMBC) and Savannah State University (SSU).

UMBC has a tradition of training STEM students from diverse backgrounds, having prepared more than 1,200 diverse undergraduate students to go on to graduate and medical study in the biomedical sciences over the last two decades. Students who complete the Meyerhoff program at UMBC are over five times more likely to graduate from or be currently attending a STEM PhD or MD-PhD program than comparable students who were accepted into the program and chose to attend another university. SSU, one of the historically black universities and colleges, has modeled its program on the UMBC program.

This initiative will support a cohort of undergraduate diversity students for four years, linking them with highquality research experiences on the NIH campus. The initiative will also test the relative effectiveness of focused programs in driving student recruitment, retention, academic achievement, graduation, and post-graduation educational and career decisions. The programs at both schools include academic assistance; financial assistance; student mentoring (family, faculty, and peer-to-peer); professional and social development; and on-campus research experiences. The results from these two pilots will provide information on key elements of success and how the successful model can be implemented throughout the country. The National Institute on Drug Abuse is a co-funding partner for the UMBC program.

Health Informatics Technology (HIT)

The Health Informatics Technology program supports activities to further research in health information technology, bioinformatics, mHealth, clinical decision support, image processing, data integration, and telehealth. This program also supports trans-NIH and government-wide activities in this area of health informatics.

Health Informatics Technology is looking at ways to harness "big data" by using an informatics approach to link early changes in brain images with the genes associated with degenerative diseases. Big datasets of longitudinal information that link medical imaging data, genomic data, and environmental and phenotypic data are emerging from a number of ongoing studies. These studies are creating a virtual data 'space' in which investigators can look for clues to better understand disease and disease progression. Researchers at the University of California at Los Angeles have recently developed a novel approach that can explore this space. Their approach provides innovative quantitative MRI markers for Alzheimer's disease patients as well as novel statistical methods that can deal effectively with large amounts of imaging and genomic data. This group has recently demonstrated that these approaches can provide markers for early changes in the brain's white matter integrity. Specifically, they demonstrated that healthy young carriers of a specific gene known to increase the chance of developing late-onset Alzheimer's disease appear to have degraded connections between brain cells in a number of regions associated with late-onset Alzheimer's disease. These results suggest that diffusion-weighted

MRI could provide an effective marker for early drug treatment of susceptible individuals long before clinical symptoms occur. These discoveries are all being made in the big data space.

Another goal for Health Informatics Technology research is empowering patients to play a greater role in coordinating their own health care and reducing or preventing redundant procedures. For example, a NIBIB supported project at the Radiological Society of North America, allows patients to share their medical images via the internet with the doctors and hospitals they choose. The current pilot network of five major medical centers will be significantly expanded in FY 2014. These efforts may help reduce repeated scans and lower costs for patients and the healthcare system.

In FY 2014, NIBIB also plans to support Technologies for Healthy Independent Living, an initiative to develop smart home technologies and mobile health that can complete health assessments for aging adults in their homes and detect health care changes that may lead to early interventions, improved quality of life, and decreased health care utilization. For example, researchers at Washington State University conducted pilot studies on the efficacy of using smart home technologies for both functional status assessment and for prompting executive planning (allowing execution of activities of daily living) in individuals with mild cognitive impairment and dementia. With these preliminary results, NIBIB started a 5-year longitudinal study of older adults performing daily activities in their own smart homes, in efforts to more rigorously evaluate the technology. By tracking residents' daily behavior over a long period of time, their intelligent software will perform automated functional assessment and identify trends that are indicators of acute health changes (such as infection or injury) and slower progressive decline (such as dementia). Understanding the natural history of functional change between aging and dementia will lead to early preventive and proactive interventions that may slow functional change, thereby delaying nursing home placement and cost of care to society.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the HIT program is \$32.241 million, a \$0.215 million decrease (0.7 percent) from the FY 2012 level. HIT will focus on mobile health, clinical decision support, and big data in FY 2014. In collaboration with other Institutes, we will initiate new funding opportunity announcements in the areas of healthy independent living and connected health. The HIT will also give priority to new investigators. Investigator initiated research and Bioengineering Research Partnership applications will be encouraged and supported.

Intramural Research Program (IRP)

The NIBIB IRP plays a key role in fulfilling the Institute's mission, particularly to advance knowledge in imaging and bioengineering research using a combination of basic, translational, and clinical science and to develop effective training programs in related fields. In FY 2014, the Laboratory of Molecular Imaging and Nanomedicine plans to continue developing molecular imaging probes that pinpoint molecular pathways with potential for clinical translation, including radiolabeled peptide probes (markers that can be traced in the body) for first-in-human studies aimed at early cancer diagnosis.

In another IRP lab, the Section on High Resolution Optical Imaging is innovating technology for real-time, high-resolution optical fluorescence imaging of specific proteins in living cells. Their

approach minimizes damage to cells from exposure to light. The group has already been able to image for the first time the development of live model organisms from single cell embryos to adults. Their aim is to create the first 4-D atlas of development, which will aid in understanding human disease processes at the molecular level.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for the Intramural Research Program is \$11.411 million, equal to the FY 2012 level. High priority research includes molecular imaging and nanomedicine - for the early diagnosis of disease, monitoring of therapeutic response, and guiding drug discovery, and also research on novel technologies for fast, "super resolution" optical microscopy of live cells to accelerate biomedical research.

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.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate for Research Management and Support is \$19.780 million, equal to the FY 2012 level. High priorities of RMS are the scientific support of NIBIB research programs and strategic planning. The apparent increase in estimated FY 2014 FTE compared to the FY 2012 actual FTE usage level is due to the effect of transferring positions previously funded from a centralized support operation (Division of Extramural Activities Support) to individual ICs as of year-end FY 2012. As a result of the DEAS transfer, estimated salaries and benefits for FY 2014 are proportionately higher than those identified for FY 2012 and previous years.

Budget Authority by Object Class (Dollars in Thousands)

	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	97	105	8
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary (in whole dollars)	\$0	\$0	\$0
Average GM/GS grade	13	12	(1)
Average GM/GS salary (in whole dollars) Average salary, grade established by act of	\$109,636	\$106,655	(\$2,981)
July 1, 1944 (42 U.S.C. 207) (in whole dollars)	\$0	\$0	\$0
Average salary of ungraded positions (in whole dollars)	\$0	\$0	\$0

		FY 2012	FY 2014	Increase or
	OBJECT CLASSES	Actual	PB	Decrease
	Personnel Compensation:	¢c 021	¢7.407	¢ 10.0
11.1	Full-time permanent	\$6,931	\$7,427	\$496
11.3	Other than full-time permanent	2,914	3,035	121
11.5	Other personnel compensation	197	209	12
11.7	Military personnel	0	0	0
11.8	Special personnel services payments	810	823	13
	Total, Personnel Compensation	\$10,851	\$11,494	\$643
12.0	Personnel benefits	\$2,889	\$3,064	\$175
12.2	Military personnel benefits	0	0	(
13.0	Benefits for former personnel	0	0	(
	Subtotal, Pay Costs	\$13,740	\$14,558	\$81
21.0	Travel and transportation of persons	\$391	\$353	(\$38
22.0	Transportation of things	36	36	(0
23.1	Rental payments to GSA	32	34	2
23.2	Rental payments to others	39	38	(1
23.3	Communications, utilities and miscellaneous charges	209	209	(
24.0	Printing and reproduction	7	7	(
25.1	Consulting services	5,616	773	(4,843
25.2	Other services	4,572	4,222	(350
25.3	Purchase of goods and services from government accounts	20,786	21,253	46
25.4	Operation and maintenance of facilities	35	34	(1
25.5	Research and development contracts	670	7,830	7,160
25.6	Medical care	4	4	(
25.7	Operation and maintenance of equipment	397	396	(1
25.8	Subsistence and support of persons	0	0	Ì
25.0	Subtotal, Other Contractual Services	\$32,079	\$34,512	\$2,43
26.0	Supplies and materials	\$855	\$752	(\$103
31.0	Equipment	2,005	2,006	
32.0	Land and structures	3	3	(
33.0	Investments and loans	0	0	(
41.0	Grants, subsidies and contributions	288,333	286,384	(1,949
42.0	Insurance claims and indemnities	0	0	(
43.0	Interest and dividends	0	0	(0
44.0	Refunds	0	0	,
	Subtotal, Non-Pay Costs	\$323,988	\$324,334	\$34
	Total Budget Authority by Object Class	\$337,728	\$338,892	\$1,164

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

Salaries and Expenses (Dollars in Thousands)

OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$6,931	\$7,427	\$496
Other than full-time permanent (11.3)	2,914	3,035	121
Other personnel compensation (11.5)	197	209	12
Military personnel (11.7)	0	0	0
Special personnel services payments (11.8)	810	823	13
Total Personnel Compensation (11.9)	\$10,852	\$11,494	\$642
Civilian personnel benefits (12.1)	\$2,889	\$3,064	\$175
Military personnel benefits (12.2)	0	0	0
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$13,741	\$14,558	\$817
Travel (21.0)	\$391	\$353	(\$38)
Transportation of things (22.0)	36	36	0
Rental payments to others (23.2) Communications, utilities and miscellaneous charges (23.3)	39 209	38 209	(1) 0
Printing and reproduction (24.0)	7	209 7	0
Other Contractual Services:			Ŭ
Advisory and assistance services (25.1)	5,616	773	(4,843)
Other services (25.2)	4,572	4,222	(350)
Purchases from government accounts (25.3)	10,532	11,247	715
Operation and maintenance of facilities (25.4)	35	34	(1)
Operation and maintenance of equipment (25.7)	397	396	(1)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$21,152	\$16,672	(\$4,480)
Supplies and materials (26.0)	\$855	\$752	(\$103)
Subtotal, Non-Pay Costs	\$22,689	\$18,067	(\$4,622)
Total, Administrative Costs	\$36,430	\$32,625	(\$3,805)

	FY 2012 Actual			FY 2013 CR			FY 2014 PB		
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	6	0	6	6	0	6	6	0	6
Reimbursable:	0	0	0	0	0	0		0	0
Total:	6	0	6	6	0	6	6	0	6
Extramural Science Program									
Direct:	22	0	22	28	0	28	28	0	28
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	22	0	22	28	0	28	28	0	28
Office of Research Administration									
Direct:	18	0	18	20	0	20	20	0	20
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	18	0	18	20	0	20	20	0	20
Office of Administrative Management									
Direct:	22	0	22	22	0	22	22	0	22
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	22	0	22	22	0	22	22	0	22
Intramural Science Program									
Direct:	19	0	19	19	0	19	19	0	19
Reimbursable:	10	0	10	10	0	10	10	0	10
Total:	29	0	29	29	0	29	29	0	29
Total	97	0	97	105	0	105	105	0	105

Details of Full-Time Equivalent Employment (FTEs)

Includes FTEs whose payroll obligations are supported by the NIH Common Fund. FTEs supported by funds from Cooperative Research and Development Agreements.

FISCAL YEAR	Average GS Grade
2010	12.5
2011	12.5
2012	12.9
2013	12.3
2014	12.3

Detail of Po	ositions
--------------	----------

GRADE	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	13	13	13
GM/GS-14	21	21	21
GM/GS-13	15	15	15
GS-12	10	11	11
GS-11	3	3	3
GS-10	1	1	1
GS-9	5	5	5
GS-8	1	1	1
GS-7	2	7	7
GS-6	0	2	2
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	79	79
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	27	27	27
Total permanent positions	70	70	70
Total positions, end of year	105	113	113
Total full-time equiv (FTE) at YE	97	105	105
Average ES salary	0	0	0
Average GM/GS grade	12.9	12.3	12.3
Average GM/GS salary	\$ 109,636	\$ 105,312	\$ 106,655

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