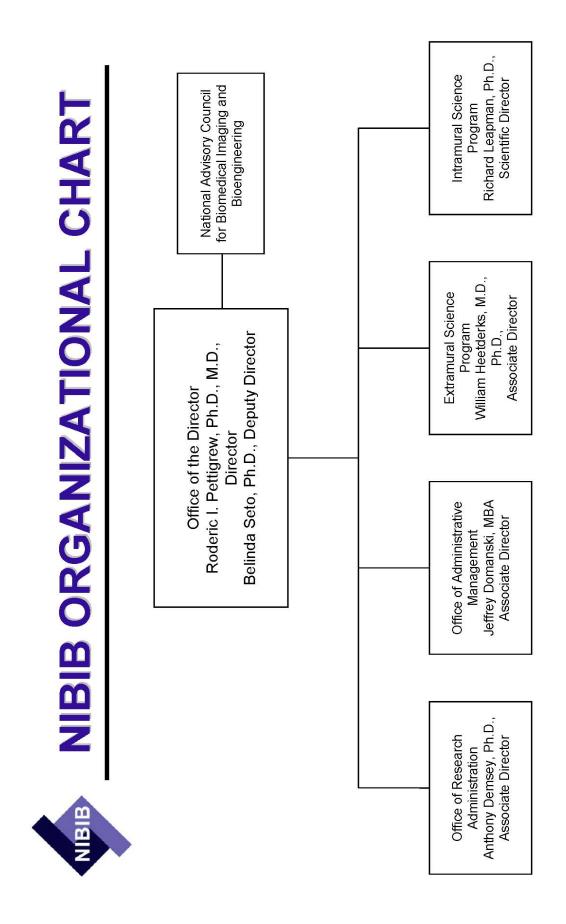
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

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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 Public Health Service Act with respect to biomedical imaging and bioengineering research, [\$316,582,000] \$325,925,000 (Public Law 111-117, Consolidated Appropriations Act, 2010)

National Institutes of Health National Institute of Biomedical Imaging and Bioengineering

Source of Funding	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Appropriation	\$308,208,000	\$316,582,000	\$325,925,000
Rescission	0	0	0
Subtotal, adjusted appropriation	308,208,000	316,582,000	325,925,000
Real transfer under Director's one-percent transfer authority (GEI)	-507,000	0	0
Comparative transfer to the National Center for Biotechnology Information (NCBI)	-49,000	-75,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	507,000	0	0
Comparative transfer to the Public Access Fund (NLM)	-51,000	-55,000	0
Subtotal, adjusted budget authority	308,108,000	316,452,000	325,925,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	308,108,000	316,452,000	325,925,000
Unobligated balance lapsing	0	0	0
Total obligations	308,108,000	316,452,000	325,925,000

Amounts Available for Obligation 1/

<u>1</u>/ Excludes the following amounts for reimbursable activities carried out by this account:
 FY 2009 - \$3,892,000
 FY 2010 - \$3,875,000
 FY 2011 - \$3,875,000
 Excludes \$13,878 Actual in FY 2009, and Estimate \$75,000 in FY 2010 for royalties.

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

			,	pliars in Thou get Mechanis	,							
	E)	(2009		9 Recoverv		I Recovery	E)	Y 2010	ΕY	2011		
MECHANISM		Actual		t Actual		Estimated		nacted		PB	Ch	ange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount		mount
Research Projects:												
Noncompeting	402	\$159.618	\$0	\$0	\$70	\$22,379	378	\$153,689	389	\$161.927	11	\$8,238
Administrative supplements	(14)	1,009	(74)	8.900	(0)	0	(14)	1.009	(14)	1.009	(0)	¢0,200 0
Competing:	()	1,000	()	0,000	(0)	0	()	1,000	()	.,	(0)	
Renewal	31	16.083	11	4,812	0	0	38	19.736	35	18.800	-3	-936
New	134	39,507	64	18,998	Ő	0	160	48.320	150	46.028	-10	-2.292
Supplements	0	00,001	7	4,003	Ő	0 0	0	0	0	0	0	_,0_
Subtotal, competing	165	55.590	82	27,813	0	0	198	68.056	185	64,828	-13	-3.228
Subtotal, RPGs	567	216,217	82	36,713	70	22,379	576	222,754	574	227.764	-2	5,010
SBIR/STTR	31	7.732	10	2.527	3	1.282	31	7,752	32	7.952	1	200
Subtotal, RPGs	598	223,949	92	39,240	73	23,661	607	230,506	606	235,716	-1	5,210
Research Centers:	590	223,949	92	39,240	13	23,001	007	230,500	000	235,710	-1	5,210
Specialized/comprehensive	6	8,296	3	1,466	3	993	6	8,420	6	8,673	0	253
Clinical research	0	0,290	0	1,400	0	993	0	0,420	0	0,073	0	200
Biotechnology	17	18.878	0	576	0	0	17	19.161	17	19.736	0	575
Comparative medicine	0	10,070	0	0	0	0	0	13,101	0	13,730	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, Centers	23	27,174	3	2.042	3	993	23	27,581	23	28,409	0	828
Other Research:	23	27,174	5	2,042	5	333	23	27,501	23	20,403	0	020
Research careers	32	4,094	0	0	0	0	32	4,155	32	4,280	0	125
Cancer education	0	4,094	0	0	0	0	0	4,155	32 0	4,280	0	125
Cooperative clinical research	0	0	0	0	0	0	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0	0	0	0	0
Other	11	445	0	0	0	0	11	452	11	466	0	14
Subtotal, Other Research	43	4,539	0	0	0	0	43	4,607	43	4.746	0	139
Total Research Grants	43 664	255,662	95	41,282	76	24,654	43 673	262,694	43 672	268,871	-1	6,177
Total Research Grants	004	200,002	95	41,202	70	24,004	0/3	202,094	072	200,071	-1	6,177
Dessert Training	CTTD-		CTTD-		CTTD-		CTTD-		CTTD-		CTTD-	
Research Training:	FTTPs		FTTPs	0	FTTPs	0	FTTPs		FTTPs	04.4	FTTPs	-
Individual awards	19	757	0 0	0	0	0 0	19	765	19 243	814	0 0	49
Institutional awards	241	10,597		-	0	-	243	10,703	-	11,384		681
Total, Training	260	11,354	0	0	0	0	262	11,468	262	12,198	0	730
Research & development contracts	15	13,556	1	4,697	4	6,117	16	14,328	16	15,695	0	1,367
(SBIR/STTR)	(2)	(13)	(0)	4,037	(0)	(0)	(2)	(13)		(13)	(0)	(0)
(SDINSTIN)	(2)	(13)	(0)	(0)	(0)	(0)	(2)	(13)	(2)	(13)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs		FTEs		FTEs	
Intramural research	30	10,928	0	355	0	35	30	11,092	33	11,447	3	355
Research management and support	59	16,608	0	188	0	609	58	16,870	59	17,714	1	844
Construction		0	-	0	-	0		0		0		0
Buildings and Facilities		0 0		0		0		0 0		Ő		Ő
Total, NIBIB	89	308,108	0	46,522	0	31,415	88	316,452	92	325,925	4	9,473

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

NATIONAL INSTITUTES OF HEALTH National Institute of Biomedical Imaging and Bioengineering BA by Program (Dollars in thousands)

	ΕY	FY 2007	FΥ	FY 2008	۴۲	FY 2009	FΥ	FY 2009	۴Y	2010	F	FY 2011		
	¥	Actual	Ac	Actual	Ac	Actual	Comp	Comparable	Ena	Enacted		PB	Change	nge
<u>Extramural Research</u> <u>Detail:</u>	<u>FTEs</u>	Amount	<u>FTEs</u>	Amount	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	Amount	<u>FTEs</u>	Amount	<u>FTEs</u>	Amount	<u>FTEs</u> <u>A</u>	Amount
Applied Science and Technology		\$153,819		\$160,047		\$167,647		\$168,154	650	\$171,595		\$176,759		\$5,164
Discovery Science and Technology		100,331		96,793		91,244		91,244		92,820		95,061		2,241
Technological Competitiveness - Bridging the Sciences		22,137		18,893		21,174		21,174		24,075		24,944		869
				725		200 005		200 5		007		100		
Subiotal, Extramora		107'017		cc1,c12		can'noz		7/C'007		∠00,43U		230,704		0,2/4
Intramural Research	5	4,265	26	7,931	30	10,928	30	10,928	30	11,092	33	11,447	б	355
Research Management & Support	54	15,828	59	16,062	59	16,708	59	16,608	58	16,870	59	17,714	۲	844
TOTAL	59	296,380	85	299,726	89	307,701	89	308,108	88	316,452	92	325,925	4	9,473

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

Major Changes in the Fiscal Year 2011 Budget Request

Major changes by budget mechanism are briefly described below. The FY 2011 budget request for NIBIB is \$9.473 million more than the FY 2010 enacted level, for a total of \$325.925 million.

<u>Research Project Grants (RPGs; +\$5.210 million; total \$235.716 million)</u>: NIBIB will continue to maintain an adequate number of competing RPGs—185 awards in FY 2011, (a decrease of 13 from FY 2010). About 389 noncompeting RPG awards, totaling \$161.927 million also will be made in FY 2011.

<u>Training (+\$0.730 million: total \$12.384 million)</u>: Training costs will increase in FY 2011 as stipends for both predoctoral and postdoctoral training positions will increase by 6%. This increase is also reflected in the FY 2011 Technological Competitiveness - Bridging the Sciences program total, as all NIBIB training activities are within that program.

<u>Research & Development Contracts (+\$1.367 million; total \$15.695 million)</u>: Increase in the Contracts mechanism reflects a high level of support in FY 2011 for trans-NIH initiatives (+\$0.705 million) and increased support for other HHS agencies through the program evaluation set-aside (+\$0.939 million). These FY 2011 increases are partially offset due to the ending of the Genes and the Environment Initiative in FY 2010 (-\$0.507).

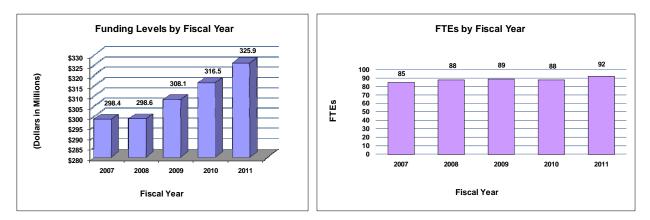
FY 2010 Enacted				\$316,452,000
FY 2011 PB				325,925,000
Net change				9,473,000
		FY 2010		
	Ena	acted Base	Chang	e from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January		*		• • • • • • •
2010 pay increase		\$2,351,000		\$14,000
b. January FY 2011 pay increase		2,351,000		25,000
c. Zero less days of pay (n/a for 2011)		2,351,000		0
d. Payment for centrally furnished services		1,268,000		25,000
e. Increased cost of laboratory supplies,		7 472 000		100.000
materials, and other expenses		7,473,000		120,000
Subtotal				184,000
2. Research management and support:				
a. Annualization of January				
2010 pay increase		\$8,518,000		\$52,000
b. January FY 2011 pay increase		8,518,000		89,000
c. Zero less days of pay (n/a for 2011)		8,518,000		0
d. Payment for centrally furnished services		1,562,000		31,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		6,790,000		116,000
Subtotal				288,000
Subtotal, Built-in				472,000

Summary of Changes--continued

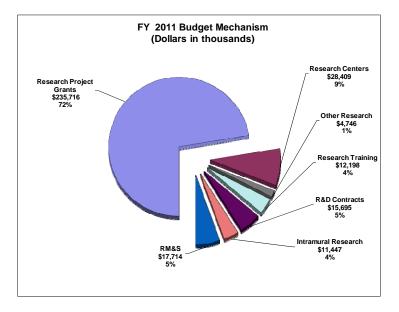
		FY 2010		
	En	acted Base	Change	e from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	378	\$154,698,000	11	\$8,238,000
b. Competing	198	68,056,000	(13)	(3,228,000)
c. SBIR/STTR	31	7,752,000	1	200,000
Total	607	230,506,000	(1)	5,210,000
2. Research centers	23	27,581,000	0	828,000
3. Other research	43	4,607,000	0	139,000
4. Research training	262	11,468,000	0	730,000
5. Research and development contracts	16	14,328,000	0	1,367,000
Subtotal, extramural				8,274,000
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	30	11,092,000	3	171,000
7. Research management and support	58	16,870,000	1	556,000
Subtotal, program		316,452,000		9,001,000
Total changes	88		4	9,473,000

Fiscal Year 2011 Budget Graphs

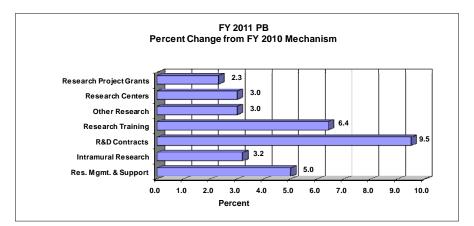
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Justification	
National Institute of Biomedical Imaging and Bioen	ngineering

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

Budget Authority

			FY 2011	FY 2011+/-
	FY 2009	FY 2010	President's	2010
	Appropriation	Appropriation	<u>Budget</u>	Appropriation
BA	\$308,208,000	\$316,582,000	\$325,925,000	\$9,473,000
FTE	89	88	92	4

This document provides justification for the Fiscal Year (FY) 2011 activities of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), including HIV/ AIDS activities. Details of the FY 2011 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The mission of the 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 both scientific and technological opportunities and in support of the next generation of researchers.

Biomedical technologies have transformed the way Americans receive health care, as well as the quality of that care. For example, a new technique called Magnetic Resonance Elastography, developed with NIBIB support and recently approved by FDA, can now replace needle biopsy for assessing the progress of some liver diseases. This technique is safer, can be done as an out-patient procedure, and is not painful. Another project in early clinical testing may, by means of advanced intraoperative imaging, reduce the surgery time for correcting the abnormal heart rhythm atrial fibrillation from 6 hours to one hour. Because atrial fibrillation is a major risk factor for stroke, this six-fold reduction in the surgery time can make this effective measure more widely available and help reduce the incidence of disabling stroke.

Any cancer diagnosis is devastating for patients and their families, but metastatic cancer often carries the worst prognosis. Cells that metastasize from a primary malignant tumor to distant organs are responsible for 90 percent of cancer-related deaths, a number that exceeds 500,000 every year in the United States alone. Consequently, metastases are critical biological problems to address in cancer research. Circulating tumor cells (CTCs), which detach from the original tumor and enter the bloodstream, represent the link between the primary malignant tumor and its metastases for most cancers. Analysis of blood samples for CTCs is being developed

as an alternative to invasive biopsies for the detection, characterization and monitoring of many types of cancer. The ability to isolate these cells and decipher their unique biology could improve our understanding of how cancer spreads and kills. This is especially important for lung cancer, the leading cause of cancer death in the United States. Researchers supported by NIBIB have developed a unique microfluidic device capable of efficient separation of CTCs from whole blood. This technology has broad implications both for advancing cancer biology research and for the clinical management of cancer, including detection, diagnosis, and monitoring.

In low-resource settings, especially in developing countries, diagnostic capabilities are minimal, inadequate, or nonexistent. The result can be delayed treatment which can transform a minor problem into a life-threatening one. New and innovative point-of-care diagnostic technologies designed specifically for such settings may have a major impact on global public health by providing timely patient treatment. One NIBIB-supported researcher is addressing this need by developing a novel, paper-based, microfluidic diagnostic card that is used without an instrument to diagnose infectious diseases like dengue fever and measles. In principle, these paper assays could be widely deployed and the cost per test could be in the range of a dollar.

Lessons learned from the current influenza pandemic have shown that rapid distribution and administration of vaccines are critical. The current hypodermic technologies for mass vaccination are inefficient in part by requiring a visit to the doctor's office or community-based clinics. To address this public health problem and enhance patient compliance, the NIBIB supports the development of "ouchless" vaccine patches consisting of tiny hollow needles. These patches can be self-administered and yield the same level of protection in animals as a traditional injection. The NIBIB will continue to support this ongoing effort to achieve a room-temperature patch for mass distribution.

Advances made by NIBIB-supported researchers in the basic sciences will lead to improved diagnosis and treatment of disease. An important goal of the NIBIB is to develop novel imaging techniques that can detect and characterize disease at an early stage, when treatment can be most effective. Standard radiological imaging does not aid in early detection because these approaches are not sensitive to the subtle biochemical and physiological changes that take place early in the disease process. However, molecular imaging approaches can detect these early changes. For example, these techniques can identify early stages of autoimmune diseases, such as type 1 diabetes by tracking the accumulation of immune cells in specific organs. NIBIB is supporting research to develop a new class of imaging agents to enhance early detection of disease and provide real-time monitoring of response to treatment.

Health information technology research that enables the integration of clinical, diagnostic, and treatment data with the patient's medical history in a comprehensive electronic health record will improve clinical decision-making. The ability to connect and exchange diagnostic information and medical images between health care providers, clinics, and hospitals will help provide timely information needed for effective health care and will help reduce unnecessary and duplicative procedures. A patient-centered

approach to comprehensive electronic health records will allow patients to access their own information, enabling them to play a role in their wellness by equipping them with the knowledge to ask appropriate questions about treatment options. Additionally, patients are also empowered to provide this information to any and all health care providers as needed, independent of their location or where the medical data were created or stored. The NIBIB supports research in new technologies to address issues such as: interoperability of data systems, compatibility of computer software across medical institutions, security of data during transmission, HIPPA compliance, and availability of affordable data systems for patient care providers.

A central theme of the research approaches described above is their interdisciplinary nature. The Institute's emphasis on interdisciplinary approaches to biomedical research and training has provided unprecedented opportunities for further collaborations among life scientists and physical scientists. As experience and training of investigators associated with this modern paradigm continues to develop and progress, there will be advances in biology through the quantitative, physical sciences and engineering perspectives and the development of technologies that reflect the translation of biological mechanisms, and applied technologies that will produce remarkable improvements in the health of individuals around the world.

Overall Budget Policy: The FY 2011 request for NIBIB is \$325.925 million, an increase of \$9.473 million or +3.3 percent over the FY 2010 Enacted level. NIBIB funding policies give special consideration to grant applications that bridge and integrate the life and physical sciences, and also focus on enhancing support for new investigators. In FY 2011, NIBIB will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. NIBIB will continue to support DNA-based technologies that capitalize on genomic information - an example of such being genetically targeted new imaging modalities that are being continuously developed and represent the next generation of imaging diagnostics. NIBIB will support efforts that benefit health care reform - as molecular theranostics will accelerate diagnostics and lead to more effective treatment, NIBIB-support for heath IT/Bioinformatics research will advance the development of integrated health information systems that incorporate disparate data such as clinical image data, lab results and medication, history, etc., into Physician Decision Support systems. This will lead to more effective care and better patient outcome and a reduction in over-utilization of expensive tests. NIBIB has also launched an initiative, in conjunction with NCMHD, NCRR and NIMH to develop and translate new technologies, including communication technologies to target and address health disparities. NIBIB research endeavors and partnerships have the potential to greatly benefit global health, as Point-of-Care Systems utilizing "lab on a chip" technologies and microfluidics promise early, rapid, and less expensive diagnoses of diseases, critical for making modern healthcare accessible to more of the world's population. NIBIB's effort to turn this promise into reality is evinced by our partnership with the Indian government to develop low-cost diagnostic and therapeutic technologies, with particular focus on chronic diseases, including diabetes and heart failure. Excellence in engineering whether applied to building bridges or to health care has always been about the

translation of new understanding into better results. In seeking to translate biomedical discovery into better health, NIBIB will continue to encourage research that teams biomedical engineers and physical scientists with clinical and basic biological scientists to collaboratively translate basic science. This emphasis on interdisciplinary research also extends to our strategy for reinvigorating biomedical research. We will support high-risk/high impact research and new investigators by setting aside funds for these priority areas.

Funds are included in R&D contracts to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program (TRND), the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory, as well as increased support for other HHS agencies through the program evaluation set-aside.

FY 2011 JUSTIFICATION BY PROGRAM

Program Descriptions and Accomplishments

Applied Science and Technology (AST): This program supports research, development and application of technologies for improving 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 the development of dedicated breast CT scanners. Another example is the optimization of cardiac exams using fast MRI approaches. New optical imaging techniques are enabling minimally invasive biopsies for prostate cancer and uterine cancer. Low-cost optical endoscopes have been developed to detect and ablate ovarian cancer. Research to deploy such technology is the focus of global health. 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. The promise of these efforts is earlier diagnosis, better management of chronic diseases, and more effective treatment of acute disorders.

<u>Budget Policy</u>: The FY 2011 budget estimate for the AST program is \$176.8 million, a \$5.2 million increase (3.0%) over the FY 2010 Enacted level. The highest priority is given to new investigators and early career investigators and to research initiatives that bridge 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 in FY 2011 to funding investigator-initiated research including exploratory research grants and Bioengineering Research Partnerships.

Program Portrait: Development of Novel Ultrasound Therapies

FY 2011 Level:	\$4.245 million
FY 2010 Level:	<u>\$4.194 million</u>
Change:	+\$0.051 million

Ultrasound has long been used as a safe diagnostic imaging modality. However, there is increasing evidence that ultrasound at higher intensities may also provide effective therapies for diseases or injuries, or can improve the effectiveness of drug delivery. NIBIB supports a research program that will accelerate the development of ultrasound therapies that can be used in the clinic.

One novel therapy involves ultrasound treatments that can dissolve blood clots in arteries of the heart and brain. This approach may provide effective new therapies for myocardial infarction and stroke. Other novel therapies involve ultrasound treatments for deep-vein thrombosis, atrial fibrillation and metastatic cancers. Finally, the program also supports novel ultrasound approaches that can improve the targeted delivery of drugs to specific tissues or organs.

The successful application of the ultrasound technologies developed in this program could produce a substantial health care impact across a variety of diseases.

Discovery Science and Technology (DST): This program supports the development of innovative bioengineering and biomedical imaging technologies, and related research in the life and physical sciences that will lead to improvements in human health and health care. The DST program portfolio is broad in scope and includes innovative and revolutionary research focused on biomaterials; biomedical informatics including health information technologies; biomechanics; computational modeling, simulation and analysis; drug and gene delivery devices; image processing; visual perception and display; medical devices and implant science; molecular imaging agents; nanotechnology: rehabilitation engineering; sensors and microsystems; surgical tools, techniques, and systems; telehealth, and; tissue engineering and regenerative medicine including stem cell research. Of particular note, the 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 neuroemergencies, sexually transmitted diseases, disaster readiness, and global health. The DST is currently supporting an initiative on Predictive Multiscale Models of the Physiome in Health and Disease. The goal of this solicitation is to develop mathematical and computational models that accurately describe complex medical responses at the cellular as well as clinical levels and can be used to predict response to therapy. The Program also recently began soliciting for research focused on the development of multifunctional drug and gene delivery systems that target and release the therapy at the site it is needed and will improve therapeutic efficacy and reduce toxicity. This research will include the engineering of novel delivery systems that can target therapies to particular cells and also track/monitor the delivery to determine therapeutic efficacy. The DST is also supporting a new initiative for the development of consensus standards which play a critical role in the assessment of the effectiveness of new biomedical technologies and their translation into clinical practice.

<u>Budget Policy</u>: The FY 2011 budget estimate for the DST program is \$95.1 million, a \$2.2 million increase (2.4%) over the FY 2010 Enacted level. DST will give the highest

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 increased resources.

Program Portrait: Rehabilitation Engineering

FY 2011 Level: \$12.600 million FY 2010 Level: <u>\$12.500 million</u> Change: +\$0.100 million

The NIBIB Rehabilitation Engineering Program is supporting the development of next generation tools and systems to aid persons with disability. One project is developing a battery powered knee-ankle prosthesis for above knee amputees. This artificial limb adapts to different walking speeds and uses 25 percent less metabolic energy for walking compared with conventional devices. Another project provides exercise training for persons with upper limb paralysis from stroke. NIBIB-supported investigators are developing exoskeleton robots that are strongly rooted in the basic principles of neural motor control theory and are designed to provide efficient motor retraining following stroke. In another project, quantitative analysis methods are being developed to remotely measure the tremor, rigidity and other symptoms of Parkinson's disease (PD) patients at home. This system may provide critical information for adjusting the medications in PD that typically cycles between "on" and "off" as drug levels fluctuate through the day. Another group of projects supports the development of novel neuroprosthesis systems that interface neural recording and stimulating electrodes with intelligent hardware and software for the control of paralyzed limbs, prosthetic limbs, wheel chairs and communication devices. New technologies under development will allow tetraplegics to have multiple neural interface options for controlling their environment and living independent lives in the future.

The NIBIB Rehabilitation Engineering Program currently supports 29 research projects. The NIBIB research effort is highly integrated with other NIH efforts in rehabilitation and neuroprostheses with coordination by the trans-NIH Neuroprosthesis Group led by NIBIB.

Technological Competitiveness – Bridging the Sciences: Interdisciplinary approaches to research underpin technological developments that will have a major impact on health. The NIBIB has several interdisciplinary research programs that exemplify our investment toward technological competitiveness. The Quantum Grant program seeks to accelerate the application of innovative biomedical technologies to the national health care system with the goal of reducing the burden of a major disease or public health problem. The "quantum" concept focuses approaches to solving health care problems through major breakthroughs in technologies. The Bioengineering Research Partnerships Program is another example of bridging disciplines that supports a team that would include 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 other NIH Institutes and Centers, Federal agencies, and private organizations. The medical informatics program focuses on health information technologies that enable better clinical decision-making, sharing of clinical image data, dissemination of information about the latest scientific research results and effectiveness studies. The

Howard Hughes Medical Institute (HHMI)-NIBIB Interdisciplinary Training Initiative, a public-private partnership, is creating models and environments where investigators from different disciplines come together to solve research problems.

<u>Budget Policy</u>: The FY 2011 budget estimate for the Technological Competitiveness – Bridging the Sciences program is \$24.9 million, a \$0.9 million increase (3.6%) over the FY 2010 Enacted level. High priorities in FY 2011 include increasing training stipends by 6%, developing interdisciplinary training programs, and continued support for the Quantum Grants Program, which supports the establishment of interdisciplinary research teams to address major healthcare problems.

Program Portrait: Quantum Projects in Regenerative Medicine

 FY 2011 Level:
 \$3.264 million

 FY 2010 Level:
 \$3.200 million

 Change:
 +\$0.064 million

Recent advances in reprogramming adult cells into induced pluripotent stem cells (iPSCs), the discovery of stem cells in many adult tissues, and the expanded U.S. policy on stem cell research have invigorated the field of cell-based therapeutics. The NIBIB supports multidisciplinary imaging and bioengineering research to better understand and control stem cells, their differentiation, and their development into tissues for replacement of tissues that have been damaged due to injury, age, and disease.

The NIBIB is currently supporting the development of imaging technologies to track stem cells and assess the function of engineered tissues. New optical imaging technologies allow non-destructive, non-invasive monitoring of engineered tissues in vitro, and soon, in vivo. New biomarkers offer powerful and versatile opportunities to track stem cells as they migrate throughout the body. Stem cells labeled with microscopic gas bubbles can also be tracked with ultrasound - - a non-invasive and fully biocompatible approach.

The NIBIB is supporting two "Quantun Grants" for the application of tissue engineering and regenerative medicine to the treatment of disease. One is developing pancreatic islet cells from stem cells for transplantation with the goal of eliminating the need for insulin use in diabetes. The other is developing stem cell-based engineered brain tissue to serve as a source of neural and vascular cells for the repair of stroke-injured tissue.

Taken together, these cutting-edge technologies offer new ways to understand and manipulate stem cells and their environment to maximize their potential for regenerating tissues.

Intramural Research: The Intramural Program supports the NIBIB's mission to integrate bioengineering with the life and physical sciences and to develop new technologies ranging in scale from molecular and cellular to the level of whole organ imaging. A recently established program will develop molecular imaging probes to improve understanding of disease, to enable early detection, to enhance monitoring of therapeutic responses, and to aid drug discovery including innovative approaches for chemical synthesis based on biocompatible nanomedicines. This research will include development of novel probes for positron emission tomography (PET), as well as radiological methods based on multimodal imaging. A new clinical laboratory will develop patient-based methods to detect and quantify subclinical cardiovascular disease of the myocardium and blood vessels, including correlation with genetic

determinants, and acquired determinants of cardiovascular disease resulting from common risk factors. To aid in understanding diseases at a more fundamental level, research groups have been set up to develop nanoscale super-resolution optical imaging techniques and to produce genetically encoded optical probes to track the movement of specific protein in living cells at the level of single molecules.

<u>Budget Policy</u>: The FY 2011 budget estimate for the Intramural Research Program is \$11.4 million, a \$0.4 million increase (3.2%) over the FY 2010 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.

<u>Budget Policy</u>: The FY 2011 budget estimate for Research Management and Support is \$17.7 million, a \$0.8 million increase (5.0%) over the FY 2010 Enacted level. This increase reflects NIH policy for Research Management and Support in FY 2011 and will be used to help offset increases for pay costs, centrally furnished services, and supplies and materials.

Recovery Act Implementation

Recovery Act Funding: \$77.937 million

In FY 2009, NIBIB received \$77.9 million under the Recovery Act. Of this amount, \$46.5 million was obligated in FY 2009 and \$31.4 million will be obligated in FY 2010. These funds support job creation and research and development in biomedical imaging and bioengineering in a variety of ways. These include support for summer research experiences in innovative technology research for students and teachers in NIBIB-funded laboratories. One signature project focuses on research on health information technology (HIT) to improve patient outcome and health care efficiency.

The goal of HIT is to provide comprehensive information to the physicians or clinical care providers at the point of care so they can make information-based decisions for optimal patient outcome. Achieving this goal requires the integration of disparate data such as lab test results, imaging data and medication history, etc., at the site where the patient is being seen regardless of where or when these data were acquired. NIBIB has launched three related projects with Recovery Act funds to develop the technological infrastructure for improved clinical decision support and demonstration projects to facilitate patient authorized exchange of medical images and reports between medical centers. One of these projects has a special emphasis on image data exchange in the setting of underserved areas, another has an emphasis on developing a security /patient identification system, and the third project will build a demonstration project for image sharing between major medical centers using existing open-source standards.

Budget Authority by Object

		ity by Object		
		FY 2010	FY 2011	Increase or
		Enacted	PB	Decrease
Total c	ompensable workyears:			
	Full-time employment	88	92	4
	Full-time equivalent of overtime and holiday hours	0	0	0
	I an and equivalent of everance and henday hours	Ŭ	0	0
	Average ES salary	\$0	\$0	\$0
	Average GM/GS grade	12.5	12.5	0.0
	Average Chill GO grade	12.0	12.0	0.0
	Average GM/GS salary	\$105,866	\$109,063	\$3,197
	Average salary, grade established by act of			
	July 1, 1944 (42 U.S.C. 207)	\$0	\$0	\$0
	Average salary of ungraded positions	125,478	129.242	3,764
		,	,	-1
		FY 2010	FY 2011	Increase or
	OBJECT CLASSES	Estimate	Estimate	Decrease
	Personnel Compensation:	Lotiniato	Lotinato	Decrease
11 1	Full-time permanent	\$6,023,000	\$6,450,000	\$427,000
	Other than full-time permanent	1,864,000	2,215,000	351,000
	Other personnel compensation	235,000	255,000	20,000
	Military personnel	233,000	235,000	20,000
	Special personnel services payments	501,000	724,000	223,000
11.0	Total, Personnel Compensation	8,623,000	9,644,000	1,021,000
10.0	Personnel benefits			
-		2,246,000	2,562,000	316,000
	Military personnel benefits Benefits for former personnel	0 0	0 0	0
13.0		10,869,000	-	÷
04.0	Subtotal, Pay Costs		12,206,000	1,337,000
	Travel and transportation of persons	496,000	513,000	17,000
	Transportation of things	80,000	71,000	(9,000)
	Rental payments to GSA	16,000	18,000	2,000
	Rental payments to others	40,000	32,000	(8,000)
23.3	Communications, utilities and	475.000	474.000	(4.000)
04.0	miscellaneous charges	175,000	171,000	(4,000)
	Printing and reproduction	27,000	28,000	1,000
	Consulting services	805,000	821,000	16,000
	Other services	2,002,000	1,998,000	(4,000)
25.3	Purchase of goods and services from	24 884 000	00 1 40 000	4 250 000
05.4	government accounts	21,884,000	23,140,000	1,256,000
	Operation and maintenance of facilities	518,000	416,000	(102,000)
	Research and development contracts	856,000	932,000	76,000
	Medical care	0	0	0
	Operation and maintenance of equipment	985,000	868,000	(117,000)
	Subsistence and support of persons	0	0	0
	Subtotal, Other Contractual Services	27,050,000	28,175,000	1,125,000
26.0		995,000	1,015,000	20,000
	Equipment	2,542,000	2,627,000	85,000
	Land and structures	0	0	0
	Investments and loans	0	0	0
	Grants, subsidies and contributions	274,162,000	281,069,000	6,907,000
-	Insurance claims and indemnities	0	0	0
	Interest and dividends	0	0	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	305,583,000	313,719,000	8,136,000
	Total Budget Authority by Object	316,452,000	325,925,000	9,473,000

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

Salaries and Expenses				
	FY 2010	FY 2011	Increase or	
OBJECT CLASSES	Enacted	PB	Decrease	
Personnel Compensation:				
Full-time permanent (11.1)	\$6,023,000	\$6,450,000	\$427,000	
Other than full-time permanent (11.3)	1,864,000	2,215,000	351,000	
Other personnel compensation (11.5)	235,000	255,000	20,000	
Military personnel (11.7)	0	0	0	
Special personnel services payments (11.8)	501,000	724,000	223,000	
Total Personnel Compensation (11.9)	8,623,000	9,644,000	1,021,000	
Civilian personnel benefits (12.1)	2,246,000	2,562,000	316,000	
Military personnel benefits (12.2)	0	0	0	
Benefits to former personnel (13.0)	0	0	0	
Subtotal, Pay Costs	10,869,000	12,206,000	1,337,000	
Travel (21.0)	496,000	513,000	17,000	
Transportation of things (22.0)	80,000	71,000	(9,000)	
Rental payments to others (23.2)	40,000	32,000	(8,000)	
Communications, utilities and				
miscellaneous charges (23.3)	175,000	171,000	(4,000)	
Printing and reproduction (24.0)	27,000	28,000	1,000	
Other Contractual Services:				
Advisory and assistance services (25.1)	805,000	821,000	16,000	
Other services (25.2)	2,002,000	1,998,000	(4,000)	
Purchases from government accounts (25.3)	14,059,000	14,376,000	317,000	
Operation and maintenance of facilities (25.4)	518,000	416,000	(102,000)	
Operation and maintenance of equipment (25.7)	985,000	868,000	(117,000)	
Subsistence and support of persons (25.8)	0	0	0	
Subtotal Other Contractual Services	18,369,000	18,479,000	110,000	
Supplies and materials (26.0)	995,000	1,015,000	20,000	
Subtotal, Non-Pay Costs	20,182,000	20,309,000	127,000	
Total, Administrative Costs	31,051,000	32,515,000	1,464,000	

Salaries and Expenses

		Authorizir	Authorizing Legislation			
	PHS Act/ Other Citation	U.S. Code Citation	2010 Amount Authorized	FY 2010 Enacted	2011 Amount Authorized	FY 2011 PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
	Section 402(a)	42§281	Indefinite	\$316,452,000	Indefinite	\$325,925,000
National Institute of Biomedical Imaging and Bioengineering	4 4					
Total, Budget Authority				316,452,000		325,925,000

		Appropriations His	story	
Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2002	40,206,000	39,869,000	140,000,000	111,984,000
Rescission				(33,000)
2003	120,502,000	270,494,000	283,100,000	280,100,000
Rescission				(1,821,000)
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
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
2010	312,687,000	319,217,000	313,496,000	316,582,000
2011	325,925,000			

Appropriations History

Reflects enacted supplementals, rescissions, and reappropriations.
 Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

OFFICE/DIVISION	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB	
Office of the Director	6	6	6	
Extramural Science Program	20	20	20	
Office of Research Administration	16	16	16	
Office of Administration Management	17	16	17	
Intramural Science Program	30	30	33	
Total	89	88	92	
Includes FTEs which are reimbursed from the NIH Roadm				
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)	
FISCAL YEAR	Avera	Average GM/GS Grade		
2007	12.4			
2008	12.4			
2009		12.5		
2010		12.5		
2011		12.5		

Details of Full-Time Equivalent Employment (FTEs)

Botan	of Positions		
GRADE	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	11	11	11
GM/GS-14	23	23	23
GM/GS-13	14	13	14
GS-12	8	8	11
GS-11	3	3	3
GS-10	2	2	2
GS-9	7	7	7
GS-8	1	1	1
GS-7	1	1	1
GS-6	0	0	0
GS-5	1	1	1
GS-4	1	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	72	71	75
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	69	68	69
Total positions, end of year	104	103	107
Total full-time equivalent (FTE) employment, end of year	89	88	92
Average ES salary	0	0	0
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	102,864	105,866	109,063

Detail of Positions

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

		FY 2011	
	Grade	Number	Annual Salary
Administrative Officer	GS-13	1	\$100,904
Staff Scientist	GS-12	3	\$254,565
Total Requested		4	\$355,469

New Positions Requested