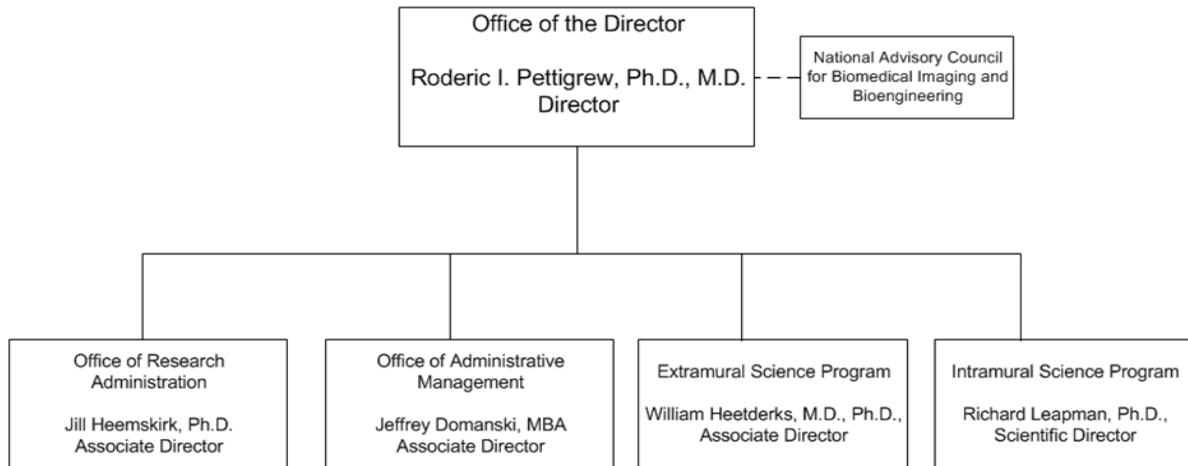


DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering (NIBIB)

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NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

**NIBIB Organizational Chart**



NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

**Appropriations Language**

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, [~~\$330,192,000~~] *\$337,314,000*.

NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

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

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$329,172	\$330,192	\$337,314
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-826	0	0
FY 2014 Second Secretary's Transfer	-65	0	0
Subtotal, adjusted appropriation	\$328,281	\$330,192	\$337,314
OAR HIV/AIDS Transfers	-2,360	-2,949	0
National Children's Study Transfers	1,082	0	0
Subtotal, adjusted budget authority	\$327,003	\$327,243	\$337,314
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$327,003	\$327,243	\$337,314
Unobligated balance lapsing	-14	0	0
Total obligations	\$326,989	\$327,243	\$337,314

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:  
FY 2014: \$1,255; FY 2015: \$5,100; FY 2016: \$5,100.

NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

**Budget Mechanism - Total<sup>1</sup>**  
(Dollars in Thousands)

MECHANISM	FY 2014 Actual		FY 2015 Enacted		FY 2016 President's Budget		FY 2016 +/- FY 2015	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	372	\$151,150	370	\$146,065	360	\$141,274	-10	-\$4,790
Administrative Supplements	(9)	331	(15)	800	(15)	800	(0)	0
Competing:								
Renewal	17	8,449	16	7,797	21	10,299	5	2,502
New	171	52,152	158	48,127	209	63,574	51	15,447
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	188	\$60,600	174	\$55,924	230	\$73,873	56	\$17,950
Subtotal, RPGs	560	\$212,082	544	\$202,788	590	\$215,948	46	\$13,160
SBIR/STTR	33	9,367	34	9,660	36	10,099	2	439
Research Project Grants	593	\$221,449	578	\$212,448	626	\$226,047	48	\$13,599
<u>Research Centers:</u>								
Specialized/Comprehensive	4	\$6,605	4	\$6,605	4	\$6,605	0	\$0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	29	38,018	29	38,018	29	38,018	0	0
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	33	\$44,622	33	\$44,622	33	\$44,622	0	\$0
<u>Other Research:</u>								
Research Careers	31	\$4,236	31	\$4,236	31	\$4,236	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	39	1,609	45	1,859	45	1,859	0	0
Other Research	70	\$5,845	76	\$6,095	76	\$6,095	0	\$0
Total Research Grants	696	\$271,916	687	\$263,165	735	\$276,764	48	\$13,599
<u>Ruth L. Kirschstein Training Awards:</u>	<u>FTTP</u>		<u>FTTP</u>		<u>FTTP</u>		<u>FTTP</u>	
Individual Awards	18	\$758	18	\$773	18	\$788	0	\$15
Institutional Awards	184	8,448	184	8,617	184	8,790	0	172
Total Research Training	202	\$9,206	202	\$9,390	202	\$9,578	0	\$188
Research & Development Contracts	17	\$14,804	19	\$23,300	18	\$19,271	-1	-\$4,029
<i>(SBIR/STTR) (non-add)</i>	<i>(0)</i>	<i>(59)</i>	<i>(0)</i>	<i>(59)</i>	<i>(0)</i>	<i>(59)</i>	<i>(0)</i>	<i>(0)</i>
Intramural Research	25	11,754	25	11,872	25	11,991	0	119
Res. Management & Support	76	19,322	77	19,516	77	19,711	0	195
<i>Res. Management &amp; Support (SBIR Admin)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>
Total, NIBIB	101	\$327,003	102	\$327,243	102	\$337,314	0	\$10,071

<sup>1</sup> All items in italics and brackets are non-add entries.

### **Major Changes in the Fiscal Year 2016 President's Budget Request**

The FY 2016 President's Budget request for NIBIB is \$10.071 million more than the FY 2015 Enacted level, for a total of \$337.314 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 2016 President's Budget.

In FY 2014 NIH launched the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative as a large-scale effort to equip researchers with fundamental insights necessary for treating a wide variety of devastating brain disorders like Alzheimer's, schizophrenia, autism, epilepsy, and traumatic brain injury. In FY 2016 NIH is requesting an increase of \$70 million for this high priority initiative. As one of the leaders of the BRAIN initiative at NIH, NIBIB is requesting an increase of \$3.0 million in its budget to support this research priority.

Research Project Grants (RPGs) (+\$13.599 million; total \$226.047 million):

NIBIB will continue to fund a substantial number of RPGs, 626 awards in FY 2016, an increase of 48 awards and \$13.599 million from FY 2015. This includes 230 competing RPGs (an increase of 56 awards and \$17.950 million from FY 2015) and 360 non-competing awards (a decrease of 10 awards and \$4.790 million from FY 2015).

Training (+\$0.188 million; total \$9.578 million):

NIH will provide 2 percent increases in FY 2016 for stipend levels under the Ruth L. Kirschstein National Research Service Award (NRSA) training program.

Research and Development Contracts (-\$4.029 million; total \$19.271 million):

NIBIB will decrease funding for R&D Contracts from the FY 2015 level. This decrease is the result of a \$5.5 million contract that is funded in alternate years and will not receive FY 2016 funds.

Applied Science and Technology (+\$6.532 million; total \$158.564 million):

NIBIB will increase funding for AST from the FY 2015 level. This includes \$1.2 million in funding for NIH's new Precision Medicine Cohort Initiative.

Discovery Science and Technology (+\$7.524 million; total \$101.595 million):

NIBIB will increase funding for DST from the FY 2015 level. This includes a \$3.0 million increase in funding for the President's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

Health Informatics Technology (-\$4.487 million; total \$23.003 million):

NIBIB will decrease funding for HIT from the FY 2015 level. This decrease is the result of a \$5.5 million contract that is funded in alternate years and will not receive FY 2016 funds.

NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

**Summary of Changes**  
(Dollars in Thousands)

<b>FY 2015 Enacted</b>				\$327,243
<b>FY 2016 President's Budget</b>				\$337,314
<b>Net change</b>				\$10,071
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
A. <u>Built-in:</u>				
1. Intramural Research:				
a. Annualization of January 2015 pay increase & benefits		\$5,222		13
b. January FY 2016 pay increase & benefits		5,222		39
c. One more day of pay (n/a for 2015)		5,222		20
d. Differences attributable to change in FTE		5,222		0
e. Payment for centrally furnished services		1,232		30
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		5,537		95
Subtotal				\$197
2. Research Management and Support:				
a. Annualization of January 2015 pay increase & benefits		\$10,997		\$27
b. January FY 2016 pay increase & benefits		10,997		81
c. One more day of pay (n/a for 2015)		10,997		41
d. Differences attributable to change in FTE		10,997		107
e. Payment for centrally furnished services		474		12
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		8,240		144
Subtotal				\$411
Subtotal, Built-in				\$607

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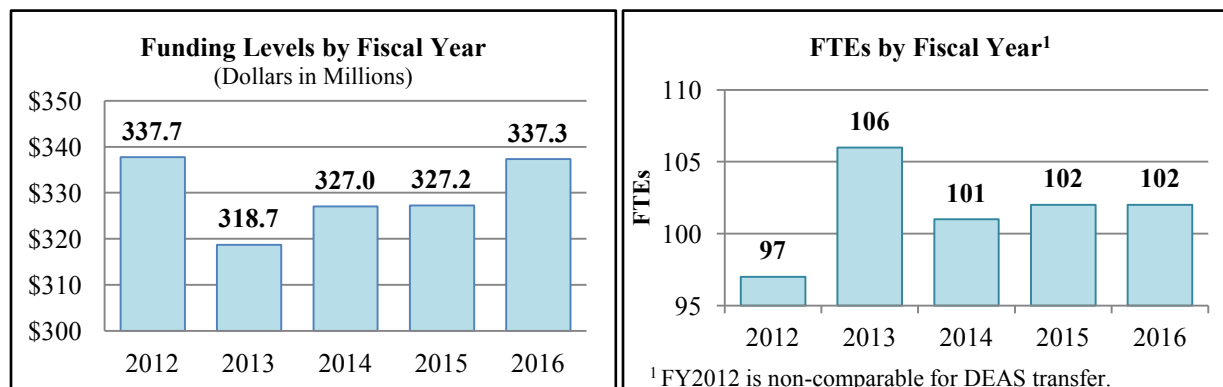
**Summary of Changes**  
(Dollars in Thousands)

CHANGES	FY 2016 President's Budget		Change from FY 2015	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	360	\$142,074	-10	-\$4,790
b. Competing	230	73,873	56	17,950
c. SBIR/STTR	36	10,099	2	439
Subtotal, RPGs	626	\$226,047	48	\$13,599
2. Research Centers	33	\$44,622	0	\$0
3. Other Research	76	6,095	0	0
4. Research Training	202	9,578	0	188
5. Research and development contracts	18	19,271	-1	-4,029
Subtotal, Extramural		\$305,612		\$9,757
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	25	\$11,991	0	-\$78
7. Research Management and Support	77	19,711	0	-216
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	102	\$337,314	0	\$9,464
Total changes				\$10,071

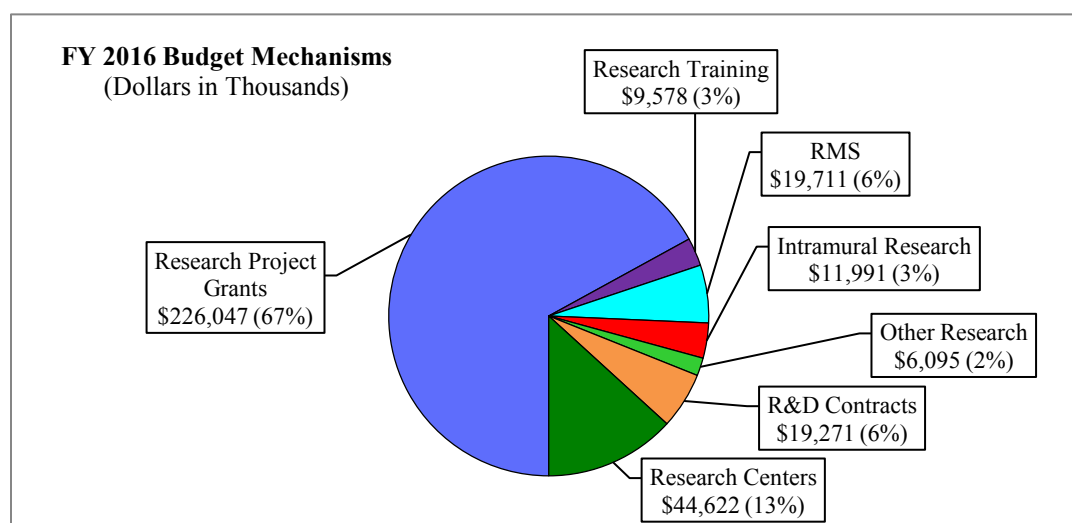
NATIONAL INSTITUTES OF HEALTH  
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# Fiscal Year 2016 Budget Graphs

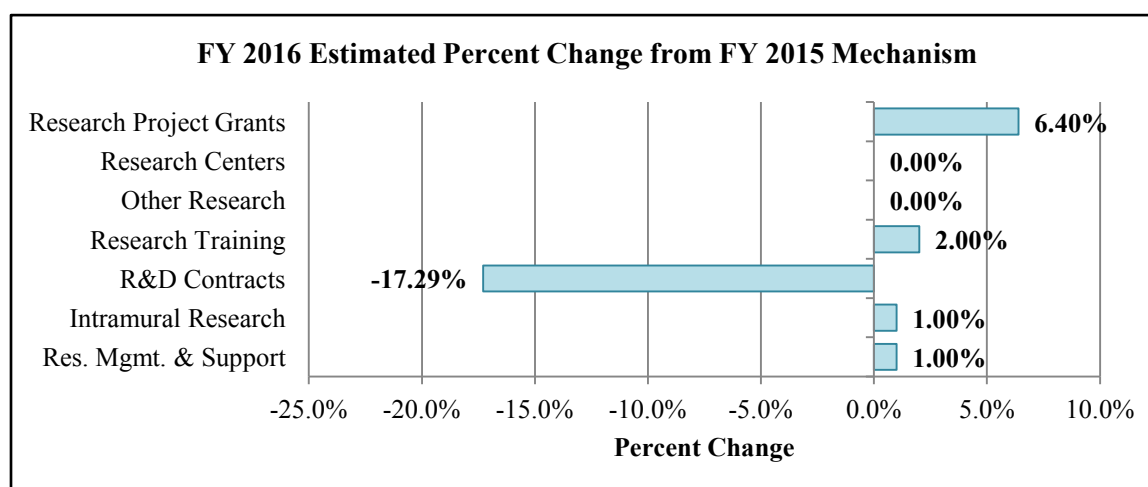
## History of Budget Authority and FTEs:



## Distribution by Mechanism:



## Change by Selected Mechanisms:



NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

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

	<b>FY 2014 Actual</b>		<b>FY 2015 Enacted</b>		<b>FY 2016 President's Budget</b>		<b>FY 2016 +/- FY2015</b>	
<b><u>Extramural Research</u></b>	<b><u>FTE</u></b>	<b><u>Amount</u></b>	<b><u>FTE</u></b>	<b><u>Amount</u></b>	<b><u>FTE</u></b>	<b><u>Amount</u></b>	<b><u>FTE</u></b>	<b><u>Amount</u></b>
<u>Detail</u>								
Applied Science and Technology		\$155,203		\$152,032		\$158,564		\$6,532
Discovery Science and Technology		96,080		94,071		101,595		7,524
Health Informatics Technology		22,566		27,490		23,003		-4,487
Technological Competitiveness - Bridging the Sciences		22,078		22,262		22,450		188
<b>Subtotal, Extramural</b>		<b>\$295,926</b>		<b>\$295,855</b>		<b>\$305,612</b>		<b>\$9,757</b>
<b>Intramural Research</b>	<b>25</b>	<b>\$11,754</b>	<b>25</b>	<b>\$11,872</b>	<b>25</b>	<b>\$11,991</b>	<b>0</b>	<b>\$119</b>
<b>Research Management &amp; Support</b>	<b>76</b>	<b>\$19,322</b>	<b>77</b>	<b>\$19,516</b>	<b>77</b>	<b>\$19,711</b>	<b>0</b>	<b>\$195</b>
<b>TOTAL</b>	<b>101</b>	<b>\$327,003</b>	<b>102</b>	<b>\$327,243</b>	<b>102</b>	<b>\$337,314</b>	<b>0</b>	<b>\$10,071</b>

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

NATIONAL INSTITUTES OF HEALTH  
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**Authorizing Legislation**

Authorizing Legislation						
	PHS Act/ Other Citation	U.S. Code Citation	2015 Amount Authorized	FY 2015 Enacted	2016 Amount Authorized	FY 2016 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite	\$327,243,000	Indefinite	\$337,314,000
Total, Budget Authority				\$327,243,000		\$337,314,000

NATIONAL INSTITUTES OF HEALTH  
National Institute of Biomedical Imaging and Bioengineering

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2006 Rescission	\$299,808,000	\$299,808,000	\$309,091,000	\$299,808,000 (\$2,998,000)
2007 Rescission	\$296,810,000	\$294,850,000	\$297,606,000	\$296,887,000 \$0
2008 Rescission Supplemental	\$300,463,000	\$303,318,000	\$304,319,000	\$303,955,000 (\$5,310,000) \$1,588,000
2009 Rescission	\$300,254,000	\$310,513,000	\$307,254,000	\$308,208,000 \$0
2010 Rescission	\$312,687,000	\$319,217,000	\$313,496,000	\$316,852,000 \$0
2011 Rescission	\$325,925,000		\$325,415,000	\$316,852,000 (\$2,779,778)
2012 Rescission	\$322,106,000	\$322,106,000	\$333,671,000	\$338,998,000 (\$640,706)
2013 Rescission Sequestration	\$336,896,000		\$337,917,000	\$338,357,294 (\$676,715) (\$16,983,210)
2014 Rescission	\$338,892,000		\$337,728,000	\$329,172,000 \$0
2015 Rescission	\$328,532,000			\$330,192,000 \$0
2016	\$337,314,000			

**Justification of Budget Request**  
***National Institute of Biomedical Imaging and Bioengineering***

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

Budget Authority (BA):

	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
BA	\$327,002,846	\$327,243,000	\$337,314,000	\$10,071,000
FTE	101	102	102	0

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

**Director's Overview**

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. Our principal means is the funding of over 800 research grants and cooperative agreements. This allows NIBIB to support over 5,000 researchers and trainees around the country.

The NIBIB effort is further amplified through leveraging both national and international partners. For example, research to develop a new MRI technology that may be useful for rapid detection of traumatic brain injury is now receiving significant funding from GE. Translation of research for a portable technology to sensitively identify rare circulating tumor cells in routine blood samples is being accelerated by collaboration with a large team supported by Johnson and Johnson. NIH efforts to develop a new way to unobtrusively measure blood pressure are being shared with the Indian government, which is funding researchers in India working on the same problem through a joint activity.

NIBIB's overarching domain is the convergence of the physical and engineering sciences with medicine and the life sciences. Work in this domain is impacting basic research and medical care in many beneficial ways. Two basic outcomes that are emerging from this work are: 1) medicine that precisely targets disease based on how it is expressed in an individual; and 2) extending quality care to everyone independent of location or economic status. The latter is achieved through technological innovation to reduce cost and complexity while advancing utility. The examples that follow highlight some of the exciting things happening in this space.

**Theme 1: Unraveling Life's Mysteries through Basic Research**

NIBIB researchers are studying a special class of proteins that are key to cell signaling using an advanced imaging technology called nuclear magnetic resonance (NMR) spectroscopy. This imaging approach allows the actual 3-D structure of the protein to be seen in its natural environment, residing in and extending across the cell membrane. In initial studies, researchers

focused on a large set of proteins called G-protein-coupled receptors (GPCRs). This is a difficult protein class to image because it crosses the cell membrane seven times. However, it is also of great importance to health. In fact, over half of the current drugs ranging from blood pressure medicines to medications for neurological disorders target GPCRs. By understanding the detailed structure of these receptor proteins, new, more precise medications could be designed to treat many different conditions. So far, drugs or other therapeutics have been found for only a small number of GPCRs. In Fiscal Year (FY) 2016, NIBIB will support research to understand the structure of additional GPCRs so that therapies to precisely treat inflammation, neurological disorders, cancer metastasis, and other diseases can be developed.

### **Theme 2: Translating Discovery into Health**

A common story in cancer therapy is treatment followed by a shrinking tumor. Unfortunately, however, this is often later followed by the tumor regrowing after developing resistance to the chemotherapy. The underlying biology of this ‘tumor’ resistance consists of cells within the tumor that have or develop resistance through genetic mutations. For some time, NIBIB researchers have been developing a technique to isolate tumor cells in the blood, a feat that requires isolation of the one in a billion tumor cells from the mix of normal blood cells. More recently they have developed a means to not only isolate these cells but also to grow and study them. In a recent proof-of-concept study, NIBIB-funded investigators at screened these circulating tumor cells for mutations in over 1,000 genes and successfully identified chemotherapies that could target the specific mutations in each patient’s tumor. This is an important step toward precision medicine in real-time, whereby therapy can track changes in the underlying tumor and optimize the treatment for an individual at a specific time point in the course of the illness.

### **Theme 3: Harnessing Data and Technology to Improve Health**

Genetic influences have a strong role in shaping how the human brain structure develops. Various regions in the brain work jointly to coordinate movement, memory, motivation, and learning. Understanding the connections between genetic data and brain structural data may enable researchers to develop methods for early screening and diagnosis of brain disorders as well as develop optimized approaches for focused drug targeting to select regions of the brain.

NIBIB-funded researchers have been working on developing mathematical methods for combining the vast volume of genetic and brain structural data for determining the structure and function of brain in normal and diseased states. These methods evaluate correlations between these data types from thousands of normal volunteers and subjects with diseases such as Alzheimer’s disease and multiple sclerosis. In order to get sufficient numbers, the researchers have developed a worldwide collaborative, called ENIGMA (Enhancing Neuro Imaging Genetics through Meta-Analysis), which includes more than 300 research teams from around the world. Some of the early results that have come from the ENIGMA collaborations have been: 1) the identification of six novel genetic variants which influence the functional activation within the brain’s reward circuitry; 2) isolating the top twenty most associated genetic variants with the development of Alzheimer’s disease; and 3) finding that some of these genetic variants were also affecting white matter integrity in young adults, potentially increasing the vulnerability of these persons to developing Alzheimer’s disease later in life.

#### **Theme 4: Preparing a Diverse and Talented Biomedical Research Workforce**

Inspiring the next generation of biomedical researchers should start early in a students' academic career. NIBIB's DEsign by Biomedical Undergraduate Teams (DEBUT) program, now in its third year, not only encourages research projects to improve health, but also fosters creative learning by undergraduate engineering students. The DEBUT program challenges students to form teams, identify a significant unmet healthcare need, and deliver a practical solution. Participants have created real-world devices to meet common and uncommon medical needs, applied for patents, and created biotech start-up companies to commercialize their inventions. In the most recent challenge, winners developed a device to improve spinal fusion surgery. Another team created a visual substitution aid for the blind or people with visual impairment to sense obstacles at head height, or warn them of a sudden drop-off, such as a curb. Other winners included a dehydration and bacterial infection assessment device that is integrated into diapers, and a device that keeps mother's breast milk from adhering to the bag or plastic tubing during tube feeding which can cause the loss of its nutritional value. DEBUT has generated excitement in Biomedical Engineering programs around the country with many instructors encouraging or requiring their students to enter the Challenge. NIBIB also recognizes the need for and value of diversity in creating high value solutions in technology, engineering, and the biological, computational, and physical sciences. To strengthen the diverse workforce, NIBIB is supporting a project aimed at increasing the number of underrepresented students in these disciplines at two universities. The project is testing the effectiveness of an intervention 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.

#### **Program Descriptions and Accomplishments**

##### **Applied Science and Technology (AST)**

Applied Science and Technology promotes, establishes, and manages biomedical imaging research programs in 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 several trans-NIH activities.

**Biomedical imaging:** In FY 2016, the program plans to support a range of imaging technologies for diagnostic and therapeutic uses. For example, innovators in MRI are studying a way to visualize disruptions in energy metabolism in the heart as an early sign of disease. The technique could help doctors identify damaged heart tissue sooner in patients with coronary artery disease or other heart disorders. The technique measures levels of the metabolite creatine, a byproduct of a biochemical reaction that fuels the contraction of the heart. Creatine levels fluctuate naturally depending on how hard the heart is working, increasing with exercise and returning to base levels at rest. Very low levels of creatine at rest, or failure to increase creatine during exercise are signs of tissue damage. In the study, researchers adopted a known MRI technique called Chemical Exchange Saturation Transfer (CEST)—used to image specific molecules in the body with high-resolution—in order to visualize creatine in the heart. CEST was found to be up to two orders of magnitude more sensitive than magnetic resonance spectroscopy, a commonly used technique for measuring creatine. CEST was highly effective at locating areas of cell death in the

hearts of swine and sheep. The team also used CEST to map exercise-induced increases in creatine over time by imaging human subjects as they flexed their calf muscles while inside an MRI scanner. The CEST technique could be used to visualize stress-induced metabolic changes, which currently require the injection of a radioactive tracer, and also to assess heart health at the beginning stages of disease and following treatment.

Another new approach called magnetic resonance fingerprinting, or MRF, is being developed to overcome limitations of some current MRI tests. MRF collects much more data in a single scan than traditional MRI. This additional data provides quantitative information about different physical properties exhibited by different types of tissue or disease state for earlier detection of illnesses such as cancer, heart diseases, multiple sclerosis, and others. In FY 2016, NIBIB will continue to support the optimization of this technology as part of an industry partnership.

Visualizing the creation of memories: Some things seem easy to remember, like a friend's birthday, your first car, and maybe where you parked your car last night. But how are these memories formed? Using advanced imaging techniques, NIBIB is building on research that is starting to unravel this mystery. Researchers have created a genetically engineered mouse that allows them to observe the movement of molecules in the brain thought to be involved in the formation of memories. The transgenic mouse carries a fluorescently labeled messenger RNA (mRNA) that can be visualized in cells without disrupting normal physiological processes. This new genetic tool allows the observation of gene expression in real time in neurons and is providing clues to the molecular changes that take place in the brain to form and store memories. In FY 2016, NIBIB will support this ongoing research to gain a more detailed understanding of how the brain manipulates molecules to make memories. This technique for imaging gene expression in living tissues provides a tool for researchers to better understand how certain genes may be involved in causing disease.

Emerging clinical technologies: Developing technology to visualize at the microscopic level helps us learn about cells and their development. New imaging technology to see larger structures and tissues more clearly is also critical for improving diagnosis and treatment of injury or disease. Spectral Computed Tomography (CT) is a promising imaging tool that researchers are currently optimizing for clinical use. This type of CT works by using special detectors that can differentiate many energy bands in a CT image, unlike conventional CTs, where only one energy is measured, or dual-energy CT, where two energies are recorded. Spectral CT is a cutting-edge technique expected to provide much better resolution of soft tissues (such as in the abdomen), and enable diagnoses to be made non-invasively that cannot be done with current MRI, radiochemical, or conventional CT approaches.

Another pioneering technique that NIBIB will support in FY 2016 is electrical impedance tomography (EIT), a method for assessing and monitoring treatment of cystic fibrosis. EIT is a noninvasive, non-ionizing functional imaging technique in which electrodes are placed on the surface of the body and low amplitude, low frequency current is applied. The patient cannot feel the current. The measurement of the voltage distribution forms images of the lungs. EIT is a safe and portable technology with no damaging side effects, and can thus be used repeatedly. This method may provide a way to assess the extent and nature of bronchial obstruction in patients and can help indicate pulmonary exacerbation – usually due to infection or inflammation. It also provides immediate feedback on the effectiveness of therapies to clear airways.

Enhanced visualization of nerves vs. tumor: Science meets art in development of techniques to “paint” nerves so they can be seen during surgery to minimize damage during tumor removal or other procedures. In FY 2016, NIBIB will support continued development of nontoxic probes that cause nerves to fluoresce. Current methods of identifying and avoiding damage to nerves during surgery include preoperative imaging, careful surgical dissection using traditional white light, and monitoring certain neurological reactions during surgery to identify impairment and intervene quickly in the hopes of preventing permanent damage. With improvement in nerve fluorescence, more intricate dissections can be performed. Potentially, this technique could also be used to repair peripheral nerves damaged by trauma. Another research team is looking to improve nerve detection with near infrared fluorescent contrast agents that target nerves and also develop compact and minimally invasive surgical instruments to simultaneously image nerve fluorescence and anatomy in real-time. Similarly, it is critical during surgery to be able to see and thus remove an entire tumor. Researchers are developing a near-infrared contrast agent to show the edges of a tumor (margins) to identify involved lymph nodes and any nearby metastatic tumor in order to reduce reoccurrence following tumor removal.

Remote-controlled image-guided interventions: Imaging technologies have proven invaluable for diagnosing illness and disease. NIBIB continues to support research to use or integrate these imaging technologies with interventions. An example of this is development of a remote-controlled catheter that can be used while a patient undergoes magnetic resonance imaging (MRI). While in an MRI scanner, this device can enhance a physician’s ability to visualize and ultimately carry out endovascular procedures, such as removing a blood clot, placing a stent, or fixing an aneurysm. Currently, these procedures are carried out under real-time x-ray imaging, referred to as fluoroscopy. Fluoroscopy is limited in that it can only be used to visualize blood vessels and not the soft tissues and organs supplied by these vessels. This is critical for guiding treatment, such as in a patient who has had a stroke – when trying to assess whether the brain tissue beyond a clot is healthy and would benefit from clot removal, or if the tissue is already dead, which could lead to a hemorrhage if the clot is removed. The remote-controlled robotic catheter can swivel and be steered using the magnetic field of the MRI machine. In addition to enabling real-time MRI during the procedure, the robotic catheter could also enhance doctors’ ability to navigate small, winding blood vessels that are currently difficult to catheterize.

Budget Policy:

The FY 2016 budget estimate for the AST program is \$158.564 million, a \$6.532 million (or 4.3 percent) increase from the FY 2015 Enacted level. This increase includes a \$1.2 million increase for the NIH’s new Precision Medicine Initiative. High priority is also 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 and multimodal 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.

**Precision Medicine.** NIH proposes to launch a national research cohort of one million or more Americans – to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing. Participants who voluntarily choose to join this effort will be able to share their genomic data, biological specimens, and behavioral data, and, if they choose, link it to their electronic health

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records (EHRs), taking advantage of the latest in social media and mobile applications, and with appropriate privacy protections in place. Bona fide researchers from across the country will have access to data voluntarily provided, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together taking advantage of infrastructure, data security and expertise already in place. NIH will help to connect these existing cohorts, but the current sponsors of the cohorts will maintain their ownership and management. Research on this scale promises to lead to new prevention strategies, novel therapeutics and medical devices, and improvements in how we prescribe drugs – on an *individual and personalized basis*.

**Program Portrait: Advances in Fetal, Neonatal, and Pediatric Imaging**

FY 2015 Level: \$5.7 million

FY 2016 Level: \$5.8 million

Change: +\$0.1 million

NIBIB is supporting a broad range of imaging research from early development to specialized technology designed specifically for children. Biomedical imaging is a crucial part of medical practice, but there are challenges in being able to perform imaging in children. For an MRI, patients must hold completely still while lying in a noisy scanner for up to an hour or more, a feat nearly impossible for a child. Children also have trouble holding their breath on command, a task that is required to prevent movements of the chest and abdomen from causing image distortion. To overcome some of the challenges children may be given anesthesia, but such a measure is far from ideal.

Researchers are using a multi-pronged, team-science approach that involves adapting MRI equipment for pediatric use, developing faster acquisition and better motion correction strategies, and implementing state-of-the-art image reconstruction techniques. This effort has greatly reduced scan time to less than 10 minutes in some cases. Through an academic-industry partnership, researchers also designed and built MRI hardware tailored to a child's body that enhances image clarity and shortens scan time (individual coils pick up the signal from different parts of the body simultaneously, rather than sequentially). The key to the technique is a special algorithm, now publically available, used to reconstruct the full MR image from these few data points with high fidelity. The researchers also created an imaging strategy that helps to correct for motion that occurs during a scan so that sharp images can be formulated even when a child is breathing. Researchers are also beginning to design coils that are completely flexible, light and can be incorporated into children's garments or blankets.

Other researchers are focusing on advanced fetal brain imaging using MRI. Like MRI in children, fetal motion limits the capability to use it as a diagnostic or monitoring tool. Researchers are developing a technology for high-resolution anatomical and physiological neuroimaging that is not sensitive to motion. This approach will focus on developing state-of-the-art image acquisition tools. Acquisition tools influence the quality and data that can be collected in imaging. The analysis of that data is also an area of research in pediatric imaging. One effort is focused on developing novel image processing technology to reconstruct 3-D images from data collected using MRI.

For infants that require care in an incubator, noninvasive imaging methods have not been possible because incubators are not compatible with imaging methods such as MRI. Researchers are overcoming this challenge by developing MR compatible incubators and enabling technologies that allow noninvasive evaluation of neonates for brain dysfunction through the assessment of biochemical and metabolic information in addition to better morphologic data. In other pediatric brain imaging efforts, NIBIB is also participating in a trans-NIH activity to map the lifespan connectome. This project will map connections in the developing and aging human brain across the lifespan from children, adolescents to older adulthood.

**Discovery Science and Technology (DST)**

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. The program also supports several trans-NIH activities.

Mechanobiology: In regulating cell growth and differentiation there is a growing understanding of the role of biomechanical stress in influencing tissue growth and remodeling. One important example is showing that increasing shear stress (frictional force against the lining of blood vessels caused by blood flow) within a blood vessel above a certain threshold triggers sprouting of collateral capillaries from those vessels. Such sprouting is a well-known process that occurs to improve circulation in tissue whose vessels are narrowing due to plaque build-up. Different types

of shear stress increases the gene activity that erodes the vessel wall and builds channels that branch off of the parent vessel. Using a clever modeling system, the investigators varied the flow parameters and used computational models to predict the conditions that might support this growth activity inside the body. Such understanding increases NIH's ability to engineer real-time, functional blood flow into implantable tissues, as well as to study the natural processes involved in rebuilding blood vessels.

Microfluidics for circulating tumor cells: Studies are underway that use a microfluidics point-of-care device, the iChip, to isolate and analyze circulating tumor cells (CTCs). The iChip microfluidic device can separate a single cancer cell from one billion blood cells without destroying the cancer cell. In a practical application of this technology, researchers have recently isolated breast cancer cells from the blood of patients and after extensive genetic analysis identified and tested the most effective cancer-killing drugs for those specific tumors. A key to this technique is not only development of the device, but also creating a system to grow enough cancer cells for genetic analysis without the cells mutating. This breakthrough for precision medicine identified which medications worked best on the tumor cells of each individual patient in the study. Going forward, this technique will be useful for identifying mutations that may occur and adjusting medications when individual tumors become resistant to some drugs but susceptible to others.

Regenerative medicine for wound healing: Chronic wounds afflict more than six million patients in the U.S. and cost an estimated \$25 billion dollars per year to treat<sup>1</sup>. Because diabetic patients are at increased risk for developing chronic wounds, these numbers are expected to rise as diabetes rates climb. A new approach to address this problem promotes tissue regeneration to treat chronic wounds. Researchers created a biodegradable scaffold that enables sustained, local delivery of gene-silencing factors called siRNA to promote tissue regeneration. The team recently used the scaffold to deliver siRNA to mice in order to locally silence a gene normally responsible for inhibiting blood vessel formation. Blood vessels are essential to the delivery of oxygen, micronutrients, and growth factors to wounds. Silencing these genes may increase the formation of new blood vessels, which may help to heal wounds. This approach leverages natural mechanisms in the cell that produce a symphony of related factors, initiating a robust "growth program" that induces formation of mature, stable vessels. While the researchers are studying this approach for wound healing, their scaffold provides the unique ability to adapt siRNA treatment to fit other clinical problems as well.

Point-of-care molecular diagnostics for low resource settings: By taking advantage of digital or single-molecule quantitative assays, researchers have found a way to use a "lab on a chip" device and a cellphone to calculate a precise concentration of molecules from a sample. With the slip chip device, no electricity is needed, which is a huge advantage over current diagnostic methods

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<sup>1</sup> Wound Repair Regen. 2009 Nov-Dec; 17(6): 763-771. Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. Chandan K. Sen, PhD, Gayle M. Gordillo, MD, Sashwati Roy, PhD, Robert Kirsner, MD, Lynn Lambert, CHT, Thomas K. Hunt, MD, Finn Gottrup, MD, Geoffrey C Gurtner, MD, and Michael T. Longaker, MD

which utilize polymerase chain reaction (PCR). PCR is used in point-of-care devices for detecting numerous conditions such as hepatitis C, influenza, and HIV. The new method also works in environments where temperature, light, and humidity cannot be controlled. This method splits a sample into amounts so small that they only contain one or no target molecules such as HIV RNA. The slip chip device splits the sample and deposits the small amounts into wells on the chip. A new process for amplification of the samples produces a bright fluorescent signal if a target molecule is present. This gives a positive (yes, if molecule is present) or negative (no, if molecule is not present) result. The concentration, or quantitative result, is calculated from the number of wells in the slip chip with a positive result. NIBIB support for this type of research can lead to faster and earlier diagnosis, and ultimately better health outcomes.

Extended preservation of donor organs: Organ transplants are common, but current technology can preserve them outside the body for a maximum of only 24 hours. Researchers have developed a new super-cooling technique to increase the amount of time human organs could remain viable outside the body. Extending the time a liver can survive outside the body would provide many benefits, including more time to prepare the patient and ease logistics at the donor hospital site, reduce the urgency of rushing the organ to its destination, and expand the donation geographical area to allow for transcontinental and intercontinental transplantations—thereby increasing the chances of patients finding better matches while simultaneously significantly reducing costs. Using this new technique, the researchers were able to store the super-cooled rat livers for three days (72 hours) and four days (96 hours) at 21 degrees Fahrenheit. All the rats who had super-cooled livers stored for three days survived three months; the survival rate for animals receiving livers stored for four days was 58 percent<sup>2</sup>. The process must go through extensive testing and refinement before it could be considered for use in humans, but the technique's achievement in being the first method to have a successful survival rate after the livers had been stored for more than one day has broad implications for the future of liver transplantation.

#### Budget Policy:

The FY 2016 budget estimate for the DST program is \$101.595 million, a \$7.524 million (or 8.0 percent) increase from the FY 2015 Enacted level. This includes a \$3.0 million increase in funding for the President's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, bringing the FY 2016 total to \$4.0 million. DST will also give high priority to supporting new and early-career investigators, and priority to investigator-initiated research grants as these are 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.

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<sup>2</sup> Berendsen T, Bruinsma B, Puts C, Saeidi N, Usta O, Uygun B, Izamis ML, Toner M, Yarmush M, Uygun K. Supercooling enables long-term transplantation survival following 4 days of liver preservation. Nat Med 2014; 20(7):790-793.

**Program Portrait: Neuro-electronics to Restore Function**

FY 2015 Level: \$3.6 million

FY 2016 Level: \$3.7 million

Change: +\$0.1 million

Several groups of NIBIB-supported scientists are developing integrative next-generation engineering technologies to activate the body's own electrical communication system to restore function after paralysis and limb loss. One group of engineers, clinicians, and neuroscientists has developed a therapy for spinal cord injury in patients with complete motor loss below the level of injury. An epidural stimulator, surgically implanted on the surface of the spinal cord, applies a very low level stimulus to increase the excitability of local neurons in the spinal cord. The stimulation is not strong enough by itself to cause muscle activation, but when combined with physical training, it enabled patients to stand and voluntarily move paralyzed limbs on command. Patients also regained functions such as the ability to sweat, regulate blood pressure, control bladder and bowel, and regain sexual function. These functions remained even when the stimulator was turned off. The researchers continue to optimize the technology and potentially deliver spinal stimulation through the skin, eliminating the need for surgery. They are also modifying this approach for use in spinal cord injury patients with upper limb paralysis.

Another group is developing a functional electrical stimulation (FES) technology for restoring function in people with paralysis. This system can restore function by electrical activation delivered through the peripheral nervous system. It consists of multiple, small, implantable modules that stimulate nerves or paralyzed muscles, receive and transmit signals, or sense changes in the body's internal environment. With training, a patient can flex non-paralyzed muscles to send signals through the networked modules, activating paralyzed muscles, and allowing patients to perform specific tasks such as holding a cup or turning a key. It can also be configured to restore functions such as hand grasp, abdominal control for maintaining posture, and standing balance and stability for moving from a wheelchair to a bed.

Two other groups are working to restore hand and arm function of amputees with lost limbs. Current prosthetics have limited range of motion and do not provide a sense of touch. One group is developing sensors implanted in the remaining limb that wirelessly transmit electrical signals to control a prosthesis so it can move in a more natural way. Ultimately researchers hope the technology will allow individual finger control of a prosthetic hand. Another group is developing a novel sensory feedback system by placing sensors in a prosthetic hand that transmit signals wirelessly to the upper arm where implanted electronics receive and process the signals, then delivers electrical stimulation to peripheral nerve fibers. These fibers give the sensation of position or force to the user, who can respond by adjusting the control of the prosthetic hand. This sensory feedback allows the amputee to both control and actually "feel" touch with the prosthetic hand.

**Bridging the Science for Technological Competitiveness**

NIBIB supports a broad range of institutional and individual research training and career development programs. These 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.

Physician-Scientists: In support of training clinician-scientists, NIBIB encourages institutional and individual research training in clinical and translational research for both M.D. and M.D.-Ph.D. researchers. Another important program provides mentored research training and supports the integration of radiology residents and residents and clinical fellows in other NIBIB-relevant disciplines, including cardiology, neurology, orthopedics, ophthalmology, and surgery. This training support allows clinician-scientists to work on cutting-edge research projects and helps these investigators support critical staff positions in their laboratories.

NIBIB also participates in a joint NIH/Department of Energy effort to support Ph.D. fellowships. The program provides training grants with a focus on developing useful radiolabeled drugs for imaging or treatment. This effort was established in response to a National Academy of Sciences recommendation<sup>3</sup>.

Multi-scale modeling: Innovation in tools and technologies is key to maintaining competitiveness in research. Increasingly, the development of computational modeling and simulation methods are vital in developing rational solutions. Modeling is a quantitative tool for learning about the anatomy and physiology of the body in health and disease. NIBIB leads an interagency effort across 10 government agencies to support multiscale modeling to understand all levels of the body including atoms, molecules, cells, tissues, organs, the whole body, and populations. In one example, research is helping to predict outcomes after anterior cruciate ligament (ACL) reconstruction surgery. ACL surgeries are usually successful at improving joint stability and allowing patients to return to normal physical activities in the short-term. However, in the long-term, as early as one year after surgery, an early sign of joint degeneration is observed.<sup>4</sup> In 10 to 15 years after surgery, 70 to 90 percent of patients will exhibit osteoarthritis (OA).<sup>5</sup> It is not currently understood why OA develops or the best approach to mitigate the risk for OA. By harnessing the power of computational modeling, data, and knowledge can be integrated to systematically test a variety of surgical outcomes to address this challenge and predict why 25 percent of ACL surgeries fail.<sup>6</sup>

Virtual medical training: NIBIB also supports several research projects to develop virtual and physical simulators for medical training of future clinicians and medical practitioners, to reduce medical errors and improve patient safety. In one, the Virtual Basic Laparoscopic Skill Trainer (VBLaST) will develop and validate a virtual version of the tasks and competency that must be demonstrated for board certification in surgery. By developing a virtual version of these tasks, the performance evaluation is improved by increasing the objectivity in the assessment, providing feedback automatically in real-time, and reducing the number of test proctors required. A virtual version also eliminates the need to replace training materials and makes the training and testing broadly accessible.

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<sup>3</sup> National Academy of Sciences. Assuring a Future U.S.-based Nuclear and Radiochemistry Expertise. Washington, DC. 2012. The National Academies Press.

<sup>4</sup> Knoll Z, Kocsis L, Kiss RM. Gait patterns before and after anterior cruciate ligament reconstruction. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2004;12(1):7-14.

Bergfeld JA, McAllister DR, Parker RD, Valdevit AD, Kambic HE. A biomechanical comparison of posterior cruciate ligament reconstruction techniques. *American Journal of Sports Medicine*. 2001;29(2):129-36.

<sup>5</sup> D'Lima DD, Chen PC, Kester MA, Colwell CW, Jr. Impact of patellofemoral design on patellofemoral forces and polyethylene stresses. *Journal of Bone and Joint Surgery*. 2003;85-A Suppl 4:85-93.

Greis PE, Holmstrom MC, Bardana DD, Burks RT. Meniscal injury: II. Management. *Journal of the American Academy of Orthopaedic Surgeons*. 2002;10(3):177-87.

<sup>6</sup> Andersen, H.N., Bruun, C., Sønergård-Petersen, P.E., 1992. Reconstruction of chronic insufficient anteriorcruciate ligament in the knee using a synthetic Dacron prosthesis A prospective study of 57 cases. *Am.J.SportsMed*. 20(1), 20-23.

In another project, researchers are developing surgical simulators that incorporate traditional teaching of skills involving hand-eye coordination and motor control, as well as nontechnical skills such as learning, coordination, and decision making under stressful situations. This first-ever cognitive simulator is capable of fully immersing the trainee in a virtual operating room complete with virtual patient interactions. The simulator also has the capability to provide realistic distractions found in an operating room. The addition of the cognitive simulator thus creates a more realistic scenario for trainees.

In FY 2016, NIBIB will also continue to support a physical simulator project to evaluate hands-on clinical skills involving the innovative use of sensor and data acquisition technology embedded in manikin-based trainers. Currently, the trainers developed by these researchers are capable of simulating over 100 different clinical presentations. Researchers are building and validating reliable technologies that can be used to ensure that minimum performance standards are met by all healthcare professionals who perform hands-on clinical examinations and procedures. In one application, a set of sensor-enabled breast examination simulators can be used to define performance standards for the clinical breast examination. Techniques used in the clinical breast examination can be quantified and improper techniques that result in missed diagnosis can be identified using sensor-enabled breast models.

#### Budget Policy:

The FY 2016 budget estimate for the Technological Competitiveness – Bridging the Sciences program is \$22.450 million, a \$0.188 million (or 0.8 percent) increase from the FY 2015 Enacted level. This increase includes funding for the implementation of NIH's 2% increase in stipend levels for trainees. Other high priorities include developing interdisciplinary training programs and supporting the Quantum Grants Program, which establishes interdisciplinary research teams to address major healthcare problems.

#### **Health Informatics Technology (HIT)**

HIT supports activities to further research in health information technology, bioinformatics, mobile health informatics, clinical decision support, image processing, data integration, and telehealth/telemedicine research programs. This division also supports trans-NIH and government-wide activities in health informatics, a field that crosses computer and information science and health care.

Software to improve interventions: As in our daily lives, medical practice is increasingly using software and algorithms to improve procedures and care. In one example, researchers are developing algorithms that can be used during endoscopic nasal surgery to eliminate the need for repeated CT scans during surgery. This type of surgery is used for treatment of advanced sinusitis and nasal polyps and places the endoscope through the patient's nostril to avoid cutting the skin. Extreme care is required to avoid damage to the sinuses, eyes, optic nerves, brain, and carotid arteries. In current practice, repeated CT images are obtained during surgery so surgeons can see the location of surgical tools relative to critical nerve structures and the area requiring surgery. This lengthens the time of the procedure, requires significant infrastructure, and exposes operators to radiation. The software will help surgeons plan and model the surgery in advance and provide virtual real time navigation during surgery.

Advancing the skill of novice ultrasonographers: Ultrasound imaging has become ubiquitous in medical practice, in part because of its many applications and portability. It can be used in hospitals, emergency rooms, and doctors' offices. Although it can be easily used in clinical practice, interpreting the images is difficult. Researchers are overcoming this challenge using algorithms to help inexperienced personnel read images. This system, designed for assessing abdominal trauma, uses a low-cost ultrasound probe connected to a tablet computer that compares the ultrasound video of a novice operator to video showing anatomical structures captured by experts. To develop this system the researchers created an extensive database of expert ultrasound videos that is now publically available, as is the software created for the system.

Active learning from accumulated data: Just one day in the hospital, particularly in a critical care unit, generates huge volumes of data about a patient. Continuous monitoring and recording of vital signs, blood tests, fluid intake and output, oxygen levels, and imaging tests, are but a few examples. But what becomes of all this data? Imagine if every patient could collectively inform the care of the next patient who needs care. Researchers are creating a database to collect, organize, and publicly distribute this detailed clinical data while preserving patient privacy. Software tools are also being developed to explore and analyze the data and inform future diagnostics and treatment. Previous research supported the development of technology to create the Multi-parameter Intelligent Monitoring in Intensive Care (MIMIC-II) database. NIBIB plans to support ongoing research to apply this technology in practice, improve software, and expand data collection. Researchers have collected data for 40,000 intensive care unit (ICU) stays and an initial analysis using the system and its data showed that positive fluid balance at the time of ICU discharge is associated with increased risk of death, particularly in patients with underlying heart or kidney disease.

Remote eye screening in diabetics: Like the development of a drug to cure a specific disease, technology and device development requires a great deal of initial research, from identifying a potential workable solution, to design, to feasibility testing and clinical testing. NIBIB supports many efforts throughout this entire process, such as one project on technology that can be used to remotely screen people for diabetic retinopathy. Increases in diabetes and long wait times for screening by an eye doctor put people at risk for vision loss. As a telemedicine procedure that can be performed in a primary care setting, the EyeArt technology helps address this issue. This advanced image analysis tool works with existing telemedicine platforms to identify at-risk diabetic patients in need of expert care. This technology is currently being validated and an application for FDA approval is pending.

#### Budget Policy:

The FY 2016 budget estimate for the HIT program is \$23.003 million, a \$4.487 million (or 16.3 percent) decrease from the FY 2015 Enacted level. This decrease is the result of a \$5.5 million contract that is funded in alternate years and will not receive FY 2016 funds. HIT will focus on mobile health, clinical decision support, and big data in FY 2016. The HIT will also give priority to new investigators. Investigator initiated research and Bioengineering Research Partnership applications will be encouraged and supported.

**Program Portrait: Toward Better Health with Mobile Informatics**

FY 2015 Level: \$1.9 million

FY 2016 Level: \$2.0 million

Change: \$0.1 million

Nearly everyone has used a smart phone, or device connected to their phone or computer, to track a health related indicator. Whether counting steps or calories, or measuring heart rate, a great deal of data is being generated. In more sophisticated medical uses, researchers are developing ways to use mobile devices for a variety of illnesses and disorders. For example, a cell-phone based tool is being used to help health care providers make more accurate diagnosis of childhood pneumonia, determine level of severity, and offer appropriate treatment. Another project is developing a smart system using wearable Bluetooth Low-Energy (BLE) devices to monitor and evaluate motor control, fall risk, and gait speed of patients after they have had a stroke. This follow-up data on activity can provide valuable information on effective recovery and may help determine optimal interventions. NIBIB has also been supporting the development of a seizure alert system that can be used daily by people with epilepsy in order to detect the onset of generalized seizures and wirelessly alert a caregiver to provide appropriate medical intervention.

Utilization of the vast quantity and variety of data that is generated through mobile interfaces can potentially transform the delivery of care and services, and personalize care to help people remain healthy and prevent disease. There are volumes and volumes of data, but making sense of it requires tools to address the unique “5V” features of mobile sensor data (volume, velocity, variety, variability, and versatility). A proper framework for using all this data is also needed to ensure privacy. Working with other NIH Institutes, NIBIB is supporting a Center of Excellence recently established to meet the need for an informatics framework to analyze mobile data. This Center will work to develop tools and software to capture and convert mobile data into usable information. Researchers will test the feasibility of the framework for two biomedical applications – reducing relapse among those who have quit smoking, and reducing readmission among those with congestive heart failure. The goal is a platform that can detect and predict risk, and also alert providers, family, or caregivers to the need for intervention as early as possible.

In collaboration with other NIH ICs, NIBIB also plans to support the development of a resource for researchers to evaluate mobile and wireless technologies more efficiently and rapidly. This activity will facilitate mobile health research across a variety of observational and clinical research studies and settings, and for a range of diseases and populations. An infrastructure will be developed that works with wireless carriers to create a registry of potential study participants.

**Intramural Research Program (IRP)**

IRP supports NIBIB’s mission to integrate bioengineering with the life and physical sciences, 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 2016, NIBIB envisions developing new technologies ranging in scale from molecular and cellular to the level of whole organ imaging. One example is the clinical translation of highly sensitive and specific tracers for diagnostic imaging by positron emission tomography (PET) to detect newly developing blood vessels, based on peptides that have high affinity for cellular markers of angiogenesis. The tracers are being tested in patients with diseases that are associated with increased angiogenesis, such as cancer and rheumatoid arthritis. To aid in understanding diseases at the molecular level, innovative technology will be developed for high-resolution fluorescence imaging of specific proteins in living cells at fast-time resolution. A prototype instrument has been constructed that doubles three-dimensional spatial resolution without any trade-off in speed or increase in phototoxicity, enabling visualization of high-speed biological dynamics at super-resolution.

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Budget Policy:

The FY 2016 President's Budget estimate for the Intramural Research Program is \$11.991 million, a \$0.119 million (or 1.0%) increase from the FY 2015 Enacted 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, communication, and evaluation of NIBIB's programs, regulatory compliance, international coordination, and liaison with other federal agencies, Congress, and the public.

Budget Policy:

The FY 2016 President's Budget estimate for Research Management and Support is \$19.711 million, a \$0.195 million (or 1.0 percent) increase from the FY 2015 Enacted level. High priorities of RMS are the scientific support of NIBIB research programs and strategic planning.

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

	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Total compensable workyears:			
Full-time employment	102	102	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$0	\$0	\$0
Average GM /GS grade	12.3	12.3	0.0
Average GM /GS salary	\$107	\$108	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$0	\$0	\$0
Average salary of ungraded positions	\$93	\$94	\$1

<b>OBJECT CLASSES</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Personnel Compensation			
11.1 Full-Time Permanent	\$7,813	\$8,025	\$212
11.3 Other Than Full-Time Permanent	2,999	3,040	41
11.5 Other Personnel Compensation	202	205	3
11.7 Military Personnel	0	0	0
11.8 Special Personnel Services Payments	1,523	1,544	21
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$12,537</b>	<b>\$12,814</b>	<b>\$277</b>
12.1 Civilian Personnel Benefits	\$3,366	\$3,405	\$38
12.2 Military Personnel Benefits	0	0	0
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$15,904</b>	<b>\$16,219</b>	<b>\$315</b>
21.0 Travel & Transportation of Persons	\$273	\$278	\$4
22.0 Transportation of Things	19	19	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	3	3	0
23.3 Communications, Utilities & Misc. Charges	189	192	3
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	\$9,433	\$3,384	-\$6,049
25.2 Other Services	2,417	2,456	39
25.3 Purchase of goods and services from government accounts	22,124	24,025	1,900
25.4 Operation & Maintenance of Facilities	\$80	\$80	\$0
25.5 R&D Contracts	220	224	4
25.6 Medical Care	71	72	2
25.7 Operation & Maintenance of Equipment	2,188	2,223	35
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$36,534</b>	<b>\$32,465</b>	<b>-\$4,070</b>
26.0 Supplies & Materials	\$723	\$734	\$12
31.0 Equipment	1,234	1,254	20
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	272,364	286,151	13,786
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$311,339</b>	<b>\$321,095</b>	<b>\$9,756</b>
<b>Total Budget Authority by Object Class</b>	<b>\$327,243</b>	<b>\$337,314</b>	<b>\$10,071</b>

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

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

<b>OBJECT CLASSES</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$7,813	\$8,025	\$212
Other Than Full-Time Permanent (11.3)	2,999	3,040	41
Other Personnel Compensation (11.5)	202	205	3
Military Personnel (11.7)	0	0	0
Special Personnel Services Payments (11.8)	1,523	1,544	21
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$12,537</b>	<b>\$12,814</b>	<b>\$277</b>
Civilian Personnel Benefits (12.1)	\$3,366	\$3,405	\$38
Military Personnel Benefits (12.2)	0	0	0
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$15,904</b>	<b>\$16,219</b>	<b>\$315</b>
Travel & Transportation of Persons (21.0)	\$273	\$278	\$4
Transportation of Things (22.0)	19	19	0
Rental Payments to Others (23.2)	3	3	0
Communications, Utilities & Misc. Charges (23.3)	189	192	3
Printing & Reproduction (24.0)	0	0	0
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	13	13	0
Other Services (25.2)	2,417	2,456	39
Purchases from government accounts (25.3)	14,101	14,101	0
Operation & Maintenance of Facilities (25.4)	80	80	0
Operation & Maintenance of Equipment (25.7)	2,188	2,223	35
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$18,801</b>	<b>\$18,874</b>	<b>\$74</b>
Supplies & Materials (26.0)	\$723	\$734	\$12
<b>Subtotal Non-Pay Costs</b>	<b>\$20,007</b>	<b>\$20,100</b>	<b>\$93</b>
<b>Total Administrative Costs</b>	<b>\$35,911</b>	<b>\$36,319</b>	<b>\$408</b>

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**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2014 Actual			FY 2015 Est.			FY 2016 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Extramural Science Program									
Direct:	25	-	25	26	-	26	26	-	26
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	26	-	26	27	-	27	27	-	27
Intramural Science Program									
Direct:	17	-	17	17	-	17	17	-	17
Reimbursable:	8	-	8	8	-	8	8	-	8
Total:	25	-	25	25	-	25	25	-	25
Office of Administrative Management									
Direct:	24	-	24	24	-	24	24	-	24
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	24	-	24	24	-	24	24	-	24
Office of Research Administration									
Direct:	21	-	21	21	-	21	21	-	21
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	21	-	21	21	-	21	21	-	21
Office of the Director									
Direct:	5	-	5	5	-	5	5	-	5
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	5	-	5	5	-	5	5	-	5
Total	101	-	101	102	-	102	102	-	102
Includes FTEs whose payroll obligations are supported by the NIH Common Fund									
FTEs supported by funds from Cooperative Research and Development Agreements	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2012	12.9								
2013	12.3								
2014	12.3								
2015	12.3								
2016	12.3								

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**Detail of Positions<sup>1</sup>**

<b>GRADE</b>	<b>FY 2014 Actual</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	12	12	12
GM/GS-14	20	20	20
GM/GS-13	17	17	17
GS-12	6	7	7
GS-11	4	4	4
GS-10	1	1	1
GS-9	4	4	4
GS-8	1	1	1
GS-7	8	8	8
GS-6	1	1	1
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	74	75	75
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
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	31	31	31
Total permanent positions	74	75	75
Total positions, end of year	105	106	106
Total full-time equivalent (FTE) employment, end of year	101	102	102
Average ES salary	0	0	0
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	105,747	106,804	108,198

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