DEPARTMENT OF HEALTH AND HUMAN SERVICES

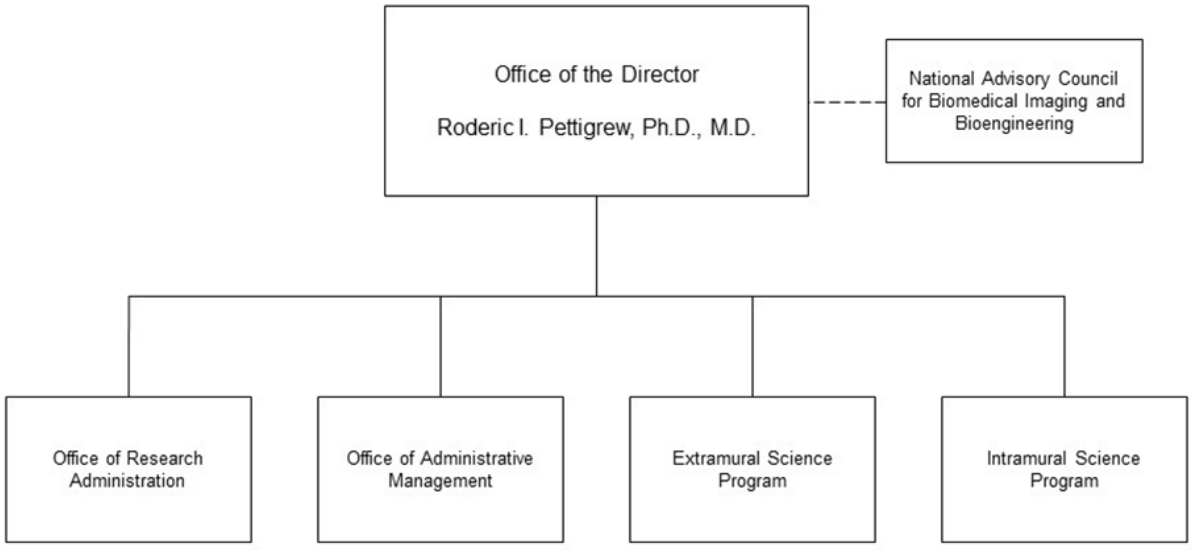
NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

FY 2017 Budget — Page No.

NOTE: The FY 2016 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

NIBIB Organizational Chart



For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, [$346,795,000]*$334,025,000*.

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	$330,192	$346,795	$343,506
Mandatory Appropriation (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(9,481)*
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	$330,192	$346,795	$343,506
OAR HIV/AIDS Transfers	-2,949	-3,289	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	$327,243	$343,506	$343,506
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$327,243	$343,506	$343,506
Unobligated balance lapsing	-20	0	0
Total obligations	$327,223	$343,506	$343,506

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2015: $1,480; FY 2016: $5,100; FY 2017: $5,100.

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget[3]		FY 2017 +/- FY 2016	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	365	$142,757	368	$144,911	403	$157,204	35	$12,293
Administrative Supplements	*(8)*	565	*(15)*	800	*(15)*	800		
Competing:								
Renewal	16	9,498	20	11,592	14	8,021	-6	-3,571
New	169	49,720	206	60,684	143	41,988	-63	-18,696
Supplements								
Subtotal, Competing	185	$59,218	226	$72,276	157	$50,009	-69	-$22,267
Subtotal, RPGs	550	$202,541	594	$217,987	560	$208,013	-34	-$9,974
SBIR/STTR	25	9,610	26	10,047	29	11,156	3	1,109
Research Project Grants	575	$212,151	620	$228,034	589	$219,169	-31	-$8,865
Research Centers:								
Specialized/Comprehensive	4	$6,641	4	$6,891	4	$6,891		$0
Clinical Research								
Biotechnology	30	38,809	31	40,268	31	40,268		0
Comparative Medicine								
Research Centers in Minority Institutions								
Research Centers	34	$45,450	35	$47,159	35	$47,159		$0
Other Research:								
Research Careers	29	$4,014	30	$4,165	30	$4,165		$0
Cancer Education								
Cooperative Clinical Research								
Biomedical Research Support								
Minority Biomedical Research Support								
Other	43	2,002	45	2,077	45	2,077		0
Other Research	72	$6,016	75	$6,242	75	$6,242		$0
Total Research Grants	681	$263,618	730	$281,435	699	$272,570	-31	-$8,865
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	20	$856	20	$888	20	$888	0	$0
Institutional Awards	211	9,017	215	9,356	211	9,356	-4	0
Total Research Training	231	$9,873	235	$10,244	231	$10,244	-4	$0
Research & Develop. Contracts	14	$21,440	12	$18,300	14	$26,495	2	$8,195
(SBIR/STTR) (non-add)[2]	*(3)*	*(131)*			*(3)*	*(59)*	*(3)*	*(59)*
Intramural Research	26	$12,345	26	$12,809	26	$13,065		$256
Res. Management & Support	71	19,967	72	20,718	72	21,132		414
Res. Management & Support (SBIR Admin) (non-add)[2]								
Office of the Director - Appropriation[2]								
Office of the Director - Other								
ORIP/SEPA (non-add)[2]								
Common Fund (non-add)[2]								
Buildings and Facilities								
Appropriation								
Type 1 Diabetes								
Program Evaluation Financing								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						-9,481		-9,481
Subtotal, Labor/HHS Budget Authority		**$327,243**		**$343,506**		**$334,025**		**-$9,481**
Interior Appropriation for Superfund Res.								
Total, NIH Discretionary B.A.		**$327,243**		**$343,506**		**$334,025**		**-$9,481**
Type 1 Diabetes								
Proposed Law Funding								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						9,481		9,481
Total, NIH Budget Authority		**$327,243**		**$343,506**		**$343,506**		
Program Evaluation Financing								
Total, Program Level		**$327,243**		**$343,506**		**$343,506**		

[1] All Subtotal and Total numbers may not add due to rounding.
[2] All numbers in italics and brackets are non-add.
[3] Includes mandatory financing.

Major Changes in the Fiscal Year 2017 President's Budget Request

Research Project Grants (RPGs) (-$8.865 million; total $219.169 million):
NIBIB will fund 589 RPG awards in FY 2017, a decrease of 31 awards from the FY 2016 Enacted level. This includes 157 competing RPGs (a decrease of 69 awards and $22.267 million from the FY 2016 Enacted level) and 403 non-competing awards (an increase of 35 awards and $12.293 million from the FY 2016 Enacted level). In addition, resources are identified to support SBIR and STTR projects to sustain the higher statutory funding threshold applicable for FY 2017.

Research and Development Contracts (+$8.195 million; total $26.495 million):
NIBIB will increase funding for R&D Contracts from the FY 2016 Enacted level. This increase is due to the funding of two contracts that are only funded in alternate years.

Summary of Changes

(Dollars in Thousands)

FY 2016 Enacted	$343,506
FY 2017 President's Budget	$343,506
Net change	$0

CHANGES	FY 2017 President's Budget		Change from FY 2016	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2016 pay increase & benefits		$4,898		$15
b. January FY 2017 pay increase & benefits		4,898		70
c. Two less days of pay		4,898		-37
d. Differences attributable to change in FTE		4,898		0
e. Payment for centrally furnished services		1,793		44
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		6,375		121
Subtotal				$214
2. Research Management and Support:				
a. Annualization of January 2016 pay increase & benefits		$10,694		$32
b. January FY 2017 pay increase & benefits		10,604		158
c. Two less days of pay		10,604		-81
d. Differences attributable to change in FTE		10,604		0
e. Payment for centrally furnished services		844		21
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		9,594		185
Subtotal				$316
Subtotal, Built-in				$529

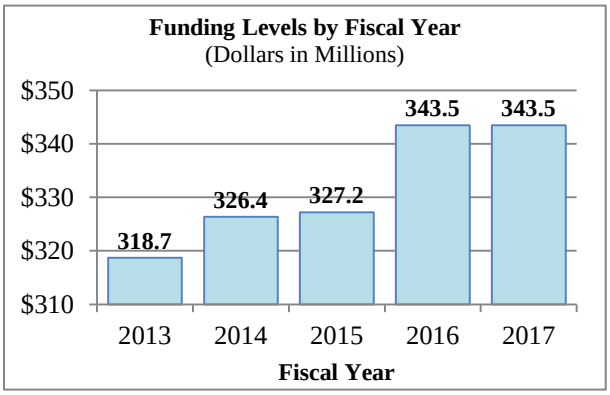
Summary of Changes
(Dollars in Thousands)

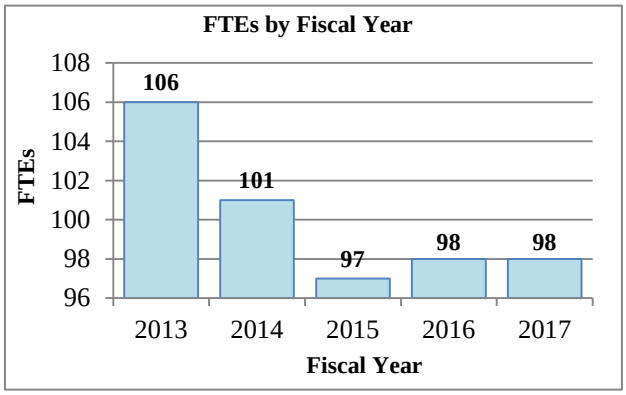
CHANGES	FY 2017 President's Budget[1]		Change from FY 2016	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	403	$158,004	35	$12,293
b. Competing	157	50,009	-69	-22,267
c. SBIR/STTR	29	11,156	3	1,109
Subtotal, RPGs	589	$219,169	-31	-$8,865
2. Research Centers	35	$47,159	0	$0
3. Other Research	75	6,242	0	0
4. Research Training	231	10,244	-4	0
5. Research and development contracts	14	26,495	2	8,195
Subtotal, Extramural		$309,309		-$670
	FTEs		FTEs	
6. Intramural Research	26	$13,065	0	$42
7. Research Management and Support	72	21,132	0	98
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	98	$343,506	0	-$529
Total changes				$0

[1] Includes mandatory financing.

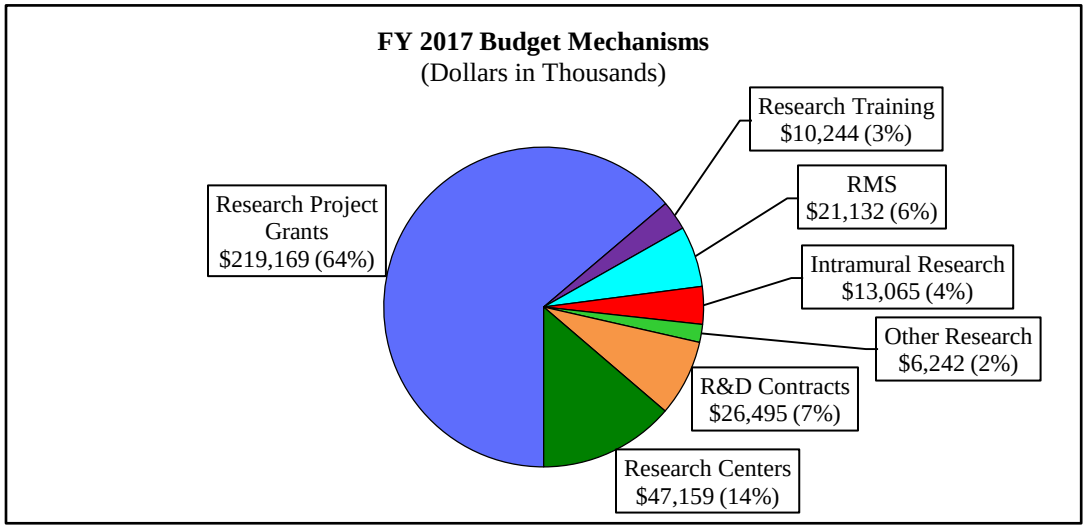
Fiscal Year 2017 Budget Graphs

History of Budget Authority and FTEs:

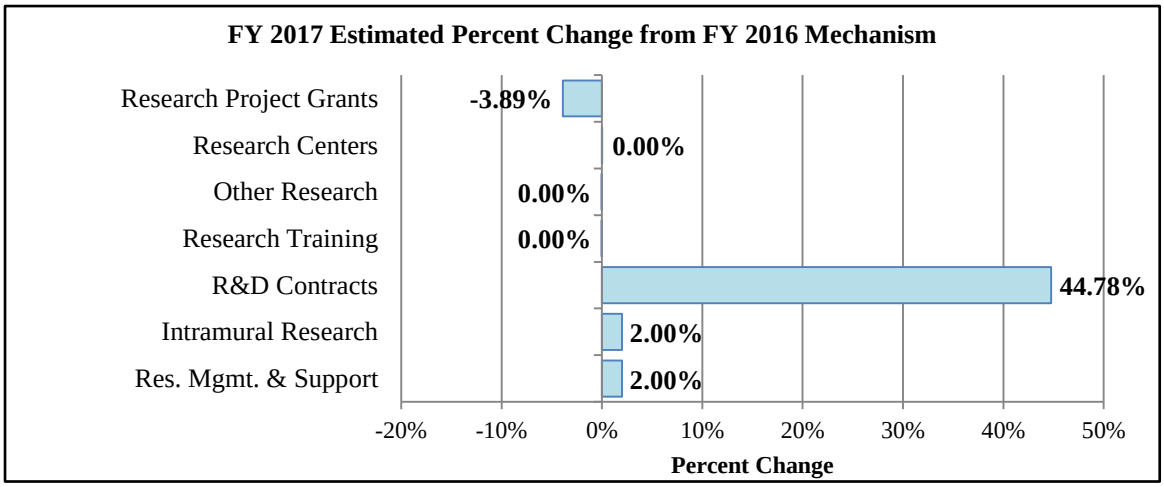




Distribution by Mechanism:



Change by Selected Mechanisms:



Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget[2]		FY 2017 +/- FY2016	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Applied Science and Technology		$147,363		$154,917		$152,942		-$1,975
Discovery Science and Technology		95,891		106,468		103,418		-3,050
Health Informatics Technology		32,004		28,737		32,905		4,168
Technological Competitiveness - Bridging the Sciences		19,673		19,857		20,045		188
Subtotal, Extramural		**$294,931**		**$309,979**		**$309,309**		**-$670**
Intramural Research	**26**	**$12,345**	**26**	**$12,809**	**26**	**$13,065**	**0**	**$256**
Research Management & Support	**71**	**$19,967**	**72**	**$20,718**	**72**	**$21,132**	**0**	**$414**
TOTAL	**97**	**$327,243**	**98**	**$343,506**	**98**	**$343,506**	**0**	**$0**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Includes mandatory financing.

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget[1]
Research and Investigation	Section 301	42§241	Indefinite	$343,506,000	Indefinite	$334,025,000
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$343,506,000		$334,025,000

[1] Excludes mandatory financing.

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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 Rescission	$337,314,000	$338,360,000	$344,299,000	$346,795,000 $0
2017[1]	$343,506,000			

[1] Includes Mandatory financing.

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 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
BA	$327,243,000	$343,506,000	$343,506,000	$0
FTE	97	98	98	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 human health by leading the development of biomedical technologies and accelerating their application. NIBIB supports research that integrates engineering with the physical and life sciences to develop tools, instruments, and emerging technologies that can be applied to a broad range of biomedical and health care problems.

Technological innovation is critical for both new biomedical discoveries and the application of those discoveries to clinical practice. One NIBIB-funded researcher is working to combine light and sound to image the living brain, building a camera that can literally capture microscopic events happening at the speed of light. Another is finding ways to dramatically expand the usefulness of MRI, including an MRI machine that may one day fit inside an ambulance. NIBIB also supports researchers who are building functional human organs-on-a-chip to replace animal models for more rapid and accurate testing of drug toxicity and efficacy. Additionally, research scientists are crafting a myriad of biomaterials to improve healthcare, such as dissolvable screws to fix bones, adhesive gels to patch wounds, and porous scaffolds to promote cartilage regeneration. Another indicator of NIBIB's successful commitment to innovation is the number of new patents resulting from NIBIB research, a measure of knowledge creation, translational value, and economic potential. Patent activity correlates positively with regional economic health and NIBIB leads the NIH in the number of new patents per $100 million in investment (Nature Biotechnology, 2014). This institute also serves as an important catalyst for emerging basic and clinical technologies and a stimulator of innovation across NIH, in academia, and in industry.

Foundation for Discovery: Basic Research. Scientific advances depend both on ideas and the tools to test those ideas. NIBIB has a critical role in the development of new tools for scientific advancement. For example, researchers using new 3D-printed gel scaffolds are able to release biomolecules into the body with exceptional control. Biomedical engineers use these gel scaffolds to supply biomolecules to injured or diseased adult tissue and test whether recreating developmental conditions can stimulate the growth of new tissue. The pattern of the scaffolds

can be created on a computer and filled with a wide variety of biomolecules such as nucleic acids, enzymes, and growth factors. The gel scaffold is a powerful research tool and might also be used to facilitate regeneration in a wide variety of tissues, including blood vessels and the heart. In addition to promoting new tissue growth, the scaffolds have the potential to be used to deliver medication to any area of the body with high precision.

NIBIB is also active in the President's BRAIN (Brain Research through Advancing Innovative Neurotechnologies) Initiative and supports development of the new neuroscience tools and technologies needed to reveal the biological basis of mental processes like cognition, emotion, perception, and action. The FY 2017 Budget requests a total of $195 million across NIH, an increase of $45 million, to continue progress on the BRAIN Initiative. Among the varied projects, this initiative supports research to develop a new methodology for a portable head-only MRI scanner to permit imaging brain function in all populations and environments worldwide. Another team is developing technology for an ambulatory PET brain imaging cap – a unique tool that could safely provide detailed insight into the functioning of the human brain during activities such as walking, playing a piano, and socializing.

The Promise of Precision Medicine. Innovations in engineering sciences will play a critical role in bringing precision medicine to patients at the bedside. NIBIB is supporting several areas of research including capturing rare circulating tumor cell clusters. Researchers have developed a microfluidic chip that is specifically designed for the efficient capture of circulating tumor cell (CTC) clusters from whole, unprocessed blood. The unique Cluster-Chip capture technique is based on the structural properties of CTC clusters rather than their size or the presence of surface proteins, making it well-suited for use with many different cancer types. Researchers recently used the Cluster-Chip to capture and analyze CTC clusters in a group of 60 patients with metastatic breast, prostate, and melanoma cancers. They found the clusters in 30-40 percent of the patients, revealing that CTC clusters are far more common than previously thought. Further analysis yielded new insights into the biology of CTC clusters, including hints that they may be involved in cancer metastasis. This new work with cancer cell clusters extends previous work in which the researchers isolated breast cancer cells from the blood of patients and used the cells to genetically determine the specific type of tumor, allowing identification of the most effective cancer-killing drugs for those patients. This breakthrough in precision medicine has the potential to improve cancer care significantly.

Applying Big Data and Technology to Improve Health. NIBIB plays an active role in NIH's Big Data to Knowledge Initiative (BD2K). Recently, awards were made to develop new strategies to analyze and leverage the explosion of increasingly complex biomedical data sets. The BD2K awards will support the development of new approaches, software, tools, and training programs to improve access to these data and the ability to make new discoveries using them. In FY 2017, NIBIB will continue to support Centers of Excellence and training initiatives to develop technologies for data sharing, integration, analysis, and management.

Stewardship to Inspire Public Trust. As stewards of the resources provided by the American people, NIBIB cultivates partnerships between public organizations and private foundations that are essential to accelerate the application of research advances to improve health and quality of life. For example, NIBIB is a leading partner in the NIH-Bill and Melinda Gates Foundation Working Group on Point of Care Diagnostics. This is a forum to develop strategies for

accelerating progress in the area of affordable diagnostic tests for use at the point of care (POC) that enable high quality, low cost diagnosis and treatment of diseases in low resource settings.

NIBIB is also encouraging the next generation of innovators through the DEsign By Undergraduate Teams (DEBUT) biomedical engineering design competition for teams of undergraduate students. Participants are judged on the significance of the problem being addressed, the potential impact on clinical care, the innovation of the design, and the existence of a working prototype. The first place winner in the most recent competition, Viral Diagnostic Technology, addressed the need for a more accessible POC viral load diagnostic device to monitor HIV treatment. The team developed a system that can help determine if a patient's medications are appropriately controlling the HIV virus in the bloodstream. The design has the potential to increase accessibility to viral load testing, which will be critical for controlling HIV worldwide. Over the years DEBUT winners have obtained patents for their inventions and launched start-up companies across the United States. One previous winner was recently invited to participate in the first-ever White House Demo Day, an event to highlight the important role entrepreneurship plays in America's economy.

Program Descriptions and Accomplishments

Applied Science and Technology (AST)

In FY 2017, this program plans to support a range of improved imaging technologies for more precise diagnostic and therapeutic uses. Such technologies allow us to see and identify molecular characteristics inside cells, obtain images faster and with better quality, and not only find the locations of tumors or damage but inform treatment by learning what goes awry inside cells.

Imaging at the speed of light: NIBIB supports a range of imaging modalities that are improving our ability to noninvasively see deeper inside the body to capture microscopic details of tissue or the activity occurring inside cells. In one BRAIN Initiative supported project, an NIBIB grantee has developed an ultrafast camera that can acquire two-dimensional images at 100 billion frames per second, a speed capable of revealing the movement of discrete light pulses and previously unobservable biological phenomena, such as the interactions of proteins within cells. The researchers are working to couple the camera to a microscope, which will provide valuable insights by allowing researchers to visualize processes such as energy metabolism occurring within a cell's mitochondria, or the way light passes through tissue, an important consideration for therapies that use lasers to destroy or repair diseased tissue. It will also help researchers understand how fluorescent signals decay over time. Such knowledge could be used to create fluorescent sensors that can detect diseases and evaluate cellular environmental conditions like pH or oxygen pressure. The camera would enable researchers to observe the behavior of fluorescently-labeled cellular components at light speed.

Seeing deep within the body using light: In another breakthrough, researchers increased the depth at which light can be used to take images of tissues in the body. A technique called photo-acoustic tomography could enable doctors to acquire high-resolution images through a patient's skin to a depth equal to the diameter of a golf ball. The technique is currently being tested in a number of clinical applications, including imaging breast tumors, detecting skin cancer, and

tracking blood oxygenation in tissues. These and other technological advances may one day allow physicians to observe tissues, structures, and cell functions deep within the body without making a single incision.

Label-free imaging to detect tumor cells: NIBIB is supporting the development of novel technologies for biocompatible imaging agents and non-invasive imaging approaches. Currently, contrast agents used in imaging modalities can be toxic for certain patients. In a new technology being developed called chemical exchange saturation transfer (CEST) MRI, natural agents in the body such as amino acids, proteins, and carbohydrates (sugars) can be used as MRI markers without the need for chemical labeling. In one example, researchers are designing technology for imaging proteins in order to tell the difference between a tumor and edema (excess fluid), or distinguish a high-grade tumor from a low-grade tumor. Another study showed the ability of CEST to detect malignant tumor cells by identifying changes in the sugar molecules attached to a specific protein. Building on basic research, CEST MRI is now being translated to research in patients.

Digitizing tissue analysis: A new technique that creates digital pictures of a tissue's chemical composition using light and a computer could be used to replace the need for dyes or stains in tissue biopsies. Pathologists use dyes and stains to ascertain critical information about tissue samples taken from a biopsy. These can be costly and require significant time and effort to apply. Once a biopsy is obtained, the new technique uses infrared light to scan a tissue section and measure the spectral pattern, which is the unique way that the light is absorbed by different chemical structures present in the tissue. This spectral information is then run through a computer, which uses pattern recognition algorithms to translate it into chemical "stain" patterns. The end result is a digital image that looks nearly identical to a traditionally stained piece of tissue. Because the technique has no physical effect on the tissue, there is no limit to the number of different computer-generated "stains" that can be created and superimposed onto each other. Such capabilities could increase the amount of information that can be derived from a single biopsy and greatly reduce the amount of effort and cost that go into staining multiple tissue sections. This method could also make analyzing tissue a more accurate process by reducing much of the between-sample variability that occurs with chemical staining.

Smart-phone diagnostics: NIBIB-supported researchers have developed a device that consists of an imaging module with a battery-powered LED light clipped onto a standard smartphone. It can record high-resolution imaging data with its camera and could allow rapid molecular diagnostics of tumors and other disease in resource-limited areas. For molecular analysis of tumors, a sample of blood or tissue is labeled with microbeads coated with antibodies that bind to known cancer-related molecules. A large-field image of more than 100,000 cells is recorded and transmitted via the cloud for remote processing. There, an algorithm distinguishes cells with beads attached to them from naked cells, based on different diffraction patterns of light. The biopsies are categorized as high-risk, low-risk, or benign depending on the number of cells that have beads attached. The researchers have successfully used the device to screen 25 women with abnormal pap smears for cervical cancer. In other tests they accurately diagnosed four patients with lymphoma. This type of technology illustrates the concept of convergence science, which brings together engineering, cloud computing, imaging, and molecular biology to create rapid diagnostics at the point of care.

Improving images with computing power: Many diseases affecting vision begin as changes to microscopic structures such as cells, nerve fibers, and blood vessels at the back of the eye. The ability to visualize these early changes could lead to quicker diagnoses and better assessment of treatments for degenerative and neurological eye diseases. Currently, eye doctors use a technology called optical coherence tomography (OCT) to image the back of the eye, but the level of detail is limited because available methods to refine the image are slow, complex and costly. NIBIB-funded researchers have overcome this challenge with an approach that greatly improves imaging resolution and relies on computing power instead of elaborate hardware. The approach, coined 'computational adaptive optics' applies additional algorithms to OCT data to correct for the eye's aberrations as well as its constant motion. This technique may enable earlier detection of eye diseases and better monitoring of disease progression, such as for age-related macular degeneration, the leading cause of vision loss in individuals over age 50. It could also be useful for assessing patients with multiple sclerosis (MS) by imaging the nerve fibers on the surface of the retina, which provides an indication of the health of patients with MS.

Budget Policy:
The FY 2017 budget estimate for the AST program is $152.942 million, a decrease of $1.975 million or 1.3 percent compared to the FY 2016 Enacted level. High priority is given to new and early-career investigators and to research that bridges the physical and life sciences. AST will place a high priority on molecular 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.

Discovery Science and Technology (DST)
In FY 2017 NIBIB plans to continue to support technological innovation to address a broad array of medical problems. The goal is science and engineering based discovery from which one can devise or invent new systems that are smaller, faster, cheaper, and more accessible to varied populations, while being more accurate than current approaches.

Point-of-care for early diagnosis and treatment monitoring: Much has been accomplished in the area of POC technologies by utilizing newer technologies based on microfluidics, engineered polymers, and platform technologies. In one example, an HIV test using whole blood can detect the virus in the earliest stage of infection when transference of the disease is most likely. Researchers estimate that the cost is about two dollars per test and the test kit can be safely disposed of after use. In another example a cell phone could be used to detect and quantify bacteria such as *E. coli* and *S. aureus*, two common bacterial pathogens that cause a variety of infections including food poisoning, skin infections, and blood infections. A third example is a noninvasive optical device that monitors the effectiveness of chemotherapy in breast cancer. Wearable by the patient or handheld by a clinician, the tumor-tracking "imaging pad" transmits near-infrared light that penetrates deep inside cancer tissue. Using this device a clinician could, in real time, identify rapid changes in the tumor's structure and metabolism that indicate its response to treatment.

Other efforts focus on asthma which, despite a high prevalence, is notoriously difficult to diagnose, characterize, and treat. Currently, there is no single diagnostic test for asthma that doctors can rely on. Building on basic research, investigators have begun to explore new ways to

diagnose asthma that are based on quantitative differences in cellular behavior rather than imprecise clinical observations. NIBIB-funded researchers have created a "one drop, one stop" handheld device that can diagnose asthma from a single drop of blood within minutes. In a small study, researchers used a previously determined biomarker to accurately identify 22 of 23 known asthmatic patients and 8 of 11 non asthmatic patients. Since the test provides a quantitative result, it could potentially be useful to determine asthma severity and to assess how well the disease is being controlled.

Using engineered bone marrow to generate platelets: NIBIB supports a broad range of research to engineer various tissues. In one example, researchers developed a 3D tissue-engineered model of bone marrow that can produce functional human platelets outside the body. Platelets, a key component of the blood that enables clotting, play an essential role in healing, and are generated by megakaryocytes in bone marrow. The unique features of this model allow production of significantly higher numbers of functional platelets than was previously possible. This is the first time researchers were able to create the complete microenvironment where platelets are formed. These findings could help scientists further understand the process by which bone marrow creates platelets in order to test ways the process could be disrupted or restored. In addition, platelets generated in this way could be used to help healing, including of recalcitrant ulcers and burns.

Engineering the immune system: Because of our understanding of the basic mechanisms of immunology, immune cells can now be engineered to recognize and attack tumor cells, making cancer vaccines a possibility. In one study, immune cells are recruited to a vaccine scaffold where they are programmed and then released to mount an immune response against tumor cells. NIBIB-funded researchers have developed this 3D vaccine system that could provide a more effective way to harness the immune response to fight cancer as well as infectious diseases. The vaccine was recently found to be effective in delaying tumor growth in mice. While the 3D injectable scaffold is being tested in mice as a potential cancer vaccine, any combination of different antigens and drugs could be loaded into the scaffold, meaning it could also be used to treat infectious diseases that may be resistant to conventional treatments.

Spinal stimulation to address paralysis: NIBIB plans to continue its efforts to gain a better understanding of severe spinal cord injury (SCI) and improve outcomes for SCI patients. In previous research a surgically implanted spinal stimulator device combined with physiotherapy allowed patients to stand independently, voluntarily move their legs, and importantly, regain bladder, bowel, sexual, and other autonomous functions, like temperature control. In a new breakthrough that builds on years of previous basic research, five patients with complete motor paralysis were able to voluntarily generate step-like movements using a new non-invasive device that delivers electrical stimulation to their spinal cords. The new strategy, called transcutaneous stimulation, delivers electrical current to the spinal cord by way of electrodes strategically placed on the skin of the lower back. Non-invasive stimulation could have many advantages over implanted devices including a lower cost and lower risk; it could be especially useful for evaluation of the potential benefit of implanting a spinal stimulator in a specific patient; however researchers indicate a need to continue to develop multiple methods for physicians and patients to choose.

Research with implanted stimulators has also progressed, and in another recent study, four research participants with SCI were able to stand and bear full weight with minimal self-balance assistance while using the implanted stimulator. Researchers recorded neuronal signals in the participants when they were sitting, transitioning from sitting to standing, and when standing in order to better understand the mechanisms involved. They found that the parameters for stimulation vary among participants, meaning the stimulation level and patterns for one person are not ideal for another.

Quantum Grants Program making great strides: NIBIB's Quantum Grants Program is designed to make a profound, quantum impact on the prevention, diagnosis, or treatment of a major disease or national public health problem. The program addresses: 1) detecting circulating tumor cells at the point of care; 2) engineering an intact brain neurovascular niche to treat stroke; 3) providing vaccinations through the mail using a biodegradable microneedle patch that does not require refrigeration and is also painless; and 4) transforming renal dialysis through an engineered bio-artificial kidney.

One additional project is addressing heart disease by optimizing the design of ventricular assist devices (VADs) and eliminating the high risk of stroke from thrombosis or significant bleeding complications. VADs are cardiac devices that are surgically implanted to help pump blood in patients with heart failure. The use of these life-saving devices is limited because they can cause clot formation and stroke, and require aggressive blood thinning regimens that carry a risk of severe bleeding. Clots are formed by platelet cell 'activation' in the blood, which can occur when mechanical devices cause turbulence. Solving this problem has been difficult because platelets are extremely sensitive to activation from any type of contact. Researchers have now developed a breakthrough technique for measuring platelet cell flexibility that involves suspending platelets in an electrical field and then oscillating the field to gently stretch the cells without activating them. Using this technique to study the behavior of platelets under various conditions, they learned that increasing the cell's flexibility with drugs reduces the tendency for activation and clotting. This opens the door to a "mechanoceutical" approach to finding treatments that increase the flexibility of platelets and reduce clotting from mechanical stress. These researchers have already made advanced VAD designs that produce far less turbulence, and they hope that simultaneously reducing the sensitivity of platelets to activation can reduce or eliminate the need for risky anticoagulant drugs and dramatically improve the usefulness of VADs for heart failure.

Budget Policy:
The FY 2017 budget estimate for the DST program is $103.418 million, a decrease of $3.050 million or 2.9 percent compared to the FY 2016 Enacted level. 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.

Program Portrait: 3D Tissue "Chips" for studying human disease and treatments

FY 2016 Level:	$5.8 million
FY 2017 Level:	$5.8 million
Change:	$0.0 million

There are many potential benefits to engineering human tissue, including the ability to restore, maintain, or improve tissue function that has been lost due to injury or disease. During the past several years tissue engineering has also enjoyed much success in developing 3D human organoids on chips, commonly referred to as tissue chips. The tissue chips have much of the complexity of tissues in the body and can be used to measure human responses to drugs including both toxicity and efficacy. They allow for real-time monitoring of physiological responses at molecular, cellular, and organ levels. Normal and disease tissue chips are also being developed to study human development and pathophysiology.

Tissue chips have been created separately for heart, liver, and lung. Now, one team of NIBIB-funded researchers is developing an integrated heart-liver-vascular model system (HeLiVa chip) that mimics the function of the human body and can be used to evaluate therapeutic drugs before being introduced to humans. The system can also be personalized to model specific genetic and disease states to test drugs for their effectiveness and toxicity in the heart and liver.

In another recent study researchers generated a novel system for growing cardiac tissue that could be used to model early heart development and test the safety of drugs prescribed during pregnancy. Cells grown in culture usually remain in a flat format limiting the ability to study development and function. Using this new technique the cells organized themselves into a microchamber – a 3D configuration of cells akin to the pump mechanism of the human heart.

Functioning human tissue on a chip may facilitate personalized medicine and overcome the cost and limitations of animal drug testing, including improving the reliability of testing results.

Interdisciplinary Training: Bridging the Sciences for Technological Competitiveness
NIBIB supports a broad range of institutional and individual research training and career development programs and scientific conferences. 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. NIBIB also supports efforts to bridge the gap between research and commercialization, and highly focused interdisciplinary approaches to solve major medical problems or to resolve technology-based medical challenges.

Enhancing and supporting diversity: NIBIB 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 STEM (Science, Technology, Engineering, and Math) 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, and early exposure to academic and industrial research experiences, professional development counseling, and social networking.

Training physician-scientists: In support of training physician-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 helps integrate radiology residency programs with other residency and fellowship programs, including cardiology, neurology, orthopedics, ophthalmology, and surgery, and provides mentored research training to individual residents and fellows in these disciplines. By allowing residents and fellows to work on cutting-edge research projects, this training support encourages them to stay in biomedical research and helps them to reach research independence.

Helping to commercialize innovation: In a partnership with the Coulter Foundation, NIBIB is supporting a program to provide NIBIB small business grantees with specialized mentoring and essential business tools for successful translation of biomedical technologies from lab to market. The researchers participate in a "boot camp" followed by eight weeks of mentored, experiential training that teaches them critical business skills to help ensure that NIBIB investments in these innovative technologies stand the best chance of reaching patients.

Budget Policy:
The FY 2017 budget estimate for the Technological Competitiveness – Bridging the Sciences program is $20.045 million, an increase of $0.188 million or 0.9 percent compared to the FY 2016 Enacted level. This increase includes funding for the implementation of NIH's two-percent 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)
NIBIB supports research in health information technology, biomedical informatics, image processing, and visual perception and display 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.

Tools for Researchers: The Neuroimaging Informatics Tools and Resources Clearinghouse (NITRC) is administered by NIBIB and provides neuroinformatics tools and resources, a neuroimaging data repository, and a cloud computing environment for researchers. Access to imaging data has provided potential savings to researchers of more than $35.3 million. NITRC recently received one of seven Department of Health and Human Services Innovates Awards.

Sharing images seamlessly: Medical images are often difficult to share among health care professionals. Unlike sharing "selfies" in the cloud or on Instagram, medical images are extremely large files that require specific software to view them. These and other difficulties often result in patients needing to have additional imaging scans taken, driving up costs, creating delays in treatment and increasing the burden for patients. To alleviate these challenges, NIBIB is supporting an image sharing project through a contract to the Radiological Society of North America (RSNA). Key to this approach is that patients control the exchange of images and radiology reports among health care professionals and facilities. To date, more than 13,000 patients at seven health care institutions have participated in this pilot project. A recent study of patient engagement noted that most patients were able to access images without the need of the available help desk. Those that did contact the help desk often needed to do so to retrieve passwords or for other usage problems. The system is continually being improved based on this type of patient feedback.

Standardizing radiology procedure names: NIBIB will continue to support a project to create and maintain a single unified source of names and codes for radiology procedures. This partnership, also with RSNA, is expected to enable the improvement in the quality, consistency, and interoperability of radiology test results in electronic medical record systems and health information exchanges through standardization.

Budget Policy:
The FY 2017 budget estimate for the HIT program is $32.905 million, an increase of $4.168 million or 14.5 percent compared to the FY 2016 Enacted level. This increase is due to the funding of a large contract that is only funded in alternate years. HIT will focus on mobile health, clinical decision support, and big data. The HIT will also give priority to new investigators. Investigator initiated research and Bioengineering Research Partnership applications will be encouraged and supported.

Program Portrait: Mobile and Wireless Health (mHealth) Research Resource

FY 2016 Level:	$0.9 million
FY 2017 Level:	$1.1 million
Change:	+$0.2 million

mHealth technologies such as wearable sensors and mobile health apps have tremendous potential to advance health research. However, few research studies currently employ mHealth technologies. This may be in part due to a reliance on consumer technologies that have not been designed for medical research purposes.

NIBIB is supporting a trans-NIH project to develop an internet-based research resource through which researchers can easily and reliably conduct mHealth research and through which technology developers can validate the clinical usefulness of new mHealth products. Participants will be able to easily provide information from their electronic medical records and select from a wide range of mobile health sensors and apps to share data. This will give researchers unprecedented access to real-time information about patient health such as fluctuations in blood pressure, heart rhythms, or blood sugar and even information about mental states.

The ultimate goal is to quickly and effectively determine the potential clinical value of a new mobile informatics technology.

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.

Imaging at the nanoscale: Researchers recently applied a new nanoscale imaging technology called serial block face scanning electron microscopy (SBF-SEM) to observe the structure of pancreatic islet cells. This imaging technology can generate high resolution images of large tissue samples at several levels, from imaging an entire islet down to subcellular hormone-secreting vesicles within cells. It offers the ability to quickly and accurately quantify the structure of islets for study at different stages of development and to compare normal and

diseased islet models. This technique has the potential to image human islets in extraordinary detail.

Pushing the boundaries of super-microscopic resolution: NIBIB researchers are also developing a probe for use in live microscopy that improves resolution and the ability to obtain images at different depths within tissue. Many types of modern biomedical microscopes use pulses of light aimed at chemical probes to image proteins, membranes, and cell structures. A specialized technique, called two-step fluorescence microscopy, uses fluorescent proteins that can be efficiently turned on and off. This photo-switchable probe, called Padron, is isolated from coral. It is distinguished from the majority of photo-switchable fluorescent proteins by its two-step behavior. Specifically, Padron requires two separate absorptions of blue light: one to turn it from off-to-on, and then one to excite it and produce a fluorescent signal. Importantly, it can be deactivated when exposed to violet light in order to repeat the two-step cycle. These features allow the researchers to exert precise control over the area of the tissue that is imaged. They showed that imaging Padron as it turned on and fluoresced improved the ability to see slices of the object at different depths, a process known as optical sectioning. Data from individual optical sections are combined to produce images of extremely high resolution. This super-resolution imaging has overcome prior limits that have impeded imaging in live tissues, particularly in thick tissue and tumors. To obtain improvements at all of these levels, NIBIB researchers will continue to collaborate and optimize results with Padron. This new technique may lead to new understanding of biological processes within living tissues, such as metabolism and DNA repair, by bringing miniscule features in cells into focus.

Budget Policy:
The FY 2017 budget estimate for IRP is $13.065 million, an increase of $0.256 million or 2.0 percent compared to the FY 2016 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. The requested level accommodates required payroll cost increases attributable to anticipated annual salary raises and higher health insurance premiums for civilian and military personnel associated with IRP.

Research Management and Support (RMS)
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 the Institute's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

Budget Policy:
The FY 2017 budget estimate for Research Management and Support is $21.132 million, an increase of $0.414 million or 2.0 percent compared to the FY 2016 Enacted level. High priorities of RMS are the scientific support of NIBIB research programs and strategic planning. The requested level accommodates required payroll cost increases attributable to anticipated annual salary raises and higher health insurance premiums for personnel associated with RMS.

Budget Authority by Object Class[1]
(Dollars in Thousands)

	FY 2016 Enacted	FY 2017 President's Budget[2]	FY 2017 +/- FY 2016
Total compensable workyears:			
Full-time employment	98	98	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	$0	$0	$0
Average GM /GS grade	12.6	12.6	0.0
Average GM /GS salary	$110	$112	$2
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$0	$0	$0
Average salary of ungraded positions	$134	$136	$2

	OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget[2]	FY 2017 +/- FY 2016
	Personnel Compensation			
11.1	Full-Time Permanent	$7,659	$7,718	$58
11.3	Other Than Full-Time Permanent	2,787	2,808	21
11.5	Other Personnel Compensation	214	216	2
11.7	Military Personnel	0	0	0
11.8	Special Personnel Services Payments	1,425	1,436	11
11.9	**Subtotal Personnel Compensation**	**$12,086**	**$12,178**	**$92**
12.1	Civilian Personnel Benefits	$3,347	$3,413	$66
12.2	Military Personnel Benefits	0	0	0
13.0	Benefits to Former Personnel	0	0	0
Subtotal Pay Costs		**$15,433**	**$15,591**	**$158**
21.0	Travel & Transportation of Persons	$296	$301	$5
22.0	Transportation of Things	12	13	0
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	276	281	5
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	$2,135	$10,045	$7,910
25.2	Other Services	4,314	4,442	128
25.3	Purchase of goods and services from government accounts	23,900	24,459	559
25.4	Operation & Maintenance of Facilities	$7	$7	$0
25.5	R&D Contracts	712	725	13
25.6	Medical Care	70	72	2
25.7	Operation & Maintenance of Equipment	2,619	2,666	47
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$33,757**	**$42,416**	**$8,659**
26.0	Supplies & Materials	$789	$803	$14
31.0	Equipment	1,264	1,287	23
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	291,679	282,814	-8,865
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	0
Subtotal Non-Pay Costs		**$328,073**	**$327,915**	**-$158**
Total Budget Authority by Object Class		**$343,506**	**$343,506**	**$0**

[1] Includes FTEs whose pay roll obligations are supported by the NIH Common Fund.

[2] Includes mandatory financing.

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	$7,659	$7,718	$58
Other Than Full-Time Permanent (11.3)	2,787	2,808	21
Other Personnel Compensation (11.5)	214	216	2
Military Personnel (11.7)	0	0	0
Special Personnel Services Payments (11.8)	1,425	1,436	11
Subtotal Personnel Compensation (11.9)	**$12,086**	**$12,178**	**$92**
Civilian Personnel Benefits (12.1)	$3,347	$3,413	$66
Military Personnel Benefits (12.2)	0	0	0
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$15,433**	**$15,591**	**$158**
Travel & Transportation of Persons (21.0)	$296	$301	$5
Transportation of Things (22.0)	12	13	0
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	276	281	5
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			-
Consultant Services (25.1)	255	260	5
Other Services (25.2)	4,314	4,442	128
Purchases from government accounts (25.3)	15,790	16,203	413
Operation & Maintenance of Facilities (25.4)	7	7	0
Operation & Maintenance of Equipment (25.7)	2,619	2,666	47
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$22,985**	**$23,578**	**$593**
Supplies & Materials (26.0)	$789	$803	$14
Subtotal Non-Pay Costs	**$24,357**	**$24,975**	**$617**
Total Administrative Costs	**$39,790**	**$40,566**	**$776**

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2015 Actual			FY 2016 Est.			FY 2017 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Extramural Science Program									
Direct:	20	-	20	20	-	20	20	-	20
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	22	-	22	22	-	22	22	-	22
Intramural Science Program									
Direct:	20	-	20	20	-	20	20	-	20
Reimbursable:	6	-	6	6	-	6	6	-	6
Total:	26	-	26	26	-	26	26	-	26
Office of Administrative Management									
Direct:	25	-	25	26	-	26	26	-	26
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	25	-	25	26	-	26	26	-	26
Office of Research Administration									
Direct:	20	-	20	20	-	20	20	-	20
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	20	-	20	20	-	20	20	-	20
Office of the Director									
Direct:	4	-	4	4	-	4	4	-	4
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	4	-	4	4	-	4	4	-	4
Total	97	-	97	98	-	98	98	-	98
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

FISCAL YEAR	Average GS Grade
2013	12.9
2014	12.3
2015	12.6
2016	12.6
2017	12.6

Detail of Positions[1]

GRADE	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	15	15	15
GM/GS-14	18	18	18
GM/GS-13	17	17	17
GS-12	7	7	7
GS-11	4	4	4
GS-10	1	1	1
GS-9	5	5	5
GS-8	0	0	0
GS-7	6	6	6
GS-6	0	0	0
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	73	73	73
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	25	25	25
Total permanent positions	73	73	73
Total positions, end of year	98	98	98
Total full-time equivalent (FTE) employment, end of year	97	98	98
Average ES salary	0	0	0
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	108,977	110,437	112,275

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