

DEPARTMENT OF HEALTH AND HUMAN SERVICES

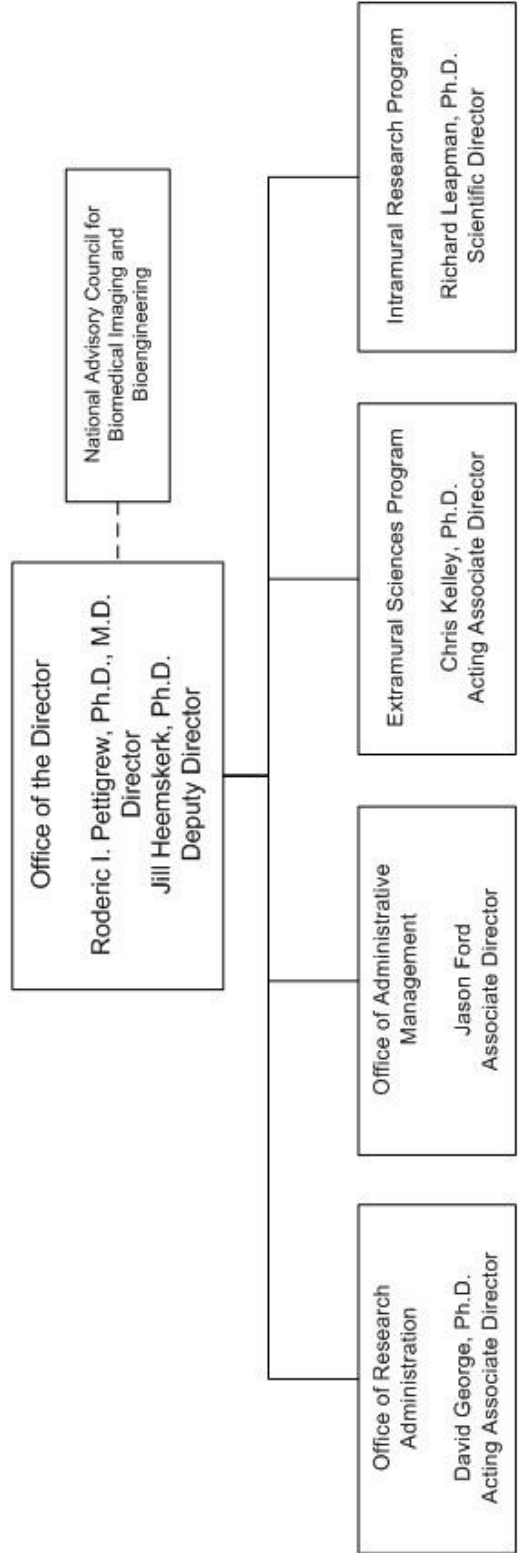
NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

<u>FY 2018 Budget</u>	<u>Page No.</u>
Organization Chart.....	2
Appropriation Language	3
Amounts Available for Obligation.....	4
Budget Graphs	5
Authorizing Legislation	6
Appropriations History	7
Justification of Budget Request	8
Detail of Full-Time Equivalent Employment (FTE)	21
Detail of Positions.....	22



NIBIB ORGANIZATIONAL CHART



NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

For carrying out section 301 and title IV of the PHS Act with respect to biomedical imaging and bioengineering research, \$282,614,000.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Amounts Available for Obligation¹
(Dollars in Thousands)

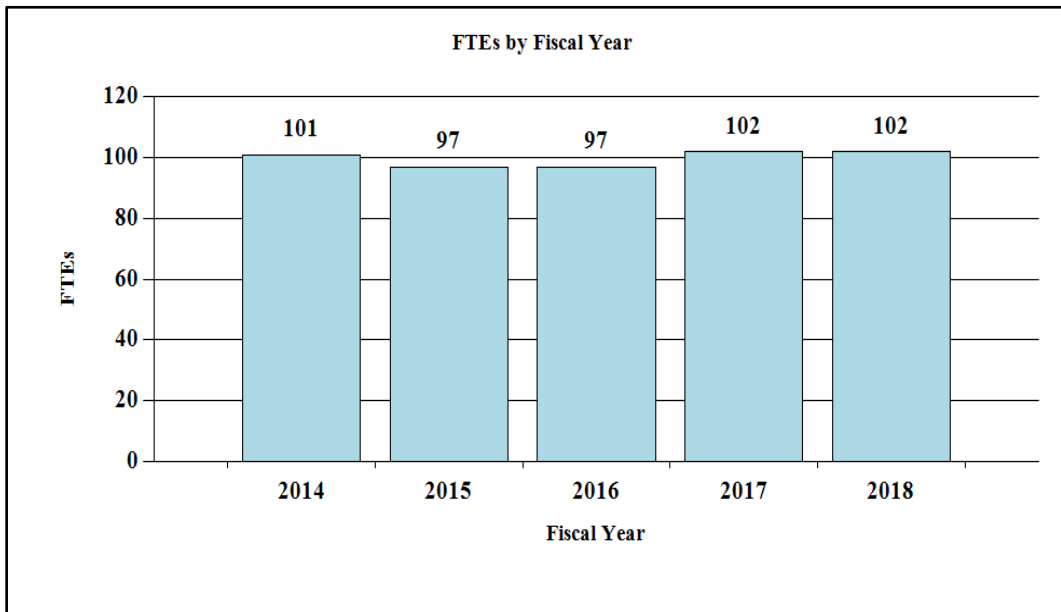
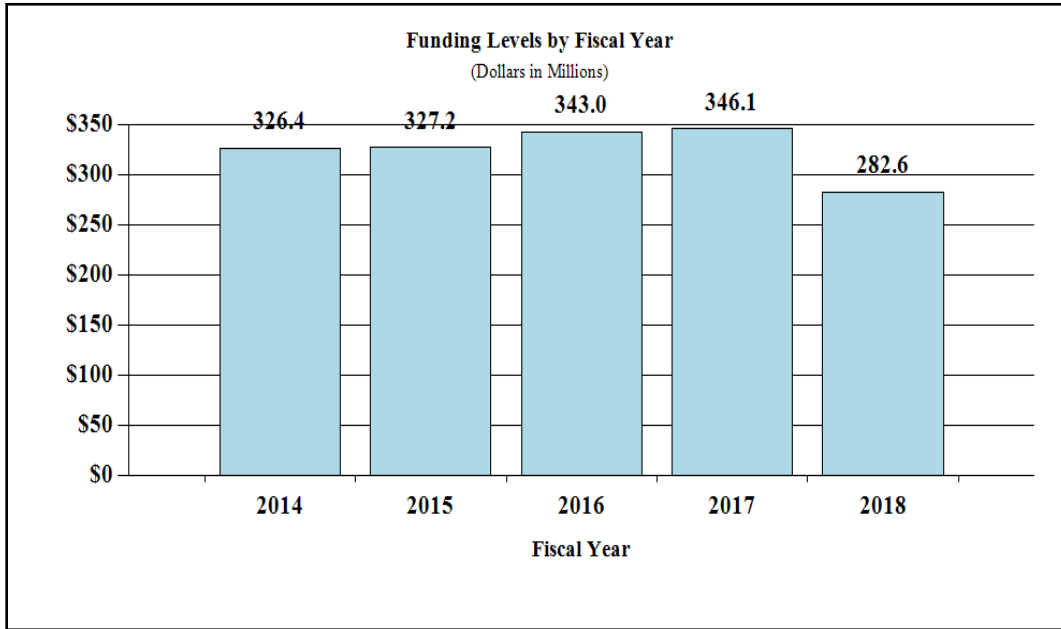
Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation	\$346,795	\$346,795	\$282,614
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	-659	0
Sequestration	0	0	0
Zika Intra-NIH Transfer	-480	0	0
Subtotal, adjusted appropriation	\$346,315	\$346,136	\$282,614
OAR HIV/AIDS Transfers	-3,289	0	0
Subtotal, adjusted budget authority	\$343,026	\$346,136	\$282,614
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$343,026	\$346,136	\$282,614
Unobligated balance lapsing	-29	0	0
Total obligations	\$342,997	\$346,136	\$282,614

¹ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2016 - \$2,740 FY 2017 - \$5,100 FY 2018 - \$5,100

Fiscal Year 2018 Budget Graphs

History of Budget Authority and FTEs:



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

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2017 Amount Authorized	FY 2017 Annualized CR	2018 Amount Authorized	FY 2018 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$346,136,000	Indefinite	\$282,614,000
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority						\$346,136,000
						\$282,614,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2008	\$300,463,000	\$303,318,000	\$304,319,000	\$303,955,000
Rescission				\$5,310,000
Supplemental				\$1,588,000
2009	\$300,254,000	\$310,513,000	\$307,254,000	\$308,208,000
Rescission				\$0
2010	\$312,687,000	\$319,217,000	\$313,496,000	\$316,852,000
Rescission				\$0
2011	\$325,925,000		\$325,415,000	\$316,852,000
Rescission				\$2,779,778
2012	\$322,106,000	\$322,106,000	\$333,671,000	\$338,998,000
Rescission				\$640,706
2013	\$336,896,000		\$337,917,000	\$338,357,294
Rescission				\$676,715
Sequestration				(\$16,983,210)
2014	\$338,892,000		\$337,728,000	\$329,172,000
Rescission				\$0
2015	\$328,532,000			\$330,192,000
Rescission				\$0
2016	\$337,314,000	\$338,360,000	\$344,299,000	\$346,795,000
Rescission				\$0
2017 ¹	\$343,506,000	\$356,978,000	\$361,062,000	\$346,795,000
Rescission				\$659,000
2018	\$282,614,000			

¹ Budget Estimate to Congress 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):

	<u>FY 2016 Final</u>	<u>FY 2017 Annualized CR</u>	<u>FY 2018 President's Budget</u>	<u>FY 2018 +/- FY 2017</u>
BA	\$343,026,019	\$346,136,000	\$282,614,000	-\$63,522,000
FTE	97	102	102	0

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

Director's Overview

The National Institute of Biomedical Imaging and Bioengineering (NIBIB)¹ conducts and supports biomedical research that integrates life sciences with engineering and the physical sciences to develop new technologies and speed their application to improve health. NIBIB is unique at NIH with its focus on creating technologies that not only address a broad range of biomedical research and health care problems, but also are available to more people in more settings, and at lower costs. The diversity of new technologies includes a cancer nano-vaccine that triggers the body's own immune response, an advanced microscope that doubles the resolution of current models, and a pocket-sized ultrasound device for imaging the heart.

To bring about these innovations, NIBIB supports convergent teams of researchers from a breadth of disciplines including engineering, biology, chemistry, mathematics, and physics. NIBIB also partners with industry, academia, and other federal agencies to coordinate and promote interdisciplinary research. NIBIB's research program supports more than 800 individual grants and the work of 5,000 researchers across the U.S. Research supported by NIBIB produces more patents per funding dollar than any other federal entity. The transformative impact of NIBIB-funded technology is illustrated in the following examples.

Catalyzing Fundamental Neuroscience. Understanding the complex networks of cells in the brain and how disruptions in these networks can lead to neurological diseases and disorders are major goals of the BRAIN Initiative®. Imaging research is a critical component of this initiative and NIBIB plays a key role in developing powerful new tools and technologies for understanding neural circuits. Current methods for non-invasive imaging, such as magnetic resonance imaging (MRI) and magnetoencephalography (MEG), have transformed neuroscience research and the diagnosis and treatment of neurological disorders. Now, even better tools must be developed to

¹ www.nibib.nih.gov

fully understand the brain. NIBIB is supporting development of next generation human brain imaging tools and technologies that can work on multiple levels from micro imaging to see parts of neurons such as individual synapses, to whole brain imaging with unparalleled clarity. Building on previous planning projects, NIBIB is supporting unprecedented technologies such as a wearable PET scanner to map brain activity during normal behavior and an implantable stent for epilepsy that could monitor brain signals and prevent seizures.

Paralysis After Spinal Cord Injury: Improving Function. Spinal cord injury (SCI) affects more than 282,000 people in the U.S. with approximately 17,000 new cases every year.² Researchers are taking several different approaches to help people paralyzed by SCI and other disorders to regain function and improve their quality of life. One group of researchers is refining an implantable functional electrical stimulation system (FES). This device builds on years of experimental research to bridge the gap between the healthy portions of the nervous system and the portions below the injury. The FES system was recently highlighted in an international sporting event called the Cybathlon, for individuals with disabilities using state-of-the-art assistive devices. A participant with an FES system developed by NIBIB won a gold medal in cycling. Previously paralyzed, FES allowed him to use the power of his own leg muscles to pedal around a 750-meter course on a three-wheeled recumbent cycle. In addition to cycling, the neural stimulators enable study volunteers to stand, step, and control their seated posture and balance. To date, 35 participants had this system implanted to restore function in their lower limbs. The system also is capable of restoring hand grasp ability in people with upper limb paralysis. Researchers are improving this system further by restoring touch sensation to facilitate agile hand control.

Health Promotion and Disease Prevention at the Point-of-Care. A key to health promotion and disease prevention is screening at-risk populations to identify symptoms and disease as early as possible. Point-of-care (POC) testing refers to the timely provision of clinical diagnostic information at the first point of medical care contact, often in decentralized settings such as in the physician's office, an ambulance, or a patient's home. POC tests that are easily accessible, convenient, and low-cost could have a profound impact on early diagnosis and prevention of many serious conditions. Examples of point-of-care technologies include tools to test "liquid biopsies" such as blood, saliva, and urine; or monitoring devices for at-home management of chronic conditions. NIBIB supports the Point-of-Care-Technology Resource Network, which accelerates projects as they move through the development pipeline to achieve goals including: development of prototype devices, creation of startup companies, and securing independent funding to pursue research, industry partnerships, clinical testing, or licensing of the technology developed.

POC research addresses problems in clinical care such as the challenge for patients to make at least two appointments—one for testing, and a return visit days or weeks later for results and the start of treatment. For some tests such as HIV, stigma continues to be a barrier for at-risk patients. Examples of NIBIB-funded research to address these problems include rapid HIV testing that can be completed at remote testing kiosks, or with an at-home kit that can be used to mail a sample to a lab; this makes the test more convenient and removes the barrier of stigma.

² <https://www.nscisc.uab.edu/Public/Facts%202016.pdf>

Another example is a microscope that can diagnose the beginning stages of cervical cancer immediately so patients do not need to make a return visit for results. NIBIB also is supporting an early stage clinical trial for at-home gonorrhea and chlamydia tests that are low cost and more convenient than currently available tests. Additionally, given the serious problem of antibiotic resistant bacterial strains, researchers are developing a rapid fluorescence-based system to determine antibiotic susceptibility, using a device that generates results within 30 minutes. This could help physicians determine the best treatment for patients with a bacterial infection.

NIBIB also co-chairs the NIH-Bill and Melinda Gates Foundation Working Group on Point-of-Care Diagnostics. This group is working to identify and collaborate on projects to develop diagnostic tests for low resource areas.

Enhancing Stewardship Through a New Award Program. NIBIB is committed to increasing the diversity of scientific ideas by investing in new and early stage investigators and has launched an effort to widen the NIH research pool and attract researchers from the STEM fields to NIH. NIBIB established the Trailblazer Award to support new and early stage investigators in pursuing research projects that may be exploratory, developmental, proof of concept, or high risk-high impact. Through this award, NIBIB will help launch the careers of investigators conducting early stage research at the interface between the life sciences and physical sciences, which includes bioengineering, biomedical imaging, informatics, telemedicine, and related efforts. NIBIB aims to encourage research ideas with the potential for high impact on human health and attract researchers who may not traditionally apply to NIH for support. Such researchers can contribute greatly and bring fresh ideas and perspectives to solving myriad health care problems. NIBIB received a tremendous response to the launch of this program, resulting in hundreds of inquiries and a large number of applications for the first deadline.

Overall Budget Policy: The FY 2018 President’s Budget request is \$282.614 million, a decrease of \$63.522 million compared with the FY 2017 Annualized CR level. These reductions are distributed across all programmatic areas and basic, epidemiology, or clinical research.

Program Descriptions and Accomplishments

Applied Science and Technology (AST)

In FY 2018, this program plans to support a range of innovative technologies to improve the early detection of disease, the ability to monitor disease progression and treatment efficacy, and the use of minimally invasive image-guided treatments for cancer, cardiovascular, neurological and other diseases.

Customizing MRI for pediatrics. Anyone who ever has had an MRI scan likely has experienced the challenge of remaining completely still for a long time while enduring loud noises. This can make MRI scans especially difficult for infants and children. Researchers are taking several different approaches to overcome these problems and are designing personalized solutions to meet various situations. In one example, researchers have developed screen-printed, flexible MRI coils that can be incorporated into fabric to create the “MRI blanket.” The blanket could be wrapped around an infant and used to conduct the MRI scan. To produce the flexible coils researchers used a type of screen-printing technology—similar to printing a logo on a t-shirt. The coils can be individually crafted to fit patients of various sizes, such as infants or

toddlers, or custom made for individual patients if needed. Because these coils are light and flexible, they can be wrapped snugly around the patient's body, which increases the sensitivity of the exam and provides clearer images. The novel coils also may be able to reduce the amount of time it takes to get an MRI scan. The coils are designed to work with MRI scanners found in most hospitals and can be reused. Researchers have developed a prototype of the MRI blanket and have built partnerships to translate this technology to clinical practice.

Creative approach to reduce CT radiation dose. Concerns about radiation exposure from computed tomography (CT) scans persist among many patients and health care providers. While the benefits of a necessary scan far outweigh risks, NIBIB is supporting efforts to develop methods that use significantly lower dose levels, yet retain the same diagnostic accuracy. In a recent Challenge supported by NIBIB, low-dose CT researchers competed to produce the best detection accuracy from a set of patient liver CT scans that used only 25 percent of the routine dose level. This was a multi-faceted effort in which NIBIB funded the development of the CT scan data set and the software tools used by radiologists to determine detection accuracy of the competing approaches. Providing the patient CT data significantly expanded the number of researchers able to work on creative ways to reduce dose in CT. More than 100 researchers from 26 countries participated in this Challenge—including many experts from outside the traditional medical imaging community, including computer scientists, physicists, mathematicians, and electrical engineers. The Challenge resulted in several important steps forward in the field. It demonstrated that the two major categories of dose-reduction techniques performed similarly. Since one of these techniques is easier to implement this could open a path forward for widespread adoption of dose-reduction methods. Also, the Challenge showed that traditional measures of image quality do not always accurately predict liver lesions, prompting further research into finding new image quality metrics that do accurately correlate with clinical findings. This effort demonstrated that it may be possible to reduce radiation doses to one-fourth of current routine levels.

Motion-correction MRI: Making images sharper. While imaging is an extremely useful medical tool, one major limitation is that it doesn't work well with movement. This makes it extremely challenging to use imaging in situations where there is constant movement such as a fetus in utero. This limits its use as a diagnostic tool, such as in studying the impact on a fetus of infections such as the Zika virus. To overcome this problem, researchers are pioneering an approach using functional MRI (fMRI) that corrects for motion and captures images of activity in fetal brains to see how networks within the brain develop. Using a standard imaging method, the new technique is made possible by the creation of post-processing techniques that enhance image quality. So far, the new technology has been tested in a small number of cases, and researchers aim to use the technology to gain a better understanding of growth and development, and factors that might influence changes in the brain such as diet, exercise, infection, or environment.

Cost-effective approach to combining imaging modalities. What's better than one imaging method? Combining methods that can take advantage of the complementary strengths of each type of imaging technique. Positron Emission Tomography (PET) is typically used to image organs in the body and is frequently used to detect cancer and cancer metastases. This method also can measure metabolic rates to help determine the aggressiveness of cancer. Magnetic Resonance Imaging (MRI) is used to see soft tissues in the body for disease detection, diagnosis,

and monitoring treatment. Combining these two methods for simultaneous PET/MRI produces images that provide molecular, functional, and anatomical information in soft tissues. While used in research settings, combining these two methods for simultaneous imaging in a clinical setting has been cost prohibitive (five to six million dollars for a combined instrument). Researchers are working to overcome this challenge by developing an MRI-compatible PET ring that can be inserted into any current MRI machine without the need to modify the MRI machine hardware. The PET ring can be inserted and removed so that one machine can produce MRI images or simultaneous MRI/PET scans. The PET ring is estimated to cost approximately one million dollars, making it more cost-effective than standard combination systems and thus more accessible in many healthcare settings.

Rapid test for TB and MRSA. Antibiotic resistance is an increasingly serious problem in healthcare. The problem is growing especially quickly for some specific illnesses such as tuberculosis (TB). Lab tests to diagnose TB can take weeks, leading to worsening of the illness for individuals and further spread of the disease. NIBIB is supporting scientists to develop a way to diagnose TB and antibiotic-resistant bacterial strains of TB in two to three hours, using a handheld microfluidic device originally created to diagnose cancer. The device combines microfluidic technology and nuclear magnetic resonance (NMR) and detects the DNA of TB bacteria in small sputum samples. Faster results assessing antibiotic resistance can quickly inform decisions as to which antibiotics to give a patient. Tests of the device on samples from healthy volunteers and TB patients identified all positive samples, with no false positives, in less than three hours. The specialized DNA probes developed by the research team reliably distinguished treatment-resistant bacterial strains. This group of researchers also is testing a similar device to quickly detect other pathogens, including *Streptococcus pneumoniae* (strep), *Escherichia coli* (*e. coli*), and methicillin-resistant *Staphylococcus aureus* (MRSA). Researchers will continue to develop further this technology into a small device that is simple to use and could be ideal for use in developing countries and rural areas.

Program Portrait: Imaging gene expression in tissues and cells

FY 2017 Level: \$3.1 million

FY 2018 Level: \$2.5 million

Change: -\$0.6 million

NIBIB is developing tools to visualize gene expression at the molecular level in tissues and cells to better understand disease processes, detect genetic defects, and to monitor gene therapy treatments. Using a new fluorescent imaging method, one group of researchers is developing a way to visualize genetic imprinting defects that determine how parents' genes are expressed in their children. Imprinting defects lead to rare diseases such as Beckwith-Wiedemann syndrome, Prader-Willi syndrome, and Angelman syndrome, and this technology is critical to discovering potential treatments for these disorders. The imaging technique was sensitive enough to show that specific cells had the defect while others did not. This observation and further development of the new fluorescent imaging technique will greatly aid in the study and potential treatment of human imprinting disorders.

In a promising approach for stroke and other brain disorders, another group of researchers is developing a technique that uses eye drops to deliver gene therapy to the brain combined with imaging to monitor the therapy. In this example, researchers used the technique to treat ischemia (lack of blood/oxygen to the brain) in a mouse model. The treatment led to a significant reduction in brain atrophy, neurological deficits, and mortality. The system developed to monitor the success of the therapy used MRI. The combination of simple delivery and non-invasive monitoring of gene expression using MRI could significantly accelerate studies of experimental gene therapy in animal models of stroke, Alzheimer's, Parkinson's, and amyotrophic lateral sclerosis (ALS). The ultimate goal is adapting these approaches to develop treatments for patients.

Discovery Science and Technology (DST)

In FY 2018, this program plans to support bioengineering-based discovery and technological innovation to address a broad array of medical problems and improve treatment access and health for all populations.

Testing toxicity with tissue chips. The process for developing new medications is long and costly, and the efficiency of the process could be dramatically improved by streamlining the testing of toxicity of potential new drugs before clinical trials. Using tissue that mimics human organs instead of animal models, such as mice, could give more reliable results since animals do not always respond to drugs in the same way as humans and toxicity to human organs can be missed. To test the potential brain toxicity of new drugs, researchers have engineered a 3D miniature version of human brain tissue that mimics the function of the brain. The tissue chip possesses many traits of brain tissue, including neurons, support cells, vascular structure, and immune cells. The tissue chip field is growing rapidly and holds promise not only for answering questions about toxicity but also to gain insight into disease mechanisms and responses to various stimuli. The "brain-on-a-chip" was tested with 60 different chemicals, some of which are known to be toxic to neural tissue. A computer model was used to look at the results and was able to identify accurately whether or not the chemical was toxic nine out of ten times. This approach is an example of multidisciplinary research that brings together stem cell biology, tissue engineering, bioinformatics, and machine learning to create a complex tissue model of the brain.

Improving transplanted neurons. Previous attempts to implant new neurons in the brain to treat neurodegenerative disorders such as Parkinson's disease failed largely because the neurons did not survive. To overcome this problem, scientists have developed a 3D micro-scaffold technology that promotes the reprogramming of stem cells into neurons, and formation of neural

connections that transmit electrical signals and replicate normal neuronal function. These functioning networks of human neural cells, supported by polymer fiber scaffolds, showed dramatically improved survival following transplantation into mouse brains. This promising new platform could make transplantation of neurons a viable treatment for a broad range of human neurodegenerative disorders.

Personalizing rehabilitation after stroke. The ability to walk can be disrupted following a stroke or due to disorders such as osteoarthritis. While many researchers have focused on restoring normal walking function, there are currently no objective criteria for prescribing treatments tailored to the specific problems faced by individual patients. To address this and make stroke rehabilitation more individualized, researchers have developed a computer model that collects data while patients walk on a treadmill. This data is used to predict realistically the best gait patients could hope for after completing physical therapy, and the computer model is designed to recommend the best rehabilitation program to help patients reach their optimal recovery. The ultimate goal of this research is to develop individualized physical therapy plans for patients and even use rehabilitation robots to help train patients, resulting in the best possible outcomes.

Nanoparticles engineered to create a cancer vaccine. Immunotherapy as a treatment for cancer is a growing field of research. For years, researchers have worked to manipulate the immune system into attacking cancer cells that can stealthily avoid the body's normal defense mechanisms. A major benefit of this approach is that immune cells have a kind of memory and could potentially attack cancer cells if they came back after treatment. Some current approaches remove immune cells from the body, alter them in a lab to attack cancer cells, and then inject the cells back into the body. An alternative approach, supported by NIBIB and tested in a few patients, used injectable nanoparticles engineered to recruit and activate immune cells inside the body. Now, researchers are working on a system to inject particles under the skin that self-assemble and then attract immune cells to boost the body's own response. This approach could potentially be applied to many different types of cancer and infectious diseases.

Vaccines in the mail. One of NIBIB's Quantum grant projects has the vision of developing vaccines that can be delivered by mail and self-administered at home. Quantum grants are designed to make a profound impact on the prevention, diagnosis, or treatment of a major disease or national public health problem. Researchers on one recently completed project designed and developed a patch that painlessly delivers vaccines using microneedles that dissolve in the skin after application. The patch does not require refrigeration, giving the potential for vaccines to be sent in the mail for self-administration. A recently completed Phase 1 clinical trial showed encouraging results.

Program Portrait: Detecting and monitoring pediatric asthma

This \$28.0 million five-year program was fully funded for all years in FY 2015 using funds redirected after the termination of the National Children's Study.

As the most common pediatric chronic disease, asthma affects more than six million children in the U.S.³ Asthma is a complex disease involving the interaction of environmental, physiological, and behavioral factors. NIBIB supports research to address complex health problems such as asthma by developing technologies to improve detection, assessment, and monitoring of health status. In line with this mission, NIBIB launched the program: Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS) to develop sensor-based, integrated health monitoring systems for measuring environmental, physiological, and behavioral factors in children. Collaborative teams of researchers are developing noninvasive health monitoring systems for pediatric asthma research and for other chronic diseases in the future.

One arm of this collaboration is developing both wearable and non-wearable sensors to monitor environmental exposure, physiological signals (such as children's activity), and behavior in children's natural environments. To date, progress is being made in creating a variety of sensors for use by individuals or in households that could measure air pollution levels, physical activity, breathing patterns, inhaler use, or heart rate.

Another arm of this research project is designing "plug and play" wireless or hardwire platforms to collect, protect, and analyze data gathered from the sensors. A third group will coordinate and house data from the PRISMS program and integrate other relevant data sources such as geographical location, air quality data, and traffic patterns.

NIBIB is planning to continue supporting this program in FY 2018. The end goal of this program is to develop validated tools that will be made available for researchers to conduct future epidemiological studies on pediatric asthma and other chronic diseases.

Health Informatics Technology (HIT)

NIBIB supports research in health information technology, biomedical informatics, image processing, and visual perception research programs. This division also supports trans-NIH and Government-wide activities in health informatics, a field that integrates computer and information science with clinical science to improve health care.

Using data to assess disease risk. The consortium for Enhancing NeuroImaging Genetics through Meta-Analysis (ENIGMA) merges imaging with genetic technology to identify differences in genetic code that contribute to neurological diseases and disorders. Recently scientists discovered variations of the genetic code that are associated with the maximum brain volume an individual achieves over a lifetime. These variations also were found to be associated with a person's individual risk for Parkinson's disease and cognitive ability. The findings provide an increased understanding of how differences in our genetic code can predispose individuals to brain disorders. The recent discoveries were the result of the collective analysis of MRI brain scans and DNA from over 32,000 people worldwide. Because of the complexity, the only way to discover how genes affect the brain is to study tens of thousands of brain scans and the corresponding genetic data. Scientists use data science methods to sort through each letter of a person's genetic code to see what influence it may or may not have on the brain. NIBIB and NIH investments in data science led to a system that allows collaboration on this massive scale. The results from studies such as this could lead to insights into a person's risk for developing a

³ <http://www.cdc.gov/nchs/fastats/asthma.htm>

disease, whether genetic or environmental, or give insight into whether a disease treatment is working.

Interoperability: getting medical devices to talk to each other. Many physicians, researchers, and consumers have a vision of a fully integrated, seamless system for delivering healthcare. But that vision remains unfilled, in part because the many devices and information systems used by physicians, hospitals, and laboratories are unable to be linked or communicate with each other. To address this tremendous challenge, one group of researchers is building a prototype of a healthcare intranet. The intranet, along with tools and software, will serve as a testing ground and use clinical cases to evaluate and assess its utility. The ultimate goal is to create a system of device interoperability that can be used to improve patient safety and healthcare outcomes. The team has developed a laboratory with extensive medical device and health IT infrastructure, simulation capability, and a platform for open-source device integration and app prototyping. The platform, known as OpenICE (Open Integrated Clinical Environment), was used to implement a number of advanced clinical alarm applications. In one example, researchers created a prototype of an interoperable healthcare ecosystem to increase the safety of Ebola-exposed persons in quarantine and the workers caring for them in a hospital or temporary clinical facility.

Sharing digital data. NIBIB has invested in research that has led to large collections of data. Giving researchers access to existing imaging data and analysis tools is the goal of the Neuroimaging Informatics Tools and Resources Clearinghouse (NITRC), administered by NIBIB. NIBIB also has supported development of Image Share, a research project that allows patients to quickly and easily share their radiological scans among their health care providers. NIBIB is also one of several NIH Institutes supporting a mobile health project to use mobile sensors in health research and practice. Data from all of these patient-centered efforts could not only benefit participants, but potentially advance research cost-effectively by providing patients and data for future studies that require a large number of participants.

Program Portrait: Easier methods for blood pressure monitoring

FY 2017 Level: \$2.2 million

FY 2018 Level: \$1.8 million

Change: -\$0.4 million

Hypertension, or high blood pressure, is a leading cause of heart attack and stroke in the U.S. It is pervasive, with about one third of American adults having high blood pressure and another third at risk for developing it. Despite available treatments, only about half of people with high blood pressure have their condition under control⁴, and the cumbersome tool for measuring blood pressure has remained largely unchanged for decades. The diagnosis and management of hypertension would be greatly improved with technology that can quickly, reliably, and passively measure blood pressure in non-clinical settings such as homes and shopping malls. NIBIB is supporting development of systems for “cuff-less” blood pressure measurement that could make measuring and tracking one’s blood pressure effortless and easily accessible.

In one approach to develop a new method for measuring blood pressure, researchers are building on a long known fact that every time the heart beats, the body moves ever so slightly. The movement is so small that it is not easily detectable in ourselves or by observing others. Although this movement can be measured with the help of new sensor technology, the underlying mechanism of the movement is still a mystery. Researchers in a multi-site, multi-disciplinary effort are creating models for revealing the elusive mechanism, and to understand the clinical implications of this data. This work is making steps toward new tools for passively measuring blood pressure, for example by developing specialized weighing scales and chairs with special sensors to more simply measure blood pressure.

Another approach is to measure the time it takes for blood to travel between two points in the arteries, for example, between the ear and the toe. This measurement is called pulse transit time and could be used as a way to measure and track blood pressure more easily and routinely. One challenge to this approach is converting the pulse transit time (measured in milliseconds) to the current blood pressure cuff measure in millimeters of mercury, such as 120/70 millimeters of mercury. Validating the new measures and correlating them with the gold standard of blood pressure cuff readings is an important ongoing goal.

Technological Competitiveness-Bridging the Sciences

To ensure a technologically competitive workforce that can accomplish its mission, NIBIB supports training across the career continuum. Programs focus on interdisciplinary training that will cultivate investigators who are able to bridge the quantitative sciences with biology and medicine. Programs are designed to 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.

Engaging the next generation of researchers. NIBIB’s DDesign by Undergraduate Teams (DEBUT) program challenges student teams to identify an unmet need or problem in healthcare and to develop a solution to it. The challenge not only engages students in active learning, but several winners have moved on to patent technologies and create companies to commercialize their projects. This past year, student teams addressed serious healthcare problems including an approach to diagnosing TB in children, another challenge of this worldwide infectious disease. The winning team created a “smart pill” that is swallowed to passively collect a gastric acid sample from pediatric patients, who are often unable to cough forcefully enough to produce a

⁴ <http://www.cdc.gov/bloodpressure/facts.htm>

sputum sample for testing. Another team designed a point-of-care device to improve the diagnosis and staging of sepsis in hospitals, which kills more people than many cancers combined. This past year, 72 teams representing 30 universities participated in the DEBUT Challenge.

NIBIB also directs concerted efforts to enhance diversity in the biomedical workforce with a program to develop innovative methods to recruit and retain individuals from diverse backgrounds into science, technology, engineering, and math (STEM) fields. These methods included 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.

Another NIBIB program targets high school teachers to help them engage the next generation of biomedical researchers. The recently completed pilot program offered high school science teachers the opportunity to participate in research conducted in bioengineering labs, and to develop advanced curricula for their students. The Bioengineering Summer Research Experience for High School Teachers included research experiences in a wide range of areas such as regenerative medicine, precision medicine, rehabilitation engineering, bio-nanomaterials, and biomedical imaging. Laboratory experiences were augmented by weekly workshops with university faculty to help translate the research experiences into a classroom curriculum. The program paid special attention to recruiting teachers from underserved areas in order to ensure that students from diverse backgrounds benefit from the experiences their teachers gained through this program.

Encouraging entrepreneurship. NIBIB supports the small business innovation research and the small business technology transfer (SBIR/STTR) programs across its scientific areas. Recent projects reached key milestones while receiving NIBIB-support. In one example, an ultrasound-based guidance system for correct needle insertion in spinal and epidural anesthesia received FDA clearance for marketing. NIBIB support of this cell phone-sized ultrasound device has enabled the start-up company to commercialize the device to anesthesiologists and explore other medical uses for the guidance system. In another example, researchers developed a screening tool for diabetic retinopathy to help identify patients in need of expert care and reduce the cost of screening, while also expanding access to screening in primary care centers through a telemedicine interface. Early screening and detection in at-risk patients can help prevent vision loss due to diabetic complications, and a clinical trial recently has started to test this device.

A major challenge in the development of new biomedical technologies is making the leap from discovery to commercialization. Many researchers are experts in solving medical problems, but may have little experience in commercializing a technology. To help researchers bridge this gap, NIBIB, along with other NIH Institutes, is supporting a program designed to provide innovators with the specialized business frameworks and essential tools for successful translation of biomedical technologies from lab to market. Through this program, NIH fosters the development of early-stage biomedical technologies by engaging innovators who are interested in understanding whether they have a compelling business opportunity and how they can package this opportunity to facilitate translation to the patient. NIBIB extends this program to SBIR/STTR and other grantees. The curriculum and customized mentoring enhance

preparations and position the companies for commercialization success. In just three years, this public-private partnership has supported 38 teams.

Intramural Research Program (IRP)

IRP supports NIBIB's mission to integrate bioengineering with the life and physical sciences, conducting research across basic, translational, and clinical science and conducting effective training programs in related fields.

A sharper ultra-microscopic image with less light. A team at NIBIB developed a new microscope that can image single, living cells at higher resolution and lower light dose than was possible previously. Biological samples, such as individual cells or tissue, are highly sensitive to light and can be damaged or even killed by traditional microscopy, especially during extended observation. This new microscope doubles the resolution of images without exposing cells to a toxic amount of light. In this advance, the researchers engineered a three-lens microscope to capture light that otherwise would be wasted. They then partnered with an expert in developing computer algorithms to design and implement methods that merge the three images into one, creating a sharper, clearer 3D image than it was possible previously to obtain. As medical researchers become ever more interested in how individual cells work, studying living organisms requires technology that can allow scientists to see some of the smallest functions in living tissue while they are occurring. This breakthrough research is exemplary of the progress achievable through multi-disciplinary efforts, bringing together experts in optics, biology, and computational imaging to achieve the goals.

Watching nerve cells develop in real time. Just a few decades ago, the idea of observing brain development in real time seemed impossible. Now, having developed new tools, researchers at NIBIB are closing in on constructing the first 3D video atlas of neurodevelopment in any organism, from single-cell egg to adult (in this case, the model organism *C. elegans* worm). When completed, this atlas will be profoundly useful in the study of neurodevelopment and neurological disorders. This first comprehensive view of how an entire nervous system is formed could increase our understanding of the fundamental mechanisms by which all nervous systems assemble. Some of the concepts developed, such as the idea to combine neuronal data from multiple embryos, can be applied to additional model animal organisms other than the worm.

Hybrid nano-vaccine for cancer immunotherapy. Cancerous tumors can evade the immune system by suppressing its ability to recognize and kill cancer cells. A goal of immunotherapy is to normalize and harness the body's immune system so that it can fight the tumors more effectively. One other approach has been to introduce a foreign DNA sequence into the body, called CpG, which occurs in bacteria but rarely in mammals. The CpG acts as a danger signal that triggers an immune response. Researchers in NIBIB have increased the efficiency and precision of delivery of the CpG by creating nano-vaccines containing CpG that are taken up by immune cells. The nano-vaccine simultaneously reduces side effects and protects the CpG from degrading within the body. The researchers successfully have demonstrated the benefits of the nano-vaccine in a mouse model of cancer.

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.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2016 Final			FY 2017 Annualized CR			FY 2018 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Extramural Science Program	-	-	-	-	-	-	-	-	-
Direct:	21	-	21	24	-	24	24	-	24
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	23	-	23	26	-	26	26	-	26
Intramural Science Program	-	-	-	-	-	-	-	-	-
Direct:	21	-	21	23	-	23	23	-	23
Reimbursable:	5	-	5	5	-	5	5	-	5
Total:	26	-	26	28	-	28	28	-	28
Office of Administrative Management	-	-	-	-	-	-	-	-	-
Direct:	25	-	25	25	-	25	25	-	25
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	25	-	25	25	-	25	25	-	25
Office of Research Administration	-	-	-	-	-	-	-	-	-
Direct:	19	-	19	19	-	19	19	-	19
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	19	-	19	19	-	19	19	-	19
Office of the Director	-	-	-	-	-	-	-	-	-
Direct:	4	-	4	4	-	4	4	-	4
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	4	-	4	4	-	4	4	-	4
Total	97	-	97	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
FISCAL YEAR	Average GS Grade								
2014	12.3								
2015	12.6								
2016	12.5								
2017	12.5								
2018	12.5								

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Detail of Positions¹

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	19	19	19
GM/GS-14	16	17	17
GM/GS-13	16	17	17
GS-12	6	8	8
GS-11	4	5	5
GS-10	2	2	2
GS-9	3	3	3
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	2	2	2
GS-1	0	0	0
Subtotal	74	79	79
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	35	35	35
Total permanent positions	74	79	79
Total positions, end of year	109	109	109
Total full-time equivalent (FTE) employment, end of year	97	102	102
Average ES salary	0	0	0
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	111,083	112,345	114,536

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