DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

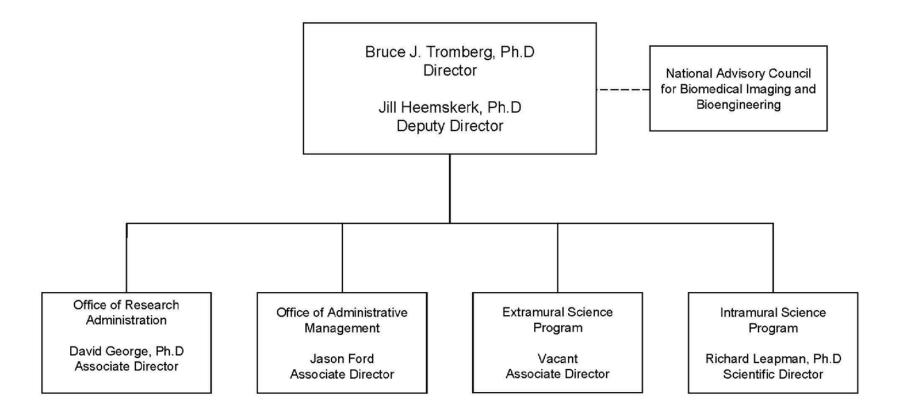
National Institute of Biomedical Imaging and Bioengineering (NIBIB)

FY 2020 Budget	<u>Page No</u> .
Organization Chart	2
Appropriation Language	3
Amounts Available for Obligation	4
Budget Mechanism Table	5
Major Changes in Budget Request	6
Summary of Changes	7
Budget Graphs	9
Budget Authority by Activity	
Authorizing Legislation	11
Appropriations History	
Justification of Budget Request	13
Budget Authority by Object Class	
Salaries and Expenses	
Detail of Full-Time Equivalent Employment (FTE)	
Detail of Positions	25



National Institute of Biomedical Imaging and Bioengineering

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, [\$389,464,000]*\$335,986,000*.

Amounts Available for Obligation¹

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation	\$377,871	\$389,464	\$335,986
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(0)	(0)	(0)
Other Mandatory financing	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-888	0	0
Subtotal, adjusted appropriation	\$376,983	\$389,464	\$335,986
OAR HIV/AIDS Transfers	-253	0	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$376,730	\$389,464	\$335,986
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$376,730	\$389,464	\$335,986
Unobligated balance lapsing	-30	0	0
Total obligations	\$376,700	\$389,464	\$335,986

(Dollars in Thousands)

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2018 - \$2,549 FY 2019 - \$5,100 FY 2020 - \$5,100

Budget Mechanism - Total¹ (Dollars in Thousands)

MECHANISM	FY 20	018 Final	FY 20	19 Enacted		FY 2020 President's		Y 2020 +/-
					В	udget	FY 20	19 Enacted
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:	201	¢1.00.00.4	150	*154542		*155 11 0	(7	**
Noncompeting	391	\$160,384	453	\$174,543	520	\$177,118	67	\$2,575
Administrative Supplements	(58)	6,342	(10)	800	(8)	686	(-2)	-114
Competing:								
Renewal	22	11,681	23	12,475	14	6,855	-9	-5,620
New	234	70,260	250	75,035	151	40,905	-99	-34,130
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	256	\$81,941	273	\$87,510	165	\$47,760	-108	-\$39,750
Subtotal, RPGs	647	\$248,667	726	\$262,853	685	\$225,564	-41	-\$37,289
SBIR/STTR	30	12,143	31	12,584	26	10,798	-5	-1,786
Research Project Grants	677	\$260,811	757	\$275,437	711	\$236,362	-46	-\$39,075
Research Centers:								
Specialized/Comprehensive	5	\$3,523	4	\$2,862	4	\$2,456	0	-\$406
Clinical Research	0	0	0	\$2,802	0	\$2,450	0	-9400
Biotechnology	29	37,924	26	34,607	22	29,696	-4	-4,911
Comparative Medicine	0	0	20	0	0	29,090	-4	-4,911
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	34	\$41,447	30	\$37,469	26	\$32,152	-4	-\$5,317
Research Centers	54	φτ1,ττ <i>1</i>	50	\$57,407	20	\$52,152	-7	-\$5,517
Other Research:								
Research Careers	22	\$2,985	28	\$3,735	24	\$3,205	-4	-\$530
Cancer Education	0	¢2,>05 0	20	\$5,755 0	0	\$5,205 0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	48	3,216	51	4,225	43	3,625	-8	-600
Other Research	70	\$6,201	79	\$7,960	67	\$6,830	-12	-\$1,130
Total Research Grants	781	\$308,459	866	\$320,865	804	\$275,344	-62	-\$45,521
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	22	\$1,118	22	\$1,118	19	\$959	-3	-\$159
Institutional Awards	247	11,913	214	10,520	184	9,027	-30	-1,493
Total Research Training	269	\$13,031	236	\$11,638	203	\$9,986	-33	-\$1,652
Research & Develop. Contracts	11	\$15,191	11	\$15,712	10	\$13,482	-1	-\$2,230
(SBIR/STTR) (non-add)	(5)	(24)	(5)	(25)	(5)	(21)	(0)	(-4)
Intramural Research	27	15,985	27	16,480	27	14,883	0	-1,597
Res. Management & Support	71	24,064	75	24,768	75	22,291	0	-2,477
Res. Management & Support (SBIR Admin)							_	
(non-add)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Construction		0		0		0		0
Construction		0		0		0		0
Buildings and Facilities		0	1.00	0	100	0		0
Total, NIBIB	98	\$376,730	102	\$389,464	102	\$335,986	0	-\$53,478

¹ All items in italics and brackets are non-add entries.

Major Changes in the Fiscal Year 2020 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2020 President's Budget for NIBIB. The FY 2020 President's Budget request for NIBIB is \$336.0 million, a decrease of \$53.5 million or 13.7 percent compared with the FY 2019 Enacted level.

Research Project Grants (RPGs) (-\$39.1 million; total \$236.4 million):

NIBIB will fund 711 RPG awards in FY 2020, a decrease of 46 awards from the FY 2019 Enacted level. This includes 520 non-competing awards (an increase of 67 awards and \$2.6 million from the FY 2019 Enacted level); 165 competing RPGs (a decrease of 108 awards and \$39.8 million from the FY 2019 Enacted level); and 26 SBIR/STTR awards (a decrease of 5 awards and \$1.8 million from the FY 2019 Enacted level). Noncompeting awards will be funded at a reduced level, 9.7% below their full commited level. The average cost of Competing RPG's will decrease by 9.7% in FY 2020 versus the FY 2019 Enacted level.

<u>Research Centers (-\$5.3 million; total of \$32.2 million)</u>: NIBIB will fund 26 Center awards in FY 2020, a decrease of 4 from the FY 2019 Enacted level.

Other Research (-\$1.1 million; total of \$6.8 million): NIBIB will fund 67 Other Research awards in FY 2020, a decrease of 12 from the FY 2019 Enacted level.

<u>Research Training Awards (-\$1.7 million; total \$10.0 million)</u>: NIBIB will fund 203 Full-Time Training Positions (FTTPs) in FY 2020, a decrease of 33 from the FY 2019 Enacted level.

<u>Research and Development Contracts (-\$2.2 million; total \$13.5 million)</u>: NIBIB will fund 10 R&D Contracts in FY 2020, a decrease of 1 from the FY 2019 Enacted level.

Intramural Research (-\$1.6 million; total \$14.9 million):

The budget request for Intramural Research includes an increase of \$0.7 million for the NIBIB Director's laboratory, which was previously funded in the National Institute of Diabetes and Digestive and Kidney Diseases. Funding for other Intramural Research activities will be reduced by 14.2%.

<u>Research Management & Support (-\$2.5 million; total \$22.3 million)</u>: In FY 2020, Research Management & Support will be reduced by 10% from the FY 2019 Enacted level.

Summary of Changes (Dollars in Thousands)

FY 2019 Enacted	\$389,464
FY 2020 President's Budget	\$335,986
Net change	-\$53,478

	FY 2020 President's Budget	Change from FY 2019 Enacted	
CHANGES	FTEs Budget Authority	FTEs Budget Authority	
A. Built-in:			
1. Intramural Research:			
a. Annualization of January 2019 pay increase & benefits	\$5,890	\$0	
b. January FY 2020 pay increase & benefits	5,890	18	
c. Paid days adjustment	5,890	22	
d. Differences attributable to change in FTE	5,890	0	
e. Payment for centrally furnished services	1,389	-154	
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	7,604	0	
Subtotal		-\$114	
2. Research Management and Support:			
a. Annualization of January 2019 pay increase & benefits	\$11,775	\$0	
b. January FY 2020 pay increase & benefits	11,775	40	
c. Paid days adjustment	11,775	44	
d. Differences attributable to change in FTE	11,775	0	
e. Payment for centrally furnished services	225	-25	
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	10,291	0	
Subtotal		\$60	
Subtotal, Built-in		-\$54	

Summary of Changes

((Dollars in Thousar	nds)				
	FY 2020 President's Budget				0	om FY 2019 acted
CHANGES	No.	Amount	No.	Amount		
B. Program:						
1. Research Project Grants:						
a. Noncompeting	520	\$177,804	67	\$2,461		
b. Competing	165	47,760	-108	-39,750		
c. SBIR/STTR	26	10,798	-5	-1,786		
Subtotal, RPGs	711	\$236,362	-46	-\$39,075		
2. Research Centers	26	\$32,152	-4	-\$5,317		
3. Other Research	67	6,830	-12	-1,130		

4. Research Training

Subtotal, Extramural

6. Intramural Research

9. Buildings and Facilities

Subtotal, Program

Total changes

8. Construction

5. Research and development contracts

7. Research Management and Support

203

10

<u>FTEs</u>

27

75

102

9,986

13,482

\$298,812

\$14,883

22,291

\$335,986

0

0

-33

-1

FTEs

0

0

0

-1,652

-2,230

-\$49,404

-\$1,483

-2,537

-\$53,424

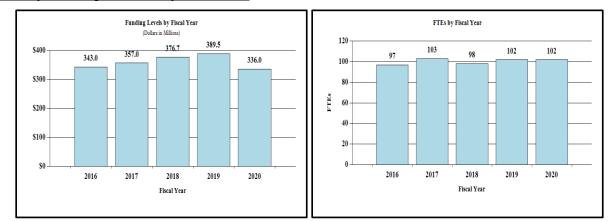
-\$53,478

0

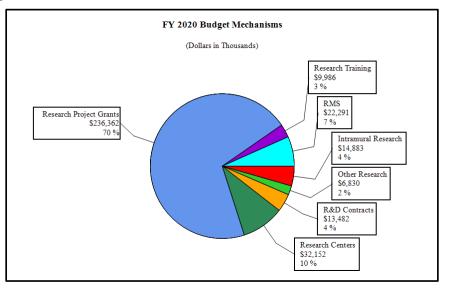
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Fiscal Year 2020 Budget Graphs

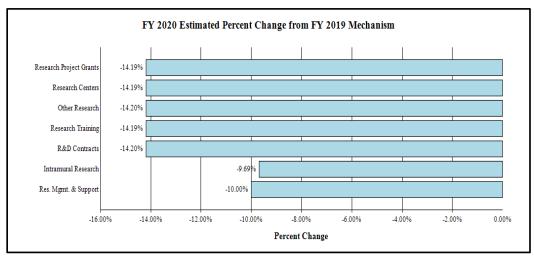
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Budget Authority by Activity¹ (Dollars in Thousands)

	FY 2	018 Final	FY 20	19 Enacted		Y 2020 ent's Budget		Y 2020 +/- Y2019
Extramural Research	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Detail</u>								
Discovery Science and Technology		\$109,465		\$113,215		\$97,153		-\$16,063
Applied Science and Technology		168,224		173,987		149,302		-24,685
Interdisciplinary Training		22,458		23,227		19,932		-3,295
Health Informatics Technology		36,535		37,786		32,425		-5,361
Subtotal, Extramural		\$336,682		\$348,216		\$298,812		-\$49,404
Intramural Research	27	\$15,985	27	\$16,480	27	\$14,883	0	-\$1,597
Research Management & Support	71	\$24,064	75	\$24,768	75	\$22,291	0	-\$2,477
TOTAL	98	\$376,730	102	\$389,464	102	\$335,986	0	-\$53,478

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

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2019 Amount Authorized	FY 2019 Enacted	2020 Amount Authorized	FY 2020 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Biomedical Imaging and			>	\$389,464,000	5	\$335,986,000
Bioengineering	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$389,464,000		\$335,986,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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
20171	\$343,506,000	\$356,978,000	\$361,062,000	\$357,080,000
Rescission				\$0
2018	\$282,614,000	\$362,506,000	\$371,151,000	\$377,871,000
Rescission				\$0
2019	\$346,550,000	\$382,384,000	\$389,672,000	\$389,464,000
Rescission				\$0
2020	\$335,986,000			

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):

			FY 2020	
	FY 2018	FY 2019	President's	FY 2020+/-
	Final	Enacted	Budget	FY 2019
BA	\$376,730,000	\$389,464,000	\$335,986,000	-\$53,478,000
FTE	98	102	102	0

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

Director's Overview

In developing transformational tools and technologies, NIBIB is expanding the Point-of-Care Technologies Research Network (POCTRN) through partnerships with other Institutes at NIH. One priority for the next generation of POCTRN is an increased focus on the translation and commercialization of new technologies. In its first iteration POCTRN has supported the development of tools and technologies to address clinical care needs in primary care settings, rapid diagnosis of sexually transmitted diseases, and cancer care.

In one recent successful example, researchers developed a small device to diagnose chlamydia within 30 minutes, eliminating the need for time-consuming laboratory tests. With rapid results, patients can receive treatment right away (at the point-of-care) and eliminate the need for a follow-up appointment, therefore reducing potential disease transmission and improving patient outcomes. Researchers have also conducted a study to determine if patients are amenable to collecting tissue samples themselves using a swab, which in the future could be collected at home and sent in for testing. Self-collection was found to be easy and the preferred method, which could encourage more people to get tested. In the future, different modules could be used with the same device to detect multiple diseases. The device is already approved for marketing in Europe. A trial to test for both chlamydia and gonorrhea is underway in the U.S. to support approval for use from the Food and Drug Administration (FDA). Through its point-of-care program, NIBIB focuses on bringing healthcare closer to the patient, where it is more convenient, accessible, and cost effective.

Machine learning and artificial intelligence are emerging transformational tools that could be beneficial for researchers and healthcare services, particularly in medical imaging. These tools have potential uses in diagnosing and optimizing treatments for a range of diseases, and offer new ways to collect, analyze, and use data to make decisions or take specific action. In FY 2020 this new program priority at NIBIB will support the design and development of tools that emulate and enhance the human ability to analyze complex sets of data, including medical images.

In one example of this growing field, researchers used an artificial intelligence-based approach to produce higher quality images from medical scans. This approach can be used to reduce the radiation dose needed for computed tomography (CT) and positron emission tomography (PET), and to reduce the time it takes to obtain an image with magnetic resonance imaging (MRI). Researchers used a set of 50,000 MRI brain scans from the NIH-supported Human Connectome Project to train a system to reconstruct clear, accurate medical images that were higher quality and produced sharper images than existing methods. Another key advance is that the system produces images almost instantly after a patient is scanned so a technician can determine immediately if the scan needs to be repeated. This could greatly reduce the need for patients to schedule repeat scans.

Transformative technologies are also being made possible with new types of materials and electronics. NIBIB-supported researchers created a small, flexible ultrasound patch that can be worn like a band-aid to accurately monitor blood pressure. The idea to utilize ultrasound technology in a wearable device is a new approach that could lead to other avenues for monitoring and diagnosing illness. In this example, ultrasound is capturing signals from blood vessels. Most wearables, to date, can only measure signals at or near the surface of the skin such as body temperature. Further research is needed to make the patch wireless and confirm the accuracy of the blood pressure readings over time.

Overall Budget Policy:

The FY 2020 President's Budget request for NIBIB is \$336.0 million, a decrease of \$53.5 million or 13.7 percent compared with the FY 2019 Enacted level. Noncompeting RPGs will be awarded at a reduced level, 9.7% below their full commited level. The average cost of Competing RPGs will decrease by 9.7% in FY 2020 versus the FY 2019 Enacted level. Competing RPGs will achieve a 10% success rate. The budget request for Intramural Research includes an increase of \$0.7 million for the NIBIB Director's laboratory, which was previously funded in the National Institute of Diabetes and Digestive and Kidney Diseases. Funding for other Intramural Research activities will be reduced by 14.2%, the same as the aggregate reduction for Extramural funding mechanisms. Research Management & Support will be reduced by 10% from the FY 2019 Enacted level.

Program Descriptions and Accomplishments

Discovery Science and Technology (DST)

The next frontier in biomedical research will leverage technological advances, which will help drive scientific progress and lead a path toward the future of medicine where faster, better, less costly approaches are more broadly applicable. Flexible electronics, ink-jet printable materials, and harnessing the increasing computing power of smartphones are a few of the advances that will enable future discoveries and help propel them to become useful tools for medical practitioners and individuals. The DST program supports the development of innovative biomedical engineering technologies and the subsequent translation of those technologies into applications for the benefit of public health.

Building on years of basic research combined with the ability to easily print electrodes and other materials, platform technologies are emerging for a range of blood tests. These rapid diagnostic

and screening tests have the potential to be game changers in preventing and minimizing the effects of illness. For these devices to be feasible, it is important that they can be quickly and easily produced, or scalable for manufacturing. As a test case of this type of technology, researchers designed a sensor platform to detect a protein biomarker (HER-2) for diagnosing one type of breast cancer. This test uses electrochemical detection, a method that measures electric currents that are generated from reactions in the test compounds. The benefits of the device are numerous: it can be manufactured for 25 cents, gives results in 15 minutes, and of great importance to patients, it uses a small blood plasma sample instead of tissue, thus eliminating the need for painful biopsy.

Program Portrait: Commercializing biomaterials with multiple applications

Biomaterials increasingly play an integral role in restoring function and facilitating healing due to injury or disease. This multidisciplinary field combines biology, physics, chemistry, tissue engineering, and materials science to create solutions to complex medical problems. Recently, researchers created a shape memory polymer to treat a variety of vascular problems. This biomaterial solution is a new approach to embolization, a procedure for obstructing or reducing blood flow in damaged blood vessels.

Approximately 150,000 new patients are diagnosed each year with one type of vascular disorder called chronic venous insufficiency, with medical costs totaling \$500 million per year.¹ Venous insufficiency occurs when veins are weakened and bulge outward. This can lead to debilitating pain that makes it difficult for people to walk or stand for a prolonged period. This disorder is more common in women, particularly after multiple pregnancies, and primarily affects middle-aged and older adults. This novel biomaterial works by blocking blood flow to the diseased veins, which can improve healing. To use this biomaterial, the polymer is compressed onto a catheter and inserted in a vein near the treatment site, where the foam expands to induce stable clot formation. Prior to this technology, metal coils were used but can result in complications including inflammation and puncturing blood vessels. Research is ongoing to find other neurovascular uses for this product, such as the stabilization of brain aneurysms.

This new biomaterial was recently FDA-approved for use in the U.S. Its development was supported, in part, by NIBIB's Small Business Innovation research (SBIR) program. The research team also participated in NIBIB's Concept to Clinic Commercializing Innovation (C3i) program, which has expanded to include other NIH Institutes. This program provides NIH grantees with the essential business training and specialized mentoring needed to successfully move biomedical technologies from the lab to market as in this example. In the four years of this innovative program, 37 SBIR/STTR companies and 17 researchers with NIH independent research grants have participated. Of those, six companies have been selected by the program to pitch their inventions to investors. Many of these innovations are still in the research development pipeline but two have received FDA clearance for marketing in the U.S.

Budget Policy:

The FY 2020 President's Budget request for the DST program is \$97.2 million, a decrease of \$16.13 million or 14.2 percent compared with the FY 2019 Enacted level. DST will also give

¹ <u>https://www.ncbi.nlm.nih.gov/books/NBK430975/</u>

high priority to supporting new and early-career investigators, and priority to investigatorinitiated 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.

Applied Science and Technology (AST)

Imaging research is the primary focus of the AST program, which supports the development of innovative biomedical imaging technologies that are cost-effective, accessible, transform our understanding of biological and disease processes, and enable patient centered healthcare. Medical imaging is no longer limited to seeing inside the body noninvasively for diagnostic purposes. Increasingly, imaging is used to identify functional and molecular differences in diseases and disorders to better inform and monitor treatment. With a broad range of research focus areas AST supports the discovery of ways to improve medical imaging technologies from ultrasound to x-rays. The program is integrating Artificial Intelligence applications to medical imaging to reduce diagnostic errors, decrease image-acquisition time, increase the information content of images, optimize the use of contrast agents, and lower the amount of ionizing radiation used to perform scans.

Developing transformative tools and technologies can address problems with the current onesize-fits-all imaging machines, which do not always produce high quality images in smaller patients, especially children. One novel approach to overcome this challenge is the development of printed, flexible MRI coils that can be customized for patients of all shapes and sizes to improve image quality. The printed coils can be embedded in blankets and wrapped around pediatric patients, so they do not need to hold as still, hold their breath, or be sedated while the imaging scan is being performed.

Another example of customized medical imaging is the MRI "glove coil" which is designed to image joints in motion and visualize the mechanics of bone and soft tissue. Current modalities enable imaging while a person is motionless, which can reveal valuable information such as whether a ligament is torn following injury, or if a pinched nerve is the cause of severe pain. However, the ability to see inside the body while moving will enhance our understanding of the complex interaction between bone, muscles, and other soft tissues. In this proof-of-concept example, researchers created wearable imaging coils that were sewn into a glove. The design allowed for typical hand movements while wearing the glove, such as grasping an object or playing the piano. This new type of imaging may also prove useful for better understanding disorders such as repetitive strain injuries and help guide treatment and recovery. Both examples are efforts to accommodate movement and motion, making imaging more informative, and adaptable for patients, while improving image quality.

Program Portrait: New uses for imaging with light and sound

Photoacoustic imaging combines the advantages of light and sound waves into one technology, leveraging the strength of each method, while minimizing their weaknesses. A team of researchers combined these methods and developed a novel imaging scan that could revolutionize breast cancer screening. This new photoacoustic method takes just 15 seconds to perform, is painless, and does not use radiation. Up to 50 percent of women do not get screening mammograms due to discomfort.² This technique could eliminate this significant barrier.

The technology, called Photoacoustic computed tomography (PACT) works by sending pulses of harmless laser light deep into tissue toward a target. When the target is hit with the light, it causes vibrations. The sound waves from the vibrations return a detailed image of the target, similar to ultrasound images. So far, PACT has been tested in a small number of women and correctly identified known breast tumors. The next step is to conduct additional studies in a larger population.

In another example of optical imaging (imaging with light), researchers have developed a device to measure blood glucose using laser light. This noninvasive method does not require a blood sample drawn from a finger prick for glucose monitoring, a procedure people with diabetes must undergo multiple times per day. In this approach, a safe laser light is projected though the skin. The device then measures the shifts in wavelengths, which correspond to different components found in the skin such as glucose molecules, proteins, or fat molecules. In a small, preliminary study of healthy participants, the device was found to be as effective as a finger prick test. This new approach could provide an easier way for people to monitor blood glucose levels and could be a convenient and reliable way to measure levels during sleep, a particularly vulnerable time for children with diabetes.

Budget Policy:

The FY 2020 President's Budget request for the AST program is \$149.3 million, a decrease of \$24.7 million or 14.2 percent compared with the FY 2019 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.

Interdisciplinary Training (IDT)

NIBIB's interdisciplinary training programs encourage diversity while supporting training for the next generation of researchers. A broad range of training programs, from the undergraduate to the junior faculty level, focus on training the next generation of bioengineers and bioimagers, increasing the number of clinician-scientists, and enhancing the participation of underrepresented populations in biomedical imaging and bioengineering research. NIBIB's Enhancing Science, Technology, EnginEering, and Math Educational Diversity (ESTEEMED) Research Education

² <u>https://www.ncbi.nlm.nih.gov/pubmed/21275649</u>

Experiences supports educational activities that increase the diversity of the biomedical research workforce through early preparation for underrepresented undergraduate students in STEM fields. NIBIB has also started a program to support training in translational research. This program will provide supplemental funding to support Translational Research Scholars from engineering or other quantitative backgrounds to engage in research through NIH's Clinical Translational Science Awards Program. This new program promotes team science and will accelerate the development and application of new biomedical technologies in clinical settings.

Program Portrait: Engaging the next generation of researchers

The next frontier in biomedical research includes yet unknown discoveries that will be realized by the next generation of researchers. NIBIB's Design by Undergraduate Teams Challenge engages students in identifying real-world healthcare problems and learning to develop creative solutions in a team environment. The most recent award-winning projects focused on providing simple, low-cost modifications to various surgical techniques. In this year's contest, 36 entries were submitted from 25 different universities in 15 states across the U.S. The first-place winner designed a minimally invasive brain retractor that provides safer access during neurological surgeries. The device has the potential to decrease recovery time, reduce major complications that endanger the patient, and reduce the need for post-operative care. Second place was awarded to a team that developed a device to protect soft tissues surrounding the tibia during total knee replacement surgery. The third-place team was recognized for development of a device to aid in epidural needle placement. The device is designed to provide an objective measure of bioimpedance-the resistance that different tissues have to electricity-that will alert the technician to the needle's location and when it has reached the correct epidural space. These undergraduate teams offer a preview of the next generation of researchers and provide inspiring examples of a team approach to solving real-world health care problems.

Budget Policy:

The FY 2020 President's Budget request for the IDT program is \$19.9 million, a decrease of \$3.35 million or 14.2 percent compared with the FY 2019 Enacted level. 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)

The HIT program supports the development of activities in health informatics, systems engineering, imaging informatics, telehealth, mobile health, point-of-care, artificial intelligence, and machine learning technologies to develop solutions to real-world healthcare problems. NIBIB-supported research in these areas is building toward practical, patient-centered applications such as using data to help doctors make clinical decisions, developing technologies to monitor a patient's treatment in their own home, and improving medical images with the next generation of intelligent data analysis tools and support systems.

Telemedicine and mobile health technologies are transforming healthcare delivery, with the potential to provide broader access for a range of illnesses to patients in their own homes or a nearby clinic. One example of using telemedicine to help monitor patients in their own home is a system to detect a dangerous drop in white blood cells in patients receiving chemotherapy. The reduction in immune cells can lead to patients contracting infectious diseases, leading to, in the

worst case, death, and in the best case a disruption in the patient's chemotherapy schedule while the infection is treated. Some patients end up hospitalized, increasing overall costs.

Many relatively common, but significant problems in real-world healthcare settings such as this can create a burden on patients and the healthcare system. In this project, researchers gathered input from patients to help define the problem and create a home-based solution. They determined that a device to monitor white blood cell levels at home would allow these patients to easily detect dangerous drops in white cells. This would enable immediate treatment, and researchers estimate that this could prevent about half of the 110,000 infections that occur in chemotherapy patients in the U.S. each year.

The tabletop prototype device is designed to be used easily at home. It operates by taking a video of blood moving through extremely small capillaries at the base of the fingernail just below the skin. From the video, the device can count the number of white blood cells. In just one minute a reduction in the normal number of white cells expected can be detected. The system was found to be 95 percent accurate in determining whether an individual's white cell levels dropped to a dangerous level.

Key to making discoveries in next frontier of biomedical research will be the ability to maximize the use of data. By analyzing large data sets of human brain scans taken at various life stages, researchers hope to provide effective early diagnosis and prediction of brain disorders, such as Alzheimer's disease. NIBIB-supported scientists developed a set of 4D software tools using advanced techniques that merge data from different types of brain scans such as MRI and PET, and genetic data. The tools are being designed so that they will be widely available to other researchers. Preliminary data showed improved diagnoses of multi-stage Alzheimer's disease when compared with other state-of-the-art methods. The tools may one day provide a practical solution to help physicians provide better diagnoses and predictions of brain disorders.

Budget Policy:

The FY 2020 President's Budget request for the HIT program is \$32.4 million, a decrease of \$5.41 million or 14.2 percent compared with the FY 2019 Enacted level. 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.

Intramural Research Program (IRP)

The IRP supports NIBIB's mission to integrate bioengineering with the life and physical sciences by conducting basic, translational, and clinical science research and conducting effective training programs in related fields. Researchers are working to create optical imaging technologies that provide unprecedented combinations of high resolution and speed to study living cells in real time. Others create "theranostic" imaging probes that combine therapeutic and diagnostic capabilities to improve early diagnosis, monitor therapeutic responses, and guide drug discovery and development. Still others are collaborating to create the world's first complete 3D video atlas of neurodevelopment of the organism *C. elegans* to accelerate basic research for understanding neurological disorders.

One area of focus is theranostic nanomedicines, which combine both therapy and diagnostics into one technique. Intramural researchers developed a "smart" anti-cancer nanoparticle with precisely targeted tumor-killing activity. The state-of-the-art nanoparticle features an exceptionally sturdy shell capable of carrying large loads of chemotherapeutic drugs through the circulatory system to the tumor without the leakage that can damage healthy tissue. The nanomedicine is photothermal-responsive, so the cancer-killing load of the particle is released only when it enters the tumor cells and is activated by laser light. The responsiveness to light can also be used to track the particle as it moves through the body. In a mouse model the thermo-chemotherapy combo eliminated nearly 100 percent of breast tumors and efficiently killed cells attempting to metastasize from the breast to the lung. The typically toxic effects of chemo on the mice were eliminated due to the precise targeting and release of the drugs inside the tumor.

Intramural investigators are also engaged in research in the growing field of machine learning. Machine learning is a way to train algorithms (instructions for computing) to "think" for themselves. Instead of being fully programmed (by humans), machine learning uses very large datasets to teach algorithms to adapt and learn from the data being analyzed. NIBIB researchers are developing new machine learning-based approaches to automate the analysis of image datasets produced by optical and electron microscopes. These microscopes can obtain enlarged images of tiny objects such as the inside of a cell. The current method to separate and distinguish structures in these images is painstakingly slow and inefficient. The machine learning approach is a way to automate the process for distinguishing structures and particles within cells and tissues in images.

Current efforts are focused on finding the right algorithms or instructions to work effectively on specific sets of data. Future work will be focused on finding ways for the algorithms to learn without the need for such large datasets to train them. This type of automated approach is essential for analyzing very large datasets, the results of which can improve our understanding of the complex biological processes, such as blood clotting and neuronal development.

Supporting NIH-wide initiatives

NIBIB also plays a role in important trans-NIH initiatives including the *All of Us* Research Program, with a focus on patient-centered healthcare such as developing a platform for sharing medical images. Like a genomic assay or a blood work up, medical imaging scans contain data that can help identify biomarkers for disease or monitor treatment effects and are an integral part of an individual's health records. NIBIB laid the foundation for information systems that could easily share large files of medical images and give patients control over who receives the images. This effort not only puts patients in charge of their own healthcare, it can eliminate the need for repeat scans if a patient requires treatment by another physician.

NIBIB's history and expertise in technology development creates ideal partnerships to discover alternatives to addictive pain medications such as opioids through NIH's Helping to End Addiction Long-term (HEAL) Initiative. NIBIB has also been actively involved in the Stimulating Peripheral Activity to Relieve Conditions (SPARC) Initiative which is leading to a better understanding of the peripheral nervous system and how to develop medical devices that

could target specific nerve pathways to treat a range of diseases and disorders including chronic pain.

NIBIB also has had an active role in the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative since its inception and continues to support research leading to developing tools and technologies that are improving our fundamental understanding of the brain and neurological disorders and diseases.

Budget Policy:

The FY 2020 President's Budget request for IRP is \$14.93 million, a decrease of \$1.6 million or 9.7 percent compared with the FY 2019 Enacted level. The budget request includes an increase of \$0.7 million for the laboratory of the NIBIB Director, while funding for other Intramural Research activities will be reduced by 14.2%. High-priority research includes molecular imaging and nanomedicine – for the early diagnosis of disease, monitoring of therapeutic response, and guiding drug discovery, and also research on novel technologies for fast, "super resolution" optical microscopy of live cells to accelerate biomedical research.

Research Management and Support (RMS)

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, coordination and liaison with other Federal agencies, Congress, and the public. NIBIB's communication efforts include development of tools to help educate and inform the public about the research supported by NIBIB.

Budget Policy:

The FY 2020 President's Budget request for RMS is \$22.31 million, a decrease of \$2.57 million or 10.0 percent compared with the FY 2019 Enacted level. High priorities for RMS include the scientific support of NIBIB research programs and strategic planning.

Budget Authority by Object Class¹ (Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total co	mpensable workyears:			
	Full-time equivalent	102	102	0
	Full-time equivalent of overtime and holiday	0	0	0
	hours		-	
	Average ES salary	\$0	\$0	\$0
	Average GM/GS grade	12.8	12.8	0.0
	Average GM/GS salary	\$120	\$120	\$0
	Average salary, grade established by act of July	\$0	\$0	\$0
	1, 1944 (42 U.S.C. 207)			
	Average salary of ungraded positions	\$145	\$145	\$0
	OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
	Personnel Compensation			
11.1	Full-Time Permanent	8,327	8,359	32
11.3	Other Than Full-Time Permanent	3,093	3,105	12
11.5	Other Personnel Compensation	443	444	2
11.7	Military Personnel	0	0	0
11.8	Special Personnel Services Payments	1,807	1,814	7
11.9	Subtotal Personnel Compensation	\$13,670	\$13,721	\$52
12.1	Civilian Personnel Benefits	3,870	3,943	73
12.2	Military Personnel Benefits	0	0	0
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	\$17,540	\$17,665	\$125
21.0	Travel & Transportation of Persons	320	288	-32
22.0	Transportation of Things	30	27	-3
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	209	188	-21
24.0	Printing & Reproduction	11	10	-1
25.1 25.2	Consulting Services Other Services	419 4,282	377	-42
23.2		4,282	2,472	-1,809
25.3	Purchase of goods and services from government accounts	25,908	22,705	-3,203
25.4	Operation & Maintenance of Facilities	710	639	-71
25.4 25.5	R&D Contracts	198	039	-198
25.5 25.6	Medical Care	21	19	-198
25.0 25.7	Operation & Maintenance of Equipment	3,400	2,830	-570
25.8	Subsistence & Support of Persons	5,400	2,050	-576
25.0	Subtotal Other Contractual Services	\$34,945	\$29,048	-\$5,896
26.0	Supplies & Materials	1,360	1,203	-157
31.0	Equipment	2,545	2,227	-319
32.0	Land and Structures	2,545	2,227	-517
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	332,503	285,330	-47,173
42.0	Insurance Claims & Indemnities	0	200,000	0
43.0	Interest & Dividends	ů 0	0	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	\$371,924	\$318,321	-\$53,603
	Total Budget Authority by Object Class	\$389,464	\$335,986	-\$53,478

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

Salaries and Expenses (Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	\$8,327	\$8,359	\$32
Other Than Full-Time Permanent (11.3)	3,093	3,105	12
Other Personnel Compensation (11.5)	443	444	2
Military Personnel (11.7)	0	0	0
Special Personnel Services Payments (11.8)	1,807	1,814	7
Subtotal Personnel Compensation (11.9)	\$13,670	\$13,721	\$52
Civilian Personnel Benefits (12.1)	\$3,870	\$3,943	\$73
Military Personnel Benefits (12.2)	0	0	0
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$17,540	\$17,665	\$125
Travel & Transportation of Persons (21.0)	\$320	\$288	-\$32
Transportation of Things (22.0)	30	27	-3
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	209	188	-21
Printing & Reproduction (24.0)	11	10	-1
Other Contractual Services:			
Consultant Services (25.1)	419	377	-42
Other Services (25.2)	4,282	2,472	-1,809
Purchases from government accounts (25.3)	16,038	14,211	-1,827
Operation & Maintenance of Facilities (25.4)	710	639	-71
Operation & Maintenance of Equipment (25.7)	3,400	2,830	-570
Subsistence & Support of Persons (25.8)	6	5	-1
Subtotal Other Contractual Services	\$24,854	\$20,535	-\$4,320
Supplies & Materials (26.0)	\$1,360	\$1,203	-\$157
Subtotal Non-Pay Costs	\$26,785	\$22,251	-\$4,534
Total Administrative Costs	\$44,325	\$39,916	-\$4,409

	FY 2018 Final			FY 2019 Enacted			FY 2020 President's Budget		
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Extramural Science Program									
Direct:	20	_	20	20	-	20	20	_	20
Reimbursable:	20	_	20	20	_	20	20	_	20
Total:	22	-	22	22	-	22	22	-	22
Intramural Science Program									
Direct:	23	-	23	23	-	23	23	-	23
Reimbursable:	4	-	4	4	-	4	4	-	4
Total:	27	-	27	27	-	27	27	-	27
Office of Administrative Management									
Direct:	27	-	27	27	-	27	27	-	27
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	27	-	27	27	-	27	27	-	27
Office of Reseach Administration									
Direct:	19	-	19	19	-	19	19	-	19
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	19	-	19	19	-	19	19	-	19
Office of the Director									
Direct:	3	-	3	7	-	7	7	-	7
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	3	-	3	7	-	7	7	-	7
Total	- 98		<u>-</u> 98	- 102		102	- 102		- 102
Includes FTEs whose payroll obligations are su	ipported by t	he NIH Com	mon Fun	d.	1		1	1	
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2016		12.5							
2017		12.9							
2018		12.8							
2019		12.8							
2020	12.8								

Detail of Full-Time Equivalent Employment (FTE)

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	
Total, ES Positions	0	0	0	
Total, ES Salary	0	0	0	
GM/GS-15	14	14	14	
GM/GS-14	23	23	23	
GM/GS-13	17	17	17	
GS-12	9	9	9	
GS-11	1	1	1	
GS-10	2	2	2	
GS-9	3	3	3	
GS-8	0	0	0	
GS-7	4	4	4	
GS-6	0	0	0	
GS-5	0	0	0	
GS-4	0	0	0	
GS-3	0	0	0	
GS-2	1	1	1	
GS-1	0	0	0	
Subtotal	74	74	74	
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	33	37	37	
Total permanent positions	74	74	74	
Total positions, end of year	107	111	111	
Total full-time equivalent (FTE) employment, end of year	98	102	102	
Average ES salary	0	0	0	
Average GM/GS grade	12.8	12.8	12.8	
Average GM/GS salary	120,163	120,163	120,163	

Detail of Positions¹

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