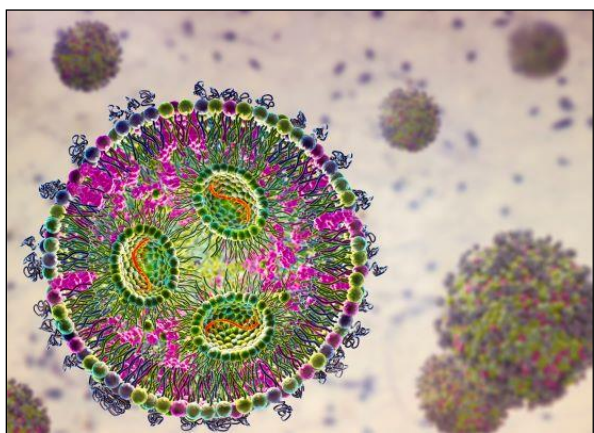
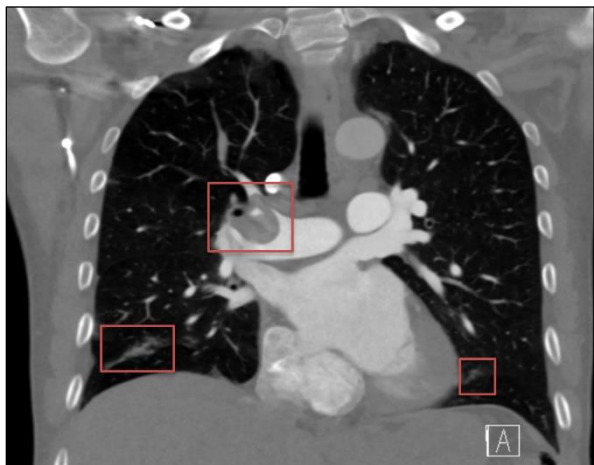


National Institute of Biomedical Imaging and Bioengineering



CONGRESSIONAL JUSTIFICATION
FY 2025

Department of Health and Human Services
National Institutes of Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

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General Notes

1. FY 2024 funding levels cited in this document are based on the Continuing Resolution in effect at the time of budget preparation (Public Law 118-35) and do not include HIV/AIDS transfers.
2. Detail in this document may not sum to the subtotals and totals due to rounding.

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Director's Overview

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has unique capabilities for developing groundbreaking technologies to improve health and better understand complex biological systems. NIBIB is committed to supporting and disseminating solutions that will achieve our mission to transform, through technology development, our understanding of disease and its prevention, detection, diagnosis, and treatment. Innovations in technology depend on building strong partnerships and supporting a diverse biomedical workforce. NIBIB is investing in programs to increase its impact while establishing itself as an essential technology development partner for current and future health challenges.



*Bruce J. Tromberg,
Ph.D., NIBIB Director*

Cultivating Collaborations to Create Innovations in Technology

The urgency of the COVID-19 pandemic prompted swift innovations in biomedicine. Enabled by congressional COVID-19 supplemental funding, NIBIB responded by developing and expanding urgently needed COVID-19 tests, building digital health platforms, and advancing artificial intelligence (AI) and machine learning methods for pulmonary imaging. To develop tests, NIBIB introduced the Rapid Acceleration of Diagnostics (RADx[®]) Tech innovation funnel, where projects were quickly reviewed by a team of experts and awards were made in a milestone-driven funding structure. Success of the program was dependent on the collaboration of over 900 stakeholders from government, academia, and private industry, who partnered to produce 7.8 billion tests and test products and secure 55 U.S. Food and Drug Administration (FDA) emergency use authorizations (EUAs). Test production through NIBIB's RADx Tech helped shift testing from primarily central laboratories to at-home and point-of-care (POC) settings.

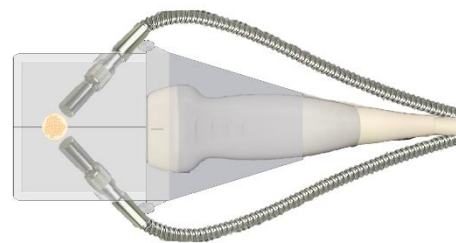
The successes achieved during the COVID-19 pandemic have led NIBIB to leverage lessons learned and rethink its approach to technology development to address critical, unmet national and global health care needs, bolstering the capacity to mitigate current and emerging health threats, including identifying and eliminating infectious disease outbreaks. The RADx Tech infrastructure and operational processes are being employed to build new programs that accelerate technology development, validation, and deployment – a “RADx-ification” of NIBIB approaches and collaborations. Through funding partnerships, NIBIB is applying the RADx approach to solve a range of health problems, including developing technologies to address the maternal health crisis in the United States, technologies to reduce the spread of HIV, emergency diagnostics for mpox, diagnostics to support the elimination of hepatitis C in the United States, multiplex at-home and POC tests for respiratory viruses, technologies to treat nervous system disorders, and monitoring technologies to reduce the risk of fetal and maternal morbidity and mortality.

A specific example of “RADx-ification” is NIBIB's launch of the Blueprint MedTech program and partnership with the NIH Blueprint for Neuroscience consortium of 12 institutes, centers,

and offices. The Blueprint MedTech program is designed to overcome barriers to the development and commercialization of highly impactful devices to treat disorders of the nervous system. The program funds projects using a milestone-driven incubator/accelerator model to de-risk technologies and bring them to the stage where they can attract further investment from industry.

One Blueprint MedTech project is a non-addictive treatment for neuropathic pain using low-intensity focused ultrasound. As envisioned, it would provide a non-invasive outpatient treatment in which the clinician uses a combined imaging and therapeutic ultrasound device to target and immediately treat the specific portions of the nervous system that generate pain signals. The project aims to provide patients with pain relief for up to a month after only three minutes of treatment.

Another project is developing a non-invasive imaging device to modernize the treatment of peripheral nerve injuries. The handheld photoacoustic device provides high-resolution images of peripheral nerve structures, enabling the quantitative assessment of nerve damage that has occurred due to trauma or other causes. The non-invasive technology combines light (photo) and sound (acoustic) waves to create detailed images. This would add precision to clinical decision making, allow more targeted surgery approaches, and enable post-operative monitoring of nerve regeneration, ultimately improving outcomes. If successful, the device would greatly improve the treatment of and recovery from debilitating peripheral nerve injuries.



Prototype of handheld device to improve treatment of peripheral nerve injuries. Credit: Muyinatu “Bisi” Bell and Sami Tuffaha, Johns Hopkins University, Baltimore, Maryland.

Further, NIBIB has expanded the long-standing Point-of-Care Technologies Research Network (POCTRN) which formed the basis for the rapid success of RADx Tech in delivering COVID-19 tests during the pandemic. NIBIB, in partnership with seven other NIH institutes and centers, is expected to invest nearly \$11 million (in FY 2024) in six technology research and development centers around the country and a coordinating center that will harness the momentum of the network to advance home-based and POC health technologies for a range of health care applications. Each center in the network identifies unmet clinical needs and collaborates with innovators to develop technology-based solutions and ready them to receive follow-on funding and/or regulatory clearance. One new center will focus on technologies for equitable cancer care by improving early cancer detection in low-resource settings, while a second will address global primary care needs for vulnerable populations through the development of technologies to address nutrition, infectious diseases, and cancer. POCTRN will continue to utilize the RADx Tech infrastructure to build new programs and partnerships to compress the technology development pipeline, minimizing risk and maximizing gain.

Investing in equitable technologies and a diverse research workforce

Supporting applied research, experimental development, pre-commercialization, and standards-related efforts that will facilitate the adoption of a broad range of new technologies, as well as



FDA authorized the Fastep COVID-19 Antigen Pen Home Test from Azure Biotech, Inc. NIBIB photo by Chia-Chi (Charlie) Chang

improving equity and accessibility of health care technologies, are priorities for NIBIB. Despite the paradigm shift to self-testing that most people experienced during the pandemic, the COVID-19 diagnostics rollout insufficiently addressed the needs of important populations, including people with low or no vision, reduced dexterity or motor skills, and older adults. In partnership with a wide range of advocacy organizations and agencies, RADx Tech established the COVID-19 Test Accessibility program to address the design of at-home tests. Key successes for the program include a published document for test developers that defines best practices for universal design along with support for an EUA for the first at-home test that conforms to accessible design principles: the Azure pen. This extremely simple test has only two parts, its use requires far fewer steps than other marketed tests, and there is no need to transfer liquids, manipulate small parts, or understand complex instructions. NIBIB continues to support the development of high-performance COVID-19/flu multiplex tests designed to be used independently by people with disabilities to ultimately provide a universally improved testing experience.

Recognizing the unmet need for high-quality imaging databases to support the development of reliable AI algorithms, NIBIB supported the Medical Imaging and Data Resource Center (MIDRC), a first-of-its-kind, comprehensive national COVID-19 medical image repository with broadly representative data, unbiased AI algorithm development and validation capabilities, and a dedicated bias awareness tool. The multi-institutional network received \$30 million in COVID-19 supplemental funds that it has efficiently allocated to amass a curated public database that includes high-quality medical images and associated clinical data. This collaborative platform is enabling the user community to develop new valuable analytical tools and processes to increase the diagnostic power of medical imaging, thereby developing trustworthy, powerful advanced AI systems that help achieve the Nation's great aspirations. The initial NIBIB investment has been leveraged to secure additional funding from other federal agencies and non-government partners with the goal of expanding this important resource to other disease areas.

A key effort of MIDRC is to facilitate the development of trustworthy algorithms – from creation to testing and validation – which depend on reliable data. The MIDRC database allows researchers to pull the specific data that they need to build an algorithm for their specific clinical use. As a showcase of its success, MIDRC released 29 AI algorithms and more than 13 terabytes of data to the public, engaging over 600 registered users worldwide. Approximately 80 percent of the data ingested into MIDRC is freely accessible to the public for research use, and the remaining 20 percent of the data is in a separate, sequestered dataset for validating algorithms. One MIDRC-supported publication has identified nearly 30 unique factors that can introduce

bias into an AI model.¹ The MIDRC sequestered dataset is a uniquely valuable validation tool, allowing developers to use different data to evaluate and test their model.

Research achievements like those described above are dependent on a diverse and strong biomedical workforce. Technology development is an inherently inclusive and interdisciplinary field that requires diverse approaches, perspectives, and ideas to be successful. NIBIB's approach to improve and achieve diversity, equity, inclusion, and accessibility (DEIA) goals is intrinsic to its vision to shape the future of health. NIBIB's DEIA activities are inspired by its organizational values of collaboration, innovation, and technical excellence. NIBIB will continue to support and optimize programs that overcome barriers to sustain the many talented individuals and organizations contributing to better health for all.

To promote a diverse and strong biomedical workforce, NIBIB established an undergraduate research education program called Enhancing Science, Technology, EnginEering, and Math Educational Diversity (ESTEEMED) in 2018. In five years, the effort has supported 15 programs at academic institutions and engaged 259 students. A unique feature of the program is that participants are exposed to hands-on biomedical engineering research in their freshmen and sophomore years. The program also provides mentoring, community-building, and educational and career development activities to prepare participants for academic success in college and facilitates participation in their institutions' honors programs by preparing students to excel in their junior and senior years. The goal of the program is to increase the number of students that go on to pursue a Ph.D. or M.D./Ph.D. degree and subsequent research career in biomedical engineering. Students in the program have recounted their experiences and described how support from program mentors and other peer participants has led them to overcome challenges while successfully completing their undergraduate studies.

NIBIB has also increased its ongoing investment in developing equitable technologies and promoting diversity in the research workforce through newly launched centers and programs. In January 2023, NIBIB launched the intramural Center for Biomedical Engineering and Technology Acceleration (BETA Center), a multi-institute NIH resource that accelerates the development, validation, and dissemination of high-impact biomedical technologies to address urgent national and global health needs. During its short tenure, the Center has engaged 74 affiliate investigators from 15 NIH institutes. The BETA Center is also creating and supporting new education and training opportunities at NIH for biomedical imaging and bioengineering students and fellows at all levels. The BETA Center Director, who is also the NIBIB Associate Director for DEIA, is helping to recruit diverse biomedical engineering talent to NIH using evidence-driven approaches to expand DEIA across the NIH intramural research programs. The Center will emphasize technologies for health disparities research and workforce training.

To strengthen the biomedical engineering workforce, NIBIB launched the historically black colleges and universities (HBCU) Biomedical Engineering, Imaging, and Technology Acceleration (BEITA) initiative. The HBCU BEITA initiative will establish and strengthen programs in technology development at HBCUs. In addition to enhancing the U.S.

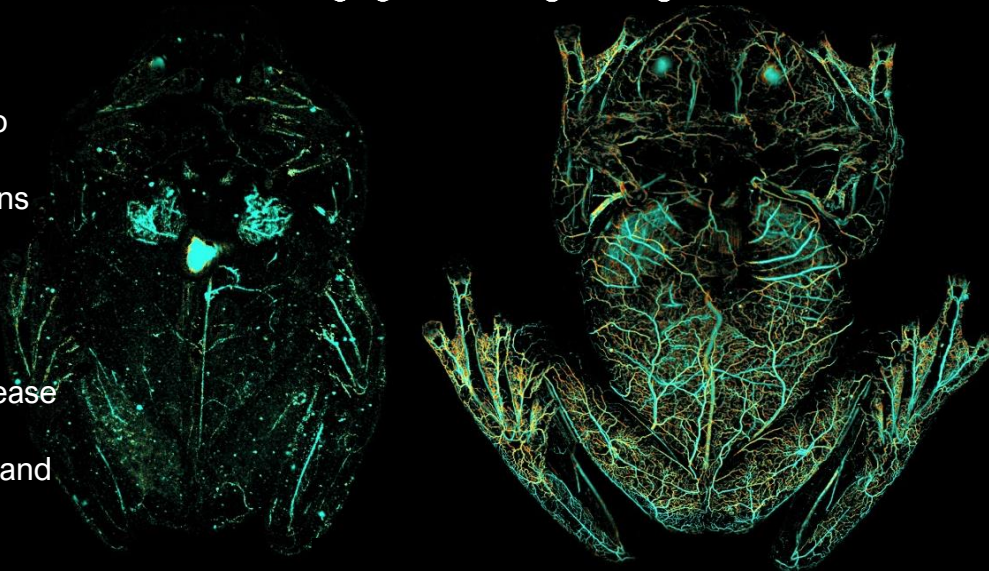
¹ Drukker K., et al., Toward fairness in artificial intelligence for medical image analysis: identification and mitigation of potential biases in the roadmap from data collection to model deployment, *J. Med. Imag.* 10(6), 061104 (2023), doi: 10.1117/1.JMI.10.6.061104.

bioengineering and imaging research capacity, this program will enrich the technology workforce by preparing students at HBCUs for careers in biomedical engineering and imaging.

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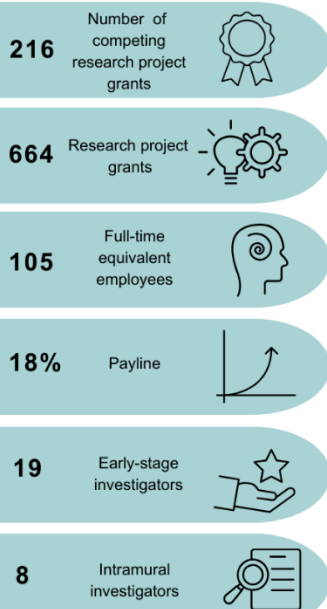
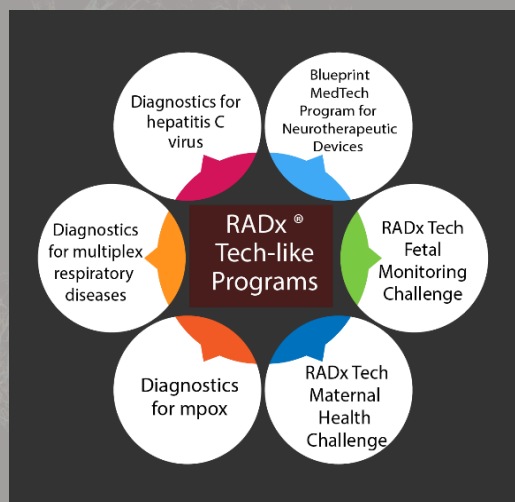
NIBIB is committed to supporting and disseminating solutions that will achieve our mission to transform, through technology development, our understanding of disease and its prevention, detection, diagnosis, and treatment.



Bruce J. Tromberg, Ph.D.,
NIBIB Director

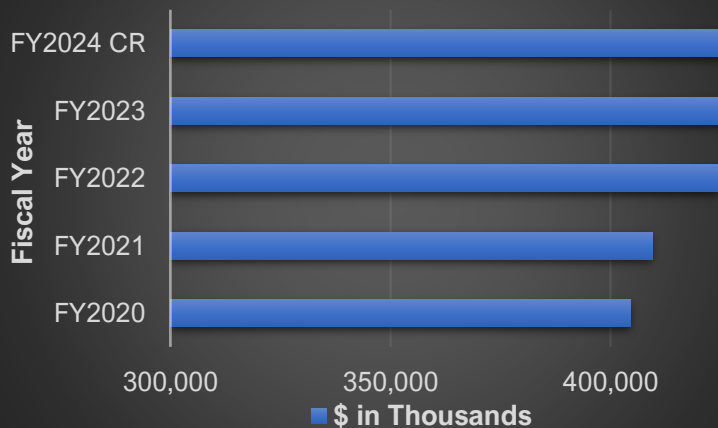
NIBIB Partnerships

The successes achieved during the pandemic have led NIBIB to leverage lessons learned and rethink its approach to technology development to address critical, unmet health care needs. The RADx Tech infrastructure is being utilized to build new programs that accelerate technology development, validation, and deployment – a “RADx-ification” process to engage partners in urgently needed areas such as neurological disorders and maternal health.



NIBIB by the Numbers
Average
FY 2020 - 2023

NIBIB Funding History



FY 2025 President's Budget is \$441,944,000. Note: In addition to the base budget, NIBIB received supplemental and intradepartmental delegation of authority funds of \$658 million in FY 2020, \$651 million in FY 2021, \$640 million in FY 2022, and \$0 million in FY 2023.

DEIA at NIBIB

Technology development is an inherently inclusive and interdisciplinary field that requires diverse approaches, perspectives, and ideas to be successful. NIBIB is strongly committed to increasing and supporting diversity, equity, inclusion, and accessibility (DEIA) at NIBIB and throughout the biomedical research community by supporting and optimizing its programs.



Since 2019, NIBIB's summer intern research experience program has hosted about 14 interns. This year in a planned expansion there were 22 interns, about a 57 percent increase over previous years.

Early Career Researchers

NIBIB's unique Trailblazer R21 program awards are geared toward early-career investigators that are pursuing a broad range of biomedical research. Underrepresented groups are strongly encouraged to apply to the program. The program exemplifies NIBIB's commitment to fostering the growth and diversity of the bioengineering workforce. A signature element of the grant application is the lack of a requirement to include preliminary data that demonstrates project feasibility, which is often needed for other NIH grant mechanisms. Successes include:

- ~41 grants funded on average FY 2019-2023
- ~ 87 percent funded grants (FY 2018-2020) resulted in peer-review publication
- ~ 64 percent funded trailblazer PIs (FY 2018-2020) received subsequent NIH funding

Enhancing Science, Technology, Engineering, and Math Educational Diversity (ESTEEMED)

NIBIB undergraduate research education program that provides mentoring, community-building, educational, and career development activities and hands-on research experience to students.

- 259 students engaged total
- 95 active students enrolled in undergraduate programs
- 15 institutions
 - 2 Historically black colleges and universities
 - 3 Hispanic-serving institutions

NIBIB-Supported Technologies

Biomedical Engineering and Technology Acceleration (BETA) Center

A multi-institute NIH resource that accelerates the development, validation, and dissemination of high-impact biomedical technologies to address urgent national and global health needs

- Established January 2023
- 74 affiliate investigators from 15 NIH institutes
- Recruited and funded 16 students in NIH training programs (undergraduate, post-baccalaureate, and graduate levels)
- Experts and resources that span the spectrum of bioimaging and bioengineering fields

RADx Tech Updates



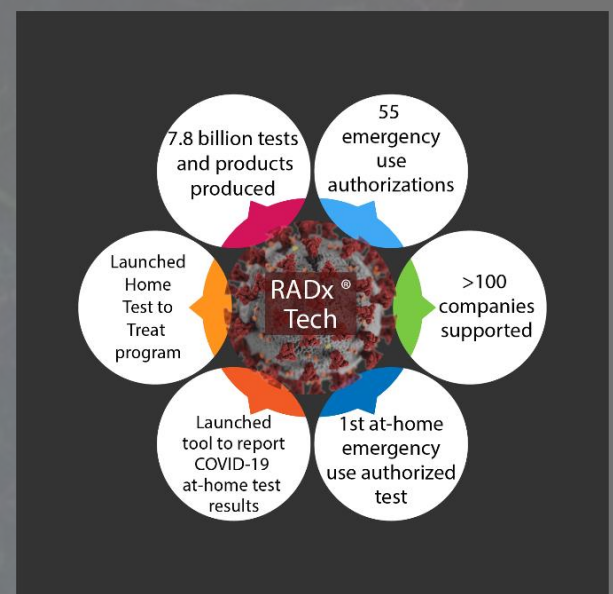
RADx® Tech continues to speed commercialization of innovative point-of-care and more accessible home-based tests for nationwide COVID-19 testing.



Multi-coil array that makes up a head-only scanner for magnetic resonance imaging (MRI). The new design will make MRI more compact and portable.



The first wireless, cable-free wearable device with printed electronic circuits that monitor cardiovascular signals and multiple biochemical levels at the same time.



Major Changes in the 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 2025 President's Budget for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). The FY 2025 President's Budget request for NIBIB is \$441.9 million, an increase of \$1.3 million or 0.3 percent compared with the FY 2023 Final level.

Research Project Grants (RPGs) (-\$10.3 million; total \$296.9 million):

NIBIB will fund 661 RPG awards in FY 2025, a decrease of 35 awards from the FY 2023 Final level. This includes 468 noncompeting awards, a decrease of 20 awards and \$4.1 million from the FY 2023 Final level; 172 competing RPGs, a decrease of 15 awards and \$6.7 million from the FY 2023 Final level; and 21 SBIR/STTR awards which is equal to the FY 2023 Final level. Noncompeting awards will be funded at the FY 2024 committed level. The average cost of competing RPGs will stay equal to the FY 2023 Final level.

Research Centers (-\$1.7 million; total \$32.2 million):

NIBIB will fund 26 Center awards in FY 2025, a decrease of 1 award and \$1.7 million from the FY 2023 Final level.

Other Research (-\$0.3 million; total \$10.2 million):

NIBIB will fund 89 Other Research awards in FY 2025, a decrease of 4 awards and \$0.3 million from the FY 2023 Final level.

Research Training Awards (-\$0.7 million; total \$10.3 million):

NIBIB will fund 188 Full-Time Training Positions (FTTPs) in FY 2025, a decrease of 18 FTTPs from the FY 2023 Final level.

Research and Development (R&D) Contracts (+\$2.9 million; total \$23.0 million):

NIBIB will fund 12 R&D Contracts in FY 2025, an increase of 2 contracts from the FY 2023 Final level.

Intramural Research (+\$2.7 million; total \$28.0 million):

Intramural Research will increase by 10.9 percent from the FY 2023 Final level, due to NIBIB organizing a trans-NIH Center for Biomedical Engineering and Technology Acceleration (BETA Center) that will accelerate the development, validation, and dissemination of high-impact biomedical technologies to address urgent national and global health needs. The BETA Center will be comprised of researchers with specialized expertise in areas such as biomedical imaging, biosensing, engineered/synthetic biology, nano/biomaterials, artificial intelligence, modeling, computation, and informatics. As part of this effort, NIBIB's intramural full-time equivalent (FTE) employees are projected to increase by 12 from FY 2023.

Research Management & Support (RMS) (+\$8.7 million; total \$41.3 million):

RMS will increase by 26.7 percent from the FY 2023 Final level. NIBIB has continued to expand its communication, information technology, budget and administrative efforts and website presence to provide timely information to researchers, and Congress. Increased RMS activity will include the organization of an Information Technology Review Board to evaluate new data analytic tools for extramural modeling and human resources/budget systems. As part of these efforts, NIBIB's RMS employees are projected to increase by 25 FTE from FY 2023.

BUDGET MECHANISM TABLE

NATIONAL INSTITUTES OF HEALTH National Institute of Biomedical Imaging and Bioengineering

Budget Mechanism * (Dollars in Thousands)

Mechanism	FY 2023 Final		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
<u>Research Projects:</u>								
Noncompeting	488	\$207,962	468	\$203,834	468	\$203,834	-20	-\$4,128
Administrative Supplements	(22)	\$1,727	(28)	\$2,195	(28)	\$2,195	(6)	\$468
<u>Competing:</u>								
Renewal	17	\$9,637	14	\$9,609	14	\$9,609	-3	-\$28
New	170	\$74,142	158	\$67,455	158	\$67,511	-12	-\$6,631
Supplements	0	\$0	0	\$0	0	\$0	0	\$0
Subtotal, Competing	187	\$83,779	172	\$77,064	172	\$77,120	-15	-\$6,659
Subtotal, RPGs	675	\$293,468	640	\$283,093	640	\$283,149	-35	-\$10,319
SBIR/STTR	21	\$13,722	21	\$13,750	21	\$13,750	0	\$28
Research Project Grants	696	\$307,190	661	\$296,843	661	\$296,899	-35	-\$10,291
<u>Research Centers</u>								
Specialized/Comprehensive	5	\$6,839	4	\$4,450	4	\$4,450	-1	-\$2,389
Clinical Research	0	\$0	0	\$0	0	\$0	0	\$0
Biotechnology	22	\$27,119	22	\$27,766	22	\$27,766	0	\$647
Comparative Medicine	0	\$0	0	\$0	0	\$0	0	\$0
Research Centers in Minority Institutions	0	\$0	0	\$0	0	\$0	0	\$0
Research Centers	27	\$33,959	26	\$32,216	26	\$32,216	-1	-\$1,743
<u>Other Research:</u>								
Research Careers	27	\$3,588	28	\$3,807	28	\$3,807	1	\$219
Cancer Education	0	\$0	0	\$0	0	\$0	0	\$0
Cooperative Clinical Research	0	\$0	0	\$0	0	\$0	0	\$0
Biomedical Research Support	0	\$0	0	\$0	0	\$0	0	\$0
Minority Biomedical Research Support	0	\$0	0	\$0	0	\$0	0	\$0
Other	66	\$6,928	61	\$6,437	61	\$6,437	-5	-\$491
Other Research	93	\$10,516	89	\$10,244	89	\$10,244	-4	-\$272
Total Research Grants	816	\$351,665	776	\$339,303	776	\$339,359	-40	-\$12,306
<u>Ruth L. Kirschstein Training Awards:</u>	<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>	
Individual Awards	7	\$377	12	\$665	12	\$665	5	\$288
Institutional Awards	199	\$10,654	179	\$9,633	176	\$9,633	-23	-\$1,021
Total Research Training	206	\$11,031	191	\$10,298	188	\$10,298	-18	-\$733
Research & Develop. Contracts	10	\$20,065	12	\$22,780	12	\$22,979	2	\$2,914
SBIR/STTR (non-add)	(0)	(\$151)	(0)	(\$151)	(0)	(\$151)	(0)	(\$0)
Intramural Research	35	\$25,262	47	\$27,520	47	\$28,003	12	\$2,741
Res. Management & Support	88	\$32,602	113	\$40,726	113	\$41,305	25	\$8,703
SBIR Admin. (non-add)		(\$248)		(\$248)		(\$248)		(\$0)
Construction		\$0		\$0		\$0		\$0
Buildings and Facilities		\$0		\$0		\$0		\$0
Total, NIBIB	123	\$440,625	160	\$440,627	160	\$441,944	37	\$1,319

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

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, \$441,944,000.

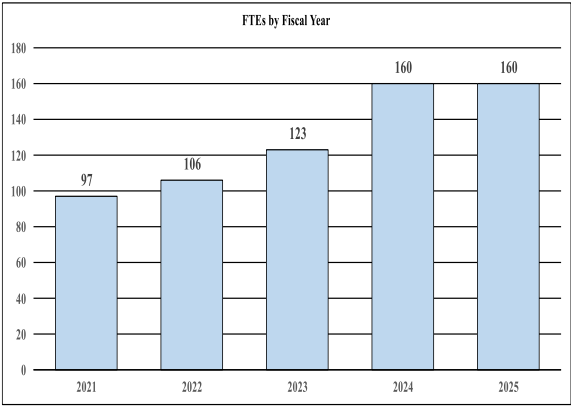
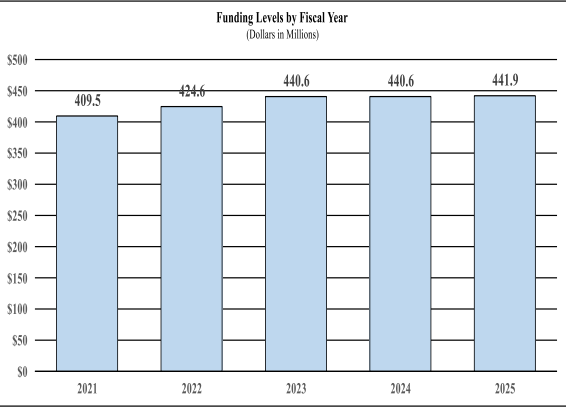
SUMMARY OF CHANGES

NATIONAL INSTITUTES OF HEALTH National Institute of Biomedical Imaging and Bioengineering

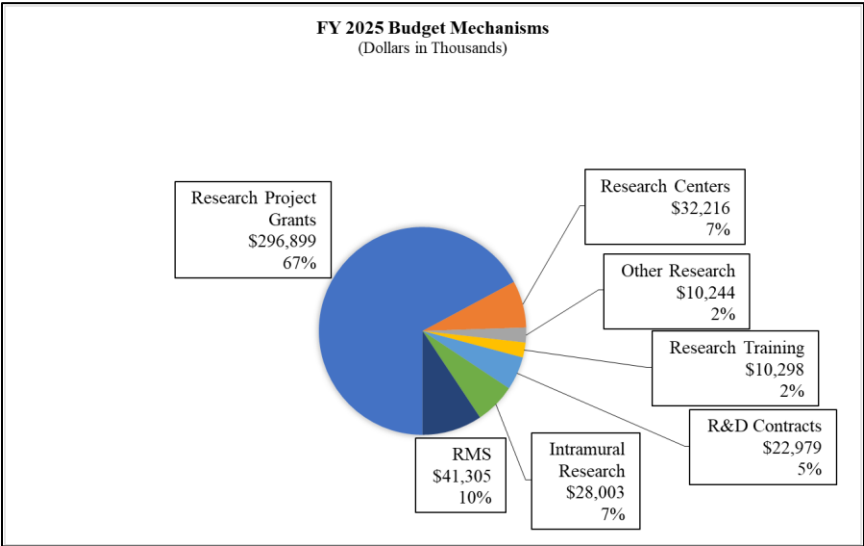
Summary of Changes (Dollars in Thousands)

CHANGES	FY 2023 Final		FY 2025 President's Budget		Built-In Change from FY 2023 Final	
	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
<u>1. Intramural Research:</u>						
<u>A. Built-in cost changes:</u>						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$7,131		\$9,162		\$84
b. FY 2024 effect of FY 2024 pay & benefits increase		\$7,131		\$9,162		\$278
c. FY 2024 paid days adjustment		\$7,131		\$9,162		\$27
d. Differences attributable to FY 2024 change in FTE		\$7,131		\$9,162		\$2,971
e. FY 2025 effect of FY 2024 pay & benefits increase		\$7,131		\$9,162		\$112
f. FY 2025 effect of FY 2025 pay & benefits increase		\$7,131		\$9,162		\$147
g. FY 2025 paid days adjustment		\$7,131		\$9,162		\$0
h. Differences attributable to FY 2025 change in FTE		\$7,131		\$9,162		\$0
i. Payment for centrally furnished services		\$3,157		\$3,385		\$228
j. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		\$14,962		\$15,456		\$980
Subtotal, IR built-in cost changes						\$4,828
<u>2. Research Management and Support:</u>						
<u>A. Built-in cost changes:</u>						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$15,851		\$21,750		\$188
b. FY 2024 effect of FY 2024 pay & benefits increase		\$15,851		\$21,750		\$616
c. FY 2024 paid days adjustment		\$15,851		\$21,750		\$61
d. Differences attributable to FY 2024 change in FTE		\$15,851		\$21,750		\$4,849
e. FY 2025 effect of FY 2024 pay & benefits increase		\$15,851		\$21,750		\$262
f. FY 2025 effect of FY 2025 pay & benefits increase		\$15,851		\$21,750		\$364
g. FY 2025 paid days adjustment		\$15,851		\$21,750		\$0
h. Differences attributable to FY 2025 change in FTE		\$15,851		\$21,750		\$0
i. Payment for centrally furnished services		\$0		\$0		\$0
j. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		\$16,727		\$19,555		\$864
Subtotal, RMS built-in cost changes						\$7,204
CHANGES	FY 2023 Final		FY 2025 President's Budget		Program Change from FY 2023 Final	
	No.	Amount	No.	Amount	No.	Amount
<u>B. Program:</u>						
<u>1. Research Project Grants:</u>						
a. Noncompeting	488	\$209,690	468	\$206,029	-20	-\$3,661
b. Competing	187	\$83,779	172	\$77,120	-15	-\$6,659
c. SBIR/STTR	21	\$13,722	21	\$13,750	0	\$28
Subtotal, RPGs	696	\$307,190	661	\$296,899	-35	-\$10,291
2. Research Centers	27	\$33,959	26	\$32,216	-1	-\$1,743
3. Other Research	93	\$10,516	89	\$10,244	-4	-\$272
4. Research Training	206	\$11,031	188	\$10,298	-18	-\$733
5. Research and development contracts	10	\$20,065	12	\$22,979	2	\$2,914
Subtotal, Extramural		\$382,761		\$372,636		-\$10,125
6. Intramural Research	35	\$25,262	47	\$28,003	12	-\$2,086
7. Research Management and Support	88	\$32,602	113	\$41,305	25	\$1,498
8. Construction		\$0		\$0		\$0
9. Buildings and Facilities		\$0		\$0		\$0
Subtotal, program changes						-\$10,713
Total built-in and program changes	123	\$440,625	160	\$441,944	37	\$1,319

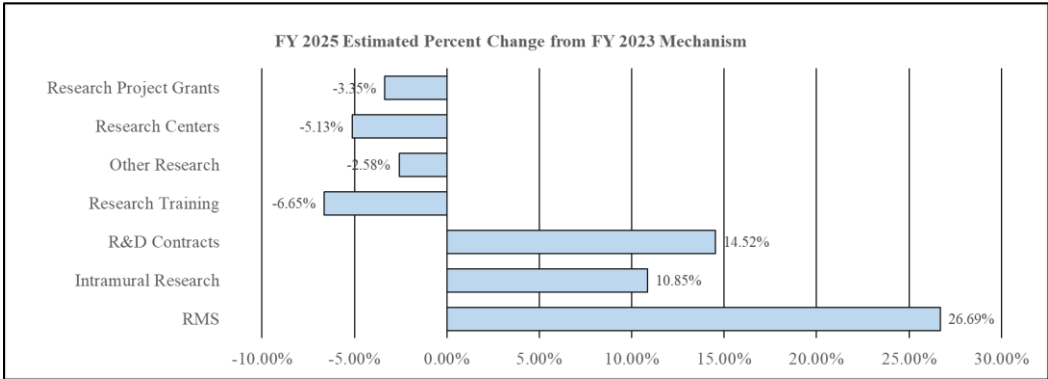
History of Budget Authority and FTEs:



Distribution by Mechanism:



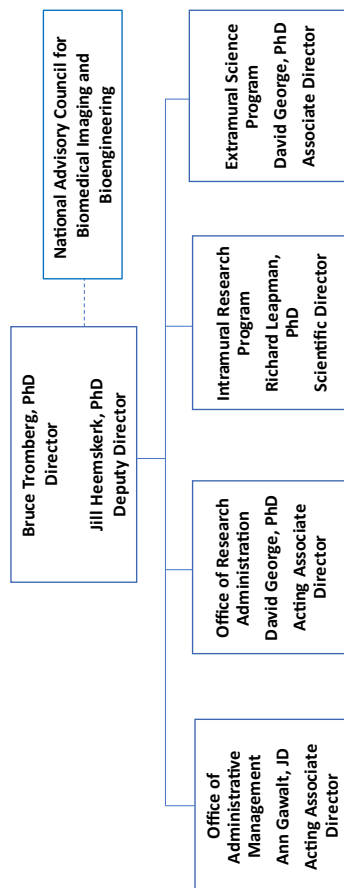
Change by Selected Mechanisms:





Overall Organizational Chart

National Institute of Biomedical Imaging and Bioengineering



BUDGET AUTHORITY BY ACTIVITY TABLE

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

Budget Authority by Activity *
(Dollars in Thousands)

	FY 2023 Final		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023 Final	
<u>Extramural Research</u>	<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		\$126,472		\$123,042		\$123,126		-\$3,346
Applied Science and Technology		\$188,132		\$183,030		\$183,155		-\$4,977
Interdisciplinary Training		\$25,948		\$25,244		\$25,261		-\$686
Health Informatics Technology		\$42,210		\$41,065		\$41,093		-\$1,117
Subtotal, Extramural		\$382,761		\$372,381		\$372,636		-\$10,125
Intramural Research	35	\$25,262	47	\$27,520	47	\$28,003	12	\$2,741
Research Management & Support	88	\$32,602	113	\$40,726	113	\$41,305	25	\$8,703
TOTAL	123	\$440,625	160	\$440,627	160	\$441,944	37	\$1,319

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

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 2023 Final	FY 2024 Continuing Resolution	FY 2025 President's Budget	FY 2025 +/- FY 2023
BA	\$440,625,000	\$440,627,000	\$441,944,000	\$1,319,000
FTE	123	160	160	37

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

Overall Budget Policy: The FY 2025 President's Budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is \$441.9 million, an increase of \$1.3 million or 0.3 percent compared with the FY 2023 Final level.

Program Descriptions and Accomplishments

To fulfill its mission, NIBIB spreads its investment in research and training across its extramural and intramural research programs. Key research areas drive the design, development, and dissemination of innovative technologies to improve human health. Core investment areas for NIBIB include biomedical imaging technologies, engineered biological systems, sensors and point-of-care (POC) devices, therapeutic systems and technologies, data science, modeling, and computation, and training a diverse biomedical workforce.

Division of Applied Science and Technology (DAST)

Biomedical imaging technologies are powerful tools that reveal fine details of anatomy to help clinicians and scientists understand human biology and disease. Advancements in these technologies can range from guiding surgery or delivery of a treatment to a portable, personalized medical imaging device for use in emergency or resource-limited settings. DAST supports a broad range of focus areas that span the basic and clinical research spectrum with the common goal of developing technologies that are more accessible, cost effective, and improve human health. Examples of advancements from investments by DAST include:

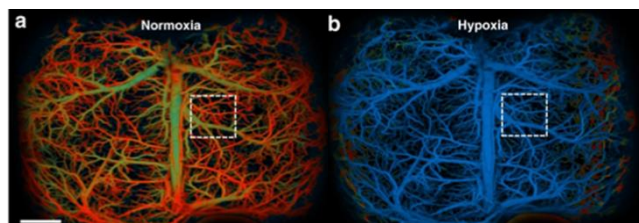
Ultra-fast imaging to study brain function

While advancements have been made, there is much to learn about how the human brain functions in health and disease. Brain imaging systems have been limited as research tools by their inability to produce high-resolution images that can measure real-time changes in the brain. NIBIB-supported researchers are developing a new photoacoustic imaging system that can

visualize functional and molecular changes in the brain that result from major brain disorders (such as stroke) while the changes are happening.

The researchers developed ultrafast functional photoacoustic microscopy (UFF-PAM) to image blood vessel function in real time across an entire mouse brain. In a mouse model of stroke, UFF-PAM detected an unexpected narrowing of blood vessels originating from the area of the stroke and spreading across the brain.² Researchers observed that this caused a clear reduction in oxygen to the brain beyond where the stroke initiated. In a clinical setting, this imaging technique could be further

developed to indicate the extent of potential damage from a stroke to better inform treatment. In a separate study, UFF-PAM showed a surge in oxygen around the placenta in the presence of alcohol. This is a significant finding because the placenta normally works to keep the oxygen concentration low as a fetus develops. This result suggests that fetal abnormalities could be due to a toxic increase in oxygen in response to alcohol.



UFF-PAM image of whole brain blood oxygenation in mice under normal conditions (normoxia) on the top and dramatically reduced oxygen (hypoxia) on the bottom. Credit: Zhu, X., et al. Light Sci Appl 11, 138 (2022).

Ultrasound delivers oxygen to tumors to make treatment more effective

Unlike most tissues and cells in our bodies, tumors can grow under low-oxygen (hypoxic) conditions and become more resistant to cancer treatments like radiation. One type of cancer that is especially hypoxic and resistant to radiation therapy is head and neck cancer. NIBIB-funded researchers led a study that used ultrasound plus tiny bubbles to deliver oxygen and a cancer drug that inhibits cancer growth (lonidamine) specifically at the tumor site. Researchers cast ultrasound waves directly at the tumor, causing the bubbles to burst and release oxygen and the cancer drug. Mice given oxygen, radiation, lonidamine, and metformin (which enhances radiation treatment) had a higher probability of survival compared with mice that received less than the full treatment regimen.³ Ongoing efforts are focused on optimizing radiation and drug doses to achieve the best results.

Imaging agents can target liver fibrosis and low-oxygen areas in the body

NIBIB supports the development of non-invasive imaging techniques, such as magnetic resonance imaging (MRI), to enable earlier disease detection and more successful subsequent treatments. Current MRI technologies are partially limited by contrast agents, which are compounds that are given to the patient prior to imaging that enhance the visibility of target tissues. NIBIB-funded researchers are developing a new MRI contrast agent that specifically detects collagen accumulation in fibrotic liver tissue, a signature feature of liver fibrosis. Liver

² Zhu X, et al. Real-time whole-brain imaging of hemodynamics and oxygenation at micro-vessel resolution with ultrafast wide-field photoacoustic microscopy. *Light Sci Appl*. 2022 May 17;11(1):138. doi: 10.1038/s41377-022-00836-2. PMID: 35577780

³ Quezia Lacerda et al. Improved Tumor Control Following Radiosensitization with Ultrasound-Sensitive Oxygen Microbubbles and Tumor Mitochondrial Respiration Inhibitors in a Preclinical Model of Head and Neck Cancer. *Pharmaceutics* (2023). DOI: 10.3390/pharmaceutics15041302.

REMARKABLE ADVANCES IN DIAGNOSTIC ULTRASOUND TECHNOLOGIES

NIBIB-funded researchers have been making great strides in advancing ultrasound technologies. Diagnostic ultrasound is a non-invasive technique that can produce images of internal organs or structures by using sound waves and their resulting echoes to image tissues inside the body. One common and well-known use of diagnostic ultrasound is during pregnancy to monitor the development of a fetus.

In the past two years, NIBIB has made significant advances in a new use of ultrasound: a wearable, non-invasive ultrasound patch that can monitor chronic illness or detect early warning signals of disease. Most patches in development have a major limitation — they require cables to power the device and transmit the ultrasound data, physically tethering the wearer to a control system. A team of NIBIB-funded researchers has developed a fully wireless ultrasound patch that can continuously track critical vital signals such as heart rate and blood pressure. The ultrasound system is composed of a probe, a circuit, and a battery. As the current system was designed with a focus on cardiovascular health, the ultrasound probe was typically placed on the carotid artery in this study. In combination with AI methods, the patch could track the pulsations of the carotid artery with high accuracy, allowing measurements of blood pressure and cardiac output. This ultrasound advance, which could allow the remote monitoring of critical physiological functions in the comfort of a patient's home, has the potential to revolutionize health care.

Another group is pairing cutting-edge ultrasound techniques with AI to diagnose thyroid cancer. Traditional ultrasound does not always differentiate between cancerous and benign thyroid tumors, leading to unnecessary thyroid biopsies and causing significant financial and physical burden to patients. The new method—named high-definition microvasculature imaging, or HDMI—noninvasively captures images of the tiny vessels within tumors and, based on the vessel features, automatically classifies the masses as cancerous or not. Researchers imaged tumors with HDMI and measured a dozen features related to the size and shape of the microvasculature in the images, including their density and number of branching points. The researchers used the HDMI data and biopsy data from the tumors to develop an AI algorithm that was accurate 89 percent of the time when compared to clinical assessments of biopsies. The findings indicate that HDMI could be a stronger diagnostic approach than conventional ultrasound imaging and could save patients from unneeded biopsy surgery in the future. Researchers will continue to develop AI methods to improve accuracy.

fibrosis is a condition where excessive connective tissue forms in the liver, contributing to chronic disease and leading to morbidity and mortality worldwide. Currently, an invasive biopsy is the only method to detect the onset of liver fibrosis, and biopsies at early stages of disease may miss the location of fibrosis in the organ leading to misdiagnosis. The contrast agents have shown promise in mouse models of liver fibrosis, with rapid signal detection at low doses and with low toxicity compared to traditional imaging agents.⁴ This platform could be modified to specifically target other types of tissue damage or disease, which would represent a major advance in the utility of MRI in the clinic.

NIBIB-funded researchers are also developing new MRI contrast agents that are activated in hypoxic environments. The new imaging agent uses europium, a rare-earth metal, which generates a bright MRI signal in these low-oxygen areas. However, europium is inactivated when exposed to oxygen as it travels through the bloodstream to reach the hypoxic tissue or tumor, thereby preventing an MRI signal from being detected. To keep the contrast agent in its active state, the researchers engineered a chemical cage to protect the europium as it travels throughout the body. In a mouse study, the contrast agent survived after several minutes in an oxygen-rich environment and provided a persistent MRI signal.⁵ Future studies will involve more extensive testing in mouse disease models before translation to clinical use in humans.

Budget policy: The FY 2025 President's Budget request for the DAST is \$183.2

⁴ Fast detection of liver fibrosis with collagen-binding single-nanometer iron oxide nanoparticles via T1-weighted MRI. Zhang J, et al. Proc Natl Acad Sci U S A. 2023 May 2;120(18):e2220036120. doi: 10.1073/pnas.2220036120. Epub 2023 Apr 24. PMID: 37094132

⁵ Mamunur Rashid, et al. Journal Systemic Delivery of Divalent Europium from Ligand Screening with Implications to Direct Imaging of Hypoxia. Md of the American Chemical Society 2022 144 (50), 23053-23060 DOI: 10.1021/jacs.2c10373

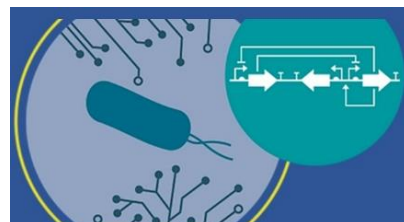
million, a decrease of \$5.0 million or 2.6 percent compared with the FY 2023 Final level.

Division of Discovery Science and Technology (DDST)

Building on decades of basic research, devices and biological processes can now be engineered to directly regulate human physiology and monitor biological functions. DDST develops broadly applicable biomedical technologies to enable new paradigms of human health. The division also works to help researchers break down translational barriers between the bench and bedside so that technologies are well-positioned for dissemination when ready. Key investment areas for NIBIB include bionics, medical devices, robotics, synthetic biology, and biomaterials. Highlights of research supported in this area include:

Engineering live DNA sensors for pathogen detection

NIBIB supports synthetic biology engineers that are designing bacteria that detect fragments of DNA from infectious pathogens. Pathogen DNA is likely to be present before symptom onset, and early detection could lead to higher rates of treatment success, especially in fast-moving, deadly diseases like sepsis. The team of engineers harnessed the natural ability of *Bacillus subtilis* to capture DNA from its surroundings. In this study, a series of genes was integrated into the bacterium's genome that included the target pathogen DNA that researchers wanted to detect. The engineered DNA sensor was able to detect many human bacterial pathogens like *E. coli*, *Salmonella typhimurium*, and *Staphylococcus aureus*.⁶ The researchers will continue to develop this low-cost, flexible approach to detect the presence of harmful bacteria and viruses in clinical samples and in the gut.



Bacterial DNA sensors contain genetic programs that direct them to detect specific organisms such as human pathogens in biological or environmental samples. Credit: Venturelli laboratory, University of Wisconsin, Madison, Wisconsin.

New skin cell function could improve healing from burns

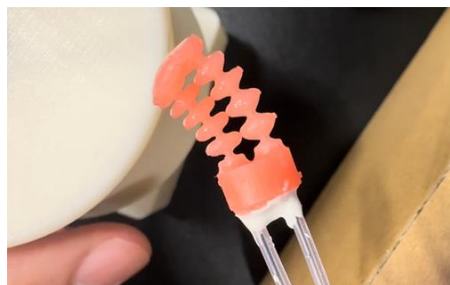
For wounds to heal, the body needs to remove damaged tissue and replace it with new, healthy tissue. Imbalances in the removal and rebuilding process result in poor healing. Previously, it was thought that immune cells removed damaged tissue while fibroblast cells rebuilt tissue. Using a miniature skin tissue model that did not contain any immune cells, NIBIB-funded researchers simulated common skin injuries, including a burn and a cut.⁷ Because damage-removing immune cells were excluded from their model, they expected that both types of injury would start closing immediately. However, the burn was seen to widen over the course of many hours, while the cut began to close within minutes. Further studies showed that the fibroblast cells were clearing damaged burn tissues through a process known as phagocytosis. This surprising discovery suggests new approaches to developing targeted therapies that can speed healing from burns.

⁶ Cheng YY et al. Programming bacteria for multiplexed DNA detection. Nat Commun. 2023 Apr 10;14(1):2001. doi: 10.1038/s41467-023-37582-x. PMID: 37037805

⁷ Megan Griebel et al. Fibroblast clearance of damaged tissue following laser ablation in engineered microtissues. APL Bioengineering (2023). DOI: 10.1063/5.0133478

Tumor-specific drug delivery with nanozymes

While some NIBIB-funded research centers on identifying new targets for future treatments, other studies focus on improving current therapies. Chemotherapy can be an effective cancer treatment, but it kills normal cells along with tumor cells, so doses must be limited to avoid severe side effects. One strategy is to deliver inactive forms of chemotherapeutic drugs throughout the body that can be activated at the target tumor site. This method could substantially reduce side effects while exposing the tumor to higher, more effective drug doses. Nanozymes are artificial enzymes, nanometers in size, that carry out a pre-determined chemical reaction. NIBIB-funded researchers are developing a nanozyme that can turn a prodrug form of a common chemotherapeutic drug, fluorouracil, into its active form. By injecting the nanozyme into breast tumors in mice, they activated the drug specifically within the tumors, shrinking them just as effectively as standard fluorouracil chemotherapy treatments but with less damage to the liver.⁸ Further work will focus on translating this approach to the clinic in hopes of increasing the effectiveness and tolerability of chemotherapy treatment.



Air pressure within the two channels of the robotic catheter tip determines whether it deflects left or right. Credit: Noah Barnes, Department of Mechanical Engineering, Johns Hopkins University, Baltimore, Maryland.

Minimally invasive surgery with a novel soft robotic system

Many minimally invasive surgeries, like the insertion of a catheter, require surgeons to maneuver tools throughout the complex anatomy of the body. It is often difficult for a surgeon to control the position of a tool inside the body. The design of an effective soft robotic system could give surgeons more control and lead to better patient outcomes. A group of bioengineers designed and evaluated a preliminary robotic system that controlled a steerable catheter tip. In simulated tests, the robotic system allowed both a novice and skilled surgeon to place the catheter tip at the desired location with sub-millimeter accuracy within 10 seconds.⁹ The system will continue to be adapted to improve the ease and accuracy of other minimally invasive surgeries.

Budget policy: The FY 2025 President's Budget request for the DDST is \$123.1 million, a decrease of \$3.3 million or 2.6 percent compared with the FY 2023 Final level.

Division of Health Informatics Technologies (DHIT)

Advancements in health informatics, sensor technologies, and POC technologies – from medical image processing to at-home telehealth programs – are transforming health care delivery and management. DHIT invests in the development of technologies that process and evaluate complex biomedical information for health care solutions that are practical and patient-centered. Applications include clinical decision-making support systems, in-home treatment monitoring, medical image improvement, next-generation intelligent image and data analysis tools, and

⁸ Zhang X, et al. Bioorthogonal nanozymes for breast cancer imaging and therapy. *J Control Release*. 2023;357:31-39. doi:10.1016/j.jconrel.2023.03.032

⁹ Barnes, N. et al. Toward a novel soft robotic system for minimally invasive interventions. *Int J CARS* 18, 1547–1557 (2023). doi.org/10.1007/s11548-023-02997-w

mobile health. Support in this area has led to exciting advancements that bring imaging, diagnosis, and treatment to a patient's home and to low-resource settings. These include:

Using Artificial Intelligence (AI) to help monitor patients after surgery

Following the millions of in-patient surgeries that are performed in U.S. hospitals each year, health care workers must determine whether patients need to be in the intensive care unit (ICU) or can recover in a non-ICU room. In the ICU, trained staff continuously monitor patients, consuming an immense number of resources that results in costs that are two to five times more expensive than non-ICU stays.¹⁰ Prior research has shown that some patients do not have a better outcome in the ICU and that a non-ICU room would have been sufficient during their recovery. Unfortunately, there is no objective standard to identify the patients who would benefit from recovery in the ICU. Using AI, NIBIB-funded researchers are developing a decision-support platform to help monitor patients after surgery and to help determine whether they would benefit from monitoring in the ICU. The study found that of the 4,669 post-surgery ICU admissions, about 237 (5.1 percent) ICU admissions were unnecessary, overall care was not improved by admittance to the ICU, and their hospital stay was significantly more expensive. Among the 8,594 non-ICU admissions, 1,029 (12.0 percent) would have had less expensive hospital stays overall if their recovery had been managed in the ICU.¹¹ Further testing of this AI decision-support system has the potential to identify the most appropriate care for each patient after surgery, reduce health care costs, and make the best use of hospital resources.

Enabling patients to produce high-quality medical images at home

During the COVID-19 pandemic, hospitals were faced with dangerous overcrowding. This led NIBIB-funded researchers to determine if some patients could potentially be monitored at home by obtaining their own diagnostic ultrasound scans. In the study, images acquired by ultrasound experts were compared with those taken by unexperienced adult volunteers. Thirty volunteers with no previous experience operating an ultrasound were provided with a portable device and a visual tutorial. In their homes, participants scanned eight different zones across their chest and sides to obtain images of their lungs. Experts then produced the same eight images from the participants in a hospital. Independent experts scored the diagnostic quality of all images without knowing who took the scans. Assessing the scores of both novice- and expert-acquired images, the researchers found



Study participants scanned themselves with ultrasound at home as part of a study aimed at uncovering whether patients could produce high-quality diagnostic images outside of the clinic. Credit: Duggan et al. Brigham and Women's Hospital

¹⁰ Loftus, Tyler J MD et al. Overtriage, Undertriage, and Value of Care after Major Surgery: An Automated, Explainable Deep Learning-Enabled Classification System. *Journal of the American College of Surgeons* 236(2):p 279-291, February 2023. | DOI: 10.1097/XCS.0000000000000471

¹¹ Loftus, Tyler J MD et al. Overtriage, Undertriage, and Value of Care after Major Surgery: An Automated, Explainable Deep Learning-Enabled Classification System. *Journal of the American College of Surgeons* 236(2):p 279-291, February 2023. | DOI: 10.1097/XCS.0000000000000471

no significant differences.¹² These findings suggest that portable ultrasound devices, developed for use in emergency settings, could potentially be used by patients in their homes to allow remote monitoring of their condition, avoid unnecessary hospital visits, and reduce health care costs.

Home Test to Treat – a pilot telehealth program brings COVID-19 tests and treatments to patients’ homes

NIBIB, in collaboration with the Administration for Strategic Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC), launched a unique, entirely virtual community health intervention program. The nationwide Home Test to Treat program provides at-home rapid COVID-19 and flu tests, telehealth sessions, and lifesaving treatments to underserved populations. Participants receive free tests and treatments without ever leaving home. The program promotes equitable health care approaches and helps to identify best practices that may save lives in future pandemics. The research team will identify and implement improvements that leave public health authorities in a much better position to respond to future emergencies at the local, state, and federal levels. Findings from this program will also inform the broader implementation of telemedicine as a lower-cost approach to routine health care in the future.

Data-driven approach aims to improve health research in Africa

NIBIB plays a leadership role in the NIH Common Fund’s Data Science for Health Discovery and Innovation in Africa (DS-I Africa) program that is building a technology research consortium across the continent. The program aims to develop and use data-driven medical technologies to lessen the disproportionate global disease burden that Africa carries. NIBIB manages the Data Coordinating Center in Cape Town, South Africa, which supports all seven research centers and seven training hubs. The Data Coordinating Center facilitates collaboration among research centers and provides access to health care data and analytical tools. The training hubs focus on instructing students how to apply data science concepts to medicine and public health and the related legal, ethical, and social issues associated with data science approaches. NIBIB will continue expanding this program through new partnerships and pilot projects.

Budget policy: The FY 2025 President’s Budget request for the DHIT is \$41.1 million, a decrease of \$1.1 million or 2.6 percent compared with the FY 2023 Final level.

Division of Interdisciplinary Training (DIDT)

Challenging health care problems continuously increases the demand for advancement in biomedical technologies, which will require a skilled and diverse workforce. DIDT supports research training to develop the next generation of interdisciplinary bioimagers and bioengineers. NIBIB supports training programs from undergraduate education to early career investigators with advanced degrees. Through its signature programs, DIDT works to bring specialized experiences and mentorship to college students to build enthusiasm for bioengineering and bioimaging careers. Several undergraduate-level programs that underscore NIBIB’s commitment to workforce diversity and development are highlighted below:

¹² Nicole Duggan et al. Novice-performed point-of-care ultrasound for home-based imaging. *Scientific Reports* (2022). DOI: 10.1038/s41598-022-24513-x.



Prototype of the EpicPen. Credit: Purdue University, West Lafayette, IN

Design by Biomedical Undergraduate Teams (DEBUT) Challenge

NIBIB continues to expand its premiere bioengineering design competition for undergraduate students, the DEBUT Challenge. DEBUT offers undergraduate student teams the opportunity to develop technology solutions to unmet needs in health care and has grown to include 15 prizes from NIH institutes and offices and 1 non-profit partner. In 2023, DEBUT received its highest number of proposals to date – 100 designs from 451 students.

The 2023 winning project was a low-cost, epinephrine

auto-injector (the “EpicPen”). Unlike single-use injectors, this one is reloadable and reusable. Its economical design could provide more people with access to the life-saving drug. The second-place team redesigned the speculum, an instrument used in gynecological exams. The new model is designed to cause less pain and does not inhibit a physician’s line of sight. The third-place winners created a device to position and immobilize the breast during MRI-guided breast biopsies, making more of the breast accessible to biopsy than the current methods. The DEBUT program is a glimpse into the innovative technology that NIBIB anticipates these students will bring to the future of bioimaging and bioengineering.

Team-Based Design in Biomedical Engineering Education

This program supports undergraduate courses that are focused on team-based biomedical design projects. These projects aim to prepare future biomedical researchers to develop and accelerate the translation of biomedical technologies for improved health. Projects incorporate activities that address topics like health equity and universal design and encourage interaction between students at different career/education levels.

An important component of research capacity building is co-curricular activities, which are activities that complement the curriculum and take place outside of a traditional classroom. Co-curricular activities are an integral part of engineering education and often lead to increased student engagement. NIBIB-funded researchers, as a part of the Team-Based Design in Biomedical Engineering Education program, have developed a valuable method for undergraduate biomedical engineering students to collaborate with non-profit organizations on a common project that establishes strong co-curricular activities to build organizational research capacity. Their research followed two case studies with different non-profits: (1) students provided programming and assistive technologies to children with severe disabilities and (2) students helped repurpose donated medical devices for humanitarian aid. For both the students and non-profits to mutually benefit from the activity, the researchers created a framework built on three basic ideas.¹³ The collaboration between students and non-profits identified clear roles for both parties that ensured accountability and clear lines of communication. Students needed to understand how concepts they learned in the classroom were translated into practice in real-world applications. It was important to both students and non-profits to produce value for the

¹³ Reddy, A. et al. Co-curricular Immersion as a Public–Private Capacity Building Activity. *Biomed Eng Education* 3, 165–178 (2023). doi.org/10.1007/s43683-022-00098-9

end-user. Researchers believe this method can be scaled to larger groups and utilized in other educational settings.

Academic Research Enhancement Awards (AREA)

To increase research capacity and the biomedical workforce in the United States, NIH aims to catalyze research at academic institutions that have not historically received significant NIH support. Toward this goal, NIBIB participates in AREA, a program that provides grants to undergraduate-focused institutions that do not receive substantial NIH support. AREA seeks to improve the student biomedical research experience while enhancing the research environment at applicant institutions. NIBIB was able to support seven grants in FY 2023 which was a significant increase from the two grants supported in FY 2022.

In one awarded project, undergraduate students have the opportunity to participate in research efforts to develop a new assay to detect viral nucleic acids. This assay is designed to be more amenable to infectious pathogen detection in resource-limited settings than what is currently available. In another project, students are exposed to state-of-the-art biophotonic research to help detect early signs of stroke in children with sickle cell disease. Students are learning about computational analysis and designing and building optical instruments to gain valuable experience in human subject research.

Budget policy: The FY 2025 President's Budget request for the DDT is \$25.3 million, a decrease of \$0.7 million or 2.6 percent compared with the FY 2023 Final level.

Intramural Research Program (IRP)

The IRP plays a key role in fulfilling NIBIB's mission to advance knowledge in biomedical imaging and bioengineering research using a combination of basic, translational, and clinical science. Through effective training programs in these fields, the IRP also contributes to the U.S. biomedical technology workforce. An exciting new NIBIB bioengineering center that will serve as a key resource for NIH, along with new IRP research advances, are described below.

Accelerating innovation through collaboration and biomedical workforce diversity

NIBIB launched the BETA Center in January 2023 to provide intramural researchers across NIH with resources to drive promising technology innovations to commercialization and to increase DEI in the biomedical research workforce. Research includes biomedical imaging, biosensing, engineered biological systems, nano/biomaterials, AI, modeling, computation, and informatics. In its first year, the BETA Center has attracted 74 affiliated investigators from 15 different NIH institutes. The Center plans to (1) connect investigators across NIH with resources for imaging and engineering; (2) create a makerspace on the NIH campus to accelerate technology development through the design-build-test engineering process; (3) build bridges among NIH institutes and form new models of public-private partnership; (4) drive innovation and entrepreneurship at NIH; and (5) respond rapidly to urgent national biomedical challenges.

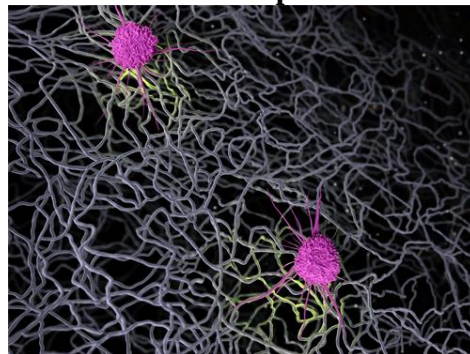
The BETA Center also expanded the long-standing NIBIB Biomedical Engineering Summer Internship Program (BESIP) to include students from underrepresented schools. A 2023 summer cohort brought together undergraduate students from minority-serving institutions, HBCUs, Hispanic-serving institutions, and a deaf-serving university. This program provided students

with their first in-person research experience in biomedical engineering labs. Four of these BETA Center-supported interns were accepted to present their work at the Biomedical Engineering Society Annual Meeting in Seattle.

Toward improving medical implants with new insights about the immune response

When a medical device is introduced into the body, a range of immune responses can occur. The triggered immune responses can harm or heal the body, and researchers have yet to determine why a specific response is elicited. Currently, when a person needs a medical device like a pacemaker implanted into their body, they are given an immunosuppressant to stymie any harmful immune response. Sometimes immunosuppressants are ineffective or pose serious risks to vulnerable patients.

NIBIB researchers in the Section on Immunoengineering implanted two biomaterials known to elicit opposite immune reactions into the injured muscles of mice to find a reason for the different reactions. One mouse was implanted with pig collagen tissue, which elicits a helpful immune response and has shown promise in treating abdominal injuries. The other mouse was implanted with a plastic used for orthopedic implants which can trigger harmful long-term inflammation. Cells from the mice were analyzed, and as expected the mice implanted with the pig collagen showed signs of repair while those implanted with the plastic showed little repair.¹⁴ The pig collagen mice had higher levels of dendritic cells, which help to regulate the immune system, at the site of implantation. Through further experiments, the researchers determined that a specific type of immune cell – the natural killer cell – was secreting chemical signals to summon the dendritic cells to the implantation area. The team will apply what they have learned to develop methods that dampen autoimmunity while amplifying regenerative processes.



The authors of a new study found that a pro-regenerative extracellular matrix recruited a cell type associated with self-tolerance and anti-inflammation to the implantation site. Credit: NIH Medical Arts

Specialized inner ear structures may help researchers understand deafness

NIBIB's Section on Mechanobiology studies the physical properties of specialized structures in the inner ear to better understand mechanisms related to deafness. Human hearing depends on elaborate mechanical and physical properties of the inner ear. NIBIB intramural researchers used atomic force microscopy (AFM) to map the patterns of stiffness of inner ear cell types from normal mice and mice that are deficient in genes that are associated with deafness. In the deafness mouse model, the AFM images revealed reduced stiffness in the specialized inner ear structures when compared to normal mice.¹⁵ The results of this study revealed previously unappreciated complexities of the mechanical properties of inner ear cells and suggested new underlying mechanisms of deafness.

¹⁴ Ravi Lokwani et al. The CD103-XCR1 axis mediates the recruitment of immunoregulatory dendritic cells after traumatic injury. *Nature Materials* (2023).

¹⁵ Baba Hosseini, H. et al. (2022). Unbalanced bidirectional radial stiffness gradients within the organ of corti promoted by triobp. *Proceedings of the National Academy of Sciences*, 119(26). doi.org/10.1073/pnas.2115190119

Budget policy: The FY 2025 President's Budget request for the IRP is \$28.0 million, an increase of \$2.7 million or 10.9 percent compared with the FY 2023 Final level.

Research Management and Support (RMS)

Effective support for research management activities, including administration, budget, logistics, scientific review, and communications, plays a major role in NIBIB's ability to achieve its mission successfully and efficiently. Through effective planning, NIBIB has aligned its programs and staffing to achieve its mission, including establishing DEIA workforce initiatives within NIBIB and filling key leadership positions throughout the Institute. The NIBIB Associate Director for DEIA and the Scientific Diversity Officer will be responsible for planning, developing, implementing, and evaluating diversity programs and initiatives. RMS also helped expand partnerships and collaborative networks which have been key in addressing critical unmet national and global health care needs. NIBIB is dedicated to using multiple mechanisms and pathways to promote public communication and understanding of how NIBIB brings together advances in engineering and the physical and life sciences that are essential for improving health and quality of life.

Budget policy: The FY 2025 President's Budget request for RMS is \$41.3 million, an increase of \$8.7 million or 26.7 percent compared with the FY 2023 Final level.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	\$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	\$408,498,000	\$411,496,000	\$403,638,000
Rescission				\$0
Supplemental				\$60,000,000
2021	\$368,111,000	\$407,109,000	\$417,815,000	\$410,728,000
Rescission				\$0
2022	\$422,039,000	\$431,081,000	\$421,617,000	\$424,590,000
Rescission				\$0
2023	\$419,493,000	\$437,991,000	\$437,752,000	\$440,627,000
Rescission				\$0
2024	\$440,625,000	\$440,627,000	\$440,627,000	\$440,627,000
Rescission				\$0
2025	\$441,944,000			

¹ Budget Estimate to Congress includes mandatory financing.

AUTHORIZING LEGISLATION

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

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2024 Amount Authorized	FY 2024 CR	2025 Amount Authorized	FY 2025 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	\$440,627,000	Indefinite	\$441,944,000
National Institute of Biomedical Imaging and Bioengineering	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$440,627,000		\$441,944,000

AMOUNTS AVAILABLE FOR OBLIGATION

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

Amounts Available for Obligation ¹

(Dollars in Thousands)

Source of Funding	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Appropriation	\$440,627	\$440,627	\$441,944
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(\$0)	(\$0)	(\$0)
<i>Other Mandatory financing</i>	(\$0)	(\$0)	(\$0)
Subtotal, adjusted appropriation	\$440,627	\$440,627	\$441,944
OAR HIV/AIDS Transfers	-\$2	\$0	\$0
Subtotal, adjusted budget authority	\$440,625	\$440,627	\$441,944
Unobligated balance, start of year	\$0	\$0	\$0
Unobligated balance, end of year (carryover)	\$0	\$0	\$0
Subtotal, adjusted budget authority	\$440,625	\$440,627	\$441,944
Unobligated balance lapsing	-\$35	\$0	\$0
Total obligations	\$440,590	\$440,627	\$441,944

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2023 - \$4,177

FY 2024 - \$10,200 FY 2025 - \$10,200

BUDGET AUTHORITY BY OBJECT CLASS

NATIONAL INSTITUTES OF HEALTH National Institute of Biomedical Imaging and Bioengineering

Budget Authority by Object Class¹ (Dollars in Thousands)

	FY 2024 CR	FY 2025 President's Budget
Total compensable workyears:		
Full-time equivalent	160	160
Full-time equivalent of overtime and holiday hours	0	0
Average ES salary	\$0	\$0
Average GM/GS grade	13.1	13.1
Average GM/GS salary	\$147	\$150
Average salary, Commissioned Corps (42 U.S.C. 207)	\$0	\$0
Average salary of ungraded positions	\$145	\$148
OBJECT CLASSES	FY 2024 CR	FY 2025 President's Budget
Personnel Compensation		
11.1 Full-Time Permanent	\$13,120	\$13,488
11.3 Other Than Full-Time Permanent	\$6,022	\$6,190
11.5 Other Personnel Compensation	\$686	\$705
11.7 Military Personnel	\$0	\$0
11.8 Special Personnel Services Payments	\$2,130	\$2,189
11.9 Subtotal Personnel Compensation	\$21,957	\$22,572
12.1 Civilian Personnel Benefits	\$8,070	\$8,340
12.2 Military Personnel Benefits	\$0	\$0
13.0 Benefits to Former Personnel	\$0	\$0
Subtotal Pay Costs	\$30,027	\$30,912
21.0 Travel & Transportation of Persons	\$428	\$437
22.0 Transportation of Things	\$97	\$100
23.1 Rental Payments to GSA	\$0	\$0
23.2 Rental Payments to Others	\$0	\$0
23.3 Communications, Utilities & Misc. Charges	\$17	\$17
24.0 Printing & Reproduction	\$0	\$0
25.1 Consulting Services	\$7,793	\$8,037
25.2 Other Services	\$10,290	\$10,516
25.3 Purchase of Goods and Services from Government Accounts	\$31,553	\$31,212
25.4 Operation & Maintenance of Facilities	\$13	\$13
25.5 R&D Contracts	\$358	\$366
25.6 Medical Care	\$367	\$381
25.7 Operation & Maintenance of Equipment	\$3,965	\$4,053
25.8 Subsistence & Support of Persons	\$0	\$0
25.0 Subtotal Other Contractual Services	\$54,339	\$54,578
26.0 Supplies & Materials	\$1,563	\$1,597
31.0 Equipment	\$3,773	\$3,856
32.0 Land and Structures	\$391	\$399
33.0 Investments & Loans	\$0	\$0
41.0 Grants, Subsidies & Contributions	\$349,977	\$350,032
42.0 Insurance Claims & Indemnities	\$0	\$0
43.0 Interest & Dividends	\$15	\$15
44.0 Refunds	\$0	\$0
Subtotal Non-Pay Costs	\$410,600	\$411,032
Total Budget Authority by Object Class	\$440,627	\$441,944

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Salaries and Expenses
(Dollars in Thousands)

Object Classes	FY 2024 CR	FY 2025 President's Budget
<u>Personnel Compensation</u>		
Full-Time Permanent (11.1)	\$13,120	\$13,488
Other Than Full-Time Permanent (11.3)	\$6,022	\$6,190
Other Personnel Compensation (11.5)	\$686	\$705
Military Personnel (11.7)	\$0	\$0
Special Personnel Services Payments (11.8)	\$2,130	\$2,189
Subtotal, Personnel Compensation (11.9)	\$21,957	\$22,572
Civilian Personnel Benefits (12.1)	\$8,070	\$8,340
Military Personnel Benefits (12.2)	\$0	\$0
Benefits to Former Personnel (13.0)	\$0	\$0
Subtotal Pay Costs	\$30,027	\$30,912
Travel & Transportation of Persons (21.0)	\$428	\$437
Transportation of Things (22.0)	\$97	\$100
Rental Payments to Others (23.2)	\$0	\$0
Communications, Utilities & Misc. Charges (23.3)	\$17	\$17
Printing & Reproduction (24.0)	\$0	\$0
<u>Other Contractual Services</u>		
Consultant Services (25.1)	\$7,793	\$8,037
Other Services (25.2)	\$10,290	\$10,516
Purchase of Goods and Services from Government Accounts (25.3)	\$20,537	\$20,163
Operation & Maintenance of Facilities (25.4)	\$13	\$13
Operation & Maintenance of Equipment (25.7)	\$3,965	\$4,053
Subsistence & Support of Persons (25.8)	\$0	\$0
Subtotal Other Contractual Services	\$42,599	\$42,783
Supplies & Materials (26.0)	\$1,563	\$1,597
Subtotal Non-Pay Costs	\$44,703	\$44,934
Total Administrative Costs	\$74,730	\$75,845

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE)

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

Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2023 Final			FY 2024 CR			FY 2025 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	53	-	53	60	-	60	60	-	60
Total:	53	-	53	60	-	60	60	-	60
Extramural Science Program									
Direct:	26	-	26	35	-	35	35	-	35
Reimbursable:	3	-	3	2	-	2	2	-	2
Total:	29	-	29	37	-	37	37	-	37
Office of Research Administration									
Direct:	3	-	3	6	-	6	6	-	6
Total:	3	-	3	6	-	6	6	-	6
Office of Administrative Management									
Direct:	3	-	3	10	-	10	10	-	10
Total:	3	-	3	10	-	10	10	-	10
Intramural Science Program									
Direct:	24	-	24	34	-	34	34	-	34
Reimbursable:	11	-	11	13	-	13	13	-	13
Total:	35	-	35	47	-	47	47	-	47
Total	123	-	123	160	-	160	160	-	160
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								
2021	13.0								
2022	13.0								
2023	13.1								
2024	13.1								
2025	13.1								

DETAIL OF POSITIONS

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

Detail of Positions ¹

GRADE	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Total, ES Positions	0	0	0
Total, ES Salary	\$0	\$0	\$0
General Schedule			
GM/GS-15	23	26	26
GM/GS-14	29	32	32
GM/GS-13	24	37	37
GS-12	13	16	16
GS-11	5	7	7
GS-10	1	1	1
GS-9	2	2	2
GS-8	0	0	0
GS-7	2	2	2
GS-6	0	0	0
GS-5	0	0	0
GS-4	1	1	1
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	101	125	125
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Junior Assistant	0	0	0
Subtotal	0	0	0
Ungraded	33	35	35
Total permanent positions	100	125	125
Total positions, end of year	134	160	160
Total full-time equivalent (FTE) employment, end of year	123	160	160
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	13.1	13.1	13.1
Average GM/GS salary	\$139,734	\$147,000	\$149,940

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