

and Bioengineering

National Institute of Biomedical Imaging and Bioengineering

CONGRESSIONAL JUSTIFICATION FY 2022

Department of Health and Human Services National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

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Images on cover: Upper left: A 3D-printed scaffold with grooves that carry live cells for implantation. *Credit: Jeff Fitlow/Rice University.* Upper right: Researchers have designed HIV-like particles that initiate a strong immune response from lab-grown human immune cells by folding DNA into a virus-like structure. *Credit: Veneziano et al., Massachusetts Institute of Technology.* Lower left: Label-free multiphoton image of live normal and cancerous tissue. *Credit: You et al., University of Illinois-Urbana-Champaign.* Lower right: Depiction of the range of possible interactions between proteins with multiple binding sites. *Credit: Errington et al., University of Minnesota.*

Director's Overview

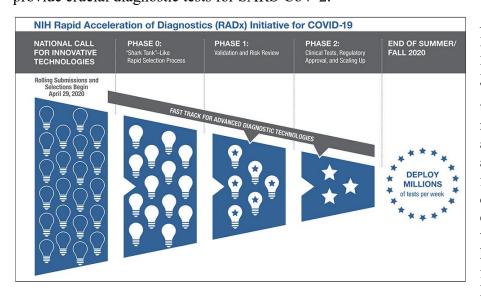
NIBIB's mission is to harness engineering to transform the understanding of disease and its prevention, detection, diagnosis, and treatment. NIBIB serves as the NIH hub for new technologies that are essential to improving the health of patients at risk from any disease or disorder. NIBIB's success in response to COVID-19 has demonstrated the power of engineering to address the most difficult biomedical challenges. NIBIB has brought key tools from the bioengineering arsenal to bear against the pandemic: technologies for diagnostics, digital health, and artificial intelligence (AI). These successes illustrate the strength of the engineering approach to quickly move solutions from blackboard to benchtop to bedside and even into the home.

During the Spanish flu epidemic more than 100 years ago, social distancing was the primary tool available to reduce the spread of the virus and save lives. While still needed in the COVID-19 pandemic,



Bruce J. Tromberg, Ph.D., Director

engineering discoveries can now dramatically speed the nation's return to normal activities. Testing is a critical point of control and NIBIB has risen to the challenge to provide crucial diagnostic tests for SARS-CoV-2.



NIBIB established the Rapid Acceleration of Diagnostics (RADxSM) Tech innovation funnel that is expanding the national testing capacity at unprecedented scale and speed. This is a fast-tracked, milestonedriven approach that employs vigorous vetting of proposals by hundreds of experts from across the country. RADxSM Tech reviewed

over 700 testing proposals and identified the most promising solutions in which to invest through a phased, competitive "Shark Tank" strategy. At this writing, RADxSM Tech has awarded contracts to manufacture and deliver 29 new tests for SARS-CoV-2 with more in the pipeline. With the FY 2020 investment, RADxSM Tech is increasing the U.S. testing capacity by several million tests per day and improving public access with novel tests designed for clinical, point-ofcare (POC), and home settings. These new tests include innovative solutions such as inexpensive tests that can provide results in minutes, tests that use comfortable self-administered swabs or saliva, and small desktop devices that have the accuracy of lab-based real-time reverse transcription polymerase chain reaction (RT-PCR) tests. RADxSM Tech innovations in laboratory testing have also increased the speed and throughput of testing in clinical labs, allowing results to be returned within a day. More broadly, the success of the RADxSM Tech program demonstrates the enormous potential for engineering to rapidly translate NIH discoveries into vital health solutions for the public across the biomedical spectrum.

NIBIB designed the RADxSM Tech innovation funnel to compress the customary technology development timeline from years down to just months. This was accomplished by employing, in parallel, expert teams to address technical, regulatory, clinical, and commercialization requirements. Challenges in all these areas typically hamper commercialization of new technologies and cause long delays in bringing lifesaving technologies to the public. This streamlined approach shaved years off the sequential and circuitous development path that new technologies must follow, which requires seeking funding from multiple disjointed sources. RADxSM Tech was able to validate, de-risk, scale up, manufacture, and deploy novel tests through a seamless pipeline that got them to the market at unprecedented speed. NIBIB believes



Examples of point-of-care devices for diagnosing SARS-CoV-2, the virus that causes COVID-19. Results are processed in 15 to 30 minutes and may be integrated with digital health platforms. Credit: Visby Medical, Luminostics, Inc., Quidel Corp., and Ellume.

this approach is a generalizable model to speed the delivery of new healthcare technologies for any disease or disorder and plans to apply elements of this strategy across its translational technology portfolios as resources allow.

In the immediate term, RADxSM Tech is expanding the U.S. COVID-19 testing capacity, while its longer-term impact will drive economic growth in the U.S. medical device industry. Because industry is naturally risk-averse, progress proceeds through iterative optimization of successful technologies. RADxSM Tech is de-risking and introducing novel technologies to the marketplace, where industry can build upon the innovation. New RADxSM Tech-like platforms can be adapted by industry for a range of public health needs, including emerging biomedical threats and chronic diseases such as cancer, heart disease, and diabetes. By supporting the growth and innovation in the medical device industry, RADxSM Tech will contribute importantly to keeping the U.S. at the forefront of biomedical discovery.

The second pillar of NIBIB's three-part response to the COVID-19 crisis focuses on digital health solutions for managing population health and individual safety during the pandemic. NIBIB has invested supplemental funds to develop the multi-functional SAFER-COVID app platform to speed the return to work and school while keeping the public safe. In its current form, the app captures self-reported data on an individual's symptoms, and test results.

Individuals can integrate these self-reported data with wearables and electronic medical records to help inform their readiness to safely return to work and resume normal activities. The app is being modified to accept results of newly developed RADxSM-initiated tests from readers and smartphones to provide individuals with confirmation of health status for work, travel, and school. In addition, NIBIB is collaborating with the National Cancer Institute to develop seven novel digital health solutions that could be integrated into the app to provide broad benefits in controlling the spread and improving treatment of COVID-19. These solutions include digital contact tracing to inform users when they have been in contact with someone who tests positive for SARS-CoV-2, monitoring of patient health, and vital signs for underserved and remote populations, and wearable sensors for biometrics such as heart rate and respiratory rate that can indicate the onset or worsening of illness. Connected to medical providers, these sensors may provide lifesaving early warning signals of the unexpected relapses that have been observed in COVID-19 patients. De-identified data from the app will be shared with the research community through the NIH RADxSM initiative data hub. These data will support research to further control the pandemic; for example, allowing researchers to develop new deep learning algorithms to predict individual risk of COVID-19. Like the RADxSM



Credit: CareEvolution, LLC.

testing technologies, these digital health innovations will provide platforms for new approaches to managing public and individual health that can be applied broadly to transform the future of healthcare across the biomedical spectrum.



CT scan of lungs of COVID-19 patient with areas described by radiologists as resembling grains of ground glass. Credit: Radiological Society of North America (RSNA).

The third pillar of response is the use of AI in conjunction with medical imaging technologies for COVID-19 patients. NIBIB launched a multi-institutional national Medical Imaging and Data Resource Center (MIDRC) to accelerate the development and validation of AIbased imaging tools. These new methods will be deployed for early detection, prognosis, and optimization of therapies in COVID-19 patients (see program portrait). The NIBIB effort leverages the unique technical capabilities and commitment of our bioimaging community. Together with

the RADxSM initiative technologies and digital platforms, NIBIB is making technological advances that can dramatically improve the practice of healthcare in the U.S. These same advances can later be applied to help prevent and manage other health care problems, both chronic and acute.

COVID-19 is only one of several diseases where the global burden falls disproportionally on minority populations. To address this type of health disparity, NIBIB is co-sponsoring the NIH

Common Fund initiative: Harnessing Data Science for Health Discovery and Innovations in Africa. This program is leveraging data science technologies and prior NIH investments to develop solutions to the most pressing public health problems through partnerships with academic, government, and the private sectors. In addition to a disproportionate share of disease burden, there is a critical medical workforce shortage and a need for clinical decision-making in Africa. Extensive mobile phone coverage provides opportunities for technology innovation in this region. Research projects may include development of AI tools to provide decision support for mobile and other POC technologies, establishment of large health datasets to reveal disease patterns and risks, and applying computational approaches to accelerate discovery of new diagnostics, treatments, and vaccines.

In addition, NIBIB formed partnerships with other NIH Institutes and Centers and the Bill and Melinda Gates Foundation to launch the NIH Tech Accelerator Challenge for Global Health. This collaboration is developing POC diagnostics for sickle cell disease, malaria, and anemia for global settings. NIH has awarded a total of \$1 million to six winners for their work in the design and development of non-invasive, handheld, digital technologies to detect and diagnose sickle cell disease, malaria, and anemia. Examples of these promising technologies include a hand-held lateral flow test that can simultaneously detect multiple pathogens (e.g., SARS-CoV-2 and malaria) and a smartphone app that uses an algorithm and images of fingernail beds to detect anemia and screen for sickle cell disease.

Successful technology development, like drug development and other treatment approaches, is reliant upon and builds on previous basic research. NIBIB continues to invest in foundational research such as the sensor technologies upon which digital platforms for monitoring health may be created. The development of sensors provides the technical window for continuously monitoring human biology and pathology as in the ability to 3D print sensors directly onto organs such as the lungs. These hydrogel-based sensors are being developed to support robot-assisted medical treatments and to monitor how well organs function during and after a surgical procedure. Other potential uses of this technique include electrodes that interface with the nervous system to treat pain, bioscaffolds with engineered cells that can regenerate tissues, and efficient and accurate application of surgical glues and skin grafts. These advances are made possible by building on the foundational research that supported the development of materials such as the biogels and circuitry to record and transmit data from the sensor.

By continuing to build on ongoing basic research in materials, electronics, and biosystems, future biomedical sensors may enable faster, more integrated wearable diagnostic devices and enhance clinical decision-making by gathering more patient-specific data. Continued research is needed to improve early detection capabilities and provide more robust data to enhance prevention and management of diseases at both a population level, such as detection and surveillance needs for infectious diseases, and at an individual level for early detection and treatment of both acute and chronic diseases.

<u>Overall Budget Policy</u>. The FY 2022 President's Budget request for NIBIB is \$422.0 million, an increase of \$11.3 million or 2.75 percent compared with the FY 2021 Enacted level. Noncompeting research project grants (RPGs) will be awarded at a reduced level, 2.0 percent below their full committed level. The average cost of Competing RPGs will decrease by 0.2

percent in FY 2022 versus the FY 2021 Enacted level. All activities will be increased by 2.75 percent, the same as the aggregate increase for Extramural funding mechanisms. Research Management & Support will be increased by 2.75 percent from the FY 2021 Enacted level.

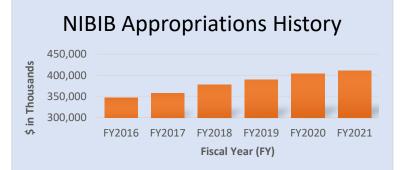
NIBIB-8



National Institute of Biomedical Imaging and Bioengineering Engineering the Future of Health

History of NIBIB Research

NIBIB harnesses engineering to expand the understanding of disease prevention, detection, diagnosis, and treatment to fulfill its mission. NIBIB-supported research has pioneered groundbreaking advances to create technologies that are essential to extending the health span by personalizing diagnosis and treatment, and significantly improving quality of life. As the hub at NIH for expanding technologies across diseases and disorders, NIBIB support is driving research to benefit patients and healthcare professionals and promote further biomedical discovery. NIBIB invests in five major areas of research: sensing and imaging of health and disease; engineered biosystems; quantitative data science, modeling, and computation; advanced therapies and treatments; and workforce training.



FY 2022 President's Budget is \$422,039,000. Note: In addition to the base budget, NIBIB received \$560 million in supplemental appropriations in FY 2020.

Current Activities: COVID-19 Diagnostics

The RADxSM Tech program is one component of the RADxSM initiative at NIH to speed innovation in developing, commercializing, and expanding manufacturing of technologies for COVID-19 testing. NIBIB is providing substantial support to innovative point-of-care and home-based technologies, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2. The impact of the RADxSM initiative will be millions of COVID-19 diagnostic tests delivered per day to Americans.

RADxSM Tech supported home and point-of-care devices for diagnosing SARS-CoV-2. Credit: Visby Medical, Luminostics Inc., Quidel Corp., Ellume USA, LLC.





Bruce J. Tromberg, Ph.D., became NIBIB Director in January 2019. He received his Ph.D. from the University of Tennessee in 1988. He joined the faculty at the University of California at Irvine in 1990, where he was a professor of biomedical engineering and surgery. He later became the Director of the Beckman Laser Institute and Medical Clinic.

Credit: NIBIB/NIH

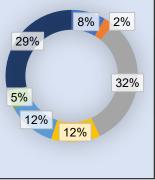
Facts and Figures*

- 98 Full-time Employees
- 300 Principal Investigators
- 17% Pay Line
- 229 Research Project Grants
- 68 Funded Early-Stage Investigator Awards
- 64% increase in Early-Stage Investigator Awards (FY17 to FY 20)
- *Data represent average of FY 2016-2020.

COVID-19 NOSI Spending by Topic

| Therapeutic Agent | NIBIB has invested \$8.4 million (as of Sept. 2020) |
|--------------------------------|--|
| Telemedicine | of COVID-19 supplemental funds |
| | to create, adapt, and apply technologies that |
| ■POC | address critical unmet needs revealed by |
| | COVID-19. Additional research projects are |
| COVID Diagnosis - Radiology | expected to be supported in FY 2021. |

- Digital Health
- COVID Diagnosis -Wearable Sensors
- Sensor, Imaging and Platform Development



National Institute of Biomedical Imaging and Bioengineering Engineering the Future of Health

Current Activities: COVID-19 Artificial Intelligence Tools

NIBIB is building a medical CT image repository for scientists to create artificial intelligence tools for improved COVID-19 diagnosis, treatment, and monitoring. NIBIB has also helped award contracts to develop digital health solutions Credit: RSNA. for the COVID-19 pandemic.



CT scan of lungs of COVID-19 patient.

Research Accomplishments: Trailblazer R21

The Trailblazer R21 Award is an opportunity for New and Early-Stage Investigators to pursue research programs of high interest to NIBIB. For example, most medicines

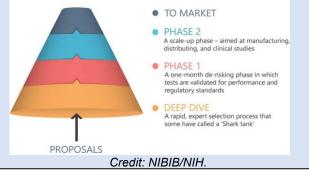


work by binding to and blocking the effect of disease-causing molecules. Now, to accelerate the identification of potential new medicines, researchers have created a computer model that mimics the way molecules bind.

Credit: Errington et al., University of Minnesota.

Future Initiatives: Innovation Funnel

NIBIB established the RADxSM Tech program to help engineer a response to the COVID-19 pandemic by developing and commercializing COVID-19 diagnostics at an unprecedented speed and scale. NIBIB created a new funding process that leveraged an existing Point-of-Care network to help get these diagnostic technologies to market in less than a year. It helps companies address the many hurdles that slow the process, including technical, regulatory, and commercialization requirements. The longer-term impact of this process is driving business development in the U.S. medical device industry and demonstrates a method for sustainable, dynamic product development for new health technologies. RADxSM Tech can serve as a model to bring critical research from the blackboard to the bench to the bedside and to your home in response to public and individual health crises.



Current Activities: WISE

In the past 15 years, there has been an ongoing effort to close the recognized gender gap in the global science community by promoting and inspiring women and girls to participate in STEM fields. NIBIB is committed to supporting women grantees and recognizes the impact their exceptional research contributions have made on the NIBIB community. The features highlight many research areas critical to NIBIB's mission, such as prosthetic technologies, engineering heart tissue, therapeutics for women's cancers, implantable scaffolds for bone regeneration, imaging tools, biomaterials for tissue regeneration, and more.



From left to right: Gordona Vunjak-Novakovic, Ph.D.; Charlotte Gaydos, Dr.P.H., M.P.H.; Quyen Nguyen, M.D., Ph.D.; Ranu Jung, Ph.D.; and Carla Pugh, M.D., Ph.D. Credit: NIBIB/NIH.

Resources:

- NIBIB website: https://www.nibib.nih.gov
- COVID-19: https://www.nibib.nih.gov/covid-19
- Downloadable science topic sheets: https://www.nibib.nih.gov/newsevents/nibib-fact-sheets
- WISE: https://www.nibib.nih.gov/scienceeducation/women-science-andengineering
- Medical imaging app: https://www.nibib.nih.gov/Understanding-Medical-Scans-App
- Video gallery: https://www.nibib.nih.gov/newsevents/multimedia/video-gallery

Major Changes in the Fiscal Year 2022 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 2022 President's Budget request for NIBIB, which is \$422.0 million, an increase of \$11.3 million or 2.75 percent compared with the FY 2021 Enacted level. NIBIB will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (\$8.0 million; total \$297.0 million):

NIBIB will fund 663 RPG awards in FY 2022, an increase of 5 awards from the FY 2021 Enacted level. This includes 458 noncompeting awards (an equal number of awards with an increase of \$5.3 million from the FY 2021 Enacted level); 173 competing RPGs (an increase of 5 awards and \$2.3 million from the FY 2021 Enacted level); and 32 SBIR/STTR awards (an equal number of awards with an increase of \$0.4 million from the FY 2021 Enacted level). Noncompeting awards will be funded at a reduced level, 2.0 percent below their full committed level. The average cost of competing RPGs will decrease by 0.2 percent in FY 2022 versus the FY 2021 Enacted level.

<u>Research Centers (\$0.9 million; total of \$33.5 million)</u>: NIBIB will fund 27 Center awards in FY 2022, unchanged from the FY 2021 Enacted level.

Other Research (\$0.3 million; total of \$11.7 million):

NIBIB will fund 96 Other Research awards in FY 2022, unchanged from the FY 2021 Enacted level.

<u>Research Training Awards (\$0.3 million; total \$12.1 million)</u>: NIBIB will fund 226 Full-Time Training Positions (FTTPs) in FY 2022, the same as the FY 2021 Enacted level.

<u>Research and Development Contracts (\$0.5 million; total \$18.8 million)</u>: NIBIB will fund 9 R&D Contracts in FY 2022, equal to the FY 2021 Enacted level.

Intramural Research (\$0.6 million; total \$21.6 million): Intramural Research will be increased by 2.75 percent, the same as the aggregate increase for Extramural funding mechanisms.

<u>Research Management & Support (\$0.7 million; total \$27.3 million)</u>: Research Management & Support will increase by 2.75 percent from the FY 2021 Enacted level.

Budget Mechanism - Total¹

(Dollars in Thousands)

| MECHANISM | FY 20 |)20 Final | FY 2021 Enacted | | | President's | FY 2022 +/- | |
|---|--------------|--------------------|-----------------|--------------------|------------|--------------------|-----------------|-------------|
| | | | | | В | udget | FY 2021 Enacted | |
| | No. | Amount | No. | Amount | No. | Amount | No. | Amount |
| Research Projects: | | | | | | | | |
| Noncompeting | 447 | \$176,465 | 458 | \$192,302 | 458 | \$197,590 | 0 | \$5,288 |
| Administrative Supplements | (8) | 523 | (8) | 1,800 | (8) | 1,850 | (0) | 5(|
| Competing: | (0) | 020 | (0) | 1,000 | (0) | 1,000 | (*) | |
| Renewal | 12 | 7,017 | 0 | 0 | 0 | 0 | 0 | (|
| New | 210 | 86,324 | 168 | 82,183 | 173 | 84,461 | 5 | 2,278 |
| Supplements | 0 | 00,021 | 0 | 02,100 | 0 | 0 | 0 | _,_, |
| Subtotal, Competing | 222 | \$93,341 | 168 | \$82,183 | 173 | \$84,461 | 5 | \$2,27 |
| Subtotal, RPGs | 669 | \$270,330 | 626 | \$276,285 | 631 | \$283,901 | 5 | \$7,61 |
| SBIR/STTR | 32 | 12,786 | 32 | 12,750 | 32 | 13,101 | 0 | 35 |
| Research Project Grants | 701 | \$283,116 | 658 | \$289,035 | 663 | \$297,001 | 5 | \$7,960 |
| | ,01 | \$200,110 | 000 | \$20,000 | 000 | \$257,001 | | \$1,500 |
| Research Centers: | | | | | | | | |
| Specialized/Comprehensive | 4 | \$10,941 | 4 | \$3,955 | 4 | \$4,064 | 0 | \$109 |
| Clinical Research | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (|
| Biotechnology | 22 | 26,972 | 23 | 28,671 | 23 | 29,459 | 0 | 78 |
| Comparative Medicine | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (|
| Research Centers in Minority | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (|
| Institutions Research Centers | 26 | \$37,913 | 27 | \$32,626 | 27 | \$33,523 | 0 | \$897 |
| | | | | | | | | |
| Other Research: | | | | | | | | |
| Research Careers | 25 | \$3,681 | 27 | \$3,388 | 27 | \$3,481 | 0 | \$93 |
| Cancer Education | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (|
| Cooperative Clinical Research | 0 | 0 | 0 | 0 | 0 | 0 | 0 | (|
| Biomedical Research Support | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Minority Biomedical Research Support | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Other | 55 | 6,572 | 69 | 8,042 | 69 | 8,263 | 0 | 22 |
| Other Research | 80 | \$10,253 | 96 | \$11,430 | 96 | \$11,744 | 0 | \$314 |
| Total Research Grants | 807 | \$331,282 | 781 | \$333,091 | 786 | \$342,269 | 5 | \$9,17 |
| | FTTD | | FTTD | | FTTD | | FTTD | |
| Ruth L Kirschstein Training Awards: | <u>FTTPs</u> | | FTTPs | ¢(70 | FTTPs | ¢ | <u>FTTPs</u> | ¢ 1. |
| Individual Awards | 9 | \$505 | 12 | \$679 | 12 | \$698 | 0 | \$19 |
| Institutional Awards Total Research Training | 192 201 | 10,541 \$11,046 | 214 226 | 11,061 \$11,740 | 214 226 | 11,365 \$12,063 | 0 | 30- \$32 |
| Total Research Training | 201 | \$11,040 | 220 | \$11,740 | 220 | \$12,003 | 0 | \$32. |
| Research & Develop. Contracts | 8 | \$18,053 | 9 | \$18,350 | 9 | \$18,855 | 0 | \$50 |
| (SBIR/STTR) (non-add) | (2) | (136) | (3) | (140) | (3) | (144) | (0) | (4 |
| | | | | . , | | . / | | · · |
| Intramural Research | 26 | 18,596 | 32 | 20,980 | 32 | 21,557 | 0 | 57 |
| Res. Management & Support | 66 | 25,662 | 70 | 26,565 | 70 | 27,296 | 0 | 73 |
| SBIR Admin. (non-add) | (0) | (0) | (0) | (230) | (0) | (236) | (0) | (0 |
| Construction | | 0 | | <u></u> | | 0 | | |
| | | 0 | | 0 | | 0 | | |
| Buildings and Facilities Total, NIBIB | 92 | 0 \$404,638 | 102 | 0 \$410,726 | 102 | 0 \$422,039 | 0 | \$11,31 |

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

For carrying out section 301 and title IV of the PHS Act with respect to biomedical

imaging and bioengineering research, [\$410,728,000] *\$422,039,000*.

Summary of Changes

(Dollars in Thousands)

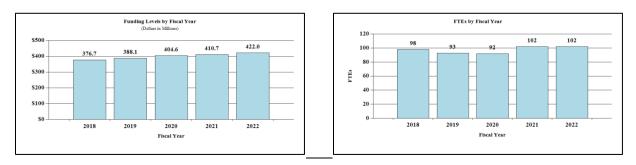
| FY 2021 Enacted | \$410,726 |
|----------------------------|-----------|
| FY 2022 President's Budget | \$422,039 |
| Net change | \$11,313 |

| | FY202 | l Enacted | | President's ıdget | from | n Change FY 2021 acted |
|--|-------|---------------------|------|----------------------|------|------------------------------|
| CHANGES | FTEs | Budget Authority | FTEs | Budget Authority | FTEs | Budget Authority |
| <u>A. Built-in:</u> | | | | | | |
| 1. Intramural Research: | | | | | | |
| a. Annualization of January 2021 pay increase & benefits | | \$6,487 | | \$7,107 | | \$17 |
| b. January FY 2022 pay increase & benefits | | 6,487 | | 7,107 | | 180 |
| c. Paid days adjustment | | 6,487 | | 7,107 | | 0 |
| d. Differences attributable to change in FTE | | 6,487 | | 7,107 | | 0 |
| e. Payment for centrally furnished services | | 2,860 | | 3,003 | | 143 |
| f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 11,633 | | 11,447 | | 208 |
| Subtotal | | | | \$42,878 | | \$548 |
| 2. Research Management and Support: | | | | | | |
| a. Annualization of January 2021 pay increase & benefits | | \$13,436 | | \$14,070 | | \$35 |
| b. January FY 2022 pay increase & benefits | | 13,436 | | 14,070 | | 368 |
| c. Paid days adjustment | | 13,436 | | 14,070 | | 0 |
| d. Differences attributable to change in FTE | | 13,436 | | 14,070 | | 0 |
| e. Payment for centrally furnished services | | 465 | | 488 | | 23 |
| f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs | | 12,664 | | 12,737 | | 228 |
| Subtotal | | | | \$69,505 | | \$655 |
| Subtotal, Built-in | | | | \$112,383 | | \$1,203 |

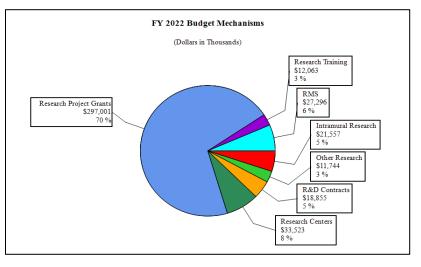
| | FY202 | FY2021 Enacted | | FY 2022 President's Budget | | Program Change from FY 2021 Enacted | |
|---------------------------------------|-------|----------------|------|-------------------------------|------|---|--|
| CHANGES | No. | Amount | No. | Amount | No. | Amount | |
| B. Program: | | | | | | | |
| 1. Research Project Grants: | | | | | | | |
| a. Noncompeting | 458 | \$194,102 | 458 | \$199,440 | 0 | \$5,338 | |
| b. Competing | 168 | 82,183 | 173 | 84,461 | 5 | 2,278 | |
| c. SBIR/STTR | 32 | 12,750 | 32 | 13,101 | 0 | 351 | |
| Subtotal, RPGs | 658 | \$289,035 | 663 | \$297,001 | 5 | \$7,966 | |
| 2. Research Centers | 27 | \$32,626 | 27 | \$33,523 | 0 | \$897 | |
| 3. Other Research | 96 | 11,430 | 96 | 11,744 | 0 | 314 | |
| 4. Research Training | 226 | 11,740 | 226 | 12,063 | 0 | 323 | |
| 5. Research and development contracts | 9 | 18,350 | 9 | 18,855 | 0 | 505 | |
| Subtotal, Extramural | | \$363,181 | | \$373,187 | | \$10,006 | |
| | FTEs | | FTEs | | FTEs | | |
| 6. Intramural Research | 32 | \$20,980 | 32 | \$21,557 | 0 | \$29 | |
| 7. Research Management and Support | 70 | 26,565 | 70 | 27,296 | 0 | 75 | |
| 8. Construction | | 0 | | 0 | | 0 | |
| 9. Buildings and Facilities | | 0 | | 0 | | 0 | |
| Subtotal, Program | 102 | \$410,726 | 102 | \$422,039 | 0 | \$10,110 | |
| Total built-in and program changes | | | | | | \$11,313 | |

Fiscal Year 2022 Budget Graphs

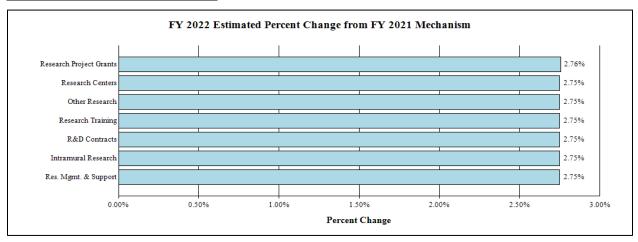
History of Budget Authority and FTEs:

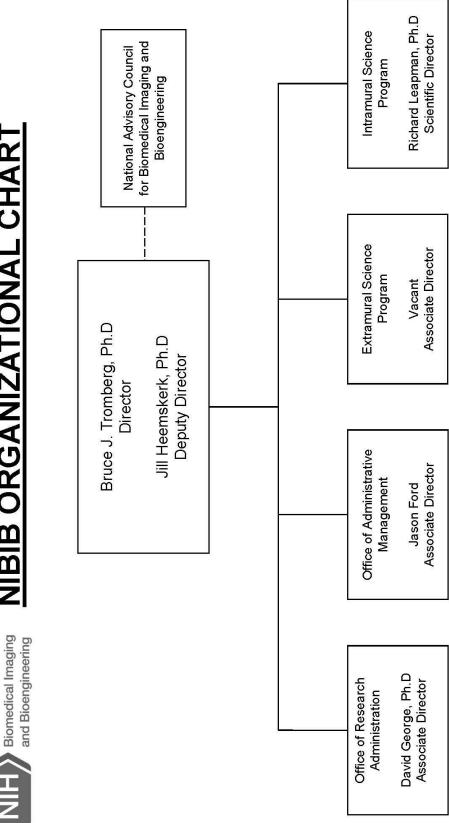


Distribution by Mechanism



Change by Selected Mechanisms





NIBIB ORGANIZATIONAL CHART

National Institute of

Budget Authority by Activity¹

(Dollars in Thousands)

| | FY 2 | 020 Final | | Y 2021 nacted | Pre | Y 2022 sident's udget | F | 7 2022 +/- Y 2021 nacted |
|----------------------------------|------------|---------------|------------|------------------|------------|-----------------------------|------------|-----------------------------------|
| 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> |
| Detail | | | | | | | | |
| Discovery Science and Technology | | \$117,159 | | \$118,070 | | \$121,323 | | \$3,253 |
| Applied Science and Technology | | 180,083 | | 181,482 | | 186,481 | | 4,999 |
| Interdisciplinary Training | | 24,037 | | 24,224 | | 24,893 | | 669 |
| Health Informatics Technology | | 39,101 | | 39,405 | | 40,490 | | 1,085 |
| Subtotal, Extramural | | \$360,380 | | \$363,181 | | \$373,187 | | \$10,006 |
| Intramural Research | 26 | \$18,596 | 32 | \$20,980 | 32 | \$21,557 | 0 | \$577 |
| Research Management & Support | 66 | \$25,662 | 70 | \$26,565 | 70 | \$27,296 | 0 | \$731 |
| TOTAL | 92 | \$404,638 | 102 | \$410,726 | 102 | \$422,039 | 0 | \$11,313 |

¹ 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 2022 | |
|-----|---------------|---------------|---------------|--------------|
| | FY 2020 | FY 2021 | President's | FY 2022 +/- |
| | Final | Enacted | Budget | FY 2021 |
| BA | \$404,638,000 | \$410,726,000 | \$422,039,000 | \$11,311,000 |
| FTE | 92 | 102 | 102 | 0 |

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

Program Descriptions

Extramural Research: NIBIB's Extramural Research Program (ERP) supports a range of programs using multiple mechanisms to improve health and advance research. This includes development of technologies to rapidly assess and respond to urgent healthcare concerns, evaluating and guiding the treatment of chronic diseases, and optimizing therapeutic outcomes in a wide range of surgical and medical settings. Five key research themes are at the core of NIBIB's Divisions and programs: 1) sensing and imaging health and disease, 2) engineered biosystems, 3) advanced therapies and cures, 4) data science and computation, and 5) bioengineering workforce training.

Applied Science and Technology

This Division supports the development of innovative biomedical sensing and imaging technologies to transform our understanding of biological and disease processes for improving diagnostics, image-guided therapies, and monitoring of health status. In addition to developing innovative sensing and imaging tools, data science approaches such as AI are being used to extract more information from traditional sensing and imaging technologies.

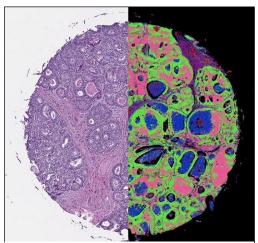
An example of NIBIB-supported research in this area includes a new method to map and understand the functional origin of signaling networks in the brain. Engineers have created a system using high-density electroencephalography (EEG) to detect the location and path of normal and abnormal brain signals. This project is part of NIBIB's involvement in the NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. While EEG has been used for decades to track brain signals, this more powerful version can track signals across much larger areas of the brain. Artificial intelligence is then used to identify where these stronger signals originate and travel through the brain, with great accuracy. The research team tested the system in patients with epilepsy to pinpoint the source of epileptic seizures. More accurate identification of the epileptic source allows surgeons to remove only seizure onset areas and spare surrounding brain tissue. This technique is also noninvasive while the standard preoperative testing requires surgically implanted EEG to identify the region. This adds risks of infection, complications, and costs. In the future, this technique could also be applied to the diagnosis and treatment of Alzheimer's, Parkinson's, stroke and even depression.

Some medical imaging methods use tracers or contrast agents to better visualize disease. A new method to create radioactive tracers, specifically for positron emission tomography (PET) imaging, allows them to attach radioactive atoms to compounds that have previously been difficult or even impossible to label. PET scans use radiotracers, which are made up of a radioactive atom that is attached to a specific molecule, which is selected depending on the purpose of the scan. The tracers bind to the targets in organs and tissues, or selectively accumulate in a specific area of the body (such as tissues with high metabolism) following injection or ingestion into the body. Then, a PET scanner is used to help doctors visualize and quantify the amount of the tracer and thereby observe changes or disease in the body. The advance will make it easier to track medications as they travel through the body and to identify and diagnose tumors and other diseases.

When medical imaging, such as PET, identifies a tumor in the body, a biopsy is often performed to further characterize the lesion. For patients who have a biopsy, it is frustrating to wait to find out if it is benign or malignant. As digital cameras give us instant photos, digital biopsies that combine standard microscopy, infrared light, and AI can identify important molecular

characteristics of biopsy samples without dyes or labels, speeding up the process. The standard way to test biopsies for cancer is to treat the tissue with staining solutions that reveal cellular details and help a pathologist identify whether a sample is cancerous and, if so, give some idea of its severity. This process can take several hours or longer and results can vary, even among highly skilled pathologists. This new technique was created by adding an infrared laser and specialized lenses to the standard visible light microscope found in labs and clinics.

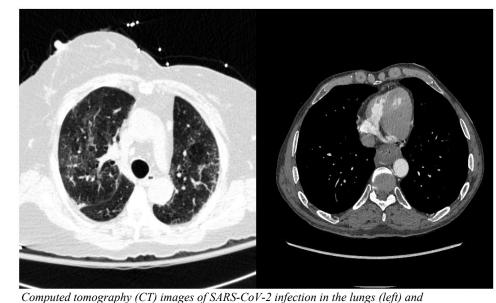
A computer program then combines the standard visible or white light and infrared signals that bounce off the biopsy sample under the microscope. The result is an image that mimics the type obtained if the sample were stained in a traditional pathology lab. The addition of AI allows information contained in the sample that cannot be seen with the human eye to be "seen" with this technique. Producing faster results and reducing costs are some of the benefits of this technique.



Machine-learning tools can analyze the data from the infrared-optical hybrid microscope to create digital versions of standard dyes, left, or to identify tissue types based on their chemical composition, right. Credit: Rohit Bhargava, University of Illinois at Urbana-Champaign.

MEDICAL IMAGING AND DATA RESOURCE CENTER FOR RAPID RESPONSE TO COVID-19 PANDEMIC

Building on prior workshops and planning, supplemental funding allowed implementation of this unique resource, one of NIBIB's three main technology pillars for addressing the pandemic. This ambitious effort is harnessing the powers of artificial intelligence and medical imaging to fight COVID-19. The multi-institutional collaboration will create new tools that physicians can use for early detection and personalized therapies for COVID-19 patients. MIDRC is assembling a large repository of COVID-19 chest images with associated clinical data and analyzing these data to speed the understanding of this variable and currently unpredictable disease. This work will apply advanced computational methods to a trove of patient imaging, health, and outcomes data to identify multi-faceted disease "signatures" that are associated with the range of patient outcomes and responses to treatments. Once identified, these signatures will provide urgently needed tools for physicians to confidently assess disease severity, identify individualized treatments, and improve outcomes for COVID-19 patients.



Computed tomography (CT) images of SARS-CoV-2 infection in the lungs (left) and manifestations in the cardiovascular structures of a different patient (right). The MIDRC project will use medical images such as these, along with associated clinical data, and apply advanced computational algorithms for the diagnosis, assessment of severity, and prediction of response to treatment, to improve patient management and outcomes. Credit: University of Chicago.

Discovery Science and Technology

This Division supports the development and demonstration of biomedical technologies and engineering approaches that will lead to new types of medical interventions that meet identified clinical needs for improving human health.

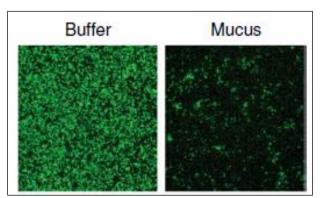
For example, researchers have developed a groundbreaking process for multi-material 3D printing of lifelike models of the heart's aortic valve and the surrounding structures that mimic the exact look and feel of a human. These patient-specific organ models can be used in

preparation for minimally invasive procedures. Building on years of foundational research, the researchers were early adopters of using 3D printing for medical purposes. This organ model was specifically designed to help doctors prepare for a procedure that places a new heart valve inside a patient's damaged valve and is much less invasive than open heart surgery. Physicians can use the models to determine the size and placement of the valve, and integrated sensors give physicians the electronic pressure feedback that can be used to guide and optimize the selection and positioning of the valve within the patient.

Repairing or replacing damaged tissues can resolve critical health problems and improve a patient's quality of life. To address genetic disorders, researchers supported by NIBIB and other NIH Institutes and Centers are seeking ways to repair DNA in a living cell for patients with gene mutations that cause disease. This type of research has been ongoing for decades and now researchers have designed a more precise and versatile genome editing system. The new system, called prime editing, improves upon the powerful CRISPR-Cas9 genome editing system. So far, researchers have reported 175 successful DNA edits using their prime editing system. They are hopeful that prime editing could potentially be used to correct about 89 percent of known disease-causing mutations in DNA. There are approximately 3 billion base pairs (letters) in the human genome and devastating diseases can occur when only one letter of a cell's DNA is incorrect. It is challenging to change just one DNA letter to a different letter using classic

CRISPR-Cas9, but the prime editing technique may enable this change much more easily. This type of basic research is one example of how engineered biology can have potentially farreaching impacts.

Another example of biology and engineering joining forces to address critical healthcare needs is demonstrated by a study to find ways to combat drug-resistant bacteria. Each year millions of people are infected with antibioticresistant bacteria, meaning the germs have found ways to overpower antibiotics and continue to grow. NIBIB-funded scientists have been working to find alternative solutions for treating bacterial infections, especially



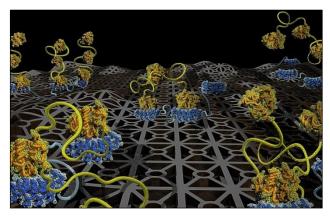
Left: A biofilm of bacteria as shown by green color in the image. Right: three hours after treatment with mucus, the number of bacteria is dramatically reduced. Credit: Ribbeck lab, Massachusetts Institute of Technology.

antibiotic-resistant bacteria, by studying mucus—which lines many passageways throughout the body. Mucins are a type of protein that give mucus its gel-like structure and are studded with glycans, or chains of sugar molecules. Researchers have found that mucus does not kill bacteria on its own, but the glycans disarm harmful pathogens in mucus by limiting genes that control their pathways of communication or toxin production. Future research will focus on identifying which glycans can tame a specific pathogen and how they bind together so that this concept can be translated to clinical applications.

In addition to bacteria becoming resistant to medicines, certain cancers can mutate and become drug resistant. Researchers are using modeling to counter drug resistance by identifying new mutations computationally, then engineering drugs to overcome these mutations and kill the cancer cell or pathogen. Computer modeling uses mathematics, statistics, physics, and computer

science to study the mechanism and behavior of complex systems by computer simulation. The need to design new drugs that overcome resistance is crucial to fight a mutated virus in a population of people or a mutated protein that causes drug resistance in a population of tumor cells. Researchers are continuing to refine their models with the aim of incorporating this type of information into the process of rational drug design. The approach could significantly improve the ongoing challenge of developing drugs that combat resistant cancers as well as resistant bacterial and viral infections that occur when diseases spread throughout a population.

Modeling can also be used to develop medicines for a variety of diseases and conditions. Most medicines work by binding to and blocking the effect of disease-causing molecules. But to identify the exact drug compounds that will bind to a disease target involves a trial-and-error process that is timeconsuming and expensive. To help streamline the identification of effective compounds, a team of biomedical engineers developed a mathematical computer model that predicts how molecules with two or more binding sites will interact with each other and how changes in those structures could enhance or reduce binding. Instead of using trial and error in a test tube, this approach uses stateof-the-art computational modeling methods and is a major step toward more rapid and significantly less costly drug development. A



Depiction of the range of possible interactions between proteins with multiple binding sites. The computational model predicts how molecules with two or more binding sites will interact with each other and how changes in those structures could enhance or reduce binding. Credit: Errington et al., University of Minnesota.

computational model contains numerous variables that characterize the system being studied. In this example, a computational model allows researchers to simulate how changes in the molecular properties of drugs impact their binding to specific targets. With this capability, researchers can quickly zero in on precise molecular structures and parameters that a new medicine will need to be a good candidate to test in an animal model against a specific disease.

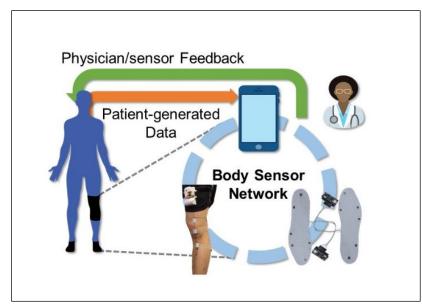
NIBIB also supports the development of technologies for advancing therapies and cures. One example aims to minimize the paralyzing damage in spinal cord injury (SCI) that is caused by the body's immune response to the injury. To do this, engineers have developed nanoparticles that lure immune cells away from the spinal cord, allowing regeneration that has restored spinal cord function in mice. When the spinal cord suffers a traumatic injury, the body's immune system floods the area and creates an environment that aims to quickly shore up the injury yet also inhibits regenerative processes that can successfully rebuild and reconnect delicate damaged nerves. The engineers have designed an approach that reduces immune cells at the site of the injury while also promoting greater regeneration. The nanoparticles can be injected into the bloodstream directly after an injury, where they reprogram the immune cells, resulting in a dramatic reduction in the number of immune cells that enter the wound area. The smaller number of immune cells results in the cells switching from an inflammatory reaction to a regenerative one. In small studies, mice that received the nanoparticle therapy showed enhanced locomotor

function. This nanoparticle technology may have applications in treating the significant number of diseases that are caused by an immune response, ranging from arthritis to sepsis.

Health Informatics and Technology

This Division supports development of data science, information technology, and POC technology for processing and evaluating complex biomedical information and developing solutions to real-world healthcare problems. Research in this area includes development of practical, patient-centered applications for clinical decision-making support systems, POC or inhome diagnostics or treatment monitoring, improvements in medical imaging through advanced methodologies, next-generation intelligent image and data analysis tools, and mobile health and telemedicine solutions.

For example, traditional, large-scale imaging modalities can be enhanced with the use of AI and machine learning, an approach to AI in which a computer algorithm (a set of rules and procedures) is developed to analyze and make predictions from data that is fed into the system. Neural networks are a machine learning approach modeled after the brain in which algorithms process signals via interconnected nodes called artificial neurons. These artificial neural networks have been used successfully to recognize and predict patterns of neural signals involved in brain function. In one example, researchers are using these AI approaches to enhance the benefits of computed tomography (CT), which is often used as a diagnostic tool for assessment of lung cancer in patients. To help guide treatment options, researchers have created an artificial neural network that analyzes lung CT scans to provide information about lung cancer severity. A multidisciplinary team from biomedical informatics, radiology, data science, electrical engineering, and radiation oncology joined together to create a machine learning neural network designed to obtain consistent, fast, and accurate information using CT scans from adults with non-small cell lung cancer, which accounts for 85 percent of lung cancer diagnoses. In one study, this approach showed that the neural network accurately predicted overall survival among the patient groups. It also accurately classified benign versus malignant nodules and was able to further categorize those nodules into low, medium, and high-risk groups. This allows for intensified treatment for patients in the high-risk group as well as reducing unnecessary treatments for patients in the low-risk group. This type of advance demonstrates how radiologists can use new tools to deliver consistent and useful clinical information.



Wearable mHealth system for knee osteoarthritis. Knee and foot sensors gather and analyze movement data, allowing patient-specific clinical intervention. Credit: Sunghoon Ivan Lee, University of Massachusetts, Amherst.

Computer algorithms and software are not only improving large-scale medical technology such as traditional imaging, but are increasingly being integrated into wearable technology that is bringing health information and interventions directly to us. In one example, a wearable mHealth system is being developed to improve therapy for knee osteoarthritis (OA). OA is a leading cause of disability because of pain, stiffness, and decreased range of motion. Studies have shown that too excessive or too limited levels of clinically recommended therapy often increase pain, suggesting that everyone has an optimal treatment level. NIBIB-funded

engineers have developed a flexible, wearable system that will gather and assess a patient's movement biomechanics that affect pain, quality of life, and rehabilitation progression. The clinical data gathered from this system will enable the development of personalized OA therapy. The system is designed to monitor patients in real-world settings during activities of daily living in their home and community settings.

Health informatics is also supported through NIBIB's National Centers for Biomedical Imaging and Bioengineering program. This program focuses on supporting a national network of research and technology centers to develop cutting-edge biomedical imaging, bioengineering, and bioinformatic innovations with potential for commercialization. These Centers create critical and unique technology and methods at the forefront of their respective fields and apply them to a broad range of basic, translational, and clinical research problems. One Center generates state-of-the-art data science technology and tools that enable the Laboratory of Neuroimaging Resource, a valuable, secure online resource for sharing, visualizing, and exploring neuroscience data. To date, this resource has provided approximately 160 million data downloads for more than 180,000 users and has been enhanced with more than 1.2 million data uploads. The archive hosts 26 widely used data resources such as Alzheimer's Disease Neuroimaging Initiatives, among others. These data, with associated tools provided by the Center, have resulted in major scientific discoveries in neuroscience, such as revealing the genetic architecture of the human cerebral cortex. NIBIBsupported scientists, along with other researchers, combined genetic data with brain magnetic resonance imaging from more than 50,000 people to generate a genome-wide analysis of how human genetic variation influences human cortical surface area and thickness. From this analysis, they identified genetic differences that are associated with cortical structure, some of which affect signaling and gene expression. The researchers were able to make observations about the overlap between the genes that impact brain structure and development. These findings provide important data for further research in neurological diseases.

Workforce Development

The Interdisciplinary Training Division continues to invest in training the next generation of researchers, including investment in diversity programs and support for researchers throughout the career path. For undergraduates, NIBIB started the Enhancing Science, Technology, EnginEering, and Math Educational Diversity (ESTEEMED) training program. This effort supports educational activities that enhance the diversity of the biomedical research workforce through early preparation of students in STEM fields during their first two years of undergraduate education. In addition to academic and research skill acquisition, programs are expected to include career development, mentoring, and community building for their participants, and strong evaluation plans. Through 2019, the ESTEEMED program provided support for 68 scholars at ten different universities.

Each year, NIBIB recognizes teams of undergraduate bioengineering students with its Design by Biomedical Undergraduate Teams (DEBUT) challenge. In 2020, this trans-NIH

TRAILBLAZER PROGRAM TO SUPPORT EARLY-CAREER INVESTIGATORS

NIBIB's Trailblazer program exemplifies its commitment to supporting early-career investigators. This program supports exploratory and developmental research that integrates engineering and physical sciences with life and biomedical sciences. A Trailblazer project must be exploratory, developmental, high risk-high impact, and non-incremental. The program prioritizes the growth of the scientific workforce by targeting new investigators and strongly encourages underrepresented groups to apply. This effort has led to several discoveries. including development of a metamaterial that boosts the performance of magnetic resonance imaging. Made of plastic and copper, it is a costeffective approach that has potential to improve the quality of MRI imaging up to four times over current methods. The advance also predicts that the new metamaterial may produce high-quality images using lower-field MRI machines-the type routinely used in clinics-almost 14 times faster than current technology.

Since the initiation of the Trailblazer program in 2016, NIBIB has been able to increase the funding of new investigators by 40 percent, a trend we expect to continue in the near future.

and public-private challenge awarded \$1 million in total prizes. In this year's competition, DEBUT received 86 applications from 46 universities in 20 states, engaging a total of 410 students. NIBIB, along with its NIH partners, selected five winning teams for designs that excel according to four criteria: the significance of the problem being addressed; the impact on clinical care; the innovation of the design; and the existence of a working prototype. Teams that could not build a prototype due to the pandemic-related loss of access to labs were also able to compete this year based on the conceptual strength of their designs.

The top DEBUT prize went to the team that developed a low-cost microscope that could help diagnose Onchocerciasis, often called river blindness, a parasitic disease that causes extreme discomfort and, eventually, blindness. It affects more than 20 million people worldwide. The method can diagnose the disease more accurately than the current standard of care and can also be used to monitor the parasitic load over time to evaluate the effectiveness of treatment.



Dr. Bruce Tromberg presents The 2020 DEBUT awards remotely. Credit: NIBIB image via video conference.

Second place was awarded to a team for their development of an osmotic concentrator for urinary biomarkers to diagnose tuberculosis (TB). Confirming a TB diagnosis involves invasive sputum samples, which can be difficult for children and people who are immunocompromised. A urine-based test would be both cheaper and easier to collect. However, because urine is 95 percent water, there are currently no tests that are sensitive enough to accurately diagnose TB. This new device concentrates urine so that the biomarkers can be detected by lateral flow strip tests. Additional prizes went to teams that developed simple and low-cost diagnostics and treatments for applications such as monitoring progression of HIV/AIDS, treatment of cervical cancer, detecting birth defects, monitoring seizures, and detecting kidney injuries.

<u>Budget Policy</u>: The FY 2022 President's Budget request for Extramural Research Programs (ERP) is \$373.2 million, an increase of \$10.0 million or 2.75 percent compared with the FY 2021 Enacted level. ERP will give high priority to supporting new and early-career investigators, and priority to investigator-initiated research grants as these are the foundations 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.

Intramural Research Program: NIBIB's Intramural Research Program (IRP) continues to support a wide range of research in basic and clinical science. The Intramural Program is helping to address the COVID-19 pandemic in multiple ways, including collaborations with other NIH Institutes and Centers to quantify the extent of undetected novel coronavirus infections in the U.S., as well as the possible immunity conferred by prior infections with other coronaviruses.

For example, NIBIB's Section on Immunoengineering has developed a high-performing assay, specifically for this study, to detect the prevalence of SARS-CoV-2. This trans-NIH effort is surveying 10,000 people in a sample of diverse geography, race, sex, and ethnicity.

Other examples of cutting-edge research in the Intramural Program include new image processing algorithms that reduce the post-processing time of microscope images by up to

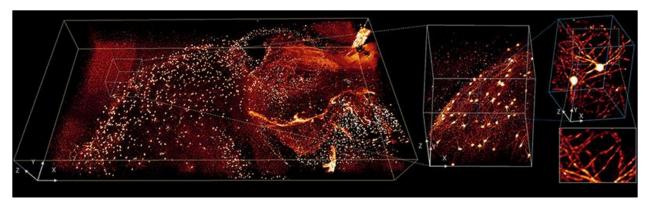


Image shows brain tissue from a mouse. The glowing areas show the presence of different antibodies. Source: NIBIB.

several thousand-fold. This is important because, although the high-resolution videos themselves can be captured quickly, they can contain terabytes of data and require weeks or even months of processing to extract their full information. The new algorithms are also enabling new generations of microscopes that rely on neural networks—a form of AI—to produce and analyze images. Several NIH Institutes and Centers have contributed to the effort, which is expected to help answer previously intractable questions about biology and human health.

With its unique ability to use engineering principles to rapidly transform scientific discoveries into dynamic healthcare solutions, NIBIB is, at unprecedented speed and scale, addressing our nation's critical public health needs. Future research has the potential to speed the delivery of new healthcare technologies for any disease or disorder and improve the health of all Americans.

<u>Budget Policy:</u> The FY 2022 President's Budget request for IRP is \$21.6 million, an increase of \$0.6 million or 2.75 percent compared with the FY 2021 Enacted level. The Clinical Center Management Fund assessment increased by 5 percent while all other activities will be increased by 2.75 percent, the same as the aggregate increase for Extramural funding mechanisms. High-priority research includes molecular imaging and nanomedicine—for the early diagnosis of disease, monitoring of therapeutic response, and guiding of drug discovery—and research on novel technologies for fast, "super resolution" optical microscopy of live cells to accelerate biomedical research.

Research Management and Support: The research management and support (RMS) effort contributes to achieving NIBIB's mission through efficient management and oversight of administrative operations, budget, communications, and strategic planning. NIBIB has expanded its communication efforts and website presence to provide timely information to researchers, Congress, and the public about its activities related to addressing the COVID-19 pandemic.

<u>Budget Policy</u>: The FY 2022 President's Budget request for RMS is \$27.3 million, an increase of \$0.7 million or 2.75 percent compared with the FY 2021 Enacted level. High priorities for RMS include the scientific support of NIBIB research programs and strategic planning.

Appropriations History

(Dollars in Thousands)

| Fiscal Year | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation |
|---------------|--------------------------------|-----------------|------------------|----------------|
| 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 | \$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 | | | |

¹ Budget Estimate to Congress includes mandatory financing.

Authorizing Legislation

| | PHS Act/ Other Citation | U.S. Code Citation | 2021 Amount Authorized | FY 2021 Enacted | 2022 Amount Authorized | FV 2022 President's Budget |
|--|----------------------------|-----------------------|---------------------------|--------------------|---------------------------|----------------------------|
| Research and Investigation | Section 301 | 42§241 | Indefinite | | Indefinite | |
| National Institute of Biomedical Imaging and Bioengineering | Section 401(a) | 42§281 | Indefinite | \$410,726,000 | Indefinite | 5422,059,000 |
| Total, Budget Authority | | | | \$410,726,000 | | \$422,039,000 |

Amounts Available for Obligation¹

| Source of Funding | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget |
|-------------------------------------|---------------|-----------------|----------------------------------|
| Appropriation | \$403,638 | \$410,728 | \$422,039 |
| 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 | 0 | 0 | 0 |
| Subtotal, adjusted appropriation | \$403,638 | \$410,728 | \$422,039 |
| OAR HIV/AIDS Transfers | 1,000 | -2 | 0 |
| HEAL Transfer from NINDS | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | \$404,638 | \$410,726 | \$422,039 |
| Unobligated balance, start of year | 0 | 0 | 0 |
| Unobligated balance, end of year | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | \$404,638 | \$410,726 | \$422,039 |
| Unobligated balance lapsing | -22 | 0 | 0 |
| Total obligations | \$404,616 | \$410,726 | \$422,039 |

(Dollars in Thousands)

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2020 - \$2,452 FY 2021 - \$5,100 FY 2022 - \$5,100

Budget Authority by Object Class¹

(Dollars in Thousands)

| | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 Enacted |
|--|--------------------|----------------------------------|-----------------------------------|
| Total compensable workyears: | | | |
| Full-time equivalent | 102 | 102 | 0 |
| Full-time equivalent of overtime and holiday hours | 0 | 0 | 0 |
| Average ES salary | \$0 | \$0 | \$0 |
| Average GM/GS grade | 12.7 | 12.7 | 0.0 |
| Average GM/GS salary | \$130 | \$133 | \$3 |
| Average salary, Commissioned Corps (42 U.S.C. 207) | \$0 | \$0 | \$0 |
| Average salary of ungraded positions | \$122 | \$125 | \$3 |

| OBJECT CLASSES | | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 | |
|----------------|---|-----------------|-------------------------------|---------------------------|--|
| | Personnel Compensation | _ | _ | _ | |
| 11.1 | Full-Time Permanent | 9,072 | 9,444 | 371 | |
| 11.3 | Other Than Full-Time Permanent | 3,856 | 4,230 | 374 | |
| 11.5 | Other Personnel Compensation | 419 | 480 | 62 | |
| 11.7 | Military Personnel | 0 | 0 | 0 | |
| 11.8 | Special Personnel Services Payments | 1,715 | 1,904 | 189 | |
| 11.9 | Subtotal Personnel Compensation | \$15,061 | \$16,057 | \$996 | |
| 12.1 | Civilian Personnel Benefits | 4,862 | 5,120 | 258 | |
| 12.2 | Military Personnel Benefits | 0 | 0 | 0 | |
| 13.0 | Benefits to Former Personnel | 0 | 0 | 0 | |
| | Subtotal Pay Costs | \$19,923 | \$21,177 | \$1,254 | |
| 21.0 | Travel & Transportation of Persons | 146 | 149 | 3 | |
| 22.0 | Transportation of Things | 79 | 80 | 1 | |
| 23.1 | Rental Payments to GSA | 5 | 5 | 0 | |
| 23.2 | Rental Payments to Others | 0 | 0 | 0 | |
| 23.3 | Communications, Utilities & Misc. Charges | 98 | 100 | 2 | |
| 24.0 | Printing & Reproduction | 10 | 10 | 0 | |
| 25.1 | Consulting Services | 8,452 | 8,089 | -363 | |
| 25.2 | Other Services | 3,171 | 3,228 | 57 | |
| 25.3 | Purchase of goods and services from government accounts | 23,772 | 24,347 | 575 | |
| 25.4 | Operation & Maintenance of Facilities | 170 | 196 | 26 | |
| 25.5 | R&D Contracts | 1,480 | 1,507 | 27 | |
| 25.6 | Medical Care | 18 | 19 | 1 | |
| 25.7 | Operation & Maintenance of Equipment | 3,949 | 4,070 | 121 | |
| 25.8 | Subsistence & Support of Persons | 0 | 0 | 0 | |
| 25.0 | Subtotal Other Contractual Services | \$41,012 | \$41,456 | \$444 | |
| 26.0 | Supplies & Materials | 843 | 883 | 40 | |
| 31.0 | Equipment | 2,341 | 2,383 | 42 | |
| 32.0 | Land and Structures | 1,439 | 1,465 | 26 | |
| 33.0 | Investments & Loans | 0 | 0 | 0 | |
| 41.0 | Grants, Subsidies & Contributions | 344,831 | 354,332 | 9,501 | |
| 42.0 | Insurance Claims & Indemnities | 0 | 0 | 0 | |
| 43.0 | Interest & Dividends | 0 | 0 | 0 | |
| 44.0 | Refunds | 0 | 0 | 0 | |
| | Subtotal Non-Pay Costs | \$390,803 | \$400,862 | \$10,059 | |
| | Total Budget Authority by Object Class | \$410,726 | \$422,039 | \$11,313 | |

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

Salaries and Expenses

(Dollars in Thousands)

| OBJECT CLASSES | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|-----------------|----------------------------------|---------------------------|
| Personnel Compensation | _ | _ | _ |
| Full-Time Permanent (11.1) | \$9,072 | \$9,444 | \$371 |
| Other Than Full-Time Permanent (11.3) | 3,856 | 4,230 | 374 |
| Other Personnel Compensation (11.5) | 419 | 480 | 62 |
| Military Personnel (11.7) | 0 | 0 | 0 |
| Special Personnel Services Payments (11.8) | 1,715 | 1,904 | 189 |
| Subtotal Personnel Compensation (11.9) | \$15,061 | \$16,057 | \$996 |
| Civilian Personnel Benefits (12.1) | \$4,862 | \$5,120 | \$258 |
| Military Personnel Benefits (12.2) | 0 | 0 | 0 |
| Benefits to Former Personnel (13.0) | 0 | 0 | 0 |
| Subtotal Pay Costs | \$19,923 | \$21,177 | \$1,254 |
| Travel & Transportation of Persons (21.0) | \$146 | \$149 | \$3 |
| Transportation of Things (22.0) | 79 | 80 | 1 |
| Rental Payments to Others (23.2) | 0 | 0 | 0 |
| Communications, Utilities & Misc. Charges (23.3) | 98 | 100 | 2 |
| Printing & Reproduction (24.0) | 10 | 10 | 0 |
| Other Contractual Services: | _ | _ | _ |
| Consultant Services (25.1) | 8,452 | 8,089 | -363 |
| Other Services (25.2) | 3,171 | 3,228 | 57 |
| Purchases from government accounts (25.3) | 23,772 | 24,347 | 575 |
| Operation & Maintenance of Facilities (25.4) | 170 | 196 | 26 |
| Operation & Maintenance of Equipment (25.7) | 3,949 | 4,070 | 121 |
| Subsistence & Support of Persons (25.8) | 0 | 0 | 0 |
| Subtotal Other Contractual Services | \$39,514 | \$39,930 | \$416 |
| Supplies & Materials (26.0) | \$843 | \$883 | \$40 |
| Subtotal Non-Pay Costs | \$40,689 | \$41,152 | \$463 |
| Total Administrative Costs | \$60,612 | \$62,328 | \$1,717 |

Detail of Full-Time Equivalent Employment (FTE)

| | FY 2020 Final | | FY 2021 Enacted | | | FY 2022 President's Budget | | | |
|---|-----------------|---------------|-----------------|----------|----------|----------------------------|----------|----------|-------|
| OFFICE/DIVISION | Civilian | Military | Total | Civilian | Military | Total | Civilian | Military | Total |
| | | | | | | | | | |
| Extramural Science Program | | | | | | | | | |
| Direct: | 17 | - | 17 | 19 | - | 19 | 19 | - | 19 |
| Reimbursable: | 2 | - | 2 | 2 | - | 2 | 2 | - | 2 |
| Total: | 19 | - | 19 | 21 | - | 21 | 21 | - | 21 |
| Intramural Science Program | | | | | | | | | |
| Direct: | 21 | - | 21 | 27 | - | 27 | 27 | - | 27 |
| Reimbursable: | 5 | - | 5 | 5 | - | 5 | 5 | - | 5 |
| Total: | 26 | - | 26 | 32 | - | 32 | 32 | - | 32 |
| Office of Administrative Management | | | | | | | | | |
| Direct: | 26 | - | 26 | 27 | - | 27 | 27 | - | 27 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 26 | - | 26 | 27 | - | 27 | 27 | - | 27 |
| Office of Reseach Administration | | | | | | | | | |
| Direct: | 17 | - | 17 | 18 | - | 18 | 18 | - | 18 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 17 | - | 17 | 18 | - | 18 | 18 | - | 18 |
| Office of the Director | | | | | | | | | _ |
| Direct: | 4 | - | 4 | 4 | - | 4 | 4 | - | 4 |
| Reimbursable: | - | - | - | - | - | - | - | - | - |
| Total: | 4 | - | 4 | 4 | - | 4 | 4 | - | 4 |
| Total | 92 | - | 92 | 102 | - | 102 | 102 | - | 102 |
| Includes FTEs whose payroll obligations a | are supported l | oy the NIH Co | mmon Fun | d. | | | | | |
| FTEs supported by funds from Cooperative Research and Development Agreements. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| FISCAL YEAR | Average GS Grade |
|-------------|------------------|
| 2018 | 12.8 |
| 2019 | 13.1 |
| 2020 | 12.7 |
| 2021 | 12.7 |
| 2022 | 12.7 |

Detail of Positions¹

| GRADE | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget |
|--|---------------|--------------------|----------------------------------|
| Total, ES Positions | 0 | 0 | 0 |
| Total, ES Salary | 0 | 0 | 0 |
| General Schedule | | | |
| GM/GS-15 | 12 | 16 | 16 |
| GM/GS-14 | 21 | 21 | 21 |
| GM/GS-13 | 18 | 21 | 21 |
| GS-12 | 2 | 2 | 2 |
| GS-11 | 2 | 2 | 2 |
| GS-10 | 2 | 2 | 2 |
| GS-9 | 2 | 2 | 2 |
| GS-8 | 0 | 0 | 0 |
| GS-7 | 0 | 2 | 2 |
| GS-6 | 0 | 0 | 0 |
| GS-5 | 0 | 0 | 0 |
| GS-4 | 0 | 0 | 0 |
| GS-3 | 0 | 0 | 0 |
| GS-2 | 0 | 0 | 0 |
| GS-1 | 0 | 0 | 0 |
| Subtotal | 59 | 68 | 68 |
| 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 |
| Subtotal | 0 | 0 | 0 |
| Ungraded | 33 | 34 | 34 |
| Total permanent positions | 59 | 68 | 68 |
| Total positions, end of year | 92 | 102 | 102 |
| Total full-time equivalent (FTE) employment, end of year | 92 | 102 | 102 |
| Average ES salary | 0 | 0 | 0 |
| Average GM/GS grade | 12.7 | 12.7 | 12.7 |
| Average GM/GS salary | 127,921 | 129,878 | 132,833 |

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