DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

NATIONAL ADVISORY COUNCIL FOR BIOMEDICAL IMAGING AND BIOENGINEERING

Summary of Meeting[1]
January 19, 2022

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 58th meeting on January 19, 2022, by Zoom for the Open Session and Closed Session. Dr. Bruce Tromberg, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) presided as Council chairperson. In accordance with Public Law 92-463, the meeting was open to the public from 12:00 p.m. to 4:04 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 4:11 p.m. to 5:04 p.m. for the consideration of grant applications.

Council members present:

Dr. Samuel Achilefu, Washington University School of Medicine, St. Louis, MO
Dr. Gilda Barabino, Olin College, Needham, MA
Dr. Jennifer Barton, University of Arizona, Tucson, AZ
Dr. Simon Cherry, University of California, Davis, Davis, CA
Dr. Tejal Desai, University of California, San Francisco, San Francisco, CA
Dr. Maryellen Giger, University of Chicago, Chicago, IL
Dr. Paula Hammond, Massachusetts Institute of Technology, Cambridge, MA
Dr. Amy Herr, University of California, Berkeley, Berkeley, CA
Dr. Ranu Jung, Florida International University, Miami, FL
Dr. Kathryn Nightingale, Duke University, Durham, NC
Dr. Manu Platt, Georgia Institute of Technology, Atlanta, GA
Dr. Bruce Rosen, Massachusetts General Hospital, Charlestown, MA

Ex officio member attending:
Dr. Zane Arp *(on behalf of Dr. Jeffrey Shuren)*, U.S. Food and Drug Administration, Silver Spring, MD
Dr. Vincent Ho, Uniformed Services University of the Health Sciences, Bethesda, MD
Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD
Dr. Sohi Rastegar, National Science Foundation, Arlington, VA

Ex officio members absent:
Mr. Xavier Becerra, Department of Health and Human Services, Washington, DC
Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Dr. Jeffrey Shuren, U.S. Food and Drug Administration, Silver Spring, MD

Chairperson:
Dr. Bruce J. Tromberg

Executive Secretary:
Dr. David T. George

Also Present:

Approximately 274 observers attended the open session, including NIBIB staff, and members of the general

[1] For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a conflict of interest may occur. This procedure only applies to applications that are discussed individually, not to "en bloc" actions.

public.

Call to Order: Dr. David T. George

Dr. David T. George called to order the 57th meeting of the National Advisory Council for Biomedical Imaging and Bioengineering. He reminded attendees that the morning session of the meeting was open to the public and welcomed attendees.

I. Director's Remarks: Dr. Bruce Tromberg

A. Staff Updates

Dr. Tromberg welcomed the following new staff: Ms. Stephanie Jackson, administrative official; Ms. Kara Penny, administrative officer; Alice Ma, analyst in the Division of Applied Science and Technology; Kejuana Lilly, analyst in the Office of Scientific Review; Brian Quillin, grants management specialist; Courtney Dodson, grants management specialist; and Moira McCormick, research scientist in the Section on Mechanobiology in the Intramural Research Program. In the Information Technology (IT) department, Dr. Tromberg also welcomed Mr. Ryan Dava, IT member; Mr. LaVorn Colclough, desktop support technician; Mr. Cory Berkland, IT member; Mr. Warren Daniels, IT member; Mr. Anthony Dorian, IT systems administrator; Mr. Harsha Maduri, SharePoint administrator; Mr. Suryatheja Muppalla, IT member; and Ms. Donna Gregory, IT communications.

B. Honors and Awards

Dr. Tromberg congratulated three council members on new positions. First, he congratulated council member Dr. Ranu Jung, who was named the founding executive director of the Institute for Integrative and Innovative Research at the University of Arkansas. He also congratulated council member Dr. Samuel Achilefu, who was named the inaugural chair of the University of Texas Southwestern Medical Center's department of biomedical engineering. Finally, Dr. Tromberg congratulated council member Dr. Tejal Desai, who was named dean of the Brown School of Engineering.

Dr. Tromberg next congratulated NIBIB Data and Technology Advancement (DATA) national service scholar and Fogarty International Center scholar Dr. Judy Gichoya, who was named the 2021 Most Influential Radiology Researcher by AuntMinnie.com. Dr. Tromberg then congratulated members from the bioengineering community who were elected to the National Academy of Medicine in 2021: NIBIB grantees Dr. Guillermo Antonio Ameer, Dr. Linda G. Griffith, Dr. Carla Pugh, Dr. Elisa Konofagou, Dr. Andrés J. Garcia, and council member and NIBIB grantee Dr. Achilefu.

C. Budget

Dr. Tromberg noted that the NIH is still operating under a continuing resolution at the FY21 appropriation level. The interim payline for parent R01s is 10% (15% for new investigators), with most awards being paid at reduced levels pending a final FY22 appropriation. The proposed funding for NIBIB by the Senate, House, and President are roughly $421 million, $431 million, and $422 million, respectively.

Dr. Tromberg next talked about NIBIB supplemental funding for COVID-19 in FY20-22, which totals nearly $1.5 billion. He noted that this additional funding has been a significant addition beyond NIBIB's base level of funding levels, but since these funds have come from COVID-19 supplements, they may not continue.

D. Program Announcements, Opportunities, and Updates

DS-I Africa: Dr. Tromberg noted that the NIH Common Fund's Harnessing Data Science for Health Discovery and Innovations in Africa (DS-I Africa) program received nearly $75 million in October. All of

the related awards have been announced. The awards include seven research hubs; seven research training programs; four sites for ethical, legal, and social implications (ELSI) research; and one open data science platform and coordinating center. Dr. Tromberg highlighted the fact that NIBIB is funding one of the research hubs and the open data science platform and coordinating center, and that Dr. Tiffani Baily Lash is managing the NIBIB effort.

SPARC: Dr. Tromberg next talked about new initiatives within the Stimulating Peripheral Activity to Relieve Conditions (SPARC) program. Two initiatives fall under SPARC-V, which focuses on vagus nerve mapping and physiology. The first initiative, called REVA (Reconstructing Vagal Anatomy), aims to create detailed maps of the human vagus nerve, and will have a new solicitation published around January 26, 2022. The second initiative is for the VNS (vagus nerve stimulation) Endpoints from Standardized Parameters (VESPA) Center (U54). This center will implement a large multisite clinical study of the multi-organ effects of VNS. A request for application (RFA) for this center has been issued, with applications due April 1, 2022. There will be informational webinars about this RFA on January 21, 2022, and February 2, 2022.

Dr. Tromberg also highlighted the recent announcement of the Neuromod Prize, a competition that aims to incentivize the selective neuromodulation of multiple autonomous functions without off-target effects. This nearly $10 million competition will have three phases, with submissions for the first phase due by April 28, 2022. There will be an informational webinar about this competition on February 7, 2022. Drs. Michael Wolfson and Andrew Weitz are the NIBIB program directors leading the SPARC effort.

NIH HEAL Initiative®: An RFA, titled Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management, which is co-led by NIBIB and NCCIH (National Center for Complementary and Integrative Health), was recently announced as a part of the NIH HEAL (Helping to End Addiction Long-term) Initiative®. Dr. Tromberg and NCCIH director Dr. Helene M. Langevin described this RFA in a video, of which Dr. Tromberg showed a segment. Applications are due on February 11, 2022. Dr. Guoying Liu is leading the NIBIB effort.

Funding Opportunities in Diversity, Equity, Inclusion, and Accessibility Areas: Dr. Tromberg highlighted three funding announcements in areas related to diversity, equity, inclusion, and accessibility.

The first funding opportunity is an RFA for Technology Development to Reduce Health Disparities, which is supported by NIBIB and NIMHD (National Institute on Minority Health and Health Disparities). This R01 requires formal collaboration with public health agencies, healthcare organizations, or community-based organizations serving populations that experience health disparities. In terms of review criteria, this RFA adopts the Plan for Enhancing Diverse Perspectives (PEDP). Application due dates are February 11, 2022; January 26, 2023; and January 26, 2024. Dr. Zeynep Erim is leading the NIBIB effort.

The second funding opportunity is an RFA for New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research, which is supported by NIBIB and NHGRI (National Human Genome Research Institute). Dr. Tromberg noted that this R01 is not necessarily to support a particular technology itself, but rather to support new investigators. Applications will be reviewed internally, and due dates fall on February 22 from 2022 to 2024. Dr. Zeynep Erim is leading the NIBIB effort.

The third funding opportunity is a program announcement with special receipt, referral, and/or review considerations (PAR) for Small Grants for New Investigators to Promote Diversity in Health-Related Research, which is supported by NIBIB, NHGRI, and NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases). This R21 is a parent-like RFA with no restrictions on topic but encourages new investigators to promote diversity and health-related research. The next application due date is February 16, 2022, with standard due dates through June 16, 2024. Dr. Zeynep Erim is leading the NIBIB effort.

Technology to Improve Maternal Health Virtual Workshop: Dr. Tromberg highlighted a virtual workshop,

"Technology to Improve Maternal Health," which took place on January 18, 2022. This workshop was hosted by NIBIB and was co-supported by NICHD (*Eunice Kennedy Shriver* National Institute of Child Health and Human Development) and the Office of Research on Women's Health (ORWH). There were around 600 registrants for the webinar, with more than 300 participants at the start of the workshop, according to NIBIB program director Dr. Ilana Goldberg, who organized the event. Dr. Tromberg spotlighted some statistics that were shared at the workshop related to disparities in maternal morbidity and mortality, noting that such statistics galvanized the community to hold this workshop, which had 13 NIH ICs on the organizing committee. More information about this workshop, including session videos, can be found on the webinar webpage. Lastly, Dr. Tromberg mentioned a Notice of Special Interest (NOSI) issued by NIBIB and others that is focused on Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health; the next due date is April 5, 2022.

NIH Technology Accelerator Challenge for Maternal Health: In early December, the NIH Technology Accelerator Challenge for Maternal Health (NTAC: Maternal Health) was launched. This challenge aims to spur the development of prototypes for low-cost, point-of-care molecular, cellular, and/or metabolic sensing and diagnostic technologies in the maternal health space. The challenge is supported by NIBIB, NICHD, and ORWH. Cash prizes total up to $1 million across finalists and semi-finalists, with consideration for follow-on support from the Bill & Melinda Gates Foundation. The registration deadline is April 1, 2022, with a submission deadline of April 22, 2022. Drs. Lash and Gilliland are leading the NIBIB effort.

DEBUT Challenge: The 2022 Design by Biomedical Undergraduate Teams (DEBUT) Challenge was recently announced. This initiative challenges undergraduate teams to design technology solutions to unmet health needs. Dr. Tromberg noted that there will be a new prize this year in rehabilitative and assistive technologies for $15,000, bringing the cash prize total to $130,000. Also new this year: commercialization training will be offered to NIH winners. The submission deadline for the challenge is May 31, 2022, with winners being announced on August 26, 2022. Dr. Erim is leading the NIBIB effort.

Small Business Programs-supported Technology Received FDA Clearance: Dr. Tromberg highlighted a technology supported by the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs that recently received 510(k) clearance from the U.S. Food and Drug Administration (FDA). This technology improves low-dose computed tomography (CT) image contrast by up to 75% without compromising imaging speed or quality. Dr. Tromberg mentioned that the lead investigator who developed this technology, Dr. Danny Wang, participated in the NIBIB Concept to Clinic: Commercializing Innovation (C3i) Program, and that NIBIB program staff Dr. Qi Duan and Todd Merchak have managed this project. Dr. Tromberg noted that this technology has the potential to be highly impactful and emphasized this path for technology commercialization.

Featured Intramural Investigators: Dr. Tromberg spotlighted some achievements of NIBIB intramural investigators. Dr. Alexander Cartagena-Rivera was recently selected as a featured mechanobiology scientist in the "Faces of *Cell*" column by Cell Press. His work and recent *Cell* paper focus on quantitatively measuring forces in biological systems. Additionally, NIBIB intramural researchers Dr. Yicong Wu and Dr. Hari Shroff recently authored a *Nature* paper focused on super-resolution microscopy, which details a method to improve both lateral and axial resolution in confocal microscopy by more than twofold.

NIH BETA Center Director Update: A search for the director for the new trans-NIH BETA (Biomedical Engineering & Technology Accelerator) Center is underway; the application deadline was on December 8, 2021. The mission of the Center is to accelerate technology-driven interdisciplinary research, training, clinical translation, and dissemination at NIH and to attract and expand diverse biomedical engineering talent. Dr. Tromberg expressed hope that this senior-level position might be filled by the next council meeting.

E. RADx® Updates

RADx Tech Impact: Dr. Tromberg started his discussion about the RADx® initiative by highlighting the cumulative impact of test production culminating from the "innovation funnel"; he noted that the production of tests and test products supported by RADx has increased by more than a factor of two since the last council meeting. As of December 2021, 1.5 billion tests and test products have been produced, with commercial products including lab-based, point-of-care, and at-home tests. He estimated that approximately 6.3 million tests and test products were produced per day in December 2021. So far, the RADx initiative has resulted in 37 emergency use authorizations (EUAs); six of these EUAs were for over-the-counter (OTC) tests. Additional information about RADx-supported projects can be found on the website dashboard.

Dr. Tromberg also highlighted the WhenToTest.org website, an online tool that makes COVID-19 testing recommendations for both organizations and individuals based on personalized risk factors. The tool integrates local vaccination rates, R-naught values (recently modified for the omicron variant), as well as local prevalence of the virus to develop testing recommendations. Further, the resource offers guidance about pooling and testing implementation, as well as a "playbook" for COVID-19 testing at schools, along with links to trusted testing supplies. Dr. Tromberg noted that there are well over 30,000 website users around the world, with approximately 3,000 users accessing the website each day.

Dr. Tromberg next mentioned Say Yes! COVID Test, a public health effort in collaboration with the Centers for Disease Control and Prevention (CDC). The program has been deployed in 975 separate zip codes, encompassing 770 cities in 84 counties within 10 states. The COVID-19 tests distributed in this program have largely been the Quidel QuickVue test; Dr. Tromberg noted that nearly 7 million tests were purchased for this program. The tests were fulfilled primarily by a direct-to-consumer pathway, and Dr. Tromberg said that this program was an inspiration for the recent government website which allows all Americans to order free COVID-19 tests. Further, he noted that this platform shows how research can be leveraged for new clinical studies and can be used to gain new insight and shape guidance.

Variant Surveillance: Dr. Tromberg spoke about "Project Rosa," a RADx effort that is developing a variant surveillance tool with three main goals: to determine the positivity of a COVID-19 sample, to discover the lineage of the variant, and to identify mutations of biological interest. The tool uses genotyping markers in order to accomplish these goals; this strategy is faster and cheaper than next-generation sequencing methods and could be adapted in approximately 50% of labs in the U.S. This surveillance tool was developed before the omicron variant emerged; however, in a 2-week period, four genotyping markers were identified that could distinguish the delta variant from the omicron variant. This rapid turnaround time demonstrates that this tool can be quickly modified as new variants appear to aid in viral surveillance.

Impact on National Policy: Dr. Tromberg highlighted the launch of the COVIDtests.gov website, noting that 42 million households ordered tests when the site was still in the pre-launch phase, representing a phenomenal response from the public. He also spoke of the recent announcement by the President that an additional 500 million tests will be purchased for Americans. Dr. Tromberg noted that these policies draw from the following RADx-supported initiatives: tests that culminated from the "innovation funnel"; the Say Yes! COVID Test program; the Variant Task Force, which assesses the performance of antigen tests (including their ability to detect the omicron variant); and the Independent Test Assessment Program (ITAP), a collaboration with the FDA.

Ongoing Challenges: Dr. Tromberg wrapped up his discussion of RADx by describing some ongoing challenges. He first described the evolution of COVID-19 testing. In April 2020, approximately 5 million tests were performed in the U.S., and the bulk of the testing was done in laboratory settings. However, in December 2021, approximately 400 million tests were performed in the U.S.; half of these were OTC tests. This large-scale deployment of OTC tests represents a paradigm shift in COVID-19 testing during the course of the pandemic. However, because many OTC tests do not have a reporting component, a significant amount of real-time testing information is lost. Dr. Tromberg also talked about some of the confusion surrounding OTC tests, such as proper technique when performing the test and the timing of when to take a test. He highlighted some of his recent interviews on these topics, which appeared in The Washington Post,

ABC News online, CBS News online, The New York Times, NPR, and The Wall Street Journal.

Dr. Tromberg also noted that the demand for COVID-19 tests currently exceeds the supply. In response to this issue, he spoke about the development of Independent Test Assessment Program (ITAP). This program, which was established in October 2021, aims to accelerate OTC FDA authorizations. Dr. Tromberg likened the assessment of incoming projects to the process of the RADx Tech "innovation funnel," which begins with a "deep dive" phase that is followed with a customized assessment and workplan for approved companies. He noted that two EUAs culminated from this program within the first two months, which have contributed approximately 100 million OTC tests to the U.S. market. He also noted that additional companies have submitted applications to the program, which may result in additional testing capacity in the coming months.

F. Discussion

Dr. Kathryn Nightingale noted that the lack of reporting from OTC COVID-19 tests is a concern. Dr. Tromberg said that several COVID-19 tests incorporate mobile apps, and that NIBIB is working with some of these companies to develop streamlined reporting of test results. Dr. Desai asked about NIBIB's influence in other public health areas beyond the pandemic, and how to increase the messaging that engineers are playing a role in addressing public health challenges. Dr. Tromberg noted that engineers need greater representation, not only in technical areas but in leadership areas, and he urged the council members to think imaginatively of new academic programs and partnerships that can best leverage the engineering community. Dr. Achilefu noted that the COVID-19 supplemental funding is likely to end soon, but that this investment could be utilized for other kinds of diseases or other urgent issues. Dr. Tromberg noted that Dr. Lash's presentation, to take place later during this council meeting, will discuss a concept clearance for POCTRN (Point of Care Technology Research Network). This network, along with the RADx innovation partnerships developed during the pandemic, could be leveraged to facilitate advances for other public health issues.

II. NIBIB Special Council Lecture: Dr. Noni Byrnes, Director, NIH Center for Scientific Review (CSR): Initiatives to Address Bias in Peer Review

Dr. Byrnes described NIH's Two-Stage Peer Review System; the first level is the peer review study sections, and the second level of review is conducted in program and council meetings, based on scientific merit. In FY21, NIH received 88,000 applications and 66,600 were reviewed by CSR. They handled applications for 182 special initiatives (including those that are part of the BRAIN Initiative® and RADx® Initiative).

CSR is attempting to mitigate bias. Dr. Byrnes summarized various studies and papers that looked at reviewer bias based on race and gender. She also discussed a 2019 NIH study that found that there was a lower rate of funding for topic clusters that are favored by minority Principal Investigators (PIs). In a study removing identifiers of grant applications, it was found that Black PI scores did not improve, but the scores of white PIs were slightly, but significantly, worsened. The conclusion reached by CSR is to try to find ways to diminish the importance of PI identity during peer review.

CSR is exploring ways to create a more blinded review process. In 2021, the CSR/Common Fund collaboration granted Transformative Research Awards (tR01) using a mostly blinded review process. A quarter of respondents said that the anonymized process positively affected their decision to apply and believed that it was a more effective way to fund projects, not people, as well as limit institutional prestige bias and applicant demographic bias. CSR believed the process was successful and is planning on continuing to review tR01s using this method.

Two separate working groups suggested reorganizing the currently scored review criteria into three scored factors—the importance of science, the feasibility and rigor, and the investigators and environment. This would allow for a multi-stage, partially blinded-review process where the importance of the science and feasibility and rigor would be a blind review.

CSR is also focusing on training study section chairs on ways that they can help reduce bias in study section discussions. In August, CSR also implemented bias awareness training for reviewers. It has been very well received by the reviewers and there is some early evidence that it is helping during study section discussions. CSR is also encouraging reviewers to report observed bias to CSR—whether that bias be against a grantee or another reviewer.

Additionally, CSR is attempting to diversify and broaden the pool of reviewers using a new tool, the CSR Reviewer Finder Tool, which can help SROs (Scientific Review Officer) to find "lesser-known qualified reviewers."

Dr. Byrnes concluded by saying that it is important to change the culture at the NIH and communicated CSR's commitment to having diversity, including race, gender, and career stage, in the review process, especially on Special Emphasis Panels. Techniques to improve diversity in the review process include raising collective awareness, using tools, and providing SRO training. She showed that in the last year since CSR has begun focusing on these issues, there has been a significant increase in women and under-represented minorities in study sections due to the efforts of CSR staff.

Council members were supportive of the changes, asked if CSR had plans to make bias training required for all reviewers in the future, and discussed the difficulties of identifying various biases in the review process. Dr. Byrnes acknowledged the challenges and reemphasized the importance of using a multipronged approach and that there would be no one single solution to the problem. Concerns were brought up regarding some of the suggested changes to the review criteria and there could be some adverse effects if the proposed changes were instituted. Dr. Byrnes emphasized that the recommendations are preliminary and were still making their way through the NIH approval process.

III. Diversity, Equity, Inclusion, and Accessibility Work Group: Dr. Zeynep Erim, Dr. Gilda Barabino, Dr. Roderic Pettigrew

A. UNITE Updates

Dr. Erim described UNITE as being made up of three groups: Health Disparities/Minority Health/Health Equity Research, an external workforce, and an internal workforce. UNITE is attempting to understand racial disparity by understanding stakeholder experiences through listening and learning and is committed to transparency, communication, and accountability with internal and external stakeholders.

UNITE is also expanding the NIH Science Education Partnership Award (SEPA) Program to focus on the K-12 STEM community with resources aimed at increasing career opportunities for underrepresented groups and with more outreach and engagement with HBCUs (Historically Black Colleges and Universities)/TCUs (Tribal Colleges and Universities)/HSIs (Hispanic Serving Institutions)/MSIs (Minority Serving Institutions). In addition, the FY22 performance plan element for Institute and Center Directors will be held accountable for diversity, equity, inclusion, and accessibility.

New RFAs were published (RFA-RM-21-021 and RFA-RM-21-022) for transformative research on addressing health disparities and advancing minority health. They will provide up to $24 million in the first three years and up to $60 million over five years.

Dr. Erim also brought the "Ending Structural Racism" website to the attention of council. The website has relevant diversity information along with UNITE accomplishments.

B. NIBIB Diversity Efforts

In August of 2021, an internal NIBIB working group met and developed a list of recommendations for how NIBIB can increase diversity and influence NIBIB's community based on different career levels. They chose to highlight five projects that could have the most impact on NIBIB's community as they are specifically relevant to the engineering community.

The five areas of focus that came out of the working group were:

1.) Funding opportunities to enhance:
    a. Diversity of the NIBIB workforce
    b. Health equity/health disparities research
2.) Building bioengineering departments at HBCUs
3.) Enhancing undergraduate education
4.) Encouraging entrepreneurship
5.) Focusing on diversity, equity, inclusion, and accessibility (DEIA) in the NIBIB workforce

In the area of funding opportunities, NIBIB has already discussed and implemented three new FOAs:

1.) Technology Development to Reduce Health Disparities
2.) New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research
3.) Small Grants for New Investigators to Promote Diversity in Health-Related Research

Currently, there are only two HBCUs with accredited bioengineering departments. The goal for NIBIB is to strengthen HBCUs and include them in bioengineering growth while directly targeting the bioengineering pipeline. NIBIB will consider using different mechanisms of support, collaborating with other agencies and industry, engaging leaders from institutions with relevant experience, and creating a best practices toolkit for assisting other institutions to follow. The next step is to have a roundtable with HBCU leaders to assess the interest and needs of the community.

To enhance undergraduate education, NIBIB will continue to focus on its program "Enhancing Science, Technology, Engineering, and Math Educational Diversity" (ESTEEMED), which supports students during the critical transition to college and through their freshman and sophomore years with an emphasis on cohorts, mentoring, and research experiences. In addition, the Biomedical Engineering Summer Internship Program (BESIP) will focus on expanding diversity and providing funding for multiple years. Finally, NIBIB will focus on its Summer Research Experiences for high school science teachers.

To expand entrepreneurship training, NIBIB will expand and build on its existing Concept to Clinic: Commercializing Innovation (C3i) program, focusing on increasing diversity, connections to industry, access to networks, and supporting travel to meetings with VC/AC (venture capitalists/angel capitals) and investor conferences.

To increase DEIA in the NIBIB Workforce, NIBIB is re-examining the demographics of its workforce, taking inventory, listening to staff concerns, and planning interventions, such as the Racial and Ethnic Equity Plan (REEP) required by UNITE. Two key positions in implementing these plans are the Director of the NIH BETA Center, who will also be the Associate Director for Scientific Diversity, Equity and Inclusion, and the NIBIB DEIA Officer.

C. Discussion

Drs. Gilda Barabino and Roderic Pettigrew opened the conversation with the fact that the working group was specifically interested in the expansion of bioengineering programs at HBCUs. Dr. Pettigrew expressed enthusiasm for the idea and outlined some of the challenges that HBCUs face in creating bioengineering departments including the immense resources and funding that will be needed to accomplish this goal. Council also expressed great enthusiasm for the idea and discussed bringing in partners to help provide the resources and funding needed to accomplish this goal. Council also discussed the importance of highlighting

the societal value of having bioengineering departments at HBCUs and the need for not just funding and space, but also the people interested in seeing this through.

IV. POCTRN/RADx Concept Clearance: Dr. Tiffani Lash

Dr. Lash provided an overview of Point-of-Care Technologies Research Network (POCTRN). Over its years of existence, POCTRN has maintained the belief that clinical need drives technology development. It is unique because instead of using traditional NIH funding mechanisms, NIBIB uses cooperative agreements that provide flexibility to support centers which, in turn, support grants. POCTRN centers address the entire development pipeline, and the resources they provide can be extremely helpful in areas where there is a need for flexibility, as has been seen with the success of RADx.

The RADx application funnel, utilizing existing POCTRN platforms, reviewed a total of 814 applications and supported more than 100 organizations. The program has produced 1.5 billion COVID-19 tests and test products, and, as of January 2022, 37 tests have received an EUA from the FDA.

In the past, POCTRN has also seen success with addressing the entire technology pipeline by supporting the first sexually transmitted infection (STI) point-of-care device to receive FDA 510(k) clearance. Other successes include "I want the kit," an STI kit that can be sent to patient's homes, self-administered, and returned by mail to receive the results. This kit was especially successful in low-resources settings.

Dr. Lash expressed that there has been a lot of interest in this using these types of funding mechanisms in areas outside COVID-19, including cancer, maternal health, drug abuse, infectious diseases, aging, nursing, neuroscience, artificial intelligence, tuberculosis, global health, and primary care. To maximize flexibility, Dr. Lash presented for concept clearance using both cooperative agreements and contracts. The concept is that there would be three centers: a Clinical Studies Center, a Coordination and Commercialization Center, and a Validation and Testing Center. The intent is that, moving forward, these centers would help accelerate the technology development pipeline from beginning to end, support full-scale development of technologies, create efficient evaluation and implementation methods, support clinical studies and large-scale operations, and increase the number of women and minorities participating as well as develop new training opportunities.

Council was highly supportive of this concept.

V. BRAIN Initiative® Non-Invasive Brain Functional Imaging Technology Development Concept Clearance: Dr. Shumin Wang

This initiative focuses on BRAIN three priority areas. The first is creating maps at multiple scales—from synapses to the whole brain. The second focus is on producing a dynamic picture of the functioning brain by developing and applying improved methods for large-scale monitoring of neural activity. The final focus is to develop innovative technologies to understand the human brain and treat its disorders and to create and support integrated human brain research networks. These goals grew out of recommendations made by the BRAIN Workgroup 2.0, which met in 2019 to evaluate the achievements made during the first phase of the BRAIN Initiative.

Two non-invasive imaging workshops were held in 2021. The first was a Dissemination Workshop in February and the second was a Transformative Workshop in March. A Request for Information was published in 2021. The main findings of these workshops were:

1.) Completely new modalities that could significantly broaden the applicability of brain functional imaging.
2.) Much finer resolution offered by a possible order of magnitude sensitivity improvement of MEG (Magnetoencephalography), PET (positron emission tomography), and fMRI (Functional magnetic resonance imaging or functional MRI).

3.) Opportunities exist for further technology development.

Encouraged by the potential opportunities for the NIBIB community, the three overarching goals of this new concept are as follows: to continue the momentum by supporting multi-disciplinary, synergistic and integrative approaches for bridging the gap between multiple scales/aspects; to guide further development by emphasizing technologies suggested at the workshops and by the community; and to encourage out-of-the-box thinking.

To encourage high-risk projects, Dr. Wang proposed the use of phased cooperative agreement awards. It is believed that this would be more effective for promoting innovation while reducing risk. Phase 1 would prove the feasibility of new brain functional/connectivity imaging and provide up to three years with a limited budget. Phase 2 would fully develop a functional prototype generating a? first-in-human imaging result and provide funding up to four years, but not exceeding five years in total with no budget cap.

Council discussed the details of the proposal. There were concerns that five years is a short timeline to go from out-of-the-box, high-risk ideas, to first-in-human. Dr. Wang informed council that NIH does not have grants that last longer than five years. There was generally strong support for the concept and a lot of good feedback for Dr. Wang to bring back to the BRAIN initiative.

VI. Adjournment

The open session of the NACBIB meeting was adjourned at 4:04 p.m.

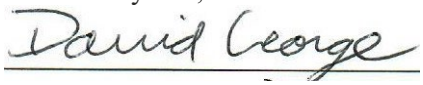
VII. Closed Session

Review of Council Procedures and Regulations: Dr. David T. George

The grant application review portion of the meeting was closed to the public in accordance with provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and I0(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). The closed session was adjourned at 5:04 p.m.

Certification:

We certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.[2]



David T. George, Ph.D.
Executive Secretary
National Advisory Council for Biomedical Imaging and Bioengineering
Associate Director for Research Administration
National Institute of Biomedical Imaging and Bioengineering

Bruce J. Tromberg, Ph.D.
Chairperson
National Advisory Council for Biomedical Imaging and Bioengineering
Director,
National Institute of Biomedical Imaging and Bioengineering

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[2] These minutes will be approved formally by the Council at the next meeting on May 17, 2022, and corrections or

notations will be stated in the minutes of that meeting.