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]
May 19, 2021

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 56th meeting on May 19, 2021, 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 3:38 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 3:46 p.m. to 4:33 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. 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. Bruce Rosen, Massachusetts General Hospital, Charlestown, MA
Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

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, National Institutes of Health, Bethesda, MD
Dr. Francis Collins, National Institutes of Health, Bethesda, MD

Chairperson:
Dr. Bruce J. Tromberg

Executive Secretary:
Dr. David T. George

Also Present:

Approximately 225 observers attended the open session, including NIBIB staff, and members of the general public.

[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.

Call to Order: Dr. David T. George

Dr. George called to order the 56th 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. Welcome and Opening Remarks

Dr. Tromberg thanked Dr. Gordana Vunjak-Novakovic for her service on the council. While her term has been completed, Dr. Vunjak-Novakovic has agreed to extend her service on the council.

Dr. Tromberg also welcomed the following NIBIB staff: Julia Ringel, Tareq Al-Shargabi, Donna Gregory, Stacey Warr, Shanna Frierson, Imran Omair, Naledi Simons, Sonca Hoang, Leticia Noel, Dr. Karen Olsen, Khalil Chugtai, Djanira Murchison, and Lale Esven.

B. Budget

Dr. Tromberg spoke about the President's proposed FY22 budget, which includes approximately $51 billion in NIH funding (an increase of approximately $9 billion compared with FY21). Notably, this increase includes a proposed $6.5 billion for the creation of Advanced Research Projects Agency for Health (ARPA-H).

He also spoke about NIBIB's funding, which averaged over $1 billion per year in FY20 and FY21 due to the additional funding support the Rapid Acceleration of Diagnostics (RADx^{SM}) initiative. However, the annual appropriation for FY21 of $411M was the smallest increase that NIBIB has received in the last five years. To fund a comparable number of competing R01 awards as previous years in light of this small increase, some funding policy changes were implemented. These changes included deeper administrative reductions for higher-cost competing awards (15 percent for R01s and U01s for established investigators with non-modular budgets and 10 percent for P41s) and small reductions for non-competing awards (two percent for R01s, U01s, and P41s). These changes will allow NIBIB to fund 19 more R01s than if these policies had not been implemented.

C. Honors and Awards

Dr. Tromberg congratulated Dr. Cato Laurencin, an NIBIB grantee and previous council member, who was recently elected to the National Academy of Sciences. Dr. Laurencin is the first surgeon in history to be elected to the National Academy of Engineering, the National Academy of Medicine, the National Academy of Sciences, and the National Academy of Inventors.

Dr. Tromberg congratulated Dr. Ranu Jung, an NIBIB grantee and current council member, who will be featured on *PBS' Human: The World Within* in June. Dr. Jung also recently received an honorary doctorate from Aalborg University in Denmark.

Dr. Tromberg congratulated Dr. Kaitlyn Sadtler, NIBIB Stadtman Investigator and Chief of the Section for Immunoengineering, who received the 2021 Outstanding Recent Graduate Award from John Hopkins School of Medicine. Dr. Sadtler is also featured in a children's book about women in science.

D. Program Announcements, Opportunities, and Updates

Bridge2AI: This Common Fund program aims to generate flagship data sets and best practices for the collection and preparation of Artificial Intelligence (AI)/Machine Learning (ML)-ready datasets. The program has recently published a Research Opportunity Announcement for data generation projects. There

will be a total of 5-8 awards, with $96 million in funding over four years. Letters of intent are due on July 20, 2021, and applications are due on August 20, 2021. There is also a Notice of Intent to Publish (NOITP) for the Integration, Dissemination, and Evaluation (BRIDGE) Center (U54). Dr. Grace Peng is leading the NIBIB effort.

Blueprint MedTech: This program, inspired by the RADx[SM] initiative, is a collaboration among 14 NIH ICs that aims to accelerate the development of cutting-edge medical devices to diagnose and treat disorders of the nervous system. Four NOITPs were recently published (Prototype Developer, Incubator Hubs, Translator, and Small Business Translator) and upcoming Funding Opportunity Announcements are estimated to be released in July 2021, with an estimated due date of October 20, 2021. Dr. Michael Wolfson is leading the NIBIB effort.

Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health: The Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health is a new Notice of Special Interest (NOSI) for Small Business Innovation Research with the goal of developing innovative technologies to quantitatively predict an increased risk for maternal morbidity and mortality. This initiative accepts applications on the standard STTR and SBIR due dates through April 6, 2023. Dr. Ilana Goldberg is leading the NIBIB effort.

Parent R21 Grant Program: Following feedback from Council at the January 2021 Council meeting, NIBIB will sign onto the Parent R21 Grant Program. Two notices have been published announcing NIBIB's rejoining of this program—one for clinical trial research and one for non-clinical trial research. The project duration is two years, and preliminary data is allowed in the parent R21 program. As before, the two-year budget cost is $275,000. Dr. Randy King is leading the NIBIB effort.

BRAIN Initiative Workshops: Dr. Tromberg highlighted two BRAIN (for Brain Research Through Advancing Innovative Neurotechnologies®) Initiative workshops held earlier this year, which both focused on non-invasive imaging technologies. Videos from both workshops are available through the NIH VideoCast (videos from the first workshop can be found here and here; videos from the second workshop can be found here, here, and here). Dr. Shumin Wang is leading the NIBIB effort in this initiative.

The DEBUT Challenge: Submissions for the Design by Biomedical Undergraduate Teams (DEBUT) challenge are due by June 1, 2021. An additional prize was added this year: the Technologies for Cancer Prevention, Diagnosis and Treatment Prize ($15,000), supported by NCI. Winners will be announced on August 25, 2021. Dr. Zeynep Erim is leading the NIBIB effort in this challenge.

DATA National Service Scholars: NIBIB is participating in the inaugural Data and Technology Advancement (DATA) National Service Scholars Program, led by the NIH's Office of Data Science and Strategy. This program brings talented professionals with experience in and knowledge of data and computer sciences and related fields to advance high-impact programs at NIH. Dr. Tromberg highlighted the three scholars that are assisting in NIBIB efforts: Dr. Judy Gichoya, who is assisting in the NIH Common Fund program Harnessing Data Science for Health Discovery and Innovation in Africa; Dr. Mohammad Ghassemi, who is assisting in the NIH BRAIN Workspace to Organize the Knowledge Space platform; and Dr. Rui Sá, who is assisting in the collaborative network project, Medical Imaging and Data Resource Center (MIDRC).

MIDRC Updates: Dr. Tromberg outlined the infrastructure of MIDRC (Medical Imaging and Data Resource Center), which currently includes five technology-development projects involving data ingestion. In total, over 40,000 imaging studies have been ingested into MIDRC. Of these, more than 2,000 curated and annotated imaging studies have been released, with the goal of releasing 60,000 imaging studies by September 2021. In parallel, 12 collaborative research projects are pursuing AI/ML development. These research projects are focused on predicting COVID-19 outcomes, such as disease severity or length of hospital stay, by using multi-modal data from electronic health records, clinical studies, and the integration of imaging studies.

E. RADx Updates

RADx Impact: Dr. Tromberg provided a summary of the impact of RADx with respect to COVID-19 testing. Of note, the RADx[SM] initiative has supported over 100 companies, and 23 tests have received emergency use authorization (EUA) from the U.S. FDA, with one test achieving the first over-the-counter (OTC) EUA. As of April 2021, the cumulative capacity of manufactured tests is around 300 million, and roughly 2 million tests/products were produced per day in that month. Dr. Tromberg projects that more than 5 million tests will be produced each day by June 2021.

One of the OTC COVID-19 tests (the Quidel QuickVue test) is currently being used in a collaborative effort between the NIH and CDC to assess the effectiveness of at-home testing three times per week in reducing community transmission over a period of four weeks. The initiative, called Say Yes! COVID Test, is currently underway in Greenville, NC, and Chattanooga, TN, and the surrounding counties.

RADx Anniversary Celebration: Dr. Tromberg highlighted the virtual RADx anniversary event that took place on April 29, which was attended by approximately 450 participants and was led by NIH Director Dr. Francis Collins and featured special guests. He played a video montage that was created for the event, which was composed of media clips covering the initiative during the past year, along with a credits video which thanked the enormous community involved with the RADx effort. Dr. Tromberg noted that the event should be available for viewing on NIH VideoCast soon.

Senate Appropriations Committee Visit: Members of the Senate Appropriations Committee visited NIH campus on May 17. Part of this visit included a brief talk by Dr. Tromberg and a demonstration of various COVID-19 tests that were developed and supported by RADx.

In Closing: Dr. Tromberg ended his presentation by featuring a recent *Nature Biotechnology* editorial which discussed the RADx[SM] initiative. This editorial concluded with a call to action that stressed the importance a robust infrastructure and reimbursement system to empower community testing and diagnostic-led medicine. Dr. Tromberg noted that it will be important to leverage the investments culminating from the RADx[SM] initiative, and to make sure that such investments can be applied to other pathogens, diseases, and other global health challenges.

F. Discussion

Council member Dr. Samuel Achilefu asked about the FY21 budget and if pay-line implications will continue into future years. Dr. David George noted that greater cuts to the larger awards to established investigators would be sustained in though their future years whereas the cuts to the non-competing[2] and P41s are planned only for this year. These funding policies would be re-assessed following future-year appropriations. Council member Dr. Paula Hammond asked about the NIH appropriations process and how budgets are set. Dr. Jill Heemskerk responded that the budget for RADx and the NIBIB base budget were independent of one another.

II. NIBIB Diversity Equity and Inclusion Efforts: Dr. Zeynep Erim

Dr. Zeynep Erim, director of the Division of Interdisciplinary Training, presented an update on NIBIB's diversity, equity, and inclusion efforts—a central program of which is the NIH-wide UNITE initiative.

UNITE stands for:

[2] Correction to the minutes by Dr. George

Understanding stakeholder experiences through listening and learning;
New research on health disparities/minority health equity;
Improving the NIH culture and structure for equity, inclusion, and excellence;
Transparency, communication, and accountability with our internal and external stakeholders; and
Extramural research ecosystem: changing policy, culture, and structure to promote workforce diversity.

NIBIB is participating in three funding opportunity announcements published through UNITE: Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and HD (R01 Clinical Trial Optional), Transformative Research to Address Health Disparities and Advance Health Equity (U01 Clinical Trial Allowed), and Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (U01 Clinical Trial Allowed).

Dr. Erim described a new initiative, Support for Research Excellence (SuRE), an R16 grant that supports capacity building at institutions that enroll a significant number of underrepresented students and receive limited NIH research project grants. The initiative provides mentored and non-mentored funding ($125k/year and $100k/year, respectively) for faculty with no prior research or NIH-research funding. SuRE also supports a National Resource Center to assist SuRE-eligible institutions to build research capacity, conduct outreach and training, and collect and report data on the program.

NIBIB is also planning to participate in two new funding mechanisms designed to eliminate funding disparities. The Diversity R01 supports New Investigators from diverse backgrounds, including those from groups that are underrepresented in health-related sciences. The Diversity R21 supports small grants for new investigators to promote diversity in health-related research.

Dr. Erim described a new initiative, Bioengineering Technologies for Ending Health Disparities, for which she is seeking concept clearance. The initiative joins with the National Institute on Minority and Health Disparities (NIMHD) to promote technology development to end health disparities and improve minority health.

The initiative includes the use of the design, build, test, deploy approach to create novel, or adapt existing, technologies to enhance access and delivery to underrepresented groups. The technologies should be effective, affordable, culturally acceptable, and easily accessible/deliverable. Stakeholder and community participation must be built into the design, testing, usability, and delivery of the technologies. The program includes an annual grantee meeting and entrepreneurial training. One goal of the program is to make grantees ready for Small Business Education and Entrepreneurial Development (SEED) or SBIR phase 2 funding by the end of the award.

Examples of technologies to be supported include remote, in-home, and point-of-care diagnostics and treatments; devices that integrate diagnosis and treatment; mobile systems that can operate in low-resource settings; and diagnostics and treatments that do not require special training.

Dr. Tromberg explained that this initiative is a natural fit with the bioengineering community, which has a track-record of developing innovative technologies specifically designed to address the needs of underserved communities. The Council members commented that AI is likely to be a key player in the development of the types of technologies developed through the diversity initiative. The Council members applauded the use of the full-size NIH R01 as the funding mechanism, which has not generally been the case in diversity-targeting initiatives in the past. In response to questions from Council members about mechanisms to help with commercialization of technologies, Dr. Erim stated that the program would be looped into the existing C3i program to facilitate entrepreneurial training and technology commercialization.

III. NIBIB Diversity Working Group: Dr Gilda Barabino and Dr. Roderic Pettigrew

The co-chairs of the newly formed Diversity Working Group, Dr. Gilda Barabino and Dr. Roderic Pettigrew led the council brainstorming discussion addressing diversity, equity, and inclusion in NIBIB and biomedical research in general. The robust discussion generated a wide range of views and potential approaches to the problem of the lack of diversity in the biomedical research enterprise.

Dr. Barabino opened the discussion by stressing that the events of the past year have shed light on an opportunity for NIBIB and all of NIH to address the staggering racial disparities that exist in the health of underrepresented groups as well as the access to research resources for underrepresented scientists.

A number of council members highlighted the need to begin potential interventions as early as possible, such as at the middle-school and high-school levels, for communicating the opportunities available for students to become involved in biomedical science and engineering.

It was suggested that direct funding to diverse students during the graduate-student-to-post-doc transition could be extremely valuable. A post-doc carrying their own funding would be a very attractive candidate to a laboratory seeking such individuals. A related point was made that the unpaid internship is a practice that puts individuals with less means at a distinct disadvantage compared to those who could afford to undertake such internships. It was also suggested by several council members that faculty members need to proactively expand their networks from which they recruit to increase opportunities for diversity.

Given the data on the very low percentage of NIH research grants awarded to researchers from underrepresented groups, council members highlighted the need to address potential bias in grant reviews. A related suggestion was to add a broader-impacts review criteria on how a particular research proposal would enhance diversity and global well-being and therefore contribute to a more equitable world. For instance, would a proposed technology be expensive to develop and ultimately available only to a select few who could afford it, or would it be low-cost and potentially be made widely available to underrepresented groups in low-resource settings?

Council members discussed the concept of "what is measured is what gets managed," meaning that when have data and metric and incentives, accomplishments will be motivated. An example was given wherein institutions were awarded and recognized for increasing diversity in their recruiting and then deans of other institutions pressed their own faculties to follow suit.

Another point made was that there is a smaller market for developing treatment for diseases that affect minorities and that this ultimately reduces the research investment for such diseases. More money is awarded for research on diseases that affect the majority of a population. Special SBIR programs and other mechanisms exist that target rare and orphan diseases, but much work remains to increase incentives to study diseases that disproportionately affect underrepresented groups.

Dr. Tromberg thanked the Council and the Diversity Working Group for a vibrant and productive discussion and stressed that this will be an ongoing dialogue. The design-build-test-deploy rubric of bioengineering is a good model to use for increasing diversity in biomedical science. Thus, NIBIB and the bioengineering community have an opportunity to be leaders on this issue and be a model for the rest of NIH, as well as other government agencies and commercial enterprises.

IV. Update on the BRAIN Initiative: Dr. Bruce Rosen BRAIN

Dr. Bruce Rosen presented an update on the BRAIN initiative entitled "BRAIN…mapping brain activity at the speed of thought." He explained that three areas of emphasis were being pursued to lay the groundwork for an increase in BRAIN funding from the 21st Century Cures Act that will occur in FY23.

The first area is Organizing Resources for Brain Cell Type Access and Manipulation Across Species. The

goals are the development of tools for cell access in rodents and non-human primate brains, human cells, and tissue with the long-term goal of new therapeutic strategies for human brain disorders.

The second emphasis is the Phase III Brain Cell Census that will build on the success of the development of the mouse brain cell census and enable the shift to the construction of a human brain cell atlas.
The third area is Next-Generation Technologies for Brain Microconnectivity Analysis, described as a "wiring diagram" of the human brain, which Dr. Rosen described as a "daunting task."

A workshop series was conducted in February and March of 2021 on brain connectivity, which addressed the state of the art in mapping complete neural circuits, opportunities for advancing connectomics technologies, and challenges in mapping mammalian brain circuits. Workshop participants identified resources necessary to enhance study of brain function using specific cell type targeting and manipulation reagents that could then be broadly disseminated to the entire neuroscience community.

An additional workshop in February focused on the human brain cell census and explored the current landscape, gaps, and opportunities in tissue quality, collection, and processing pipelines. The participants explored what steps would be needed to develop a wiring diagram of the mammalian brain. The goal is to foster the next generation of brain circuit-based therapeutics and drive innovations in artificial intelligence and machine learning.

Several additional workshops were organized by NIBIB program director Dr. Shumin Wang on the Dissemination of Non-Invasive Imaging Technologies, which focused on a wide range of technologies that have been developed through the BRAIN initiative and how those technologies can be further advanced and broadly disseminated.

BRAIN issued a notice that BRAIN grant applicants are expected to submit their data to one of the BRAIN data archives using the elements required in the Resource Sharing Plan.

BRAIN data scholar Mohammed Ghassemi, PhD, is creating the BRAIN Initiative Workspace to Organize the Knowledge Space (BRAINWORKS). The tool is a web application that uses AI to organize the neuroscience knowledge space as an intuitive and interactive knowledge graph.

The BRAIN Initiative is taking steps to promote scientific excellence by enhancing diversity, equity, and inclusion. BRAIN Diversity Supplements are administrative supplements to currently active BRAIN grants to support the training of underrepresented individuals and enhance the diversity of the neuroscience workforce. The awards will support a defined pathway across career stages for outstanding graduate students who are from diverse backgrounds underrepresented in neuroscience research.

Dr. Rosen concluded by adding that beginning in Spring 2021, The BRAIN Initiative will include a new component in most FOAs requiring that applications include a Plan for Enhancing Diverse Perspectives (PEDP).

V. Adjournment

The open session of the NACBIB meeting was adjourned at 3:38 p.m.

VI. 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 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). The closed session was adjourned at 4:46 p.m.

Certification:

We certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.[3]

David George

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

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

[3] These minutes will be approved formally by the Council at the next meeting on September 14, 2021, and corrections or notations will be stated in the minutes of that meeting.