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 20, 2020

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 53rd meeting on May 20, 2020, by videoconference. Dr. Bruce J. 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 2:57 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 3:28 p.m. to 5:00 p.m. for the consideration of grant applications.

Council members present:

Dr. Samuel Achilefu, Washington University School of Medicine, St. Louis, MO
Dr. Jennifer Barton, University of Arizona, Tucson, AZ
Dr. Richard Buxton, University of California, San Diego, La Jolla, CA
Dr. Maryellen Giger, University of Chicago, Chicago, IL
Dr. David Grainger, University of Utah, Salt Lake City, UT
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. 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. Alex M. Azar, 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:

255 observers attended the open session by viewing the live videocast, including NIBIB staff and members of the 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. David T. George called to order the 53rd 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 J. Tromberg

A. Remembering Dr. Robert Nerem

Sadly, NIBIB National Advisory Council member Dr. Robert (Bob) Nerem passed away in March. Dr. Tromberg expressed his gratitude for Dr. Nerem's lifelong commitment to bioengineering. He was a global leader in the bioengineering community and instrumental in the creation of NIBIB. NIBIB will deeply miss him.

B. Farewell to Council Members

Dr. Tromberg thanked Dr. David Grainger and Dr. Richard Buxton for serving on the NIBIB Council. Drs. Grainger and Buxton have agreed to extend their terms as NIBIB Council members through the fall.

C. News

NIBIB Staff Updates: Dr. Tromberg welcomed Dr. Luisa Russell as director of the NIBIB Biochemical Engineering program and Dr. Joan Greve as a scientific program manager in the NIBIB Division of Interdisciplinary Training. He also welcomed Mr. Robert Moore as a new analyst in the Office of Scientific Review, and Ms. Kaluthanthrige Peiris as a web developer in the Office of Science Policy and Communications. Dr. Tromberg announced the return of Dr. William Heetderks as a Senior Advisor to the NIBIB Director.

Awards: Dr. Tromberg congratulated Dr. Grace Peng on her election as a member of the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows for the creation of the Interagency Modeling and Analysis Group and the Multiscale Modeling Consortium, and promotion of new neurotechnology development.

Harnessing Data Science for Health Discovery and Innovation (DS-I) Africa Update: The Common Fund has launched a webpage for DS-I Africa (https://commonfund.nih.gov/africadata). The DS-I Notices of Intent to Publish and Funding Opportunity Announcements (FOAs) have all been announced. Lastly, a senior level Data Scholar is being onboarded to the DS-I Africa team.

NIH Tech Accelerator Challenge for Global Health: Through this Challenge, NIH will offer $1,000,000 in prizes to reward and spur the development of platform concepts and prototypes of non-invasive, multiplexed diagnostic technologies for sickle cell disease, malaria, and anemia, diseases with high global and public health impact. Proposals for the NIH challenge in collaboration with the Bill and Melinda Gates Foundation are due June 2, 2020.

Design by Biomedical Undergraduate Teams Challenge (DEBUT): Submissions for DEBUT are due June 1, 2020. Since many teams were unable to complete projects due to COVID-19, the DEBUT rules have changed. Each team will receive an ideation and prototype score. The higher of the two scores will be the team's final score. Winners will be announced on August 25, 2020.

National Centers for Biomedical Imaging and Bioengineering (NCBIB) (P41 Program): NIBIB has reissued the NCBIB (P41) program. Center will be limited to 15 years of funding from NIBIB. Additionally, the letter of intent is due 12 weeks prior to the application due date.

COVID-19 Pandemic: The world has turned to social distancing and scientific research to help thwart the COVID-19 pandemic. Dr. Tromberg emphasized that this is a time to showcase the strengths of bioengineering research and make tangible changes to improve people's health.

NIBIB received $60 million from the Coronavirus Aid, Relief, and Economic Security Act. With this supplement, NIBIB released three Notices of Special Interest for COVID-19. Research areas include point-of-care (POC) diagnostics, sensors/imagers for physiological monitoring, imaging/artificial intelligence (AI) algorithms for monitoring/diagnosing lung infection, digital health platforms for data integration, technologies /simulation platforms to help train and protect healthcare workers, oxygenation systems, high-confidence disinfection technologies, and novel therapies to treat COVID-19.

One of the areas of the great interest to NIBIB is utilizing imaging and AI for diagnosis and monitoring of COVID-19. Funding in this area should help stimulate national imaging networks. Another high interest area is digital health platforms and the development of apps for mobile devices to help predict risk.

As of May 17, 2020, the United States had conducted about 400,000 diagnostic tests/day and over 11 million tests in total. Testing capacity will need to be greatly increased to enable a return to regular daily activities. Increased diagnostic testing will help prevent additional lockdowns in the event of a second wave in the fall, as well as future pandemics.

Rapid Acceleration of Diagnostics (RADx): A fourth COVID-19 supplemental bill was signed into law on April 24, 2020. The Paycheck Protection and Healthcare Enhancement bill provided $500 million to NIBIB for the development of millions of diagnostic tests by fall 2020. On April 29, 2020, NIH and NIBIB launched RADx to expand the number, type, and access to diagnostic tests for SARS-CoV-2. Additionally, RADx will optimize the performance and use of tests.

NIBIB has a national Point-of-Care Technologies Research Network (POCTRN) that has focused on developing POC diagnostics for more than ten years. POCTRN has four centers located throughout the U.S. and one coordinating center. NIBIB is leveraging the network and its expertise to rollout RADx-Tech, just one of the components of the larger RADx initiative at NIH. RADx Tech is anchored by Mr. Todd Merchak and Dr. Tiffani Lash at NIBIB.

POCTRN has pivoted its research priorities to COVID-19 and issued a solicitation for the development of SARS-CoV-2 diagnostic tests on April 29, 2020. Projects are evaluated on a rolling basis. There are three phases of the RADx-Tech innovation funnel. Projects selected for Phase 0 or "Shark-tank-like" process are evaluated by a panel of experts which identifies project risks and develops a work plan with specific milestones for each project. Projects in Phase 1 address the risks identified in Phase 0 and must meet the milestones to move forward. Projects in Phase 2 will scale up the production of tests and seek regulatory approval.

As of May 19, 2020, there were 1726 proposals started, 261 proposals completed, and 46 proposals had entered the Shark-tank-like process in the innovation funnel. The sources of submissions are varied. So far, about half of the proposals have been submitted by small businesses. There have been 56 academic entrants, 27 from start-up companies, 22 from mid-size businesses, and 12 from large businesses. Most projects are developing new technologies, but there are some scale-up proposals. More than 400 experts have volunteered to support RADx project review and management.

The NIH RADx initiative has four components: RADx-Tech, RADx Underserved Populations (RADx-UP), RADx Radical (RADx-Rad), and RADx Advanced Testing Program (RADx-ATP). RADx-UP focuses on implementing strategies to enable and enhance testing of COVID-19 in underserved, under-resourced, rural, and/or vulnerable populations. RADx-Rad will develop non-traditional approaches or advance new applications of existing technologies to expand testing. RADx-ATP will rapidly scale-up advanced technologies to increase and enhance testing throughput.

NIBIB Serosurvey: Dr. Kaitlyn Sadtler, Chief of NIBIB's Section for Immunoengineering, is the study lead in a joint clinical study with the National Institute of Allergy and Infectious Diseases, the National Center for Advancing Translational Sciences, and the National Cancer Institute (NCI). The study is quantifying undetected cases of coronavirus infection. The study will survey 10,000 people, with appropriate representation for race, sex, and ethnicity. Dr. Sadtler has developed a high-performing, robust assay to detect the prevalence of antibodies to SARS-CoV-2. Dr. Tromberg shared a highlight video on Dr. Kaitlyn Sadtler from a local news outlet.

Expanding COVID-19 Testing: Tools for COVID-19 testing efforts must be developed and then deployed to communities, and data from the tests need to be seamlessly integrated and archived. Digital health platforms will help achieve this goal. NIBIB has been collaborating with NCI, the National Library of Medicine, National Institute on Minority Health and Health Disparities, Fogarty International Center, and NIH Office of the Director to create digital health platforms. Dr. Tromberg demonstrated an app that is in development with Care Evolution to assess individual risk of COVID-19.

Operation Warp Speed (OWS): On May 15, 2020, from the Rose Garden at the White House, President Trump announced the establishment of Operation Warp Speed. This is an integrated response to COVID-19 with three arms, including vaccines, therapeutics, and diagnostics. The lead of OWS is Dr. Moncef Slaoui. Dr. Peter Marks leads the vaccine effort, Dr. Janet Woodcock is heading the therapeutics element, and Dr. Bruce Tromberg leads the diagnostics component.

Closing Thoughts: The spotlight has turned to technology development and bioengineering research to help stop the COVID-19 pandemic. The NIBIB budget has been expanded quickly, and NIH has invested heavily in testing technologies. This bolus of money has galvanized the bioengineering community, and Dr. Tromberg is asking the Advisory Council to help relay NIBIB's mission and vision. Dr. Tromberg ended his presentation by sharing a video of Dr. Collins singing a rendition of "Imagine."

Discussion: Many Council Members celebrated NIBIB's COVID-19 response and initiatives. Several Council Members asked what other complementary projects NIH Institutes are working on and how NIH Institutes are collaborating to make use of funds provided by Congress. Dr. Tromberg explained that Dr. Collins has Trans-NIH teams that meet regularly to discuss new and ongoing efforts. Institute leadership and staff are in constant contact with one another to continue developing new programs and initiatives. NIH and other agencies such as BARDA and FDA are in discussions about proposals.

II. Concept Clearance

A. Blueprint Neurotherapeutics for Medical Devices Program

Michael Wolfson, Ph.D., presented the concept clearance for the Blueprint Neurotherapeutics program for medical devices. Dr. Wolfson explained that a portfolio analysis of translational neurotechnology programs showed success for diagnostic and therapeutic device development when based on proven technology platforms. However, projects attempting to develop completely novel breakthrough technologies have been far less successful.

To increase the development of novel medical neurotechnologies, Dr. Wolfson proposed following the successful model of the NIH Blueprint Neurotherapeutics (BPN) and POCTRN programs. BPN and POCTRN combine the strengths of academia, industry, and government to de-risk breakthrough devices that may otherwise stall at early steps towards translation.

The proposed Blueprint Neurotherapeutics program would match technology developers with commercialization and disease experts to support the entire ecosystem around new technology. Successful applicants will receive funding for activities to be conducted in their laboratories, plus no-cost access to

contracted drug discovery and development services and consultants.

Program progression is milestone-driven with projects assessed at each milestone to continue to the next step. The steps include critical design review, preclinical safety and effectiveness, first-in-human approval, and clinical safety and effectiveness.

A broad group of stakeholders across the Blueprint and BRAIN Initiative, representing fourteen ICs, are supportive of this program. Anticipated research includes a range of types of interventions (minimally invasive, non-invasive, wearable sensors, assistive robotics) to address disorders including depression and addiction, Alzheimer's and Parkinson's disease, motor deficits, and mobility disorders.

Council members were supportive of this concept.

B. BRAIN Initiative: Proof of Concept Development of Early Stage Next Generation Human Brain Imaging

Shumin Wang, Ph.D., presented the concept clearance for the re-issuance of the BRAIN initiative "Proof of Concept Development of Early Stage Next Generation Human Brain Imaging." The program supports proof-of-concept research using non-invasive human brain imaging tools for transformative high-risk/high-impact neuroscience studies. Imaging areas include MRI, NIRS, PET, MEG, EEG, molecular imaging probes, photoacoustic, and focused ultrasound, among others.

The reissuance reflects the shift in emphasis of the BRAIN initiative toward technologies with temporal resolution capable of mapping and characterizing the changes in electrical and chemical signaling underlying mental processes. The initiative also emphasizes computational techniques for real-time source localization and image reconstruction.

The program began in 2017 and averages five awards each round. The grants are designed to prepare technologies to move to full-scale development through the another BRAIN initiative: Development of Next Generation Human Brain Imaging Tools and Technologies (RFA-EB-19-002).

Council members were supportive of this concept.

C. BRAIN Initiative: Theories, Models and Methods for Analysis of Complex Data from the Brain

Grace Peng, Ph.D., presented the concept clearance for the re-issuance of the BRAIN initiative, "Theories, Models and Methods for Analysis of Complex Data from the Brain." The overarching goals of the initiative include the development of analytical tools for understanding brain function from complex neuroscience data; theories to organize/unify data and infer general principles; mathematical/statistical models to drive testable hypotheses; and methods for complex data analyses and feature detection. The initiative focuses on developing analytical tools that can be used by the larger neuroscience community to analyze behavior and functional brain circuits that include cellular and sub-second resolution.

Research projects must produce one of the following: 1) disseminatable tools that include theories, models or methods to understand brain circuits or that can be used to facilitate other projects; 2) research partnerships that strongly integrate truly diverse expertise such as theorists, modelers, data scientists, experimentalists and end users who understand the needs of the community; 3) tools validated through limited experimental data collection.

In response to the refocus of the BRAIN 2.0 initiative, new areas of emphasis will be prioritized and include theory development and integration of existing (and competing) theories; multiscale models incorporating biologically-inspired dynamical representations of neurons mechanistically linking to behavioral phenomenology; platforms incorporating machine-driven knowledge integration of competing theories for the discovery of foundational theories of the brain; and linking large-scale, cell-type data platform efforts

(e.g., cell census) to behavior for theory development.

Peng described two successful projects funded through the program. Drs. Ilya Nemenan and Sam Sober of Emory University studied bird song to develop new mathematical methods to understand how the brain corrects errors in behavior. Such an understanding can be used to improve techniques for rehabilitation in patients suffering from neurological diseases or injury. Dr. Stephanie Jones of Brown University developed the software tool "Human Neocortical Neurosolver," which allows researchers to develop and test hypotheses on the cellular and circuit level origin of non-invasively measured human brain signals obtained with EEG and other electromagnetic devices.

Council members were supportive of this concept.

III. Adjournment

The open session of the NACBIB meeting was adjourned at 2:57 p.m.

IV. 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 5:00 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

[2] These minutes will be approved formally by the Council at the next meeting on September 15, 2020, and corrections or notations will be stated in the minutes of that meeting.