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]
September 15, 2020

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 54th meeting on September 15, 2020, by Zoom for the Open Session and Closed Session. 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 3:08 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 3:25 p.m. to 4:45 p.m. for the consideration of grant applications.

The entire meeting was held by Zoom and was videocast. All observers, including members of the public, attended virtually.

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

Ad Hoc Attendees:
Dr. Gilda Barabino, Olin College, Needham, MA
Dr. Simon Cherry, University of California, Davis, Davis, CA
Dr. Kathryn Nightingale, Duke University, Durham, NC

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

[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.

Executive Secretary:
Dr. David T. George

Also Present:

Approximately 268 observers attended the open session, including NIBIB staff, and members of the public.

Call to Order: Dr. David T. George

Dr. George called to order the 54th meeting of the National Advisory Council for Biomedical Imaging and Bioengineering. He reminded attendees that the first portion of the meeting was open to the public and welcomed attendees.

I. Director's Remarks: Dr. Bruce J. Tromberg

In Memoriam

Dr. Tromberg announced the passing of Dr. Sanjiv "Sam" Gambhir, a pioneer in the field of molecular imaging and former member of NIBIB's National Advisory Council. An NIBIB grantee for more than 10 years, he developed reporter gene technologies for PET and multi-modality imaging. He helped establish PET imaging as standard practice in the clinic and as an integral tool for diagnosis of cancer in its earliest stages. His legacy in imaging and precision diagnostics will long be remembered.

Dr. Tromberg announced the passing of another pioneer, Dr. Murray Eden, who was the originator of and led NIH's Biomedical Engineering and Physical Science program from 1976-1994. His program became a principal initial component of NIBIB's Intramural Research program. Dr. Eden pioneered many firsts in introducing physical science and engineering techniques to medicine. Numerous NIH intramural researchers, including NIBIB's Scientific Director Dr. Richard Leapman and retired Scientific Deputy Director Dr. Henry Eden (no relation), were hired by and influence by the work of Dr. Eden.

B. Welcome New Council Members

Dr. Tromberg welcomed three new incoming council members: Dr. Gilda Barabino, the second president of Olin College of Engineering and professor of biomedical and chemical engineering; Dr. Simon Cherry, distinguished professor of biomedical engineering at the University of California, Davis; and Dr. Kathryn R. Nightingale, the Theo Pilkington distinguished professor of biomedical engineering, Duke University.

C. Staff News

Dr. Tromberg welcomed two former American Association for the Advancement of Science (AAAS) Fellows as staff members: Dr. Ilana Goldberg, program director, and Dr. Patty Wiley, health science policy analyst. Dr. Tromberg also welcomed two additional staffers new to NIBIB: Dr. Shravani Bobde, senior program analyst, and Dr. Rosemary Wong, program director.

Dr. Tromberg thanked departing staff for their service: Dr. Shawn Chen, who created NIBIB's Laboratory of Molecular Imaging and Nanomedicine (LOMIN), Ms. Jacklyn Ebiasah, scientific program analyst, and Ms. Saltanat Satabayeva, scientific program analyst.

D. Budget

NIBIB has obligated just over $635.6 million this quarter. That number is typically in the low $200 million range at this time of year but this substantial increase was stimulated by the COVID crisis, when NIBIB received supplemental appropriations from Congress for COVID-related programs. NIBIB spending included

grant supplement programs, common fund initiatives, and the Rapid Acceleration of Diagnostics (RADx) program.

Grants Supplement

- *Alzheimer's/NIA Program*: This highly successful program, designed to attract investigators to work on Alzheimer's and related dementias, was initially a partnership between NIBIB and the National Institute on Aging but has grown to include 21 NIH Institutes and Centers, . NIBIB awardees have received 10 to 15 supplements each year, totaling close to $5M in FY2020. Supplement requests for fiscal year 2021 funding are due Oct 17.

COVID-19 Supplement

- Three Notices of Special Interest (NOSIs) were issued on April 10, 2020 and closed after five months due to an exceptionally strong response from the extramural community. Twenty-one awards for more than $8 million have been issued so far with more in the pipeline.

Common Fund Initiatives

- *Data Science in Africa (DS-I Africa)*. In August, DS-I Africa ran a symposium that drew 1,650 participants, 54% from Africa. Future symposium topics scheduled for September and October include focus on research, training, ethical/legal/social implications, and data science.

- *NCCIH/NIBIB Heal Workshop on Quantitative Evaluation of Myofascial Pain:* The next in a series of ongoing Helping to End Addiction Long-term (HEAL) workshops to begin tomorrow (9/16-17), will include discussion of research and technology opportunities such as use of imaging and computational modeling to address myofascial pain syndrome. The workshop is co-organized by NCCIH and NIBIB with partners from NIAMS, NIDCH/NCMRR, NIDCR, and NINDS.

- *Artificial Intelligence for Biomedical Excellence (AIBLE)*. A key goal of this new NIH-wide common fund initiative is to advance the accuracy and usability of the next generation of AI by facilitating the creation of shareable resources and data sets. The program is planned for FY21-27 and will provide $160M of funding.

E. Awards

NIH Technology Accelerator Challenge (NTAC): In February, NIBIB established a challenge offering $1,000,000 in prizes to 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. In September, six winners were announced. The first prize of $400,000 went to Dr. Young Kim of Purdue University for a smartphone-based platform to detect anemia and sickle-cell disease by analyzing photos of the microvasculature of the inner eyelid. The second prize of $200,000, to Dr. Bala Raja of Luminostics, was for a smart-phone-based salivary approach that can detect malaria, anemia and COVID-19. Four third-place winners each receiving $100,000, were Dr, Saurabh Mehta of Cornell University, Dr. Erika Tyburski of Sanguina, Inc, Dr. Peter Galen working in a consortium of HEMEX, Medtronic, Case Western Reserve University and University of Nebraska, and Dr. Nicholas Durr of John Hopkins University. Winners and descriptions of each project are posted on the NIBIB website.

Design by Biomedical Undergraduates Teams Challenge (DEBUT): In 2019, 52 applications were received from 32 universities engaging 250 students. In 2020 the program grew substantially—86 applications from 46 universities were received with more than 400 students engaged. NIBIB increased the total award to $100,000 from $80,000 last year. There will be an awards ceremony October 15, 2020, at the Biomedical Engineering Society (BMES) Annual Meeting, held virtually this year. Winners are posted on the NIBIB DEBUT website.

II. COVID-19 Pandemic

Medical Imaging and Data Resource Center (MIDRC): MIDRC aims to further the use of biomedical imaging and AI approaches for diagnosis and treatment of the effects of COVID-19 in the lungs and heart. A two-year, $20 million contract, led by Dr. Maryellen Giger of the University of Chicago, will support development of a thoracic imaging and a clinical data repository for COVID-19 and develop and validate machine learning algorithms for detection and diagnosis.

Digital Health Solutions**:** Smartphone applications able to integrate symptoms, health history, electronic health records, algorithms combining test results for the virus and serological tests, and other data can be used to combat the COVID-19 pandemic. This effort, critical in linking such data to patient management and public health decision-making, was launched in collaboration with NCI, and so far, eight digital-health contracts have been awarded.

RADx: NIH received $1.5 billion in congressional appropriations for the Rapid Acceleration of Diagnostics (RADx) program, including $500 million to NIBIB for RADx Tech, one of the four RADx programs.

- *RADx Tech*: Highly competitive, rapid three-phase challenge to identify the best candidates for laboratory, point-of-care and home-based testing technologies.
- *RADx Advanced Technology Platforms (RADx-ATP):* Rapid scale-up of advanced technologies to increase speed and enhance and validate throughput – create ultra-high throughput machines and facilities.
- *RADx Underserved Populations (RADx-UP)*: Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations.
- *RADx Radical (RADx-Rad):* Develop and advance novel, non-traditional approaches, or new applications of existing approaches for testing.

RADx Tech and ATP Goals: Emphasizes scale-up of resources. Goals are to expand COVID testing technologies - number, type, and access - and optimize technologic and operational performance. There is a need to expand testing in all settings – at point of care (POC), the home, and the laboratory. To date the laboratory testing capacity is greater and very few POC tests. With the contribution of RADx Tech, we hope to increase POC tests by supporting novel technologies, in addition to developing methods for increasing throughput for lab-based tests. The goal is to meet the need for up to 6.5 million tests per day.

RADx Innovation funnel: The RADx innovation funnel was built upon NIBIB's existing Point of Care Technology Research Network (POCTRN) infrastructure; expanded with the new funding and benefiting from more than 1,000 experts assisting in the evaluation process. Approximately 3,000 applications have been initiated by applicants with 707 entering the review process to date. Each proposed technology is evaluated by diverse review teams. 125 applications entered phase 0—the "Shark Tank"-like deep-dive phase—33 progressed to Phase 1 (validation and risk review) and 16 to Phase 2 (preparation for manufacturing and scale up.) Proposals have come from a variety of sources — predominantly small businesses — but some academic centers as well. RADx Tech is anticipating over two million extra tests a day by year's end just from these 16, but many more technologies are still in the pipeline. The future goal is six to seven million tests a day.

Intramural update: NIBIB and collaborators at NIAID, NCATS and NCI, launched a national SARS/CoV-2 Serosurvey to examine mucosal immunity. As of August, 11,300 donors were enrolled. They have received and analyzed almost 9,000 samples. NIBIB intramural scientist Dr. Kaitlyn Sadtler is the study lead and principal investigator.

Efforts in diversity equity and inclusion: Dr. Tromberg will establish a new workgroup, to be co-chaired by Drs. Gilda Barabino and Roderic Pettigrew. Dr. Gilda Barabino, incoming NIBIB Council member, recently

wrote in *Science* about systemic racism in higher education; and former NIBIB Director Dr. Roderic Pettigrew discussed racial health disparities in a piece for the *National Academy of Medicine.* They will co-chair a new advisory workgroup that will explore ways to develop an inclusive workforce, reduce bias, and demonstrate the power of technology to reduce health disparities.

In Closing: The pandemic is a chance for NIBIB to implement its vision and mission, galvanize the community, and demonstrate the capabilities of bioengineering technologies to address human health.

Discussion
In response to a question about quality control of COVID tests, Dr. Tromberg noted that projects undergo rigorous review at each stage of the RADx innovation funnel and must meet specific milestones to progress. Projects are assessed and assigned scores for validity, clinical performance, and scale up. Several Council members asked how NIBIB could best capitalize on the opportunities created by RADx Tech. Dr. Tromberg said a key is in telling the Institute's story, and that he is optimistic the program will continue in some form. In response to a question about the new workgroup's strategic goals, Dr. Tromberg said he envisions the workgroup partnering with the RADx UP team to develop goals and test hypotheses. Dr. Barabino commented that there are issues of historical mistrust that will affect future vaccines. She noted that technology can be an equalizer and that design should be inclusive from the outset.

III. Concept Clearance

A. Medical Imaging and Data Resource Center

Drs. Kris Kandarpa and Guoying Liu described the newly formed Medical Imaging and Data Resource (MIDRC), which is led by the University of Chicago partnering with the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), and the Radiological society of North America (RSNA).

Dr. Kandarpa described the origin of the MIDRC. In 2017, the White House Office of Science and Technology Policy Intra-Agency Working Group on Medical Imaging recommended the establishment of a public-private forum to coordinate efforts and interests in the artificial intelligence (AI) and medical imaging communities. In the following two years, NIBIB held two workshops: AI in Medical Imaging, and Acceleration of Clinical Applications of Machine Intelligence in Medical Imaging. The workshops identified critical needs, including large and diverse medical image datasets; integration of siloed databases; development of non-redundant efficient AI tools; and creation of an ecosystem of stakeholders to develop clinically validated AI applications that improve patient management and clinical outcomes.

The workshops aligned with a September 2019 recommendation from Congress that cited opportunities for the NIH Common Fund and NIBIB to address an insufficiency of platform technologies and inadequate physical sciences input towards emerging unmet needs in medicine. The onset of COVID-19 provided a viable "use case" for creation of MIDRC. The project aims to improve COVID-19 patient outcomes by supplementing medical imaging with adjunct clinical data and applying machine intelligence to reveal in-depth beginning-to-end effects of the disease and interventions. In August 2020, NIBIB granted a contract ($20 million over two years) to the University of Chicago, the legal entity representing MIDRC, with Dr. Maryellen Giger as the lead.

Dr. Guoying Liu gave an overview of the MIDRC goals and scientific structure. The overarching goals are to move from data to deployment, and hypothesis to discovery, and to accelerate the creation and transfer of knowledge for clinical management of COVID-19. In the first three months MIDRC aims to make publicly available 10,000 curated COVID-19 chest radiographs and CTs; have 23 institutions working together within the funded MIDRC umbrella; enable more than 20 research groups using MIDRC open platforms; publicly disseminate MIDRC plans on pressing COVID-19 questions; and engage with FDA and at least five industry

collaborators.

MIDRC's two-year objectives include making publicly available 60,000 curated COVID-19 chest images and clinical data; expanding the number of institutions actively collaborating with MIDRC; enabling research groups utilizing MIDRC open platforms; engaging with FDA and industry collaborators to catalyze technology transfer and implementation; and demonstrating and validating approximately 30 COVID-19 AI products.

MIDRC is currently supporting five technology development projects creating the platforms for data intake, testing, quality assurance, distribution, and linkage to other registries; and 12 collaborative research projects which include development of machine learning algorithms for COVID-19 radiomic feature analysis for diagnosis, prognosis, monitoring, and outcome prediction in COVID-19 patients; image labelling and annotation; investigation of image-based biomarkers for radiogenomics of COVID-19; and leveraging data to conduct virtual clinical trials.

As MIDRC continues to collect and analyze data on COVID-19, it is ultimately also creating a system prepared to manage diseases involving other organs/systems that will be crucial in handling future public health crises.

B. Digital tech

Dr. Andrew Weitz described seven contracts awarded in response to a joint NIBIB/NCI program to develop digital health solutions for COVID-19. The goal of the work is development of user-friendly tools like smartphone apps, wearable devices, and software that can identify and trace contacts of infected individuals, keep track of verified COVID-19 test results, and monitor the health status of infected and potentially infected individuals. Several proposals focused on solutions for underserved communities who are disproportionally affected by COVID-19.

Dr. Weitz summarized the emphasis of each awarded contract:

- Evidation Health, Inc. (San Mateo, California): A health measurement platform for analyzing a wide range of patient-consented data, including self-reported data and wearable device data, to detect COVID-19 and differentiate it from the flu.

- IBM (Armonk, New York): An integrated solution that supports sophisticated contact tracing and verifiable health status reporting.

- iCrypto, Inc. (Santa Clara, California): A smartphone-based platform to provide irrefutable proof of testing, serologic, and vaccination status for individuals.

- physIQ, Inc. (Chicago): An artificial intelligence-based data analytics and cloud computing platform plus U.S. Food and Drug Administration-cleared wearable devices to create a personalized baseline index that could indicate a change in health status for patients who have tested COVID-19 positive.

- Shee Atiká Enterprises, LLC (Sitka, Alaska): A smartphone-based platform to monitor and support individuals with COVID-19 symptoms (who may need testing) and those who have already tested positive. The app will integrate with a Bluetooth-enabled thermometer and pulse oximeter. The approached is designed for low-resource settings and underserved populations.

- University of California, San Francisco: A GPS-based contact-tracing tool for alerting users about contact with SARS-CoV-2–infected individuals, identifying businesses that were visited by someone who later tested positive for COVID-19, and working with those businesses and public health departments on strategies to reduce the spread of the virus.

- Vibrent Health (Fairfax, Virginia): Mobile applications, data integrations, and validated machine learning algorithms to identify COVID-19 and differentiate it from the flu, and to perform contact tracing using Wi-Fi technologies.

This effort is a key component of NCI's and NIBIB's congressionally supported responses to COVID-19. These include NCI's $306 million effort to support serological science research, expand testing capacity, and develop other technologies for COVID-19, as well as NIBIB's supplemental funding to address COVID-19.

In addition, Dr. Weitz described a separate but related effort, an NIBIB contract to CareEvolution, LLC (Ann Arbor, Michigan) for SAFER-COVID, a digital health solution that integrates self-reported symptoms, data from consumer wearable devices, electronic health record and claims data, and COVID-19 test results to indicate whether users are ready to return to work and normal activities during the COVID-19 pandemic.

C. Concept Clearance National Robotics Initiative

Dr. Moria Bittman presented a concept clearance for NIH's participation in the National Robotics Initiative (NRI) program. Launched in 2011 by the Obama administration, the overarching goal of the NRI is the development and use of co-robots, robotic systems, and devices that work cooperatively as partners with, or beside people. NRI is led by NSF and NIH has participated through the funding of 16 awards by five ICs. The NIH funding has supported research on exoskeletons, surgical robots, laboratory tools, visual assists, mobility assists, cognitive assists, and virus disinfection.

The potential future NIH priority areas for funding through continued participation in NRI include infectious disease monitoring; home care and long-term personal care; therapeutic and assistive technologies; telemedicine; and general health care tasks. Dr. Bittman explained that in addition to the opportunity to fund innovative projects in NIH areas of interest, NRI has historically attracted large numbers of new investigators—88% of the NIH's NRI awards have gone to new investigators. Finally, the NRI program offers the opportunity to fund the development of new technologies as opposed to funding projects that use previously developed off-the-shelf technologies.

Council was supportive of this concept.

IV. Adjournment

The open session of the NACBIB meeting was adjourned at 3:08 p.m.

V. 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 4:45 p.m.

Certification:

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

[2] These minutes will be approved formally by the Council at the next meeting on January 19, 2021, and corrections or notations will be stated in the minutes of that meeting.

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National Advisory Council for Biomedical Imaging and Bioengineering
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