

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

**NATIONAL ADVISORY COUNCIL FOR
BIOMEDICAL IMAGING AND BIOENGINEERING**

Summary of Meeting¹

January 19, 2021

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 55th meeting on January 19, 2021, 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 3:22 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 3:34 p.m. to 4:46 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. 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. 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. 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:

Approximately 311 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. David T. George called to order the 55th 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. Staff updates

Dr. Tromberg thanked Dr. David Grainger for his service on council as this is Dr. Grainger's final council meeting.

He also welcomed many new NIBIB staffers including: Dr. Afrouz Anderson, Dr. Jennifer Jackson, Dr. Judy Wawira Gichoya, Grace Zhou, Dr. Krishna Juluru, Dr. Rui Carlos Sa, Kimberly Tam, Hank Durand, Munir Esmail, Eugene Hwang, Che Figueroa-Rodriguez, Chineze Egwudo, Dr. Parinaz Fathi, Maria Karkanitsa, Eric Krueger, Alexis Manning, Tran Ngo, Dr. Barbara Romero, and Lixia Zhang.

B. Budget

Dr. Tromberg spoke about the FY21 NIH budget, which increased by about \$1.25 billion or 3%, over the FY20 budget. NIBIB's budget increased by about \$7 million or 1.8%.

In addition, NIH received \$1.25 billion in NIH Emergency appropriations (supplement #5). \$100 million of the additional funds went to Rapid Acceleration of Diagnostics (RADx) and \$1.15 billion went to research and trials on COVID-19.

RADx received funding from multiple sources over the past year in supplements 3, 4, and 5, as well as from its partnership with BARDA, which resulted in an additional \$307 million being transferred to RADx. In total, RADx received about \$1.2 billion. NIBIB hopes to develop RADx into a core NIBIB program in the future.

C. Leadership

Dr. Francis Collins has been reappointed as NIH Director under the new administration and will stay on to lead NIH. The new administration also appointed Eric Lander, Ph.D., as Office of Science and Technology Policy (OSTP) Director and Presidential Advisor, Alondra Nelson, Ph.D., as OSTP Deputy Director for Science and Society, Frances Arnold, Ph.D. and Maria Zuber, Ph.D. as Co-Chairs of the President's Council of Advisors on Science and Technology.

D. Funding Announcements and Opportunities

Dr. Tromberg drew special attention to specific Funding Opportunity Announcements (FOAs) and programs:

- [The Katz ESI R01](#) is a new NIH Program named in memory of former NIAMS director, Stephen Katz, M.D., Ph.D. It is designed for early-stage investigators with no preliminary data allowed. The first due date is January 26, 2021.
- [The NSF-NIH Smart & Connected Health Program](#) initiative supports innovative, high-risk/high-reward research with the promise of disruptive transformations in biomedical research. The program has been a successful NSF-NIH program since 2013 and aligns with NIBIB programs/missions. The application due date is February 16, 2021.
- [The HEAL Initiative: HEALthy Brain and Child Development Study's](#) goal is understanding the impact of fetal drug exposure, the adversities on mental and behavioral health, and to inform

intervention and prevention strategies. The application deadline is March 31st, 2021.

- **The Faculty Institutional Recruitment for Sustainable Transformation (FIRST)** The program aims to hire a diverse cohort of early-stage research faculty and effect systemic and sustainable institutional culture change to address bias, equity, mentoring, and work/life issues.
- **The Music and Health FOA** goals include increasing understanding of how music affects the brain and developing evidence-based music interventions to enhance health and treat specific diseases.
- **Synthetic Biology Notices of Special Interest (NOSIs)** aim to develop tools and technologies to control and reprogram biological systems and develop biomedical technologies. Other goals include increasing the fundamental understanding of synthetic biology concepts. The NOSIs will fund R01, R21, and R35 projects.
- **The DEBUT Awards** challenge undergraduate student teams to develop technology solutions to unmet needs in any area of healthcare. The challenge will give out a total of \$115,000 in prizes this year and added a new award funded by NCI with the focus of *Technologies for Cancer Prevention, Diagnosis and Treatment*.
- **NIBIB Exploratory/Developmental R21 Update:** NIBIB will be discontinuing this Exploratory/Developmental R21 FOA which did not allow inclusion of preliminary data. Alternatives include, R03, Short-term R01, Katz R01, and the NIBIB Trailblazer R21. Dr. Randy King will elaborate in a presentation later in this council meeting.

E. Program Updates

Dr. Tromberg also updated council on various programmatic updates.

- **Data Science Innovation DS-I Africa:** This program, designed to support data science and innovation research hubs focused on addressing health problems in Africa, received more than 100 applications from all over Africa.
- **BRAIN Initiative Workshops:**
 - **Dissemination of Non-Invasive Imaging Technologies**, February 18-19, 2021
Purpose: to feature progress updates from BRAIN Initiative awardees and presentations from industry on potential pathways for follow-on dissemination.
 - **Transformative Non-Invasive Imaging Technologies**, March 9-11, 2021
Purpose: to bring together neuroscientists, tool developers/engineers, and industry partners to identify new non-invasive functional imaging tools that could be realized in the next five to ten years.
- **Diversity, Equity and Inclusion: NIBIB Community:** This new advisory council working group will focus on developing a diverse, inclusive workforce and leadership, addressing structural and systemic barriers and bias, and advancing technology for reducing disparities and improving access. This has been an NIH-wide activity to address five workstreams:
 - Understanding stakeholder experiences
 - New research on health disparities/inequities
 - Internal workforce
 - Extramural research workforce
 - Communicating with our internal and external stakeholders
- **COVID-19 Supplements:** In September, NIBIB had granted 21 awards for a total of \$8.4 million, and it currently has 37 awards with a total cost of about \$13.5 million. The supplements funded diagnosis and radiology, wearable sensors, digital health, and therapeutic agents.
- **Medical Imaging and Data Resource Center (MIDRC):** Launched in August 2020, it is a 2-year, \$20 million national network that brings together 23 institutions. 11 institutions donate data through Radiological Society of North America (RSNA) RSNA International COVID-19 Open Radiology Database (RICORD) and America College of Radiology (ACR) Covid Imaging Research Registry (CIRR) and they already have 15,000+ cases being processed for MIDRC and 10,000+ more cases being processed for donation. The first users/data contributors meeting is being planned for March 2021.

- **Digital Health Solutions for COVID-19:** SAFER-COVID became NIH's official return-to-work app and more than 150K people have used the tool to date (NIH and non-NIH). The tool helps make decisions about when it is safe to return to daily activities such as work and other social interactions. The tool is being configured to assist with at-home COVID-19 testing.
- **SARS-CoV-2 Seropositivity in the United States:** Data from the results of an NIBIB intramural program serosurvey, led by NIBIB intramural scientist Dr. Kaitlyn Sadtler, indicate that there could have been as many as 24 million cases of COVID-19 in the United States. The results seem to fit with CDC estimates that the total number of cases in the US could actually be eight times the number of diagnosed cases.

F. RADx Updates

Dr. Tromberg updated council on the status of the RADx initiatives. The goal of RADx Tech and RADx ATP is to expand COVID-19 testing technologies and optimize performance. RADx Tech received 716 applications and is not currently accepting new applications. The initiative was able to move 25 of those applications into Phase 2 scale-up and manufacturing expansion, investing more than \$500 million in those projects. It has supported 14 different technologies that have received FDA Emergency Use Authorization (EUAs), including Ellume, the first over-the-counter at home test to receive an EUA.

In addition to RADx, the NIH Small Business Education and Entrepreneurial Development (SEED) Network is leveraging the NIH Proof of Concept Network to help guide projects that are not ready for large scale funding. Those that show promise can get extra mentoring through this program and hopefully be moved into Phase 2 funding in the future.

Another challenge that RADx would like to see addressed is the gap between the number of tests being manufactured and the number of tests being sold. To do this, NIBIB has invested in a "deployment core" in the Consortia for Improving Medicine with Innovation and Technology (CIMT) a part of the Point of Care Technologies Research Network (POCTRN) RADx Program. The goal of the core is to act as a bridge between the federal government and nonprofit, academia, and states to help move tests into organizations that really need them. One tool to help with that goal is the "When to Test" website, a modeling tool that can help institutions determine how to deploy testing and how much it will cost.

Dr. Tromberg also discussed the accuracy of lateral flow assays (LFA) and some of the challenges that remain when using them. LFAs are less accurate, especially for asymptomatic carriers (~40%) but are quite accurate 5-7 days after onset of symptoms for symptomatic patients (90-95%). Therefore, the current recommendation is that LFAs should be backed up with a PCR test for asymptomatic testing.

The RADx Clinical Studies Core at UMass is doing a longitudinal sequential LFA assessment over the course of two weeks. The goal is to determine when LFAs have the equivalent value of PCR tests if it is done in sequence and how well it measures infectiousness. Other studies are being planned to determine if frequent testing can break the chain of transmission. NIBIB and RADx will also be attempting to provide a digital health platform that can guide when and how to test, integrate other platforms such as wearables, track symptoms and spread, and create an overall structure that can improve the entire testing landscape.

Dr. Tromberg concluded by saying that the demands of this pandemic cannot be met by off-the-shelf solutions and that bioengineers need to work more closely with public health officials to meet the needs of the public and to make these partnerships permanent. These partnerships are essential since getting technology adopted, providing guidance, and modifying human behavior are significant challenges external to technology development; thus, collaboration is critical.

II. Presentations

R21 Program, Randy King, Ph.D.

Randy King, Ph.D. director of the NIBIB programs on Optical Imaging and Diagnostic and Interventional Ultrasound gave a presentation on the NIBIB Exploratory/Developmental R21 Grant Program, which is set to expire in May 2021.

King explained the impetus for the initial creation of the R21 No-Preliminary-Data (NPD) program. The program was established following analysis by a 2015 task force consisting of NIBIB council members, which looked at ways to generate more innovative research proposals. The 2015 task force noted the following factors that warranted the creation of the current R21 NPD program:

- Need to Manage R21 Portfolio Spending
 - o The number of R21s had been increasing, which was affecting the R01 payline. The program aimed to dissociate the R21 payline from the R01 payline and enable placing a budget cap on total R21 funding
- Return to the Original Intent of the R21
 - o Novel, exploratory, non-incremental, high risk/high reward projects
- Better Support for Early-Stage Investigators and New Investigators (ESIs and NIs)
 - o NIBIB created the NPD and Trailblazer R21 programs

The R21 program created based on the task force recommendations featured a 2-year project period with funding levels of \$275K over 2 years (Direct Costs), no more than \$200K in any year and was open to all investigators. No preliminary data were allowed. Dr. King noted that for recent due dates nearly all applications were submitted by established investigators because New Investigators were guided into the Trailblazer R21 program.

King's presentation centered on NIBIB's intention to not renew the program. Although the program was successful in increasing the R01 payline and increasing funding to ESIs and NIs, analysis of the program revealed that the program did not generate applications with greater innovation—comparison of innovation scores of R21s before and after the no-preliminary-data R21 program was introduced suggested an unchanged level of innovation. A key problem with the program was that a high percentage of applications had to be withdrawn, which resulted in extra work for applicants, as well as for NIBIB and staff of the Center for Scientific Review (CSR). The main reason for the high withdrawal rate was the inclusion of preliminary data in the applications, which was not allowed for the R21 NPD program.

King described the several alternative options NIBIB program staff is proposing to fund innovative research:

- R03 Funding mechanism “quick-to-know” mechanism (less work for applicants to see if innovative proposal will be funded)
 - o Short application
 - o 2-year projects
 - o \$50,000 in direct cost/year
- Short term R01
 - o 2 or 3-year projects with smaller budgets
- Continuation of Trailblazer R21 program to support New Investigators
- R56-Bridge fund-PIs acquire data to submit an R01 for higher risk projects
 - o Program can provide funding to help PIs acquire data to help to eventually get an R01 for their high-risk project
- Program can choose highly innovative projects outside of the payline

Council members had concerns about the new plans to fund innovative research. A primary concern was that the \$50,000 per year direct costs allowed under the R03 mechanism was not enough money to attempt to launch a new project. Dr. King stated that these R03s would be for established investigators that would have other funding and reiterated that New Investigators would continue to have the Trailblazer R21 program. Dr. King was asked about the idea of shorter R01s—whether they would be looked at differently in review. King stated that NIBIB’s experience is that short R01s are welcomed by the review panels. Other concerns included the problem that reviewers often do not give enough weight to a smaller R01 that has more innovation—those are often viewed as not having enough preliminary findings. The point was also made that the R03 is viewed as a developmental grant and so reviewers are not accustomed to looking at R03s as particularly innovative, therefore the plan to use the R03 to spur innovation may not prove a successful mechanism.

Concerning the R56 mechanism, Dr. King explained that if an R01 is outside the payline but is very innovative, program staff can use the R56 to fund the project for a year to enable the applicant to obtain preliminary data and resubmit more competitively. The point was also made by council that the proposed use of R03s and small R01s could have unintended consequences of reducing the diversity of the investigators receiving funding. Dr. Tromberg thanked the council members for their valuable input, which he said was similar to some of his own concerns regarding ways to successfully fund innovative proposals and that all the points would be considered in moving forward with this program.

Annual Lopez Lecture: Manu O. Platt, Ph.D.

The 7th annual Lopez lecture in memory of NIBIB program director Hector Lopez, was presented by Manu O. Platt, PhD, Deputy Director, Interdisciplinary Bioengineering Graduate Program at Georgia Tech University. His talk was entitled *Biomedical Engineering and Racial Health Disparities: Opportunities in Innovation*.

His lab works on cysteine cathepsins -- mammalian collagenases and elastases --that play a major role in the pathology of atherosclerosis and tumor metastasis. His talk focused on the role of cathepsins in sickle cell disease (SCD). His research has shown that sickled cells create damage in arteries, which appears to be mediated by increased activity of cathepsin proteases that degrade the elastin and cartilage in the artery walls.

Given the enormous morbidity and mortality caused by SCD overwhelmingly in Africa and in African Americans, Dr. Platt has combined his research efforts with his work as a scientist-activist in the area of health disparities for underrepresented minorities.

Platt described studies in a mouse model of SCD aimed at inhibiting the arterial damage caused by SCD. SCD in mice upregulates cathepsin K in the mouse arteries and this is mediated by June Kinase (JNK). Inhibiting JNK in the mouse model successfully blocked the arterial damage found in the SCD mouse model and this was mediated by a reduction in the expression of cathepsin K. JNK inhibition also reduced the loss of collagen seen in the arteries of the SCD mice. Unfortunately, JNK inhibitors have not been used clinically in humans because of significant side effects.

Dr. Platt then turned to the effects of racism on health. He showed a graph of his blood pressure (BP) throughout January 2021, which clearly showed significant spikes in his BP on election day, again during the Georgia senate runoffs, the day of the insurrection at the Nation’s Capital and again during the impeachment hearing. He explained that those events, in conjunction with the pandemic and the tensions around the Black Lives Matters protests resulted in his physician finding that his BP was significantly elevated, and he was put on BP medication.

Dr. Platt’s BP changes throughout early 2021 were examples of the mental and physical stressors on people who are nervous and afraid about things happening in the country that will affect their lives and the lives of

friends and family. He cited studies by Jane Elliot and the writings of James A. Baldwin that demonstrated and explored how systemic racism in US society and institutions results in Blacks being in a constant state of anxiety, which had a dramatic effect on their health.

Dr. Platt discussed the co-morbidity and mortality of the COVID-19 pandemic and racism, and cited data that came out in December 2020 showing that nationwide, Black people were dying from COVID-19 at 2.1 times the rate of white people. A JAMA article that studied the phenomenon concluded that “structural racism underlies the disproportionately higher rates of COVID-19 infections and alarmingly high rates of death in predominantly Black communities.”

In response to the BLM movement many universities and public organizations indicated support by issuing statements that they “believe in diversity equity and inclusion.” However, the data tells a different story. Numerous studies show that from 2002-2017 there has been no improvement in the number of Blacks in medical school, earning PhDs, or obtaining tenure-track faculty positions. Dr. Platt strongly suggested that instead of saying “We believe in diversity, equity, and inclusion,” we need to face and call the problem what it is: “racism.”

Data from a 2011 Science article stated that “All things normalized, black PIs are 50% less likely to be funded than white PIs.” Despite NIH efforts to correct this disparity, 2017 data published in Science Advances showed the same discrepancy, with white PIs receiving R01 funding at twice the rate of Black PIs.

Dr. Platt observed that implicit bias can dramatically affect Black scientists’ careers and the interest of Black students in pursuing research careers.

As Chair of Admissions and Recruiting of the Georgia Tech Bioengineering Graduate Program he described five “boundary conditions” that stand in the way of recruiting Black students, which are pervasive throughout the whole process—from getting sufficient applications from black students to getting them into laboratories and through qualifying exams where subjective bias in exam scoring exists. These problems need to be countered through a dedicated multi-step effort to address implicit bias throughout every step in the admissions process including implicit bias of admission committee members.

He pointed out that historically Black Colleges and Universities (HBCUs) have consistently outperformed in producing talented Black professionals. While accounting for just 3% of four-year non-profit colleges HBCU alumni account for 50% of the professors at non-HBCUs as well as 75% of Black PhDs, 80% of Black Federal Judges, and 85% of Black Doctors.

Dr. Platt closed with an overview of the successes of the Georgia Tech ENGAGES program and a newer NIH-funded GT-ESTEEMED program demonstrating that the programs work and keep Black and Brown students in the system.

Dr. Tromberg presented Dr. Platt with the Lopez lecture award and congratulated him on a presentation of the issues surrounding racism in society and academia synthesized in bioengineering-like integrative fashion. Council members lauded Dr. Platt’s presentation, both his scientific research and his frank presentation of the social situation that exists in the country.

Discussion with council members included the fact that fighting racism in the system can be exhausting and is a reality of making progress; how it is important to deal with individual students in different ways—one has to find how each student learns best; the importance of building the administrative support for minority programs with people who deal with all aspects of the program; and how initial Federal money for programs was critical to get results that caused foundations to become interested in lending support to the programs.

III. Adjournment

The open session of the NACBIB meeting was adjourned at 3:22 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 4:46 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,
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² These minutes will be approved formally by the Council at the next meeting on May 19, 2021, and corrections or notations will be stated in the minutes of that meeting.