

**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 23, 2019

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 49th meeting on January 23, 2019, at the Bolger Center in Potomac, Maryland. 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 8:35 a.m. to 12:30 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 12:45 p.m. to 1:25 p.m. for the consideration of grant applications.

Council members present:

Dr. Sanjiv Gambhir, Stanford University, Stanford, CA
Dr. Maryellen Giger, University of Chicago, Chicago, IL
Dr. David Grainger, University of Utah, Salt Lake City, UT
Dr. John H. Linehan, Northwestern University, Evanston, IL
Dr. Carolyn Meltzer, Emory University Hospital, Atlanta, GA
Dr. Robert Nerem, Georgia Tech University, Atlanta, GA
Dr. A. Gregory Sorensen, Imris Deerfield Imaging USA, Minnetonka, MN
Dr. Daniel Sullivan, Duke University Medical Center, Durham, NC
Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

Council member absent:

Dr. Charles Mistretta, University of Wisconsin, Madison, Madison, WI

Council member attending by telephone:

Dr. Richard Buxton, University of California, San Diego, La Jolla, CA

Ad Hoc Council members attending:

Dr. Paula Hammond, Massachusetts Institute of Technology, Cambridge, MA

Ex officio member attending by telephone:

Dr. Vincent Ho, Uniformed Services University of the Health Sciences, Bethesda, MD

Ex officio members absent:

Mr. Alex M. Azar, National Institutes of Health, Bethesda, MD
Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD
Dr. Sohi Rastegar, National Science Foundation, Arlington, VA

Chairperson:

Dr. Bruce Tromberg

Executive Secretary:

Dr. David T. George

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.

Also present:

NIBIB staff present for portions of the meeting:

Ms. Roberta Albert
Dr. Tatjana Atanasijevic
Dr. Irene Avila
Mr. Angelo Bacas
Mr. Gary Berridge
Ms. Uzma Cheema
Ms. Shirley Coney-Johnson
Ms. Christine Cooper
Mr. Anthony Dorion
Dr. Qi Duan
Ms. Jacklyn Ebiasah
Ms. Kate Egan
Dr. Jill Heemsker
Mr. Ahmad El-Hendawy
Ms. Angela Eldridge
Dr. Zeynep Erim
Ms. Shirley Finney
Mr. Jason Ford
Ms. Pam Glikman
Dr. John Hayes
Dr. John Holden
Ms. Alisha Hopkins
Mr. James Huff
Dr. Thomas Johnson
Dr. Krishna Kandarpa
Dr. Randy King
Dr. Peter Kirchner
Dr. Tiffani Bailey Lash

Dr. Richard Leapman
Dr. Guoying Liu
Mr. Raymond MacDougal
Ms. Jacqueline Martinez
Dr. Rishi Mathura
Ms. Ruthann McAndrew
Ms. Jessica Meade
Mr. Todd Merchak
Ms. Anna Miglioretti
Dr. Grace Peng
Dr. Carlo Pierpaoli
Dr. David Rampulla
Ms. Julia Ringel
Dr. Seila Selimovic
Dr. Behrouz Shabestari
Mr. Shaun Sims
Ms. Ashley Storm
Dr. Manana Sukhareva
Ms. Holly Taylor
Ms. Florence Turska
Dr. Shumin Wang
Ms. Jennifer Ward
Dr. Andrew Weitz
Dr. Patty Wiley
Mr. Kwesi Wright
Dr. Ruixia Zhou
Dr. George Zubal
Dr. Steven Zullo

Non-NIBIB National Institutes of Health (NIH) employees:

Dr. Ileana Hancu, CSR, NIH, Bethesda, MD
Dr. Songtao Liu, CSR, NIH, Bethesda, MD
Dr. Nora Volkow, NIDA, NIH, Bethesda, MD

Members of the public present for portions of the meeting:

Dr. Richard Baird, Olney, MD
Mr. Milton Berrios, Bolger Center, Potomac, MD
Dr. Erin Cadwalader, Lewis-Burke Associates, Washington, DC
Ms. Casey Cappelletti, The Academy for Radiology & Biomedical Imaging Research, Washington, DC
Ms. Renee L. Cruea, The Academy for Radiology & Biomedical Imaging Research, Washington, DC
Ms. Tina Getachew, American College of Radiology, Washington, DC
Ms. Rachel Levinson, Arizona State University, Washington, DC
Dr. Cynthia McCollough, Mayo Clinic, Rochester, NY
Ms. Martha Nolan, The Academy of Radiology & Biomedical Imaging Research, Washington, DC
Dr. Ron Weiss, Massachusetts Institute of Technology, Cambridge, MA

I. Call to Order: Dr. David T. George

Dr. David T. George called to order the 49th 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.

II. Deputy Director's Remarks: Dr. Jill Heemskerk

A. Welcome

Dr. Jill Heemskerk opened the meeting by welcoming the new NIBIB Director, Dr. Bruce Tromberg, formerly Professor of Biomedical Engineering and Surgery at the University of California, Irvine and Director of the Beckman Laser Institute and Medical Clinic. She commented that NIBIB is excited and inspired by his vision for the institute. She also welcomed an incoming Council Member, Dr. Paula Hammond.

B. Staff Updates

Dr. Heemskerk welcomed new program staff to NIBIB: Dr. George Zubal, Program Director for Nuclear Medicine and CT; Dr. Irene Avila to the Division of Interdisciplinary Training; and Ms. Jacqueline Martinez to the Office of the Director. Dr. Heemskerk said farewell and offered her gratitude to three former NIBIB staff: Dr. Christine Kelley, Dr. Rosemarie Hunziker, and Dr. Shadi Mamaghani.

C. News

In Memoriam -- Dr. Steven Katz: Dr. Katz was the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases from 1995 until his passing in late 2018. He will be remembered as an outstanding researcher, clinician, and administrator who was committed to excellence, integrity, and public trust. Dr. Katz was a long-standing supporter of NIBIB and recently chaired the search committee for NIBIB's new director. He will be greatly missed across NIH.

Awards: Dr. Heemskerk congratulated NIBIB grantee Dr. Samuel Achilefu, Ter-Pogossian Professor of Radiology at Washington University School of Medicine, St. Louis, for receiving the SPIE Britton Chance Award in Biomedical Optics. He received the award for transformative advancements in optical and molecular imaging that have pushed the boundaries of cancer research and patient care.

Point of Care Technology Research Network (POCTRN): Dr. Heemskerk commented on POCTRN's success. She noted POCTRN has been supported by NIBIB for 10 years and expanded in 2018. Currently, there are five Centers that bring impactful, accessible and low-cost solutions to healthcare problems. In addition to the research performed at the Centers, grants are awarded by the Centers to support subprojects. Funding more than \$26 million in subprojects has generated a further \$93 million in capital investment, providing a path to commercialization for a range of technologies developed by the grantees. In its new expanded mode, POCTRN has seven new funding partners (NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, and ODP) contributing a total of approximately \$4 million per year. POCTRN is managed by Dr. Tiffani Lash and Mr. Todd Merchak.

Trauma Care Workshop: An upcoming interagency workshop (March 21-22, 2019), "Innovations in Technologies to Extend the Golden Hour," a collaboration between NIBIB, USHS, NHLBI, NINDS, JPC-6, DARPA, BARDA, and FDA, will discuss bioimaging and bioengineering solutions for military and civilian emergency trauma care.

D. New Initiatives

ImmuneChip: Engineering Microphysiological Immune Tissue Platforms (PAR-19-138): The goal of this initiative (with an application due date of Feb 27, 2019), co-sponsored by NCATS and NIAMS, is to develop *in vitro* "tissue chip" platforms to model the human immune system. Dr. Heemskerk commented that discussions with Council members during concept clearance at the September meeting were extremely helpful, emphasizing the importance of considering validation strategies for new models up front.

Resources for Technology Dissemination (RFA-EB-18-002): This initiative (with an application due date of Feb 27, 2019) supports lab-to-user dissemination of novel, reliable imaging and bioengineering technologies, e.g., medical devices, software, methods, and imaging agents. The research will make the most of NIH investments by providing valuable technologies to more users.

Helping to End Addiction Long-term (HEAL) Initiative: Translational Devices to Treat Pain (RFA-EB-18-003): In a partnership with NINDS and 12 other NIH institutes, NIBIB published an initiative (with multiple receipt dates starting with March 22, 2019) to develop device-based treatments and diagnostics for pain. The goal of the program is to develop new devices directed against credible neural targets, building upon the latest mechanistic knowledge about the anatomy and physiology of neural pathways involved in pain.

Design by Biomedical Undergraduate Teams (DEBUT) Challenge: Dr. Heemskerk noted that DEBUT was featured in the White House STEM Education Plan. The annual DEBUT competition, a partnership with VentureWell, is open and accepting applications until May 31, 2019. The goal of the competition is to reward undergraduate bioengineering teams for technology innovations that solve important health problems. NIBIB evaluates working prototypes on the significance of the problem being addressed, the potential impact on clinical care, and design innovation. The first-place team will receive \$20,000, second place \$15,000, and third place \$10,000. A new partner, NIH Office of AIDS Research, will award a \$15,000 HIV/AIDS prize.

Alzheimer's Supplements (NOT-AG-18-039): For the third year, NIBIB and NIA are soliciting administrative supplement proposals from NIBIB-supported investigators to develop technologies and approaches for the prevention, diagnosis, treatment, and understanding of Alzheimer's Disease and related dementias. The partnership has expanded to 24 NIH Institutes and Centers. The due date for supplement requests is Feb 26, 2019.

The BRAIN Initiative: There are 28 FOAs open for the BRAIN Initiative. BRAIN is undergoing a new advisory committee assessment, which will result in recommendations for mid-course corrections and new directions. The advisory committee has already suggested that new technology development should continue, which would be an important ongoing opportunity for the NIBIB investigator community.

E. FY19 Budget

The FY19 NIH budget increased by \$2 billion including an additional \$12.7 million for NIBIB. This reflects a 3.4% increase in the FY19 NIBIB budget. The current NIBIB R01 payline is at the 17th percentile, and 22nd percentile for New Investigators.

III. Director's Remarks: Dr. Bruce Tromberg

Dr. Bruce Tromberg opened his remarks by expressing his excitement at starting his new role as the NIBIB Director. He acknowledged Dr. Heemskerk and Dr. George for their interim leadership prior to his appointment. Lastly, he thanked Dr. Roderic Pettigrew for petitioning him to join the NIBIB National Advisory Council and appointing him as lead of the NIBIB Council task force to develop strategies for the efficient use of research dollars. He emphasized both experiences will serve him well in his role as the NIBIB Director.

Dr. Tromberg described his career at University of California, Irvine (UCI) as Professor of both Biomedical Engineering and Surgery and Director of the Beckman Laser Institute and Medical Clinic. While at UCI he managed about 200 people including 22 faculty members in 10 departments. The Beckman Laser Institute and Medical Clinic treated over 90,000 patients under his management. Dr. Tromberg also noted that he was a P41 Center Director for 20 years.

NIBIB supports basic science and technology development research to improve clinical diagnostics and

therapeutics. To reduce barriers for researchers and accelerate the translation and commercialization of NIBIB-supported technologies, Dr. Tromberg emphasized the importance of engaging NIBIB stakeholders. He highlighted that human health has become a priority at Engineering schools. Now, over 100 Biomedical Engineering Departments exist throughout the United States at academic institutions, most of which came into being since NIBIB was established as an NIH Institute in 2000. He stated that NIBIB's role in building strong bonds between medicine and engineering will form the basis for the future transformation of healthcare.

Dr. Tromberg outlined his vision for NIBIB, including:

- (1) developing the next NIBIB Strategic Plan with input from Council and stakeholders;
- (2) quantification of NIBIB's metrics of impact and outcomes; and
- (3) effective communication of the potential for NIBIB-funded technologies to contribute to both the human and economic health of the country.

Dr. Tromberg sees digital health as the future of medicine. Currently, patient health is captured in static snapshots on visits to physicians, often after health problems emerge. In the future, health will be monitored continuously throughout the day, providing far more information that can be used to prevent health problems and maintain patient health. He presented data from Rock Health showing \$27 billion has been invested in digital health since the Affordable Care Act was enacted in 2011, a six-fold increase. Dr. Tromberg also discussed data from SPIE Professional that reported the economic impact of medical imaging at \$113 billion. He emphasized each of these as important areas for NIBIB emphasis moving forward.

Dr. Tromberg offered some final comments on personalized health and technology advances. To continuously measure dynamic biology, scientists and engineers need to achieve a deeper understanding of biological signals. The effort will require new technologies with advanced components, an acceleration of the validation process, and lowering costs to increase accessibility of healthcare. The impact of this vision will prevent disease, reduce hospitalizations and associated costs, and drive economic growth.

IV. Scientific Solutions for the Opioid Crisis: *Dr. Nora Volkow*

Nora Volkow, M.D., Director of the National Institute on Drug Abuse (NIDA) gave a presentation entitled "The Opioid Crisis: What Solutions Can Science Contribute?". She began with two maps of the U.S. showing rates of opioid overdose. In 1999 there were just two counties with high overdose death rates. This contrasts sharply with several hundred counties with high overdose death rates spread across the country in 2016. In 2017 there were 70,237 drug overdose deaths in the U.S., which was nearly 10% higher than the 2016 rate.

The numbers indicate that the entire country is amid an opioid crisis fueled largely by prescribed and synthetic opioids, such as fentanyl, which accounted for twice as many overdose deaths as heroin in 2017.

She described the Trans-NIH initiative "Helping to End Addiction Long-term" (HEAL). HEAL is a \$500m/year effort to 1) improve prevention and treatment for opioid misuse and addiction, and 2) enhance pain management. NIH has released 36 funding announcements for FY 2019. The NIH is coordinating with the HHS Secretary, the Surgeon General, Federal partners, and local government officials and communities.

Existing medications including methadone, buprenorphine, and naltrexone that are very successful in treating opioid use disorder and reducing death from opioid overdoses are nonetheless highly underutilized. Therefore, a central goal of HEAL is to increase the use of these medications (Medication Assisted Treatment (MAT)) in all healthcare settings including clinics, doctors' offices, and emergency rooms.

Increasing MAT in prisons is also a HEAL goal, as studies have shown significant reductions in opioid use and overdoses while in prison and after release. The Justice Community Opioid Innovation Network (JCOIN) aims to develop a network of researchers to execute clinical trials of interventions including

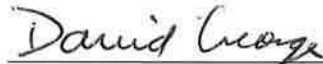
Closed Session

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 1:25 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 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 May 21, 2019, and corrections or notations will be stated in the minutes of that meeting.