

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

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

**Summary of Meeting¹
September 13, 2018**

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 48th meeting on September 13, 2018, at the Bolger Center in Potomac, Maryland. Dr. Jill Heemskerk, Acting 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 8:37 a.m. to 12:15 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 12:35 p.m. to 2:10 p.m. for the consideration of grant applications.

Council members present:

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. Karen Hirschi, Yale University, New Haven, CT
Dr. John H. Linehan, Northwestern University, Evanston, IL
Dr. A. Gregory Sorensen, Imris Deerfield Imaging USA, Minnetonka, MN
Dr. Daniel Sullivan, Duke University Medical Center, Durham, NC

Council member attending by telephone:

Dr. Sanjiv Gambhir, Stanford University, Stanford, CA
Dr. Carolyn Meltzer, Emory University Hospital, Atlanta, GA
Dr. Charles Mistretta, University of Wisconsin, Madison, Madison, WI
Dr. Robert Nerem, Georgia Tech University, Atlanta, GA

Ad Hoc Council members attending by telephone:

Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

Ex officio members present:

Dr. Richard Dickinson, attending for Dr. Sohi Rastegar, National Science Foundation, Arlington, VA

Ex Officio members attending by telephone:

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

Ex officio members absent:

Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Mr. Alex M. Azar, 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. Jill Heemskerk

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
Mr. Albricia (Nick) Aldana
Ms. Lily Bisson
Ms. Shirley Coney-Johnson
Ms. Christine Cooper
Mr. Anthony Dorion
Dr. Qi Duan
Ms. Jacklyn Ebiasah
Mr. Ahmad El-Hendawy
Dr. Zeynep Erim
Ms. Pam Glikman
Dr. John Hayes
Dr. Dennis Hlasta
Dr. John Holden
Ms. Alisha Hopkins
Dr. Rosemarie Hunziker
Dr. Thomas Johnson
Dr. Krishna Kandarpa
Dr. Randy King
Dr. Tiffani Bailey Lash
Dr. Guoying Liu
Mr. Raymond MacDougal

Dr. Shadi Mamaghani
Dr. Rishi Mathura
Ms. Jessica Meade
Ms. Anna Miglioretti
Mr. Mark Murdock
Dr. Grace Peng
Dr. David Rampulla
Ms. Julia Ringel
Ms. Saltanat Satabayeva
Dr. Seila Selimovic
Dr. Behrouz Shabestari
Mr. Shaun Sims
Mr. Russell Songco
Ms. Ashley Storm
Dr. Manana Sukhareva
Ms. Holly Taylor
Ms. Aytaj Vily
Dr. Shumin Wang
Dr. Andrew Weitz
Dr. Michael Wolfson
Dr. Ruixia Zhou
Dr. Steven Zullo

NIBIB staff attending by telephone:

Dr. Steven Krosnick

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

Dr. Paul Sato, OD, NIH, Bethesda, MD

Members of the public present for portions of the meeting:

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. Heidi Chang, McAllister & Quinn, Washington, DC
Ms. Renee L. Cruea, The Academy for Radiology & Biomedical Imaging Research, Washington, DC
Ms. Tina Getachew, American College of Radiology, Washington, DC
Dr. Elisa Konofagou, Columbia University, New York, NY
Ms. Rachel Levinson, Arizona State University, Tempe, AZ
Ms. Marsha Nolan, The Academy of Radiology & Biomedical Imaging Research, Washington, DC
Dr. Bruce Rosen, Massachusetts General Hospital, Charlestown, MA

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

Dr. David T. George called to order the 48th 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. Acting Director's Remarks: *Dr. Jill Heemskerk*

A. Welcome

Dr. Heemskerk opened the meeting by welcoming three new Council Members, Dr. Sam Gambhir, Dr. Maryellen Giger, and Dr. Robert Nerem. She announced that a new NIBIB Director had been selected. While not yet appointed, it is expected that Dr. Bruce Tromberg, Professor of Biomedical Engineering and Surgery at the University of California, Irvine and Director of the Beckman Laser Institute and Medical Clinic, will be joining NIBIB as its new Director in early 2019.

B. Staff Updates

Dr. Heemskerk welcomed new program staff to NIBIB, Dr. Qi Duan, Program Director for Image Processing and Dr. George Zubal, Program Director for Molecular Imaging and CT. She also welcomed Dr. Patricia Wiley to the Office of Science Policy and Communications, Ms. Julia Ringel to the Division of Applied Science and Technology, and Mr. Ahmad El-Hendawy to the Division of Interdisciplinary Training.

C. News

Awards: Dr. Heemskerk congratulated NIBIB Council Member Dr. Carolyn Meltzer for receiving the Association of University Radiologists (AUR) 2018 Gold Medal for unusually distinguished service and contributions to the AUR and the field of radiology. She also congratulated Dr. Richard Leapman, Scientific Director of NIBIB, who received the Microscopy Society of America Distinguished Scientist Award and the Microanalysis Society Peter Duncumb Award for creating new imaging techniques based on electron microscopy that expand current understanding of cellular fine structure and function.

NYU/Facebook Fast MRI Partnership: Facebook's Artificial Intelligence Research will collaborate with an NIBIB-funded Biomedical Technology Resource Center led by Dr. Daniel Sodickson at NYU's School of Medicine. The goal of the partnership is to reduce the length of time of an MRI scan to just 5 minutes. They expect to accomplish this by developing deep learning algorithms using Facebook's artificial intelligence technology and the more than 3 million MR images from NYU's Department of Radiology.

FDA Clearance of IMPEDE Embolization Plug: Supported by the NIBIB, a polymer memory foam designed to treat chronic venous insufficiency, developed by Shape Memory Medical, Inc. received 510(k) FDA clearance this year. Once deployed, the foam expands to block blood flow in the affected vessel. The project received initial funding during NIBIB's first year of awarding grants (2003) and progressed from an R01 to an SBIR grant.

Gadolinium Retention Workshop Report: Reports from the February workshop, co-sponsored by the American College of Radiology, Radiological Society of North America (RSNA), and National Institutes of Health, were published in Radiology and JAMA in September. The reports identify knowledge gaps about gadolinium retention and prioritize directions for research.

HIV Vaccine Workshop: An upcoming workshop (September 24-25, 2018), "A Convergence Research Approach to an Effective HIV Vaccine", a collaboration between NIBIB and NIAID, will bring biomedical engineers and virologists together to consider a collaborative pathway to develop an HIV vaccine.

DEBUT (Design by Biomedical Undergraduate Teams Challenge) Winners Announced: The teams will receive awards and give presentations at the annual Biomedical Engineering Society

conference in October. First place was awarded to a team from Johns Hopkins University for a minimally invasive brain retractor for deep-seated lesions. Second place was earned by a team from Clemson University for a tibial resection tissue protector. Third place went to a team from Georgia Institute of Technology for an epidural anesthesia placement tool intended for use during labor and delivery.

D. Science Highlights

Bacterial Biosensors: The goal of a new bacterial biosensor in development by Robert Langer of MIT, is to be an ingestible, non-invasive sensor that can detect ulcers. The bacteria in the sensors luminesce in the presence of blood and the sensor is then able to transmit a wireless signal to a smartphone. It could be possible to place up to 250 different types of bacteria on the sensor—allowing it to diagnose numerous gastrointestinal ailments including Crohn’s disease and others.

Point of Care Device Counts White Blood Cells: This novel device, designed by Carlos Castro-Gonzalez of MIT, could help prevent fatal infections following chemotherapy by quickly and easily monitoring white blood cell count. The device optically images white blood cells flowing through capillaries in the fingertips. It is non-invasive, does not require a blood draw, delivers results in one minute, and can be used in low-resource settings or at home.

Light-based Breast Cancer Screen: Created at California Institute of Technology by Lihong Wang, this technology uses optoacoustic imaging to replace traditional painful x-ray-based mammograms. It visualizes vasculature, and tumors appear as “knots” because of the complex highly vascularized nature of tumors. The images can be captured in only 15 seconds and there is no discomfort.

E. NIBIB Initiatives:

FY18 Supplement Initiatives: Dr. Heemskerk reviewed the four FY18 Supplement Initiatives issued since the May 2018 council meeting:

- C3i Participants for Advancing Innovation
- Machine Learning and Deep Learning
- Technology Dissemination
- Personalized Imaging Technologies

She commented that after the discussion at May Council, there was a great deal of interest from the community and NIBIB received many strong applications, particularly from the Machine Learning and Deep Learning and Technology Dissemination supplements.

FY19 Initiatives: Dr. Heemskerk then briefly mentioned three proposed FY19 initiatives, ImmuneChip: Engineering Microphysiological Immune Tissue Platforms, Technology Dissemination and Affordable and Accessible Monitoring of Physiological Systems, adding that NIBIB staff would be presenting them to Council for concept clearance later in the day.

Translational Research Scholars Supplement Initiative (PA-18-851): The goal of this initiative, a partnership with the National Center for Advancing Translational Sciences, is to bring engineers and physicians to work together to develop technology with a clinical perspective. The supplement will support a quantitative researcher (PhD in engineering, physical or computational sciences) to work with a Clinical and Translational Science Award (CTSA)-funded clinician-scientist peer.

NIBIB Clinical Translational Research Fellowship Program: The program is a collaboration between NIBIB's intramural staff and the NIH Clinical Center to sponsor NIBIB fellows to work with clinicians in the Clinical Center. Similar to the Translational Research Scholars Supplement Initiative, its goal is to bring in the patient and physician perspective early on in the technology development process.

Program Pointers Webinars: Interactive webinars, held approximately monthly, by NIBIB program directors offer advice on grantsmanship and NIBIB Programs and allow the extramural community to ask questions directly of NIBIB program staff.

F. Leveraging NIBIB Resources across NIH:

The BRAIN Initiative: A trans-NIH initiative, the total projected budget for the BRAIN Initiative is \$4.9 billion through 2026. In the first five years \$172 million has been spent in the area of Human Imaging/Neuromodulation. The NIBIB extramural community has received a number of these awards and is making important contributions to this effort.

Stimulating Peripheral Activity to Relieve Conditions (SPARC): SPARC is a Common fund Initiative co-led by NIBIB. Its mission is to develop therapeutic targets for peripheral neuromodulation by mapping the autonomic nervous system in relation to major organs. SPARC received \$238 million for Phase 1 (2014-2021) and is currently in the planning stages of Phase 2. NIBIB leads two of the four components of the initiative: next generation tools and technology development, and creation of a data and resource center to host an interactive atlas of human and selected animal peripheral nervous systems.

NIH Helping to End Addiction Long-term (HEAL) Initiative: NIH received \$500 million to address opioid use disorder and pain. The goal is to reduce and eliminate the need for opioids. NIBIB has partnered with NINDS and SPARC in FY19 to create an FOA to develop nonaddictive medical devices to address pain.

FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder: The goal of this challenge is to accelerate the development and review of medical devices for pain and opioid use disorder. The winners of the challenge will receive intensive FDA consultations and accelerated reviews.

All of Us: The mission of All of Us is to establish a diverse million-person cohort and collect a rich data set on all the people in the cohort. The NIBIB community could play an important role, for example in the image sharing component of All of Us, especially given the experience NIBIB has from partnering with RSNA on addressing the challenges of sharing images within electronic health records.

Dr. Heemskerk summarized by saying that, NIBIB staff are heavily involved in trans-NIH initiatives, which leads to huge benefits for the NIBIB extramural community due to the increases in funding opportunities that support the NIBIB mission.

FY19 Budget:

The house will be meeting on September 13th, 2018, to vote on a bill that includes the HHS budget. The bill includes a proposed a \$2 billion increase for NIH, which includes a 3.2% increase for NIBIB for a total proposed NIBIB budget of \$389,672,000.

III. FY 2019 Initiative Concept Clearance

A. ImmuneChip: Engineering Microphysiological Immune Tissue Platforms:

Dr. Seila Selimovic

The goal of this proposed FOA would be to develop an *in vitro* (Tissue Chip) model of a part of the human immune system or to include immune system components on existing tissue chips. The ImmuneChip will enable researchers to address mechanistic questions of health and disease of human tissues/organs, and provide improved models for therapy development. Long term outcomes of this initiative could include use in developing personalized clinical treatment. Council members supported the importance of this initiative and encouraged integrating investigators funded under this FOA with other efforts in microphysiological systems. They also encouraged early consideration of how new models would be validated so that this could be a focus of model development from the start.

Resources for Technology Dissemination: *Dr. Shumin Wang*

The goal of this proposed FOA, utilizing the U24 mechanism, is to increase the impact of NIBIB technologies by providing funding to disseminate technologies beyond the originating laboratory. Council members commented on the value of this initiative in filling a gap that would benefit the extramural community broadly. They provided valuable suggestions on focusing the initiative on the types of technologies with the greatest need, for example those used in research that do not otherwise have a viable commercialization path for dissemination.

Affordable and Accessible Monitoring of Physiological Systems: *Dr. Michael Wolfson*

The goal of this proposed FOA, utilizing the UG3/UH3 mechanism, would be to accelerate newly developed wearable and noninvasive technologies to the stage of first-in-human trials. The concept was presented as a new funding approach to overcome known roadblocks in translating technologies. The initiative would facilitate interactions with the FDA early in the project, would support projects with a well-defined end goal and would provide an uninterrupted funding stream for projects making successful progress toward milestones. Council was supportive of the concept and discussed it at length. Council members made valuable suggestions for seeking stakeholder input in defining the community's unmet needs and for involving the full breadth of expertise in the review process.

IV. The BRAIN Initiative Update: *Dr. Bruce Rosen*

Dr. Rosen spoke as NIBIB's representative to the NIH BRAIN Initiative's Multi Council Working Group. The first five years of funding of the BRAIN initiative were focused largely on technology development. Future directions are currently being discussed and the focus may be modified and/or expanded in the next five years.

Summarizing some of the recent neuroscience advancements of the BRAIN initiative, Dr. Rosen shared one example of exciting progress in the domain of the cell census. The advancements made so far have greatly exceeded the expectations of the initial RFAs focused on this research. As a result, there is currently a \$50 million initiative set aside to complete the cell census in the mouse brain, as well as support of parallel efforts to conduct a similar census for sections of the human brain. Dr. Rosen expects that in the near future, it is likely that an effort will be made to do a complete cell census of the human brain.

Dr. Rosen also expanded on other examples of encouraging work coming out of the BRAIN initiative, including neural probes, improvements to FDA-approved deep brain stimulation, neuroimaging, and brain implants. He also shared that the BRAIN initiative has created a Neuroethics working group to develop a Neuroethics roadmap to help address the complex ethical issues that will inevitably emerge related to the ethical considerations for human investigations.

He also drew attention to training support available in the BRAIN initiative, highlighting the BRAIN Initiative Fellows (F32) program, which aims to enhance the research training of promising postdocs early in their training (specifically, less than 6 months of postdoctoral training). He also mentioned the Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00), the main goal of which is to enhance workforce diversity in neuroscience. In addition, researchers on active BRAIN awards are eligible to apply for "Research Supplements to Promote Diversity in Health-Related Research" or PA-18-586. Individuals from nationally underrepresented groups—from high school to the faculty level—can receive funds for support and mentorship through an administrative supplement.

Dr. Rosen also mentioned the National Science Foundation (NSF) BRAIN initiative themes including Multi-scale Integration of Brain Dynamic Activity and Structure, Neurotechnology and Research Infrastructure, Quantitative Theory and Modeling of Brain Function, Brain-Inspired Concepts and Designs, and BRAIN Workforce Development.

He ended by emphasizing the importance of adapting to the evolving scientific landscape and informed council that an external working group has been formed to examine progress toward the goals of BRAIN 2025 Report, identify new opportunities for research and technology development, and consider opportunities to train and empower the broader neuroscience research community. The group will develop a plan for BRAIN 2.0 and make recommendations for the next five years of funding.

V. Fourth Annual Hector Lopez Lecture: Expanding the Role of Ultrasound in Diagnostics and Therapeutics *Dr. Elisa E. Konofagou*

Dr. Konofagou's talk covered the two different roles of ultrasound; the diagnostic imaging of the elastic properties of tissues, and the therapeutic aspects of drug delivery and ablation of tissue.

Elasticity imaging using ultrasound is most often used when imaging the heart. The ultimate goal of this type of imaging is to use elasticity and flow data to quantify what physicians see. Currently, Dr. Konofagou's lab can noninvasively image the principal strains on heart vessels before and after occlusion in ischemic heart models and categorize the severity of occlusion. In addition, they can image the electromechanical wave as well as create endocardial pacing activation maps.

The lab was able to use electromechanical wave imaging to map the activation sequence during different cardiac rhythms for patients with arterial flutter, with the aim of directing radiofrequency ablation to the region of the heart that is pacing abnormally. A similar technology, Pulse Wave Imaging, can be used to determine the heart vessel elasticity associated with abdominal aortic aneurysm and plaques. Dr. Konofagou also discussed the use of ultrasound Acoustic Radiation Force Imaging (ARFI) to image the stiffness of various tissues, which can help diagnose tumors and other abnormalities in a variety of organs. The lab is working to translate these technologies from animals to humans.

Dr. Konofagou finished by discussing how ultrasound can be used to treat diseases in addition to diagnosing and monitoring them. Since ultrasound always affects the mechanical and thermal aspects of tissue in small ways, it is possible to intentionally amplify and direct these effects to ablate tissue, such as cancerous tumors. Because ultrasound can be highly focused, it is able to ablate tissue deep in the body without harming surrounding tissue. This ultrasound technique can also monitor the progress of the tumor treatment while simultaneously ablating cancerous tissues. Ultrasound can also facilitate drug and gene delivery for neurodegenerative diseases by noninvasively opening the blood brain barrier, making it easier for larger molecules to pass through.

VI. Adjournment

The open session of the NACBIB meeting was adjourned at 12:15 p.m.

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 2:10 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



Jill Heemskerk, Ph.D.

Acting Chairperson,

National Advisory Council for Biomedical Imaging and Bioengineering

Acting Director, National Institute of Biomedical Imaging and Bioengineering

² These minutes will be approved formally by the Council at the next meeting on January 23, 2019, and corrections or notations will be stated in the minutes of that meeting.