

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL ADVISORY COUNCIL FOR
BIOMEDICAL IMAGING AND BIOENGINEERING**

**Summary of Meeting¹
May 23, 2018**

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 47th meeting on May 23, 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 8:30 a.m. to 12:35 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 12:50 p.m. to 1:00 p.m. for the consideration of grant applications.

Council members present:

Dr. Richard Buxton, University of California, San Diego, La Jolla, CA
Dr. David Grainger, University of Utah, Salt Lake City, UT
Dr. Karen Hirschi, Yale University, New Haven, CT
Dr. Carolyn Meltzer, Emory University Hospital, Atlanta, GA
Dr. A. Gregory Sorensen, Imris Deerfield Imaging USA, Minnetonka, MN
Dr. Daniel Sullivan, Duke University Medical Center, Durham, NC

Council members attending by telephone:

Dr. Carol Espy-Wilson, University of Maryland, College Park, MD
Dr. John H. Linehan, Northwestern University, Evanston, IL
Dr. Charles Mistretta, University of Wisconsin, Madison, Madison, WI

Ad Hoc Council members present:

Dr. Sanjiv Sam Gambhir, Stanford University, Stanford, CA
Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

Ad Hoc Council members attending by telephone:

Dr. Robert Nerem, Georgia Tech University, Atlanta, GA

Ex officio members present:

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

Ex officio members attending by telephone:

Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD
Dr. Sohi Rastegar, National Science Foundation, Arlington, VA

Ex officio members absent:

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

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
Dr. Tatjana Atanasijevic
Mr. Angelos Bacas
Ms. Lily Bisson
Dr. Xiaoyuan (Shawn) Chen
Ms. Emily Conlan
Ms. Christine Cooper
Ms. Monique Day
Ms. Jacklyn Ebiasah
Ms. Kate Egan
Ms. Angela Eldridge
Ms. Katie Ellis
Dr. Zeynep Erim
Mr. Jason Ford
Ms. Tina Gatlin
Ms. Pam Glikman
Dr. John Hayes
Dr. Dennis Hlasta
Dr. John Holden
Ms. Alisha Hopkins
Mr. James Huff
Dr. Rosemarie Hunziker
Dr. Krishna Kandarpa
Mr. Will Kane
Dr. Randy King
Dr. Peter Kirschner
Dr. Tiffani Bailey Lash
Dr. Richard Leapman

Ms. Rebecca Lenzi
Mr. Raymond MacDougal
Dr. Shadi Mamaghani
Dr. Rishi Mathura
Ms. Ruthann McAndrew
Ms. Jessica Meade
Mr. Todd Merchak
Ms. Anna Miglioretti
Mr. Joe Mosimann
Mr. Mark Murdock
Dr. Grace Peng
Dr. David Rampulla
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. Florence Turska
Ms. Aytaj Vily
Dr. Shumin Wang
Ms. Jennifer Ward
Dr. Andrew Weitz
Dr. Michael Wolfson
Mr. Kwesi Wright
Dr. Ruixia Zhou
Dr. Steven Zullo

NIBIB staff attending by telephone:

Ms. Sarah Scharf

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

Dr. Jon Lorsch, NIGMS/NIH, Bethesda, MD

Members of the public present for portions of the meeting:

Mr. Martin Berrios, Bolger Center, Potomac, MD
Ms. Casey Cappelletti, Academy of Radiology Research, Washington, DC
Ms. Renee Cruea, Academy of Radiology Research, Washington, DC
Ms. Tina Getachew, American College of Radiology, Washington, DC
Ms. Martha Nolan, Academy of Radiology Research, Washington, DC
Ms. Ariana Olshan, McAllister & Quinn, Washington, DC
Mr. Michael Peters, American College of Radiology, Washington, DC

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

Dr. David T. George called to order the 47th 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: Then and Now

Dr. Heemskerk opened the meeting by noting that NIBIB funded its first grant 15 years ago this month and presented examples of transformative technologies that were made possible with NIBIB support including:

- The ability to image the moving human fetus in utero with MRI.
- Creation of a portable ultrasound system the size of a cell phone.
- Lab-in-a-cartridge diagnostics for sexually transmitted diseases that take only 30 minutes.
- A painless microneedle patch for flu vaccination that is do-it-yourself and needs no refrigeration.
- Spinal cord stimulation to restore voluntary movement to paralyzed individuals.

B. Staff Updates

Dr. Heemskerk announced the sad news of the passing of Dr. Alexander Gorbach, Chief of the Infrared Imaging and Thermometry Unit in the Biomedical Engineering and Physical Science Shared Resource Program (BEPS) at NIBIB. She praised his research contributions in the lab, as well as his enthusiastic public outreach on behalf of NIBIB.

Dr. Heemskerk also said farewell to two departing staff members, Ms. Emily Conlan and Dr. Vinay Pai.

C. News

NIBIB-funded Cancer Vaccine Technology Licensed: Novartis has licensed cancer vaccine technology from NIBIB-funded researcher, Dr. David Mooney. The vaccine is delivered via small tablets implanted near lymph nodes and has been shown to be successful in mice. It is currently in Phase I clinical trials.

Workshop on Artificial Intelligence in Medical Imaging: NIBIB will be co-hosting a workshop on Artificial Intelligence (AI) and Biomedical Imaging with the Radiological Society of North America (RSNA), American College of Radiology (ACR), and Academy for Radiology & Biomedical Imaging Research (ARBIR) at the NIH on August 23-24. The goal is to develop a research roadmap to address AI hurdles and identify strategies for deploying AI to improve healthcare.

D. New Initiatives

Alzheimer's Administrative Supplements: The successful collaboration between the NIBIB and NIA last year to solicit administrative supplements to NIBIB-supported investigators to develop new tools, technologies and approaches for the prevention, diagnosis, treatment and understanding of Alzheimer's Disease and Alzheimer's-disease-related dementias (AD/ADRD) (NOT-EB-17-002) has been expanded to include most NIH institutes this year. This new call (NOT-AG-18-008) has a request due date of June 8, 2018.

NIBIB Administrative Supplement Initiative Concepts: NIBIB anticipates publishing four Notices to offer administrative supplements to NIBIB grants for the purposes of:

- Facilitating dissemination of new technologies developed with NIBIB funding.
- Accelerating commercialization of technologies developed within the SIBR program.
- Applying machine learning and deep learning approaches to enhance technology development.
- Developing personalized imaging approaches for all bioimaging modalities.

DEBUT: Dr. Heemskerk announced that NIBIB's annual DEBUT competition is open. In partnership with VentureWell, the goal of the competition is to reward undergraduate bioengineering teams for technology innovation. 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.

NIBIB Translational Research Scholars: In partnership with the National Center for Advancing Translational Sciences (NCATS), NIBIB will publish an initiative to support translational team research projects by providing salary and research support to a quantitative researcher with a background in engineering or computational or physical sciences, collaborating with a clinician-scientist scholar.

Concept to Clinic: Commercializing Innovation (C3i): The goal is to provide SIBR grantees and entrepreneurs with real world mentoring to speed commercialization of their products.

The Brain Initiative: The BRAIN initiative has announced new FOAs, two of which may be of particular interest to the NIBIB community. The first is “Biology and Biophysics of Neural Stimulation” (RFA-NS-18-018) and the second is “Theories, Models and Methods for Analysis of Complex Data from the Brain” (RFA-EB-17-005).

E. NIBIB Public Outreach

USA Science and Engineering Festival: Held on April 7-8, 2018 at the Walter E. Washington convention center, the USA Science and Engineering Festival drew thousands of children and families, many of whom visited NIBIB’s booth to about NIBIB by playing with the apps “Want to be a Bioengineer?” and “Surgery of the Future.”

Annual Medical Imaging Technology Showcase: The Academy for Radiology and Biomedical Imaging Research hosted its 9th Annual Medical Imaging Technology Showcase on Capitol Hill on April 10, 2018. On display for congressional staff were hands-on and interactive imaging technologies from university research departments, patient advocacy groups, industry partners, and NIBIB.

AIMBE Technology Showcase for Congressional Staffers: NIBIB’s 3rd technology showcase took place on May 4th, 2018 on the NIH campus in collaboration with the American Institute for Medical and Biological Engineering (AIMBE). Congressional staff from both the Senate and the House attended the event. NIBIB grantees demonstrated several NIBIB-funded technologies, and the staffers toured an NIBIB Intramural imaging laboratory.

F. FY18 Budget

The FY18 NIH appropriation was an increase over FY17 of \$3 billion, with \$1.1 billion targeted for specific research areas. The FY18 NIBIB appropriation is \$377,871,000—a \$19 million increase over FY17. The NIBIB FY18 R01 payline will be at the 19th percentile, and 24th percentile for Early Stage Investigators.

G. Farewell to Departing Council Members

Dr. Heemskerk thanked Drs. Carol Espy-Wilson, Karen Hirschi, Gregory Sorensen, and Daniel Sullivan for their dedicated service on NIBIB’s Advisory Council.

III. NIH Strategic Plan for Data Science: Dr. John Lorsch

Dr. Lorsch, Director of the National Institute of General Medical Sciences, spoke as a co-chair of the Scientific Data Council developing an NIH Strategic Plan for Data Science. This strategic plan was specifically requested by Congress and focuses on modernizing the data resource ecosystem, enhancing data sharing, access and interoperability, improving ability to use electronic health records, modernizing infrastructure and increasing capacity.

The first challenge for the committee was to determine the scope of what data science encompasses, so they developed a working definition of data science: “Data science is an interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are developed and used to extract knowledge and insights from increasingly large and/or complex sets of data.” They divided data science into five areas--data infra-structure; data resources; advanced management, analytics, and visualization tools; workforce development; and policy, stewardship and sustainability.

Dr. Lorsch then discussed the overall goals, strategic objectives, and implementation tactics of the strategic plan, which has since been released to the community. He emphasized the importance of leveraging existing technology in both the public and private sector, as well as determining a process for deciding how researchers would obtain approval for access to patient data. He also discussed the importance of developing and adapting existing algorithms—an issue that is important to the NIBIB community.

Dr. Lorsch finished his presentation by emphasizing the desire of the Scientific Data Council to engage a broader community and an openness to hearing more from the NIBIB community.

IV. From Concept to Clinic: Mr. Todd Merchak

Mr. Merchak discussed an enhancement to an initiative in the NIBIB Small Business Innovation Research (SBIR) program. NIBIB plans to expand an initiative called Concept to Clinic: Commercializing Innovation (C3i), which helps NIBIB grantees increase their chances of commercializing the results of NIBIB funding through education and mentorship about entrepreneurship. Start-ups require significant time, expertise and money, and many innovators would benefit from this initiative. The goal of C3i program is to increase the impact of NIH’s research investment by moving products to market to improve healthcare.

Mr. Merchak explained that this initiative was started in 2014 and has since trained 50 teams, in the hope of increasing the success of SBIR grantees. During the past four years of the program, NIBIB saw 66% of SBIR Phase I grantees move on to Phase II, almost twice the NIH SBIR average of 35%. Seven teams were able to raise more than \$75 million in private capital. One product received 510(k) clearance. NIBIB has now opened this initiative to other NIH Institutes to expand its impact across NIH.

V. Cancer Theranostics: Dr. Shawn Chen

Dr. Chen started by defining the term “theranostics,” which is a combination of the terms therapy and diagnostics. Dr. Chen’s research attempts to develop imaging agents that will help doctors diagnose cancer while also treating it.

Dr. Chen described two type of cancer theranostics—radiotheranostics and immuotheranostics. Radiotheranostics use radiotracers attached to peptides to target various cancers and deliver treatment directly to the tumor site. The goal of radiotheranostics is to enhance the efficacy of treatment, manage adverse events, improve patient outcome, and lower overall costs. Dr. Chen showed results from his Phase I clinical trial indicating that targeted radionuclide tumor therapy could be significantly more effective than traditional treatments.

Dr. Chen’s immuotheranostic research team has developed a nanovaccine that packs DNA and RNA sequences, along with anti-tumor antigens, into one small nanoparticle that modulates the immune response. He emphasized that the key to vaccines is the delivery method and its ability to stay in the lymph nodes in order to interact with the disease over time.

Dr. Chen suggested that theranostics will play an important role in the better understanding of the underlying mechanisms of cancer and the identification of new definitive biomarkers. He believes that theranostics will help doctors visualize cancer quantitatively in high resolution at the earliest stages and will ultimately help

treat cancer more successfully and improve patient outcomes.

VI. Adjournment

The open session of the NACBIB meeting was adjourned at 12:35 p.m.

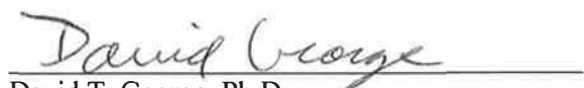
VII. Closed Session

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 1:00 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

Acting Associate Director for Research Administration

National Institute of Biomedical Imaging and Bioengineering



Jill Heemskerk, Ph.D.

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 September 13, 2008 and corrections or notations will be stated in the minutes of that meeting.