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]
January 18, 2018

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 46th meeting on January 18, 2017, 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 12:15 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 12:30 p.m. to 12:50 p.m. for the consideration of grant applications.

Council members present:

Dr. Kristi Anseth, University of Colorado, Boulder, Boulder, CO
Dr. Richard Buxton, University of California, San Diego, La Jolla, CA
Dr. Karen Hirschi, Yale University, New Haven, CT
Dr. Raphael Lee, University of Chicago, Chicago, IL
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

Council member not attending:

Dr. David Grainger, University of Utah, Salt Lake City, UT

Ex officio members present:

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:

Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Dr. Eric Hargan, 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.

NIBIB staff present for portions of the meeting:

Ms. Roberta Albert
Dr. Tatjana Atanasijevic
Mr. Angelos Bacas
Dr. Richard Baird
Dr. Michael Cheetham
Ms. Shirley Coney-Johnson
Ms. Emily Conlan
Ms. Christine Cooper
Ms. Monique Day
Mr. Emilios Dimitriadis
Mr. Anthony Dorion
Ms. Jacklyn Ebiasah
Ms. Kate Egan
Ms Angela Eldridge
Ms. Katie Ellis
Dr. Zeynep Erim
Mr. Jason Ford
Ms. Pam Glikman
Dr. John Hayes
Dr. Dennis Hlasta
Dr. John Holden
Ms. Alisha Hopkins
Dr. Rosemarie Hunziker
Dr. Thomas Johnson
Mr. Jeff Kaloz
Dr. Krishna Kandarpa
Dr. Randy King
Dr. Tiffani Bailey Lash
Dr. Richard Leapman
Dr. Guoying Liu
Mr. Raymond MacDougal
Dr. Shadi Mamaghani
Dr. Rishi Mathura
Ms. Jessica Meade
Mr. Todd Merchak
Ms. Anna Miglioretti
Mr. Joe Mosimann
Mr. Mark Murdock
Dr. David Rampulla
Ms. Vicki Rein
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
Dr. Shumin Wang
Dr. Andrew Weitz
Dr. Michael Wolfson
Mr. Kwesi Wright
Ms. Li-Yin Xi
Dr. Ruixia Zhou
Dr. Steven Zullo

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

Dr. Rajeev Agarwal, Office of Research on Women's Health, NIH
Dr. Stephen Katz, NIAMS, NIH
Dr. Michael Lauer, OD, NIH
Dr. Paul Sato, Office of AIDs Research, NIH

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
Dr. David Kaplan, Tufts University, Medford, MA
Ms. Ariana Olshan, McAllister & Quinn, Washington, DC
Mr. Michael Peters, American College of Radiology, Washington, DC
Ms. Kathy Sedgwick, NOVA Research Company, Silver Spring, MD
Ms. Ye Wan, Academy of Radiology Research, Washington, DC
Mr. David Zinn, Academy of Radiology Research, Washington, DC

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

Dr. David T. George called to order the 46th 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. Director's Remarks: Dr. Jill Heemskerk

A. NIBIB Transitions, Awards, and New Staff

Dr. Heemskerk announced that Dr. Roderic Pettigrew, NIBIB Director, has retired from federal service and joined Texas A&M as CEO of EnHealth and Executive Dean of EnMed—a new engineering medicine track in partnership with Houston Methodist Hospital.

NIBIB grantee Dr. Ranu Jung was elected to the 2017 class of the National Academy of Inventors. Her team developed the first implantable, wirelessly controlled, direct neural interface system for restoring sensation to amputees and has received U.S. Food and Drug Administration (FDA) approval to conduct a first-in-human trial for the device.

Dr. Heemskerk welcomed Ms. Anna Miglioretti, who joined the NIBIB Office of Scientific Review as an Analyst. Dr. David George has been named Acting Deputy Director of NIBIB and will continue as Acting Associate Director for Research Administration. Dr. Heemskerk acknowledged the following NIBIB staff who are serving as acting directors of NIBIB divisions and offices: Dr. Zeynep Erim, Division of Interdisciplinary Training; Dr. Krishna Kandarpa, Division of Applied Science and Technology; Dr. Steven Krosnick, Office of Program Evaluation & Strategic Partnerships; Dr. Behrouz Shabestari, Division of Health Informatics Technologies; Dr. Manana Sukhareva, Office of Scientific Review; and Dr. Michael Wolfson, Division of Discovery Science and Technology.

Dr. Heemskerk acknowledged the contributions of departing Council members Drs. Kristi S. Anseth and Raphael C. Lee and presented each with a plaque to commemorate their valuable service to NIBIB.

B. Strategic Plan Update

The strategic planning process is on hold until a new NIBIB director is appointed. Dr. Heemskerk thanked members of the council working group for their work in shaping a strategic plan framework.

C. NIBIB Activities

NIBIB Discoveries. NIBIB funded investigators as well as the NIBIB intramural program researchers have made remarkable advances. For example, metal-free magnetic resonance imaging (MRI) contrast agents, once developed and validated by NIBIB-supported investigators, will be broadly used. From super-resolution imaging to nanovaccines, the wide-ranging work of NIBIB's intramural research program demonstrates how bioengineering approaches contribute to medicine and biology. For example, Dr. Xiaoyuan Chen recently published results of a proof-of-concept study using microneedle patches to automatically manage glucose levels for type 2 diabetes without the need for frequent blood-stick testing.

Programmatic Updates. NIBIB is partnering with the National Institute on Aging (NIA) to fund supplements for Alzheimer's disease (AD) and Alzheimer's disease-related dementias projects focused on developing new tools, technologies, and approaches for prevention, diagnostics, treatment, and understanding. The supplements encourage new focus on AD in ongoing technology development projects. From this partnership, nine projects were funded in the last fiscal year, and the partners plan to repeat this year and possibly expand support.

The goal of Concept to Clinic: Commercializing Innovation (C3i) is to provide NIH grantees with essential business tools and specialized mentoring for successful translation of biomedical technology from laboratory to market. To date, 32 Small Business Innovation Research/Small Business Technology

Transfer (SBIR/STTR) companies and 13 R01 teams have participated over the past four years. The project is scaling up to strengthen the pipeline between academic research NIBIB supports and the SBIR program.

NIBIB and the National Center for Advancing Translational Sciences (NCATS) issued a follow-up Request for Applications (RFA) to develop a Microphysiological Systems Program for Translational Research in Space. The "Chips-in-Space" initiative, led jointly with the Center for the Advancement of Science in Space (CASIS), aims to develop *in vitro* models of human disease using an organ-on-a-chip approach. The International Space Station's microgravity environment helps researchers create more realistic models of diseases such as bone density loss. RFA applications are due February 8, 2018.

NIBIB is funding supplements to NCATS Clinical and Translational Science Awards (CTSA) designed to support collaboration between quantitative researchers and CTSA-funded clinician-scientists, helping both transition to independent research careers. Applications are due January 23, 2018.

High school students and teachers from six classrooms across the country connected with NIBIB Program Directors via the live-streamed Biomedical Engineering Day on December 7, 2017. The event was designed to promote biomedical engineering careers.

NIBIB and the Academy for Radiology and Biomedical Imaging Research (ARBIR) partnered in two outreach events during November 2017. Patient advocacy and industry representatives visited NIBIB to hear about advances in NIBIB-funded imaging research. During a visit to Capitol Hill with ARBIR members, NIBIB's Dr. Kris Kandarpa presented remarks on the future of medical imaging to congressional staff.

Dr. Heemskerk described several important upcoming events. NIBIB is co-sponsoring the Gadolinium Retention Workshop (February 15–16) to discuss use of gadolinium-based contrast agents for MRI. An Artificial Intelligence in Medical Imaging symposium (August 23–24) is an outcome of Interagency Working Group on Medical Imaging efforts to create opportunities for effective collaboration within diagnostic imaging research across federal agencies, industry, and academia.

NIH Activities: All of Us Initiative. The All of Us Initiative, which aims to build a data set of one-million volunteers' de-identified health information that will be accessible to researchers, has requested public input (https://allofus.nih.gov/researchpriorities) on important research questions of interest. Input is due by February 9, 2018.

D. NIH/NIBIB Budget

The federal government is operating under a Continuing Resolution (CR) at Fiscal Year (FY) 2017 funding levels. Proposed FY18 budgets from the House and Senate propose increased appropriations for the NIH budget. The CR will expire at midnight on Friday, January 19.

III. Brains, Pains, and Tissue Engineering: Dr. David Kaplan

Dr. David Kaplan presented an overview of his work exploiting the properties of fibrous proteins found in nature and their uses in tissue engineering for brain system and pain studies. Biomedical applications of silk include hollow implants and porous scaffolds for drug delivery, injectable memory foams that expand under the skin to fill voids and fully restore large-volume tissue defects, dense components such as screws and plates for orthopedic repairs, and 100% degradable implantable optical and electronic devices.

A functional 3D brain tissue "donut model" consists of a porous silk sponge on the outside and a central

region filled with collagen gel that interfaces with the silk, allowing axons to grow, connect, create synapses, and function. Silk provides stability and functionality for 1 year and 3 months in cultures. The relative transparency of the center provides a window for imaging and opportunities for static and perfusion culture. The model has been used to generate a human-induced neural stem cell (hiNSC) line that can be cryopreserved and passaged indefinitely and used to study the impact of mechanical damage on structure and function of brain tissue over time. Studies of an alternate model in which collagen gel is replaced by extracellular matrix (ECM) from fetal porcine brains revealed that fetal ECM regulates tumor growth, suggesting that ECM-related molecules may have potential therapeutic uses. Additional 3D brain tissue models have been developed for Alzheimer's disease and stroke.

An innervated human cornea tissue model that employs layered silk protein films is being used to measure peripheral nerve response to irritation and pain. The model enables study of the effects of chemical stimulation, electrical stimulation, and hyperglycemia on cells.

Discussion:

Council members asked about responses of cells embedded in silk scaffolds used in reconstructive surgery and Dr. Kaplan explained that cell response varies depending on cell type, tissue location, and material density. Typically, a lipoaspirate is infused into the scaffold rather than cells. When infused in deformable silk polymer with shape memory, the lipoaspirate survives squeezing and expansion and continues to function post injection.

Council members commented on how innovative biomaterials enable advances and the importance of supporting fundamental and discovery work that precedes development of applications. Dr. Kaplan noted that it took 15 years of fundamental work to understand the molecular biology, physics, and chemistry of silk before the first polymer applications were developed.

IV. NIBIB Director Search: Dr. Stephen I. Katz

Dr. Stephen Katz described the NIBIB Director search committee as very active and diverse and outlined the search process. He encouraged Council to submit to him names of potential candidates.

V. NIH Clinical Trials Update: Dr. Michael S. Lauer

Dr. Michael Lauer described new NIH policies on dissemination of NIH-funded clinical trial (CT) information and NIH initiatives designed to enhance the accountability and transparency of clinical research. These initiatives target key points throughout the entire CT lifecycle from concept to results reporting. The new policy is built on the premise that scientists have an ethical obligation to disseminate results of publicly funded trials. Reforms include requirements for trial registration, timely posting of results, and labeling of Funding Opportunity Announcements to indicate whether they accept CTs.

Clinical trial resources posted at https://grants.nih.gov/policy/clinical-trials.htm spell out requirements for registration and reporting of clinical trials and include videos and decision tools as well as case studies designed to help investigators determine whether NIH would consider their proposed studies to be CTs.

Discussion:

Dr. Lauer described NIH efforts to take advantage of the digital revolution to disseminate CT results accurately and quickly and simplify the trial registration and reporting processes. Council members discussed the importance of disseminating results from non-CT research and sharing lessons learned. Dr. Lauer indicated the value of publishing all results so that other investigators could avoid wasting resources by repeating past unsuccessful studies.

VI. Adjournment

The open session of the NACBIB meeting was adjourned at 12:15 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 12:50 p.m.

Certification:

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

David George

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.
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 May 23, 2018, and corrections or notations will be stated in the minutes of that meeting.