**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 23, 2020**

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 52nd meeting on January 23, 2020, 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 8:30 a.m. to 12:55 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 2:05 p.m. to 2:30 p.m. for the consideration of grant applications. The Open Session was webcasted and can be viewed at https://videocast.nih.gov/watch=35689.

**Council members present:**
Dr. Jennifer Barton, University of Arizona, Tucson, AZ
Dr. Maryellen Giger, University of Chicago, Chicago, IL
Dr. David Grainger, University of Utah, Salt Lake City, UT
Dr. Amy Herr, University of California, Berkeley, Berkeley, CA
Dr. Ranu Jung, Florida International University, Miami, FL
Dr. Bruce Rosen, Harvard Medical School, Charlestown, MA
Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

**Council member absent:**
Dr. Samuel Achilefu, Washington University School of Medicine, St. Louis, MO

**Council member attending by telephone:**
Dr. Richard Buxton, University of California, San Diego, La Jolla, CA
Dr. Paula Hammond, Massachusetts Institute of Technology, Cambridge, MA
Dr. Robert Nerem, Georgia Institute of Technology, Atlanta, GA

**Ex officio members present:**
Dr. Zane Arp (attending for Dr. Jeffrey Shuren) U.S. Food and Drug Administration, Silver Spring, MD
Dr. Sohi Rastegar, National Science Foundation, Alexandria, VA
Dr. Jeffrey Shuren, (attending half day) U.S. Food and Drug Administration, Silver Spring, 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. Vincent Ho, Uniformed Services University of the Health Sciences, Bethesda, MD

[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.

Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD

**Chairperson:**
Dr. Bruce J. Tromberg

**Executive Secretary:**
Dr. David T. George

**NIBIB staff present for portions of the meeting:**

Ms. Roberta Albert
Dr. Tatjana Atanasijevic
Mr. Angelo Bacas
Dr. Monique Binger
Ms. Lily Bisson
Dr. Moria Bittman
Ms. Shirley Coney-Johnson
Ms. Christine Cooper
Mr. Anthony Dorion
Dr. Qi Duan
Ms. Jacklyn Ebiasah
Ms. Kate Egan
Mr. Ahmad El-Hendawy
Ms. Angela Eldridge
Ms. Katie Ellis
Dr. Zeynep Erim
Mr. Jason Ford
Ms. Pam Glikman
Dr. Ilana Goldberg
Dr. John Hayes
Dr. Jill Heemskerk
Dr. John Holden
Ms. Alisha Hopkins
Mr. James Huff
Mr. Garry Jenkins
Dr. Thomas Johnson
Dr. Krishna Kandarpa
Ms. Deborah Kelly
Dr. Randy King
Dr. Peter Kirchner
Dr. Tiffani Bailey Lash
Ms. Truc Le
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. David Rampulla
Ms. Julia Ringel
Ms. Ruth Rose
Ms. Kaitlyn Sadtler
Ms. Saltanat Satabayeva
Dr. Peter Schuck
Dr. Behrouz Shabestari
Mr. Shaun Sims
Mr. Russell Songco
Ms. Ashley Storm
Dr. Manana Sukhareva
Ms. Holly Taylor
Dr. Shumin Wang
Dr. Andrew Weitz
Dr. Patty Wiley
Dr. Michael Wolfson
Mr. Kwesi Wright
Dr. Ruixia Zhou
Dr. George Zubal
Dr. Steven Zullo

**Non-NIBIB National Institutes of Health (NIH) employees:**
Mr. Ronnel Daniels, OD, NIH, Bethesda, MD
Ms. Joy Farrar, OD, NIH, Bethesda, MD
Mr. David Higgins, OD, 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

Ms. Tina Getachew, American College of Radiology, Washington, DC
Dr. Raphael Lee, University of Chicago, Chicago, IL
Dr. Josh Leonard, Northwestern University, Evanston, IL
Dr. John Linehan, Northwestern University, Evanston, IL
Dr. Edward Margerrison, U.S. Food and Drug Administration, Silver Spring, MD
Ms. Marsha Nolan, The Academy of Radiology & Biomedical Imaging Research, Washington, DC

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

Dr. David T. George called to order the 52nd 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. Bruce J. Tromberg*

### A. Welcome and Farewell

Dr. Tromberg welcomed three new Council members, Dr. Samuel Achilefu, Dr. Jennifer Barton, and Dr. Amy Herr. He thanked Dr. Sanjiv Gambhir for serving on the NIBIB Council.

### B. Budget

The appropriations bill for Health and Human Services (HHS) was passed and signed by the President in December. NIH had a 6% increase ($41.4 billion), and NIBIB's budget is about a 4% increase at $404 million. NIBIB's 2019 R01 payline is at the 19$^{th}$ percentile.

### C. News

Congressional Hearing: The Appropriations Subcommittee on Labor, HHS, and Education held a second Congressional Hearing for NIH to obtain more knowledge about NIH research and activities. Dr. Tromberg showed a short clip of the hearing. He conveyed to the Subcommittee that the health industry is moving toward continuous monitoring of biomarkers to prevent and treat disease more effectively, and to increase the 'healthspan.'

Awards: Dr. Tromberg congratulated Dr. Maryellen Giger on her AI-based software for breast cancer diagnosis, which was featured as one of TIME's best innovations of 2019.

NIBIB Staff Updates: Dr. Tromberg announced the appointment of Dr. Zeynep Erim as the Director of the Division of Interdisciplinary Training; Dr. David Rampulla as the Director of the Division of Discovery Science and Technology (DDST); and Dr. Behrouz Shabestari as the Director of the NIBIB National Technology Centers Program. Dr. Rampulla is reorganizing and renaming DDST and many of its programs. More information will be forthcoming.

Dr. Tromberg welcomed Dr. Moria Bittmann as program director for the NIBIB Biomechanical Engineering and Bioelectric Engineering programs. He thanked and congratulated Dr. Šeila Selimović as he announced her departure from NIBIB to run the Early Notification to Act, Control, and Treat (ENACT) program at the Biomedical Advanced Research and Development Authority (BARDA).

Intramural Research Updates: The research programs of Dr. Richard Leapman, Dr. George Patterson, and Dr. Peter Schuck were reviewed by NIBIB's Board of Scientific Counselors (BSC) in December 2019. Dr. Tromberg attended the review and was impressed by each researcher's accomplishments and presentations to the BSC.

Harnessing Data Science for Health Discovery and Innovation (DS-I) Africa Update: The DS-I Africa implementation plan is currently under review. A Symposium is planned for June 24-26, 2020, in Nairobi,

Kenya, to discuss focused concepts for proposal submissions. The first Notices of Special Interest are scheduled for announcement in February 2020, and the first Funding Opportunity Announcements are planned for April 2020.

NIH Tech Accelerator Challenge for Global Health: NIH launched a new collaboration with the Bill and Melinda Gates Foundation (BMGF) to develop cures for sickle cell disease and HIV on a global scale.

Together with the BMGF and the NIH Office of the Director, NIBIB has launched a new challenge to develop non-invasive platform devices with the potential to diagnose or track diseases in the vasculature (sickle cell, malaria, and HIV). Challenge winners will have the opportunity to receive additional funding from the BMGF to accelerate the commercialization of the technology. Additional partners include the National Institute of Allergy and Infectious Diseases; the National Heart, Lung and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; and the Fogarty International Center.

Interagency Modeling and Analysis Group (IMAG) Update: A meeting on the Integrating Machine Learning with Multiscale Modeling for Biomedical, Biological, and Behavioral Systems organized by Dr. Grace Peng had a report published in a *Nature* journal. Registration is open for an upcoming IMAG meeting in March 2020 that will focus on increasing diversity in the modeling workforce.

NIBIB Trailblazer (R21) Funding Opportunity Announcement (FOA): The R21 Trailblazer FOA for early stage/new investigators (ESI/NI) was reissued in January by Dr. Randy King. Dr. Tromberg reported since the issuance of the original R21 Trailblazer FOA in 2015 the proportion of R21 awards to ESI/NIs has increased from 18% in 2015 to 63% in 2019.

Alzheimer's Supplements: The National Institute on Aging has released a NOSI to fund Alzheimer's-focused supplements for projects that were not initially focused on Alzheimer's disease. NIBIB participated in the pilot program in 2017 and helped start this partnership with its first round of supplements. The supplements allow investigators to apply technological solutions to Alzheimer's and Related-Dementias. Applications are due in March 2020. Dr. Tromberg encourage the extramural community to apply.

Design by Biomedical Undergraduate Teams Challenge (DEBUT): Submissions are open for DEBUT, a collaboration between NIBIB and VentureWell that challenges undergraduate student teams to develop technology solutions to unmet needs in any area of healthcare. Two additional NIH partners, NIH Office of AIDS Research (OAR) and the National Institute of Minority and Health Disparities (NIMHD) are each providing a prize. NIMHD is seeking applications that develop technologies for underrepresented populations and/or for low-resource settings and OAR for addressing HIV/AIDS.

Notices of Special Interest (NOSIs): NIBIB recently published three Notices of Special Interest (NOSIs).

Maximizing Opportunities for Scientific and Academic Independent Careers (MOSIAC) (NOT-EB-19-020) is an early career award for postdoctoral fellows from diverse backgrounds transitioning to independent research careers. Dr. Zeynep Erim is the contact for NIBIB's participation in the MOSAIC program.

Dr. George Zubal issued the Technological Innovations for Advancing Clinical SPECT Imaging NOSI (NOT-EB-19-022) to develop new SPECT imaging technologies and SPECT analogues of PET brain radiopharmaceuticals.

Lastly, Mr. Todd Merchak issued a NOSI (NOT-EB-19-022) for SBIR/STTR grant applications with a focus on modeling and simulation, pediatric, point-of-care ultrasound, and clinical decision support technologies.

NIBIB Partnerships: Dr. Tromberg asked Council members to help brainstorm ideas to increase partnerships between NIH, National Science Foundation (NSF), US Food and Drug Administration (FDA), and National Institute of Standards and Technology (NIST). Dr. Tromberg emphasized the importance of collaboration between these agencies to propel basic science and technology development for clinical diagnostics and therapeutics.

Dr. Jeffrey Shuren said the cost of assessment of new technologies is costly for the FDA. Great areas of partnership between these agencies are creating new assessment tools that help de-risk and lower the cost of science. He thinks it is important for the agencies to pool resources, data, and expertise to move new technologies through the pipeline more rapidly while upholding high standards.

## III. Strategic Planning

The NACBIB strategic planning working groups met on January 22nd, 2020, to continue discussions for the NIBIB Strategic Plan. Each of the seven working groups reported on their progress by briefly summarizing the state of the science, gaps and opportunities in the field, and audacious goals. The summaries of each group are recounted below.

Group 1: Quantitative Data Science in Biomedical Imaging and Bioengineering (QBIB): Theory-driven Modeling and Data-driven Computation

This working group outlined opportunities for progress in areas of quantitative data science. The group suggested is important that the integration of data and methods occurs in the areas of biomedical computing, signal acquisition, signal processing, and artificial intelligence. Developing generalizable and reusable methods for multiscale modeling would create frameworks to test new hypotheses virtually. Data-driven image reconstruction algorithms for live imaging of cells, PET/MRI, adaptive optics (feedback loop), dynamic extraction of features, and intelligent medical diagnostics are also needed.

There are opportunities to more fully use simulation to create virtual/synthetic data, predict clinical outcomes, and reduce medical errors. Tools and technologies are needed to interpret and display data intelligently. New approaches to develop virtual clinical trials and create virtual twins would improve healthcare. Emerging methods and standards to evaluate technology would lead to a more effective and efficient translation of technologies.

The vast amount of healthcare data could benefit from improved interpretability and accessibility across healthcare systems. Development of new infrastructure could lead to a sustainable knowledge ecosystem. Digital healthcare would be improved if tools were to be created for biomedical data collection and analysis.

The group identified three audacious goals:

1. Comprehensive simulations of complete QBIB systems and processes such as imaging systems and processes, digital twins, virtual clinical trials over multiple populations, and precision medicine at the point-of-care.

2. Robust and explainable QBIB for accelerating biomedical discovery and medical decision-making and interventions.

3. Advanced patient safety technology assessment for the reduction of medical errors to enhance human healthcare.

Group 2: Engineered Biology

Engineered biology is an emerging discipline that integrates the tools and concepts of engineering and the life sciences. This area is driven by the need to create new technologies to improve human health and the design-build-test-learn paradigm that is foundational to all engineering disciplines. At the core of engineered biology is the ability to interrogate and control complex, functionally sophisticated biological processes. Unique challenges of applying engineering to biological systems are due to (1) endogenous cell programming that is not fully understood and (2) intrinsic heterogeneity of biological systems.

The field of engineered biology has made many advances in the past ten years that have significantly impacted public health. Regenerative medicine has constructed durable grafts for dialysis patients. Cell-based therapies like CAR-T cells for cancer immunotherapy have brought new hope to patients who have not

responded to other treatments. Organs-on-a-chip, or microphysical platforms, have improved predictive testing of drug efficacy and safety and served as effective models of disease to assess treatment regimens.

Emerging opportunities will enable biological and engineering advances. Areas of interest are cell and tissue models for biological research; single-cell analysis; computational biology; gene editing and DNA assembly; functional imaging modalities; hybrid computational models; cells as smart therapeutic factories; cell-based implanted devices; whole-organ engineering; three-dimensional printing; theranostics; machine learning; patient-specific models of disease; engineered biological functions.

Engineered biology could transform health with the help of NIBIB by focusing on these audacious goals.

1. Create injectable biological software, which coopts native cells to program tissue repair, customizes immune functions, and replaces missing physiological functions.

2. Support and extend health during aging by actively managing or improving biological processes and functions and preventing rather than treating diseases associated with degeneration.

3. Develop embedded sense-and-respond technologies that monitor and modulate physiological processes in situ, in real-time, and with advanced capabilities such as patient-specific adaptive learning and control.

4. Enable broad access to advanced therapeutic modalities by decreasing costs and extending benefits to the entire society.

NIBIB could facilitate this vision by creating and supporting consortia to build a collaborative ecosystem that supports engineering innovation, biological inquiry and translation into the clinic, and develop frameworks, technologies, and knowledge for making engineered biology interoperable, scalable and modular.

Group 3: Sensing Health and Disease

Sensor technologies provide the technical window for continuously monitoring human biology and pathology. Sensors can also deliver actionable data to inform interventional decision-making and possible therapeutic guidance. Additionally, they can produce on-demand profiling of wellness and disease biomarkers to inform individual health status or therapeutic progress clinically. Lastly, sensors are versatile and can be used in diverse environments that are customizable to a variety of interfaces and data.

Better biomedical sensors would: enable faster, more integrated diagnostics (wearables, sample-based assays, etc.); transform healthcare management into wellness management; enhance clinical decision-making through more patient-specific data; improve disease understanding in human models through less invasive data collection, reduce animal use and provide much-needed data to improve modeling (i.e., digital twin); produce new areas of medical information such as the microbiome that will become easier to study; and facilitate automated health care through integrated multiparametric sensor systems removing operator error (e.g., critical care equipment).

The group identified six major goals:

1. Improve early detection capabilities.

2. Promote personalized medicine: individual monitoring, individual reporting, individual outcomes.

3. Exploit better sensor data to enhance healthcare value.

4. Enhance commercialization/translational awareness for technology impact.

5. Stimulate sensing innovation and improvements in capabilities impact.

6. Address healthcare cost containment and value-based healthcare.

Group 4: Imaging Health and Disease

The vision espoused by this group is NIBIB as a central hub for developing, applying, and disseminating new imaging technology for both clinical and research applications driven by community of an interdisciplinary workforce of physicists, chemists, engineers, computer and data scientists, biologists, and physicians. To date, imaging technologies for medical and basic science applications have transformed the practice of medicine. For example, exploratory surgery is rare because of advanced imaging methods.

Imaging technology advances are set to change medicine and biological research in profound ways. In the future, experts think CT and Nuclear Medicine scans would use far less radiation so children could be imaged with fewer risks, and screening for diseases like lung cancer would be safer across all age groups. Light and sound could be combined to image organs deep in the body in hopes of avoiding biopsies altogether in some cases.

To enable this vision, resolution, sensitivity, and quantitative accuracy will need to be greatly improved. Improvement in these areas would allow the characterization of disease before symptoms arise and when treatment is best, least costly, and most effective. Creating low-cost, portable, and inexpensive imaging would move imaging from radiology suites to the bedside, rural settings, and potentially the home.

AI needs to be integrated with every aspect of imaging. AI tools will improve image quality and bring expertise to the interpretation of images to improve diagnosis. It is essential for productive collaborations to be built between AI and clinical decision-makers.

To help detect disease earlier and improve diagnosis and precision medicine, it is necessary to integrate multiple image types with one another and other health data. Imaging will guide more precise and less invasive treatments. Image-guided therapies will increasingly replace invasive surgery, and advanced molecular theranostics will allow physicians to diagnose and treat disease simultaneously.

Group 5: Advanced Therapies and Cures

The development of advanced therapies and cures is driven by an unmet need in medicine or society. For example, image-guided energy delivery to elicit precision biological response has been used to enhance drug delivery and modulate a specific biological function. Additional examples include immunomodulation, which has produced CAR-T cell therapy and monoclonal antibodies; medicinal patches for drug delivery, wound healing, and metabolite sensing; and stents and meshes for use in cardiac treatments.

As new therapies are created, it is vital to ensure they are engineered to be well controlled, complex, and scalable. From a clinical perspective, the therapies should be easy to use, precise, and minimize invasiveness. Building on mechanistic studies and discovery science in biology, computational science, and imaging physics will serve as foundations for novel systems.

NIBIB should continue driving technology innovation through cross-cutting trans-NIH initiatives. The group identified a potential audacious goal—to engineer a global social impact on human health. NIBIB could address grand challenges that drive the status of women's healthcare, health disparity issues, guide global ethics, and enhance the integration of mobile health and AI in the current healthcare ecosystem.

Group 6: Technology Development Pipelines

An important part of NIBIB's mission is promoting improved methods to design, build, and deliver technology to foster the improvement of healthcare. There are several aspects of the technology pipeline that need to be considered when to successfully deliver health technology, including stakeholder analysis, regulatory affairs, intellectual property, technology validation, market risk, and scale-up manufacturing.

The group outlined several opportunities to enhance current NIBIB programs:

- Expand the Biomedical Technology Resource Centers network to drive innovation further and

improve the guidelines for evaluation toward measurable translational milestones.

- Apply the Point-of-Care Technologies Research Network (POCTRN) network model across other disciplines at NIBIB.
- Establish the *Concept to Clinic: Commercializing Innovation (C3i) Program* as a cornerstone to a broader translational program.
- Lastly, expedite the translation of new technologies by bridging R01 grantees to SBIR/STTR funding by providing funds for initial product development work.

There are opportunities for NIBIB to address these issues by convening people from the large and small MedTech industry, investors, university faculty and students, and entrepreneurs to brainstorm new funding initiatives in the design, build, and deliver technology space. There is an opportunity to recognize current trends in value-based healthcare to assist innovators in generating a value proposition that describes the net impact of the new technology system or process that is convincing to reviewers. A new tool that helps innovators assess their impact could be useful. Creating a start-up company for new technology bridges clinical, technical, and business experts. Helping investigators identify partners would help create reasoned value propositions when seeking venture capital funding.

Increasing collaboration with other government agencies will improve NIBIB's technology development pipeline. Most novel NIBIB-supported translational projects and innovative products could receive multiple benefits by engaging the FDA as early as possible in the product development process. NIBIB could engage with the FDA to help grantees identify the best regulatory pathway and preclinical/clinical study plans early in technology or product development. Interactions with the patent office may also help small companies expedite patents based on peer reviewed SBIR/STTR or other translational grants.

Group 7: Biomedical Imaging and Biomedical Engineering Workforce

Developing a skilled and diverse workforce at the convergence of engineering and imaging science is central to the future of biomedical and health sciences and its impact on human health. There is a persistent lack of access and a leaky pipeline in the biomedical workforce. The bioengineering and bioimaging workforce must be diversified. Incorporating engineering systems science into medical education and public health curriculum will benefit healthcare.

Training of the biomedical workforce has seen several improvements. Pilot medical school programs have incorporated biomedical engineering and systems engineering into their core curriculum. NIH has created a Working Group of the Advisory Council to the Director on Changing the Culture to End Sexual Harassment. Many efforts at NIH and NSF require minority representation.

The group outlined their future impactful vision to improve the biomedical workforce and NIBIB's role:

1. Diversify the economic spheres where bioengineering exists.
2. Integrate team mentoring in all technology development grants.
3. Increase access to engineering in clinical environments.
4. Promote systems approaches to career pathways and population health.
5. NIBIB should continue to emphasize the bioengineering impact at NIH and leverage contributions from other institutes.

## IV. FY 2020 Initiative Concept Clearance:

### A. NIBIB Biomedical Technology Resource Centers (BTRC) - P41 Program: *Dr. Behrouz Shabestari*

Dr. Behrouz Shabestari presented an overview of the Biomedical Technology Resource Center (BTRC) P41 Program for Concept Clearance. He proposed a new name for the program: National Centers for Biomedical Imaging and Bioengineering (NCBIB).

Each P41 center includes multiple components: Technology Research and Development Projects (TR&Ds); Collaborative Projects (CPs) and Service Projects (SPs); Training and Dissemination; and Administration. The core of a P41 Center is its TR&Ds, which develop cutting-edge technologies motivated by CPs who work with the TR&Ds in an iterative relationship whereby the CPs are the test beds and drivers for the creation of new technology. SPs use the successfully established technologies that had been developed from this initial CP-driven development. Centers develop practical tools and are expected to have a national and international impact.

Over the past five years, NIBIB has supported about 30 Centers annually. The annual budget for the program is between $35M and $40M. The program has a strong national and international impact—the currently funded Centers provide technologies to 286 CPs and 259 SPs, primarily in the U.S., Europe, and Southeast Asia, as well as several projects in Australia, Africa, and South America. It is noteworthy that sources outside of NIBIB fund 80% of CPs and SPs, which includes a dozen NIH ICs as well as other agencies, including NSF, DoD, and international organizations. The scientific output of the program is impressive, with approximately 18 publications per million dollars of NIBIB support compared with about 12 publications per million from R01 grants.

The breakdown of the program areas for the current centers is the following: Imaging Health and Disease 38%; Engineered Biology, 26%; Data Science and Computation, 13%; Sensing Health and Disease, 13%; Advanced Therapies and Cures, 6%.

Dr. Shabestari made the point that although the centers are unique and distinct in their technological work, they do overlap in their clinical target and biological scales. Therefore, a proposed addition to the program is an annual cross-cutting P41 science and technology workshop, including the broader community to challenge and encourage them for push-pull interaction and dissemination of their cross-cutting innovative tools and technologies.

The reissuance of the funding opportunity announcement is slated for May 2020. New centers receive up to $750,000 in direct costs per year plus $500,000 total for major equipment. Center may request funding for five years. Funded Centers may be renewed twice for a maximum of 15 years of NIBIB support. Council members were in strong support of the program.

**B. Enhancing Science, Technology, Engineering and Math Educational Diversity (ESTEEMED) Research Education Experiences (R25) Reissuance:** ***Dr. Zeynep Erim***

The goal of the ESTEEMED program is to increase diversity in the STEM workforce. The program is modeled after the University of Maryland Baltimore County (UMBC) Meyerhoff Scholar Program. It includes a summer bridge program before freshman year of undergraduate studies; academic year activities like one-on-one mentoring, workshops, seminars, and social events; a summer research experience before sophomore year aimed to provide hands-on research skills; an advanced honors program junior and senior years. Evaluation and feedback are provided to participants throughout the program.

NIBIB has funded four awards to date with seven to ten freshman recruits each year. So far, a total of 51 students have been enrolled in programs funded by NIBIB. The program has a focus on curriculum in engineering and the physical sciences in biology and medicine. Criteria for recruiting students is not based on strict GPA requirements but instead focuses on class ranking and letters of recommendation. The new criteria aim to enhance inclusivity and retention. A limited salary for administrative support and principle investigator roles will be provided to elevate the ability of the mentors to engage with the trainees. Council members were in strong support of the program.

**C. Cyber-Physical Systems:** ***Dr. Tiffani Bailey Lash***

The Cyber-Physical Systems (CPS) program is led by National Science Foundation in consortium with NIH, Homeland Security, the US Department of Agriculture, and US Department of Transportation. The goal of the program is to improve the human quality of life and to help achieve functional independence in humans.

The CPS program awards three levels of grants (1) small – for the exploration of projects for significant impact, (2) medium – for the integration of multiple areas, (3) frontier – for emerging and innovative high-impact ideas. NIBIB typically supports the small type of grant. NIBIB has supported six projects since 2016. The program has successfully brought in new investigators to NIH who have not had prior NIH funding. The projects have included the development of smart glasses and smart textiles that improve quality of life. The discussion of the program was positive, and continued support was encouraged.

## V. The BRAIN Initiative Update: *Dr. Bruce Rosen*

Dr. Bruce Rosen briefed the council on reports to the Advisory Council to the NIH Director (ACD) from the co-chairs of the BRAIN Initiative Working Group 2.0 and the BRAIN Neuroethics Subgroup on June 14, 2019. The co-chairs presented recommendations for future areas of emphasis by the BRAIN Initiative. The findings of the Working Group were published in the report entitled "The BRAIN Initiative 2.0: From Cells to Circuits, Toward Cures." The Neuroethics Subgroup report was entitled "The Brain Initiative and Neuroethics: Enabling and Enhancing Neuroscience Advances for Society."

Major recommendations of the Working Group report were: 1) Technology development has been a productive pathway toward targeted study of circuit components and should continue to be supported; 2) The Initiative should put added emphasis on behavior paradigms and quantitative analysis, subcortical structures, and model organisms; 3) BRAIN 2.0 should balance individual-investigator research with team science; and 4) Devote ample resources to large-scale transformative projects.

Dr. Rosen described five areas for Transformative Projects cited in the Working Group report: 1) A cell type-specific armamentarium for understanding brain function and dysfunction to generate and implement methods to access and manipulate clinically relevant cell types across multiple species; 2) Generate a comprehensive human brain cell atlas that includes a highly granular census of the whole human brain; 3) Use the mouse brain connectome to map the entire mouse brain, enabling study from synapses to coordinated function and behavior; 4) Achieve specific circuit-level understanding in order to achieve interventions for a major human neurological disease; and 5) Multiple scale studies of how the brain retrieves and leverages information, from synapses to brain-wide networks, in order to bridge measures of neural activity and behavior.

The Neuroethics Subgroup report explores how the BRAIN initiative results bring to the fore questions about how findings will be understood and applied, and outlines neuroethics principles and approaches to help navigate through such issues. The need for neuroethics approaches to successfully navigate results from BRAIN was illustrated by examples of news articles that appeared following the launch of the Neuralink project by Elon Musk, which included "Scientist: Merging Your Brain With AI Would Basically Be Suicide," and "Implanting AI chips in your mind could cause you to lose yourself, says scientist."

A central Transformative Project proposed by the Neuroethics WG was titled "Understanding the basis of Consciousness: Intersection of Neuroscience and Neuroethics," which would address how neuroscience could challenge long-held assumptions about qualities such as sentience and the mind, and how neuroscience might successfully operationalize terms such as "mind" for study in the laboratory.

Dr. Rosen noted that the 6th Annual BRAIN Initiative Investigators Meeting was taking place in Arlington, VA, June 1-3, 2020. Demographics from last year's meeting showed that 31% of the more than 1,000 attendees were in the field of engineering, and 24% were in neuroimaging/radiology.

Several significant scientific advances coming out of the BRAIN initiative were highlighted: decoding of neural activity to produce spoken sentences; microscopy techniques to record real-time activity of proprioceptors during movement of Drosophila larvae; in vivo three-photon imaging of mouse brains through

intact skulls; and non-invasive neuroimaging technology used to dramatically improve participants' neuroprosthetics device control through a brain-computer interface. Federal partners are also making significant scientific advances — NSF and DARPA in areas that include multi-scale integration of brain structure and dynamic activity, brain-inspired concepts and designs, targeted neuroplasticity training, next-generation nonsurgical neurotechnology, and intelligent neural interfaces.

Dr. Rosen briefly summarized the presentation given by Dr. Tromberg to the BRAIN Multi-Council Working Group in August of 2019 entitled "NIBIB: Engineering the Future of Health." Dr. Tromberg emphasized how the BRAIN initiative is driving the push-pull relationship between technology development and the use of technology for solving problems in biology and medicine. He cited critical areas in need of development and expansion: better physics and mechanistic-based computational models to test hypotheses of brain function; using AI for improved tech performance and interpretability; conducting clinical trials of new tech; reduced barriers and improved access to the explosion in technologies, materials, and application-specific integrated circuits; and application of these technologies to the understanding of continuous, dynamic biology.

Dr. Rosen concluded by describing the vision of the new BRAIN Director Designee for BRAIN 2.0, Dr. John Ngai, University of California, Berkeley, which is "To identify and promote emerging technologies aimed at advancing fundamental knowledge of nervous system function to introduce new clinical practices for the prevention and treatment of human neurologic and neuropsychiatric diseases by the year 2025."

Ngai has also outlined strategic goals for BRAIN 2.0, a plan for selecting transformative projects, and a timeline from 2019 to 2023 to develop transformative "big ideas" projects. The final big ideas projects will be funded in 2023 when the BRAIN budget is anticipated to be approximately $800 million.

## VI. Adjournment

The open session of the NACBIB meeting was adjourned at 12:55 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 2:30 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
Associate Director for Research Administration
National Institute of Biomedical Imaging and Bioengineering

[2] These minutes will be approved formally by the Council at the next meeting on May 20, 2020, and corrections or notations will be stated in the minutes of that meeting.

Bruce J. Tromberg, Ph.D.
Chairperson
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