

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

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

**Summary of Meeting<sup>1</sup>  
January 24, 2017**

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 43rd meeting on January 24, 2017, at the Bolger Center in Potomac, Maryland. Dr. Roderic I. Pettigrew, 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 1:10 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 2:10 p.m. to 3:00 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. Carol Espy-Wilson, University of Maryland, College Park, MD  
Dr. David Grainger, University of Utah, Salt Lake City, UT  
Dr. Karen Hirschi, Yale University, New Haven, CT  
Dr. Raphael Lee, University of Chicago, Chicago, IL  
Dr. John H. Linehan, Northwestern University, Evanston, IL  
Dr. Carolyn Meltzer, Emory University Hospital, Atlanta, GA  
Dr. Charles Mistretta, University of Wisconsin, Madison, Madison, WI  
Dr. A. Gregory Sorensen, Imris Deerfield Imaging USA, Minnetonka, MN  
Dr. Daniel Sullivan, Duke University Medical Center, Durham, NC

**Ex officio members present:**

Dr. Vincent Ho, Uniformed Services University of the Health Sciences, Bethesda, MD  
Dr. Sohi Rastegar, National Science Foundation, Arlington, VA

**Ex officio members absent:**

Dr. Francis Collins, National Institutes of Health, Bethesda, MD  
Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD

**Chairperson:**

Dr. Roderic I. Pettigrew

**Executive Secretary:**

Dr. David T. George

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<sup>1</sup> For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a conflict of interest may occur. This procedure only applies to applications that are discussed individually, not to "en bloc" actions.

**Also present:**

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

Ms. Roberta Albert	Dr. Richard Leapman
Ms. Holly Atherton	Dr. Guoying Liu
Mr. Angelos Bacas	Dr. Raymond MacDougall
Dr. Richard Baird	Dr. Shadi Mamaghani
Dr. Michael Cheetham	Dr. Michael Marge
Mr. Lavern Colclough	Dr. Rishi Mathura
Ms. Emily Conlan	Ms. Ruthann McAndrew
Ms. Christine Cooper	Ms. Jessica Meade
Ms. Zoe Ann Copeland	Mr. Todd Merchak
Dr. Monique Day	Mr. Larry Morton
Mr. Anthony Dorion	Mr. Joe Mosimann
Dr. Henry Eden	Mr. Mark Murdock
Ms. Kate Egan	Dr. Grace Peng
Ms. Angela Eldridge	Dr. Carlo Pierpaoli
Ms. Katie Ellis	Dr. Edward Ramos
Dr. Zeynep Erim	Dr. David Rampulla
Mr. Jason Ford	Ms. Vicki Rein
Mr. Anthony Fransella	Dr. Mary Rodgers
Ms. Pam Glikman	Dr. Antonio Sastre
Dr. John Hayes	Dr. Seila Selimovic
Dr. Jill Heemskerck	Dr. Behrouz Shabestari
Dr. Dennis Hlasta	Mr. Shaun Sims
Dr. John Holden	Mr. Russell Songco
Ms. Alisha Hopkins	Ms. Ashley Storm
Mr. James Huff	Dr. Manana Sukhareva
Dr. Rosemarie Hunziker	Ms. Florence Turska
Dr. Thomas Johnson	Dr. Shumin Wang
Dr. Krishna Kandarpa	Dr. Michael Wolfson
Dr. Chris Kelley	Dr. Li-Yin Xi
Dr. Randy King	Dr. Huaying Zhao
Dr. Steven Krosnick	Dr. Ruixia Zhou
Ms. Kai Lakeman	Dr. Steven Zullo

**Attending by Telephone:**

Dr. Sheldon Weinbaum, City College of New York, New York, NY  
Dr. Wolff-Hughes, NIH/OD, Bethesda, MD

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

Dr. Philip Alderson, National Library of Medicine, NIH  
Dr. Janine Clayton, Office of Research on Women's Health, NIH  
Dr. Irwin Feuerstein, Office of Research on Women's Health, NIH  
Dr. Songtao Liu, Center for Scientific Review, NIH  
Jamie White, Office of Research on Women's Health, NIH  
Dr. Lamont Williams, Office of Research on Women's Health, NIH

**Members of the public present for portions of the meeting:**

Ms. Erin Cadwalader, Lewis-Burke Associates, Washington, DC  
Ms. Renee Cruea, Academy of Radiology Research, Washington, DC  
Dr. Beop-Min Kim, Korea University, Seoul, Korea  
Ms. Margot Kern, Bethesda, MD  
Ms. Martha Nolan, Academy of Radiology Research, Washington, DC  
Mr. Michael Peters, American College of Radiology, Washington, DC  
Dr. Gordana Vunjak-Novakovic, Columbia University, New York, NY

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 43rd 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. Roderic I. Pettigrew**

### **A. Welcome**

Dr. Pettigrew welcomed three new council members: David Grainger, Ph.D., Professor of Bioengineering at the University of Utah; Richard Buxton, Ph.D., Professor of Radiology at the University of California, San Diego; and Vincent Ho, M.D., M.B.A., Chair and Professor of the Department of Radiology and Radiological Services at the Uniformed Services University of the Health Sciences, serving as the ex officio member from the Department of Defense.

### **B. NIBIB Awards, Transitions, and New Staff**

Dr. Pettigrew recognized two honors bestowed on members of the NIBIB community: Council member Dr. Raphael Lee was selected as Bucksbaum Institute Senior Faculty Scholar in the Bucksbaum Institute for Clinical Excellence and NIBIB grantee and former Advisory Council member Dr. Rebecca Richards-Kortum received the MacArthur Fellowship for developing solutions to healthcare problems and inspiring the next generation of engineers and scientists.

NIBIB grantees Dr. Craig Duvall of Vanderbilt University and Dr. Michael McAlpine of the University of Minnesota were among the 20 NIH recipients of Presidential Early Career Awards for Scientists and Engineers (PECASE).

Dr. Pettigrew played a voicemail delivered by HHS Secretary Burwell to NIBIB's Deputy Executive Officer, Zoe-Ann Copeland. Secretary Burwell thanked Ms. Copeland for the development of the NIH Admin Hub, which she says is having a significant impact on the Department by making it more efficient and effective.

Dr. Pettigrew said farewell to recently departed NIBIB staff members: Mew Rattanawatkul, Desi Conway, Dr. Richard Conroy, Margot Kern, and Stacy Jones-Straehle.

Seven new staff were welcomed by Dr. Pettigrew: Michael Wolfson, Ph.D., Program Director, Division of Discovery Science & Technology; Shumin Wang, Ph.D., Program Director, Division of Applied Science & Technology; Ashley Storm, Program Analyst, Division of Applied Science & Technology; John Holden, Ph.D., Scientific Review Officer; Randy King, Ph.D., Program Director, Division of Applied Science & Technology; Andrew Weitz, Ph.D., Program Director, Division of Discovery Science and Technology; Carlo Pierpaoli, M.D., Ph.D., Stadtman Tenure-Track Investigator, NIBIB Intramural Program.

Dr. Pettigrew announced that Jill Heemskerk, Ph.D. has been appointed Deputy Director of NIBIB.

### **C. NIH/NIBIB Budget**

The FY 2017 Appropriations Continuing Resolution will fund NIH at the FY16 budget level through April 28, 2017. It also allows the dispensation of funds according to the 21st Century Cures Act. Dr. Pettigrew provided a breakdown of the funding for the 21st Century Cures Act, which authorized \$4.8 Billion in spending over the next 10 years (\$1.45B Precision Medicine; \$1.5B BRAIN Initiative; \$1.8B Moonshot; \$30M Regenerative Medicine).

## **D. NIH Activities**

**MoTrPAC:** Dr. Pettigrew highlighted the Common Fund's Molecular Transducers of Physical Activity Consortium. The goal of the Consortium is to develop a deeper understanding molecular-level effects of exercise and its effects on the human body. The Consortium is comprised of five components: Clinical Centers; Preclinical Animal Study Sites; Chemical Analysis Sites; the Bioinformatics Center; and the Consortium Coordinating Center.

**BRAIN:** The BRAIN Initiative is currently in its 3rd year. The engineering and imaging communities are well represented, with grantees from these fields making up nearly half of the total number of grantees.

**IWGMI:** The Interagency Working Group on Medical Imaging recently reported its perspective on the future direction of medical imaging. A summary of the report, co-authored by Dr. Pettigrew and published on the White House Blog, identified six goals for medical-imaging research: standardize image acquisition storage; apply big-data and data-science concepts to medical imaging; more rapid and cost-effectively diagnosis; make imaging more accessible; promulgate improved imaging practices; and improve translation of new imaging technologies.

**Cancer Moonshot and QIBA:** Dr. Pettigrew co-authored a post for the White House Blog related to the Cancer Moonshot, which is promoting the use of NIBIB-funded RSNA QIBA guidelines for quantitative imaging procedures.

**NIH-DOE collaboration:** In 2015, the Secretary of DOE established the Secretary of Energy Advisory Board Task Force on Biomedical Sciences to identify opportunities for NIH-DOE collaboration. The task force recently reported four recommendations: identify areas for joint research programs; bring diverse researchers together and cross-train junior investigators; establish facilities such as "foundries" for desirable large scale collaborative projects; inform OMB/Congress/public about strategies, activities, and benefits of enhanced collaboration.

**Yo-Yo Ma** delivered the NIH Ed Rall Cultural Lecture in December. He spoke with NIH Director Dr. Francis Collins about the impact of music on the brain. Dr. Collins discussed brain activity in areas related to executive function in musically trained and untrained individuals. Dr. Collins and Mr. Ma played a duet.

## **E. NIBIB Activities**

**Trailblazer Award:** NIBIB has received a robust response to the launch of its Trailblazer Award program, which supports first time and early stage investigators with an expanded R21 mechanism that allows up to three years of funding. The first round of applications has been received and is currently being reviewed. The NIBIB has been working in close partnership with the Center for Scientific Review to accomplish a special review process for these unique applications.

**POCTRN:** The NIBIB Point of Care Technology Research Network (POCTRN) developed a device to detect cervical cancer that has recently received FDA approval. A second POCTRN device is currently under review for FDA approval. Dr. Pettigrew presented the concept for the reissuance of the POCTRN initiative. Dr. Pettigrew noted that NIBIB has a growing relationship with the Bill and Melinda Gates Foundation for developing point-of-care technologies for underserved populations.

**IMAG:** The Interagency Modeling and Analysis Group is having its 10th anniversary meeting in March. The keynote will be Dr. Subra Suresh, president of Carnegie Mellon University. Dr. Pettigrew recognized Grace Peng for her efforts in championing the consortium.

## **F. Grantee News:**

An NIBIB-funded biosensor “tattoo” that can sense blood alcohol levels via a chemical reaction in sweat made multiple news headlines. The tattoo is placed on the forearm and wirelessly communicates blood alcohol levels to a cellphone.

Research by a BRAIN grantee made an NBC News list of “11 Surprising Predictions for 2017 from some of the Biggest Names in Science.” The grantee developed a wearable PET machine that could enable study of brain activity while a person is moving and responding to a virtual environment.

A functional-electrical-stimulation technology developed by NIBIB grantee Dr. Ronald Triolo enabled an individual who is paralyzed below the waist to compete and win a biking competition at this year’s CYBATHOLON Championship for Athletes with Disabilities. The technology provides direct stimulation to nerves that control leg muscles, allowing the user to independently pedal a bicycle.

## **G. Science Highlights**

**Hand-controlled software for navigating 3-D images:** NIBIB-funded researchers have developed software and sensors that enable surgeons to move, zoom, and rotate medical images displayed on a screen without touching it. Using this technology and virtual reality goggles, the researchers have shown that they can overlay a previously acquired MR image of the breast on a subject who has a breast cancer lesion. This could improve the success of surgical treatments by allowing surgeons to precisely identify lesions and spare healthy breast tissue during lumpectomies or complete resection.

**Magnetic bacteria for drug delivery:** An NIBIB researcher is using swarms of magnetic bacteria to deliver drugs to tumors. In animal tests, the magnetic bacteria are loaded with chemotherapy drugs and a magnetic field guides the bacteria directly to tumors. With further development, this technology could provide improved cancer treatment in humans while reducing the side effects of chemotherapy.

## **H. Future council speakers**

Dr. Pettigrew announced future Council speakers for 2017: Lihong Wang, Ph.D., Washington University, will speak at the May Council and Stephen Quake, Ph.D., Stanford University, will speak at the September Council.

## **III. Sex as a Biological Variable, Dr. Janine Clayton**

Dr. Janine Clayton, NIH associate director for Research on Women's Health and director of NIH's Office of Women's Health Research (OWHR), spoke about the importance of considering sex as a biological variable (SABV) at every stage of research from pre-clinical to translational. In 1993, NIH was required by law to include women in clinical research. Today, over half of NIH-funded clinical research participants are women. However, many pre-clinical studies have over-relied on male animals or cell lines, and therefore there is incomplete knowledge about possible sex-based differences. This, in turn, can lead to scenarios in which critical information about sex differences in diagnosis or treatment is lacking. In January of 2016, NIH issued the Rigor, Reproducibility, and Transparency initiative, part of which requires that researchers consider both males and females, not only in clinical research, but also in pre-clinical studies involving vertebrate animals. Grant applicants are expected to explain, where applicable, how SABV is factored into their research design and analyses.

Dr. Clayton mentioned that a trans-NIH SABV working group is currently reviewing how the SABV policy is being implemented. The NIH Center for Scientific Review recently reported a positive initial experience with reviewers evaluating the first round of grant applications addressing SABV. She pointed out that a

useful set of FAQs is available on the NIH grants website.

Dr. Clayton identified rehabilitation and assistive devices as an NIBIB program area that presents further opportunities for collaboration with ORWH. She pointed out that women may benefit more from stroke rehabilitation devices since it's known that women don't recover as well from stroke as men. She noted that, when developing assistive devices, a woman's build and constitution should be taken into consideration.

## **Discussion**

Council asked whether NIH is advocating for data from industry and NIH-sponsored trials to be made more accessible so that researchers can conduct meta-analyses to identify sex differences in the data without having to conduct new trials. Dr. Clayton responded that, while NIH has no purview over non-NIH trials, more trials are going to be covered under FDAAA, which would require reporting to [clinicaltrials.gov](http://clinicaltrials.gov), and that site it is currently set up to receive SABV information. NIH has also been talking with journal editors about the importance of reporting SABV and about the role of journals as gatekeepers of this information. She pointed out that there is room for improvement as a recent study found that fewer than a third of NIH-funded phase III clinical trials reported sex-specific results of any kind, even though about half of all clinical trial participants are women.

One council member noted that, when doing research on sex, aging, and the brain, it is difficult to navigate the complicated hormonal differences that occur over a person's lifetime. Dr. Clayton acknowledged that there are discipline-specific differences in how we approach issues of SABV and that members of several fields have gotten together to highlight the multiple ways researchers are currently addressing SABV. Dr. Clayton mentioned that researchers have expressed concern that, if their study was not powered to detect sex differences and they report sex segregated data, others may infer conclusions that are not valid. She also clarified that NIH is not requiring researchers to power every study to detect sex differences, but rather it is requiring that researchers factor SABV into their study design and analysis. If differences are detected in the analysis, this can generate hypotheses that can lead to further research to determine whether the initial observations are meaningful.

## **IV. Enhancing Diversity in Bioengineering and the Physical Sciences, Dr. Richard Baird**

Dr. Baird began with a history of NIH's efforts to enhance diversity in the biomedical workforce. He detailed NIBIB's support for undergraduate diversity programs at the University of Maryland Baltimore County (UMBC), through the Meyerhoff program there, and at Savannah State University. Now, NIBIB is developing a new program, based in part upon the successes of these earlier models.

Dr. Baird described the UMBC Meyerhoff and Savannah State programs and then provided outcomes, noting high rates of degree completion and subsequent enrollment in graduate programs. Dr. Baird stressed the importance of UMBC Meyerhoff's unique requirement for students to participate as a cohort in a summer program before starting school and to share housing for the first year to create a supportive community for students. Both Savannah State and UMBC offered a summer boot camp for students, mentoring across all levels (faculty, peer, alumni, and family), tutoring, and summer research experiences.

Other potential models include the UMBC BUILD program, supported by the NIH Common Fund, which is exploring whether the Meyerhoff model can be extended to improve the success of diversity students with poorer pre-college characteristics. Also of interest is the HHMI-funded Meyerhoff Adaptation project, which attempting to adapt the model for other schools; it is currently supporting similar programs at Pennsylvania State University and the University of North Carolina.

The new NIBIB Diversity Initiative will support innovative training programs for underrepresented freshmen and sophomore undergraduates pursuing STEM degrees. It will support summer bridge programs, mentoring,

research experiences and academic preparation and will provide tuition and a stipend. It will also require a link to an advanced honors program to support students in the junior and senior years, such as the NIH Maximizing Access to Research Careers (MARC) program or equivalent.

## **Discussion**

Dr. Sheldon Weinbaum from the City College of New York (CCNY), who participated via teleconference, described a successful CCNY diversity training program that was supported by NHLBI. The CCNY program included students with a range of academic accomplishment and there was no requirement for a communal living experience. The retention rate was low at the outset of the program, but increased dramatically after participants were assigned PhD students as mentors. The importance of structured mentoring was emphasized in further discussions, which highlighted a new NSF pilot program called Research Experience and Mentoring.

It was pointed out that regional partnerships between research-intensive institutions and minority-serving institutions currently exist through NIH Clinical and Translational Science Awards (CTSAs) and that these could be a natural leveraging point for linking programs and sharing resources to enhance student research options.

It was noted that there are some creative programs that already exist within Biomedical Engineering (BME) departments that could be easily adapted to include more diverse populations. For example, Georgia Tech's BME program encourages problem-based learning where students work in teams in the community. Other engineering programs have cooperative education that encourages work with industry.

A program at Morehouse College was described that was supported by the Defense Department for ten years. The importance of relieving students' financial burden was stressed so that they can focus on academic achievement, especially considering that the number of students who can expect no financial contribution from their families has grown over the years. To supply mentors for students, it was suggested that schools such as Morehouse could collaborate with Georgia Tech or Emory via a CTSA. This could be a solution for other minority serving institutions which do not have graduate programs to serve as a source of mentors.

The importance of motivating young students early in their college careers was mentioned as a strength of the proposed initiative. Attrition in the first two years of college has been a major contributor to the decline in the number of underrepresented minorities earning undergraduate degrees in engineering over the past decade.

There was a question about whether NIH has been looking at gender in their diversity and other training programs. Dr. Baird says NIBIB is currently looking at all of their training mechanisms to be attentive to and determine possible differential success across the sexes.

## **V. Engineered human tissues for regenerative medicine, Dr. Gordana Vunjak-Novakovic**

Dr. Vunjak-Novakovic from Columbia University presented her research on engineering human tissues for regenerative medicine, disease modeling, and drug development. She began by highlighting her lab's efforts to grow personalized bone. Her lab uses CT images of a bone defect to construct a personalized scaffold out of native bone matrix into which stem cells are introduced. After several weeks of culture, immature bone develops and is implanted. They have successfully tested their technology to correct bone defects in pigs.

She next discussed her lab's efforts to regenerate lung tissue. Their goal is to intervene in a targeted way by removing diseased epithelium cells from a specific region of the lung and replacing them with healthy cells. This required the development of novel catheter technologies to visualize targeted areas and to introduce decellularization fluids and healthy replacement cells.

In the final part of her presentation, Dr. Vunjak-Novakovic detailed her lab's creation of human microtissue model platforms. Use of these human cell platforms for testing the safety of new drugs and for understanding disease mechanisms could be highly informative. Her lab initially created a heart, liver, and blood platform. All tissues were derived from the same batch of human induced pluripotent stem cells (iPSCs) from a small amount of blood. In the platform, each tissue has its own culture medium, and all are perfused with the same blood substitute. She showed an image of the 3rd generation of the platform, which contains 24 cellular chambers (they've recently added tumor and skin). Dr. Vunjak-Novakovic explained how they have used the microtissue platform to engineer human bone to study pediatric bone sarcoma. Specifically, they looked at how exosomes secreted by the tumor affect healthy cells.

## **Discussion**

A question was asked about the utility of autologous cell replacement therapies and whether their high cost might limit wide-spread clinical usage. Dr. Vunjak-Novakovic responded that there is a motivation to develop autologous tissue systems to create clean experiments that then allow you to study additional factors. She also said that, the FDA often requests proof that autologous therapies work in small studies before larger tests of cells from different individuals. Thus, their autologous work can yield important insights that could later be applied to the development of more clinically-feasible therapies.

Dr. Vunjak-Novakovic was asked whether she is trying to incorporate SABV into her tissue modeling work. She answered that they do, and have noticed differences in some of their cell lines by sex. They are also currently looking at the effects of hormones on bone tumors and the heart, and a colleague is developing an endocrine system on a chip.

Finally, Dr. Vunjak-Novakovic was asked about the interconnectedness of organs in disease and whether, using her lab's multi organ-on-a-chip system, she had made any observations about how damage to one organ affects others. Dr. Vunjak-Novakovic replied that they are examining off-target effects of successful drugs on the skin, heart, and liver and they have noted that changes to cells are different when probed in isolation versus when they are connected by a shared vasculature.

## **VI. Adjournment**

The open session of the NACBIB meeting was adjourned at 1:10 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 2:00 p.m.



Certification:

We certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.<sup>2</sup>



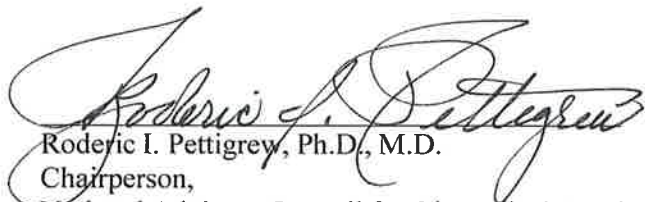
David T. George, Ph.D.

Executive Secretary

National Advisory Council for Biomedical Imaging and Bioengineering

Acting Associate Director for Research Administration

National Institute of Biomedical Imaging and Bioengineering



Roderic I. Pettigrew, Ph.D., M.D.

Chairperson,

National Advisory Council for Biomedical Imaging and Bioengineering

Director,

National Institute of Biomedical Imaging and Bioengineering

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<sup>2</sup> These minutes will be approved formally by the Council at the next meeting on May 18, 2017, and corrections or notations will be stated in the minutes of that meeting.