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 24, 2011

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 25th meeting on January 24, 2011, at the Bethesda Marriott Suites in Bethesda, 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 8:35 a.m. to 12:10 p.m. for review and discussion of program development, needs, and policy. The meeting was closed to the public from 1:00 p.m. to 2:00 p.m. for consideration of individual grant applications.

Council members present:
Dr. Philip Alderson, Saint Louis University, St. Louis, MO
Dr. Richard L. Ehman, Mayo Clinic, Rochester, MN
Dr. Gary H. Glover, Stanford University, Stanford, CA
Dr. Mae C. Jemison, Biosentient Corporation, Houston, TX
Dr. Percival McCormack, University of Illinois at Chicago, Chicago, IL
Dr. Cherri Pancake, Oregon State University, Corvallis, OR
Dr. Buddy Ratner, University of Washington, Seattle, WA
Dr. David Skorton, Cornell University, Ithaca, NY

Ad Hoc members present:
Dr. William Grimson, Massachusetts Institute of Technology, Cambridge, MA
Dr. Nola Hylton, University of California, San Francisco, CA
Dr. Etta Pisano, Medical University of South Carolina, Charleston, SC

Ex officio members present:
Dr. John McGrath, National Science Foundation, Arlington, VA
Dr. P. Hunter Peckham, U.S. Department of Veterans Affairs, Cleveland, OH
Dr. James G. Smirniotopoulos, Uniformed Services University of the Health Sciences, Bethesda, MD
Dr. Andrew Watkins, Centers for Disease Control and Prevention, Atlanta, GA

Council members absent:
Dr. Hedvig Hricak, Memorial Sloan-Kettering Cancer Center, New York, NY

Ex officio members absent:
Dr. Francis Collins, National Institutes of Health, Bethesda, MD
Dr. Anne Plant, National Institute of Standards and Technology, Gaithersburg, MD
Ms. Kathleen Sebelius, U.S. Department of Health and Human Services, Washington, DC

Chairperson:
Dr. Roderic I. Pettigrew

Executive Secretary:
Dr. Anthony Demsey

[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:

Mr. Angelos Bacas
Dr. Richard A. Baird
Ms. Sheila Barrett
Ms. Barbara Cantilena
Ms. Patty Clements
Dr. Zohara Cohen
Ms. Shirley Coney-Johnson
Dr. Richard Conroy
Ms. Zoe-Ann Copeland
Ms. Nancy Curling
Ms. Angela Eldridge
Ms. Kathryn Ellis
Dr. Zeynep Erim
Ms. Carol Fitzpatrick
Dr. David George
Ms. Marie Gill
Ms. Pam Glikman
Dr. Valery Gordon
Dr. Ruth Grossman
Dr. John Haller
Dr. John Hayes
Ms. Eunica Haynes
Dr. William Heetderks
Dr. Lori Henderson
Mr. James Huff
Dr. Rosemarie Hunziker
Dr. Thomas Johnson
Ms. Mary Beth Kester
Dr. Peter Kirchner
Dr. Brenda Korte
Dr. Richard Leapman
Mr. Eugene Lee
Mr. Vien Lim
Dr. Guoying Liu
Dr. Hector Lopez
Dr. James Luo
Dr. Alan McLaughlin
Mr. Larry Morton
Mr. Joe Mosimann
Dr. Peter Moy
Dr. Grace Peng
Dr. Karen Peterson
Ms. Vicki Rein
Dr. Mary Rodgers
Mr. Romero Rolando
Ms. Stephanie Sabourin
Dr. Belinda P. Seto
Mr. Shaun Sims
Dr. Manana Sukhareva
Ms. Florence Turska
Dr. Yantian Zhang
Dr. Ruixia Zhou

Non-NIBIB NIH employees:
Dr. Keith Crutcher, Center for Scientific Review
Dr. Maria Debernardi, Center for Scientific Review
Dr. David Filpula, Center for Scientific Review
Dr. Josephine "Jo" Pellman, Center for Scientific Review
Dr. Amy Rubinstein, Center for Scientific Review

Non-NIH Federal employees:
None

Members of the public present for portions of the meeting:
Ms. Jennifer Ayers, American Institute for Medical and Biological Engineering
Dr. Andrea Baruchin, Foundation for the National Institutes of Health
Mr. Benjamin Beeghly, National Capital Captioning
Ms. Renee Cruea, Academy of Radiology Research
Mr. Sean Gallagher, American Institute for Medical and Biological Engineering
Ms. Allyson Harkey, NOVA Research Company
Mr. Vhic Mata, Event Technology Solutions
Mr. Michael Peters, American College of Radiology
Ms. Lindsay Rice, National Capital Captioning
Mr. Ricardo Tamayo, Event Technology Solutions
Mr. Brian Washington, Event Technology Solutions

I. Call to Order: Dr. Anthony Demsey

Dr. Demsey called to order the 25th 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, welcomed attendees, and introduced Dr. Pettigrew, who formally welcomed all participants.

II. Director's Remarks

A. Xiuwen Wang

In October, an NIBIB Research Fellow, Xiuwen Wang, was struck and killed by a car on Rockville Pike. A memorial service was held on the NIH campus the following week, during which NIBIB leadership announced the establishment of the Xiuwen Wang Outstanding Early Stage Scientist Award. An article of Wang's will be published in an upcoming issue of *Chemistry.* A memorial fund also has been established through contributions from across NIH and NIBIB.

B. Council Member Achievements

Dr. Pettigrew congratulated Dr. Skorton on his election to the Institute of Medicine. Dr. Skorton was also featured on a recent CBS "Sunday Morning" television program in a piece on preventing suicide.

Dr. Pettigrew congratulated Dr. Ehman on his election to the Radiological Society of North America Board of Directors. Dr. Ehman also has been elected to the Institute of Medicine.

C. Outgoing Council Member

Dr. Ehman ended his NACBIB term last August but had agreed to serve for two additional Council meetings, of which this is the last. He will continue to serve on the NIH Council of Councils, which is comprised of one Council member from each NIH Institute and Center. The Council of Councils is charged with overseeing activities related to the NIH Common Fund.

D. Budget

NIBIB is currently operating under a Continuing Resolution, and there is still no indication of what the final budget will be. NIBIB has established its funding plans based on the assumption that the budget will be flat.

Dr. Pettigrew reported that the latest round of peer-reviewed applications continues the recent trend of a significant increase in very good scores. The exact reason for this is still unclear, but in anticipation that this trend will continue, the NIBIB payline has been set at the 11th percentile.

E. Key Conferences

On January 10–11, 2011, NIBIB co-hosted a workshop entitled "Images, Electronic Health Records, and Meaningful Use" along with the Office of the National Coordinator for Health Information Technology. The American Recovery and Reinvestment Act of 2009 included legislation that authorized the use of incentive payments through Medicare and Medicaid to encourage adoption of electronic health records. To ensure that this was implemented in a meaningful way, specific objectives and measures were defined ("meaningful use criteria"); however, none of those definitions pertained to medical images. This workshop offered an opportunity for a wide range of experts from all sectors of health care to provide input on the second phase of meaningful use criteria development.

A "Summit on Management of Radiation Dose in Computerized Tomography: Toward the Sub-mSv Exam" will be held February 24–25, 2011. This conference will address the challenge of increasing use of computed tomography (CT) and associated radiation dose. The objective is to identify specific steps toward reducing the level of radiation dose by one order of magnitude, so that the dose level is more comparable to that of routine mammography. The conference is supported by NIBIB; the National Institute of Child Health and Human Development; the National Heart, Lung, and Blood Institute; the

National Cancer Institute; the Coalition for Imaging and Bioengineering Research; the U.S. Food and Drug Administration; and the American College of Cardiology; and the American College of Radiology.

F. New Training Initiative

A new R25 training initiative, Team-Based Design in Biomedical Engineering Education, is intended to significantly change the way that translational science is introduced to engineers-in-training. In an effort to develop the next generation of translational researchers, this undergraduate program focuses on open-ended team-based design, exposes students to clinical issues and design principles, and emphasizes translation of biomedical devices, including industrial design, regulation, and commercialization concepts. The first applications have been received and will be reviewed by the Council in its closed session later in the day.

G. USA Science and Engineering Festival

The Inaugural USA Science and Engineering Festival, which introduces students to and promotes careers in science and engineering, was held in Washington, DC, in October, 2010. The week-long event saw approximately 500,000 participants, including students from kindergarten through university levels. NIBIB was among the NIH Institutes participating in the festival, and NIBIB staff led several activities and hands-on demonstrations that parents and students seemed to enjoy.

H. NIH Update

a. Institute of Substance Use, Abuse, and Addiction

NIH plans to create a new Institute focused on substance use, abuse, and addiction research, with the goal of integrating NIH's efforts to address substance abuse and addiction problems. Research portfolios from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, and other Institutes/Offices/Centers will be consolidated. A detailed reorganization plan is expected by summer 2011, with a formal plan submitted to the Secretary of Health and Human Services in fall 2011; appropriations are expected for FY 2013.

b. National Center for Advancing Translational Sciences

A second NIH reorganization effort will create a National Center for Advancing Translational Sciences, which would advance the translation of basic discoveries into therapeutics. The Center will be formed from selected translational research programs in the National Human Genome Research Institute (NHGRI), the National Center for Research Resources (NCRR), and the NIH Director's Common Fund, and the NCRR will be dissolved. Programmatic decisions will be completed by early spring 2011, with a targeted effective date for reorganization of October 1, 2011.

c. Enhancing Peer Review

Dr. Pettigrew reported the results of a recent survey on enhancing the peer review process. Program officers deemed the 9-point scoring system adequate and found that individual criterion scores are helpful in providing feedback to applicants. Clustering of applications with similar characteristics was also positively accepted. Surprisingly, approach is the one criterion that appears to correlate most strongly with overall impact score; significance, innovation, investigator, and environment, respectively, correlated less strongly. Unfortunately, it is not clear how to compare the new scoring system to the previous system, as similar analyses are not available for the previous system.

Program officers found bulleted critiques to be not very helpful in understanding factors that affect review outcome. For this reason, Scientific Review Officers now request more context and description, including a summary paragraph.

d. NIH Director's Early Independence Award

NIH has created the NIH Director's Early Independence Award, a DP5 award that helps promising Ph.D.s achieve independence more quickly by bypassing the postdoctoral training period. The application cycle

for the first round of awards closed on January 21, 2011. Ten applicants will receive up to $250,000 per year for 5 years. Each institution is limited to two applicants.

I. Research in the News

Many major media outlets are reporting that Johnson & Johnson is partnering with Quantum Grantees Mehmet Toner and Daniel Haber to move their work in microfluidic chips for point-of-care, blood-based cancer diagnosis into clinical testing in four hospitals (Massachusetts General Hospital, Memorial Sloan-Kettering Cancer Center, the University of Texas M. D. Anderson Cancer Center, and DanaFarber Cancer Institute). This research has two-fold application: the translational application is to prevent metastasis, while the basic science application will allow researchers to study cancer cells in near real-time.

TIME magazine has named work by Jeffrey Morgan at Brown University—part of NIBIB's Regenerative Medicine portfolio—one of the top 10 medical breakthroughs of 2010. Dr. Morgan developed a bio-artificial ovary that could assist in *in vitro* fertilization and shed light on the impact of various drugs and toxins on the physiology of the ovary.

A remarkable study by Daniel Vigneron and John Kurhanewicz, University of California, San Francisco, was presented at the annual meeting of the Radiological Society of North America. Drs. Vigneron and Kurhanewicz are using hyperpolarized carbon-13–labeled pyruvate as a means to examine the metabolism of prostate cancer. The significant potential translational application lies in providing a more sensitive and precise marker for the location and level of cancer in the prostate.

III. NIH Diversity Programs

NIH Principal Deputy Director Lawrence Tabak, chair of the NIH Diversity Task Force, gave an overview of NIH's efforts to promote diversity within the scientific workforce.

University of Maryland, Baltimore County President Freeman Hrabowski recently authored an editorial in *Science* about the paucity of minority representation within the scientific workforce in the United States. While many countries are increasing their investments in science, technology, engineering, and mathematics, our nation is falling behind, as is reflected in minority underrepresentation. Meeting this need calls for a greater increase in the number of young minority scientists, engineers, and mathematicians.

NIH has not had a significant impact on the diversity of the NIH-funded scientific workforce over the past 30 years. Americans of African and/or Hispanic decent remain underrepresented relative to the U.S. Census. The NIH Diversity Task Force is using several strategies to enhance the framework by which diversity-related programs are implemented—ensuring that programs clearly articulate a compelling interest in diversity and determining whether the goals articulated by the program have been met and, if so, whether the program should continue.

In 2004, NIH revised the Minority Supplement Program to broaden eligibility criteria to include multiple forms of disadvantage (race, ethnicity, socioeconomic status, and disability). The Diversity Task Force is reviewing existing individual diversity programs to promote consistency with this broadened view of eligibility as funding opportunity announcements come up for renewal. In addition, the Task Force is reviewing data on the diversity of the current NIH workforce and conducting an exhaustive literature review and meta-analysis to expand the evidence base in support of the need to promote diversity. Developing metrics by which to hold programs accountable is key to achieving representative diversity and sunsetting the programs as needed. The Task Force, which reports directly to the NIH Director, will continue to engage both internally and externally on these important issues during the review process.

Discussion

Dr. Skorton noted that there are two bureaucratic ways of dealing with diversity in public organizations: create specialized positions that focus on diversity or make diversity development part of the job descriptions of all major bureaucrats, including Institute directors, and hold them accountable through

specific goals and metrics. Dr. Tabak stated that the latter approach places responsibility on everyone's shoulders, which makes the goals more attainable. He added that educators point to the middle school years as the primary tipping point, when students decide whether to study pre-algebra.

Dr. Jemison cited the 2010 "Bayer Facts of Science" study that surveyed members of the American Chemical Society; 40 percent of respondents reported receiving strong discouragement from scientific career paths by college professors. She suggested that it is imperative to task college professors with encouraging and developing young minority scientists, perhaps through their NIH funding, so that students already interested in science and mathematics are not turned away before graduate school.

Dr. Jemison also noted that women are poorly represented in the sciences as well, and suggested that NIH pay attention to this underrepresentation also.

Dr. Ratner pointed to the NCRR Science Education Partnership Awards as one place NIH has attempted to have significant impact in elementary and middle school. Dr. Tabak commented that with the dissolution of NCRR, this program might be integrated with similar efforts within the Office of Science Education in the Office of the Director of NIH, raising its profile and facilitating operation across all Institutes and Centers.

IV. Developments in Imaging Science

Dr. Pettigrew introduced Dr. John Gore, Hertha Ramsey Cress University Professor of Radiology and Radiological Sciences, Biomedical Engineering, and Physics; Professor of Molecular Physiology and Biophysics; and Director of the Institute for Imaging Science at Vanderbilt University. Dr. Gore's research focuses on the development and application of imaging, specifically magnetic resonance (MR) imaging and spectroscopic techniques, in clinical and basic science. A pioneer in the MR field, his work explores the physical and physiological factors that affect MR signals and how those factors appear.

Dr. Gore described imaging science developments over the last decade. Imaging science is a dynamic, evolving field of multi- and interdisciplinary science that develops and improves imaging techniques to provide new or better information; understanding of the information content of imaging metrics; and applications that utilize information for research and clinical uses. Today, imaging science extends far beyond traditional radiological diagnosis to build on advances in genomics, proteomics, neuroscience, and molecular biology. Because imaging science is central to biomedical research, imaging scientists have become experts in devising and relating image-based measurements to pathology, physiology, proteomics, genomics, and metabolism.

The Vanderbilt University Institute of Imaging Science (VUIIS) is a trans-institutional, interdisciplinary center that aims to develop a world-class research program in imaging science and support imaging applications in multiple collaborations. VUIIS receives support form NIBIB, NCRR, the National Cancer Institute, the National Institute of Neurological Disorders and Stroke, and other sources. It employs 110 faculty, staff, and trainees in four centers: the Center for Small Animal Imaging, the Center for Human Research Imaging, the Center for Computational Imaging, and the Center for Molecular Probes.

The Center for Small Animal Imaging makes it possible to conduct multiple kinds of imaging (x-ray, computed tomography, florescence, optical, MR, ultrasound, etc.) on individual animals and integrate the data. The Center for Human Research emphasizes MRI. The Center for Computational Imaging develops algorithms for image processing, analysis, fusion, and visualization; conducts quantitative image analysis; and studies image informatics, integrating imaging with genotype and medical record data. This Center's quantitative image analysis work utilizes multiple modalities for integration in *in vivo* imaging, multimodal *in vivo* imaging, and proteomic information. For example, matrix-assisted laser desorption/ionization (MALDI), a mass spectrometry technique developed by the Vanderbilt University Mass Spectrometry Research Center, has been converted to an imaging technique whereby researchers can integrate tissue composition data with *in vivo* data and proteomic information to interpret MR and imaging data. Thus, MR is being used to guide discoveries in proteomics.

Advances in imaging techniques bring forward new challenges such as the need for improved imaging methods with higher spatial and temporal resolution. Additional requirements include more accurate, complex, and robust models of analysis; evaluation of the biological factors affecting measurements; assessment of the roles of different kinds of measures; integration of MRI data with other imaging modalities; and application of imaging data to predictive quantitative models of tumor development.

Much of the work in imaging research focuses on development and validation of imaging biomarkers, characteristics that can be objectively measured and evaluated as an indicator of a specific biological process or as a measure of a response to a stimulus, intervention, or perturbation. Imaging biomarkers in cancer would aid in characterization of tumor phenotype and state; assessment of therapeutic targets; monitoring response to therapy; and assessment of specific molecular features (e.g., decrease in number of specific targets or receptors). Potential quantitative imaging biomarkers include fat/water ratio, vascularity and angiogenesis, brain perfusion, and neural activation. VUIIS researchers are working to understand and better capture these biomarkers through advanced imaging techniques. For example, Dr. Brian Welch is currently engaged in developing effective fat/water images to isolate biomarkers of diabetes risk.

Both dynamic contrast MRI and diffusion MRI are being used to obtain quantitative information for use in biomarker development. Diffusion MRI can be employed to measure the consequences of cellular proliferation, which leads to increased cell density and tumor growth and is used as a quantitative biomarker of cellularity. Dynamic contrast MRI can be used to look at downstream sequelae of major changes in tumor physiology and metabolism. These techniques can be combined or overlaid in the same study.

Dr. Gore and his colleagues have developed a new diffusion measurement technique, called *temporal diffusion spectroscopy*, for examining tissue structure. Conventional MRI methods for measuring diffusion apply two gradients at a specified time apart in order to measure signal differences. Typically, the time needed to measure signal change is longer than the time needed for water to meet the cell wall. Probing changes within a cell requires a much shorter diffusion time than is possible with conventional MRI. By replacing the bipolar pair of gradients with gradients that oscillate at different, fairly high frequencies, the diffusion time can be reduced to a single cycle rather than the time between gradients. For example, at 1-kilohertz frequency, diffusion time is less than 1 millisecond, and the distance over which diffusion is measured is much smaller than one cell. Temporal diffusion spectroscopy may make it possible to distinguish cells in different phases of mitosis, and computer simulations suggest advantages for detecting subcellular changes in the nucleus and other intracellular structures. Thus, this technique has the potential to detect more sensitive biomarkers of change in tumors. Dr. Gore and his colleagues are currently applying this new technique to animal studies.

In addition to biomarker research, VUIIS investigators are using functional MRI (fMRI) to understand the brain's architecture, metabolism, and neurochemistry, and to quantify brain morphometry. VUIIS's work in quantifying brain function focuses on better understanding the main mechanism currently used for brain mapping in many applications. Researchers quantify brain function using fMRI to detect brain changes during stimuli (sensory, motor, cognitive, and pharmacological), study effects of modulators of activity (drugs), and quantify functional connectivity or the way different brain regions interact. The measurable MR signal, called the blood-oxygen-level-dependent (BOLD) effect, is used in a number of research applications but only qualitatively, because the fundamental basis for the signal is poorly understood. There is also little understanding of the relationship between the BOLD signal, underlying electrical activity, and neurotransmitter changes and inter-regional correlations of BOLD signals in a resting state.

To further explore the limits of the BOLD effect, VUIIS researchers apply very subtle vibrotactile stimulation to the finger pads of sedated but functioning squirrel monkeys. A subtle air puff blows across the subject's fingertips one after the other, and changes in the primary somatosensory areas of the monkey's brain are then recorded. The technique allows for correlations with fMRI, optical imaging of

hemoglobin changes, metabolism studies, and the effects of pharmacological modulators on brain activity.

The brain responds to stimuli via the vascular system; recent research has shown that these vascular changes evoke the BOLD effect, which is inversely related to the resting-state level of γ-aminobutyric acid (GABA). The ability to measure levels of GABA and other neurotransmitters, such as glutamate, in the resting state is critical to understanding the brain in different metabolic states. Using MR, alone and in correlation with other modalities, Dr. Gore and his colleagues have been studying variations in levels of glutamate and GABA related to BOLD activity in disorders and with drug targets. To date, most neurotransmitter studies have employed a surface coil that limits observations to the occipital lobe of the brain. However, there is a real need to measure throughout the brain robustly and with reasonable accuracy. Dr. Gore's colleagues have developed special techniques that produce fairly high resolution and split measurement of GABA levels anywhere in the brain.

Ultra-High Field Project

Advances in magnetic resonance imaging over the last 30 years have led to improvements in image resolution and contrast and signal-to-noise ratio. The newest high-field MR scanners image at 7 Tesla and provide a signal 21 times stronger than scanners imaging at 1.5 Tesla. While 7 Tesla scanners offer better sensitivity to variations in tissue, higher resolution, and faster imaging speeds, several design and engineering issues must be overcome before high-field scanners can achieve widespread clinical use. These challenges include non-uniform radio frequency fields within tissues; artifacts, distortions, and signal losses from susceptibility variations; increased specific absorption rate, leading to higher energy deposition; and a need for higher bandwidth radio frequency pulses. VUIIS has acquired a high-field MRI scanner, the 7 Tesla Philips "Achieva," one of the first 10 such instruments in the world.

The 7 Tesla MRI enables Dr. Gore and his colleagues to perform high-resolution fMRI in humans to map the sensory motor cortex using the same vibrotactile stimulation technique used on squirrel monkeys described above. Researchers can map the individual digit representations and the separation between them with more specificity and reliability than with a 3 Tesla MRI.

Investing in the emerging imaging science specialty is worthwhile, and building imaging science centers with dedicated research equipment should be a core priority. Multimodal imaging and connecting imaging information to other fields, such as proteomics, are increasingly vital in the training of the next generation of imaging scientists.

Discussion

In response to a question, Dr. Gore remarked that although temporal diffusion spectroscopy is faster than conventional MRI, the BOLD response itself takes time. However, it is possible that there may be signs of an early-phase change in the hemodynamic response function; the negative dip is more proximal to neural activity and happens quickly. Dr. Gore and his colleagues are developing new techniques to examine the spatial variation of the hemodynamic response function, which is the transient response to a stimulus. This response, known to be variable across the brain, is likely a function of distance from the major arterial input, but neural effects also are involved (e.g., delays in processing).

Many imaging developments become trends without the buy-in of clinical diagnostic radiology, which is a problem. In clinical trials, it may be important to quantitatively measure how much a tumor spreads in response to a particular treatment dose; yet, in many other applications, such quantitative measures are far less relevant. The use of imaging in the diagnostic world is less well established. Because Dr. Gore's techniques enable measurements and observations that have never been done before *in vivo,* there are limited, if any, data in humans for comparison. In some cases, a completely new data set is being developed. Much of the difficult validation work remains to be done in imaging science. Demonstrating that techniques are predictive and reliable and correlate accurately will take additional time and work.

V. Review of Council Procedures and Regulations

Dr. Demsey noted for the record that a quorum was present for this Council meeting. Dr. Demsey welcomed visitors and members of the science press, and recognized representatives of scientific society constituencies—Jennifer Ayers, American Institute for Medical and Biological Engineering; Renee Cruea, Academy of Radiology Research; Sean Gallagher, American Institute for Medical and Biological Engineering; and Michael Peters, American College of Radiology. He thanked Ms. Carol Fitzpatrick and Ms. Pam Glikman for their activities in planning the Council meeting.

A. Council Regulations, Policies, and Procedures

Dr. Demsey summarized elements of the Government in the Sunshine Act and the Federal Advisory Committee Act that govern all Advisory Council meetings. These Acts require the U.S. Department of Health and Human Services to open Advisory Council meetings to the public except when proprietary or personal information is discussed. To comply with these regulations, the NACBIB meeting is open to the public for all but the review of individual grant applications. Dr. Demsey reviewed conflict of interest, confidentiality, and lobbying guidelines.

B. Future NACBIB Meeting Date

The next NACBIB meeting is scheduled for Friday, May 20, 2011, with the site to be determined. Dr. Demsey asked Council members to inform him about conflicts with upcoming meeting dates.

C. Approval of the September 13, 2010, NACBIB Meeting Minutes

A motion to approve minutes of the September 13, 2010, NACBIB meeting was forwarded, seconded, and approved unanimously.

D. Approval of the NACBIB Operating Procedures and Biennial Report on Gender and Minority Inclusion in Clinical Trials

A motion was forwarded and seconded to approve the NACBIB operating procedures. The operating procedures were approved unanimously with no modifications. Council also approved the NABIB Biennial Report on Gender and Minority Inclusion in Clinical Trials. This report describes measures NIBIB takes to comply with NIH policies on gender and minority inclusion in clinical studies. The report was approved unanimously with no modifications and will be forwarded to NIH's Tracking and Inclusion Committee.

VI. Report of the Strategic Plan Workgroup: Dr. William Heetderks

The Strategic Plan Workgroup has refined the goals of the plan based on discussions at the last Workgroup and internal NACBIB meetings. Five goals have been identified:

1. Improve the diagnosis, treatment, and prevention of disease through development of emerging biomedical technologies.
2. Enable patient-centered healthcare through the development of health informatics, mobile health, and point-of-care technologies.
3. Transform advances in medicine at the molecular and cellular levels into therapeutic and diagnostic technologies.
4. Develop medical technologies that are low-cost, effective, and accessible to everyone.
5. Prepare a new generation of interdisciplinary engineers, scientists, and providers for the challenges and demands of future biomedical technology-based research.

The goals are now illustrated with stories based on grantee work.

Discussion

Dr. Skorton noted that the Strategic Plan meets two needs: it demonstrates how grantee work fits within NIBIB's goals, and it lays out a blueprint for the next 5 years. However, the high level of conceptualization and lesser level of detail do not provide methods or metrics that would allow future Advisory Boards, directors, or others to assess progress, success, or failure. Dr. Alderson agreed, stating that without quantitative metrics, it may be easier for politicians on appropriations committees to see failure rather than success. Dr. Heetderks responded that a separate implementation component to the Strategic Plan will in fact include tactics and metrics. Dr. Hylton stated that metrics could be developed specifically around the two parts of the mission statement: leading development and accelerating application.

Dr. Ratner noted that the vision statement could provide more specificity. He suggested editing the statement: "To profoundly change health care by pushing the frontiers of technology *to bring innovation to patient treatment and biomedical research."*

Dr. Alderson added that some of the language in the entire Plan might be too ambitious. For example, one of the strategies of Goal 2 is "Advance the engineering of biologically inspired synthetic approaches to make breakthrough discoveries that will transform medicine." Dr. Alderson suggested editing the strategy to reflect a more realistic achievement. Dr. Skorton responded that the vision statement should be aspirational, but the goals and strategies should be focused. Drs. Jemison, Ehman, and McGrath agreed that it is appropriate to include grand ideas and goals and aspirational language in the Strategic Plan.

Dr. Alderson suggested the following changes: (1) use images of people for all of the translational science examples; (2) Goal 5, "Prepare a new generation of interdisciplinary engineers, scientists, and health care providers," should explicitly emphasize training, perhaps by stating "Develop training programs to prepare a new generation…"; and (3) the last strategy for Goal 4 should include "research interdependence" rather than "research independence," to better highlight NIBIB's interdisciplinary goals.

Dr. Hylton wondered how to assess the role of NIBIB in projects that also receive funding from other Institutes. NIBIB's impact outside of the Institute would be important to address in the Plan.

Dr. Pisano stated that NIBIB also should assess the impact of new technology on human health and encourage translation into the clinic. Dr. Glover stated that the success of technologies developed by NIBIB investigators will be measured by impact. As impact is often measured in disease-based Institutes/Centers, it would be beneficial to use the Strategic Plan to foster collaborations with other Institutes in a more substantive way. Dr. Ratner proposed that some of the Plan capture how technological developments made discoveries in basic science possible.

Dr. Skorton remarked that the mission statement and Goal 1 say the same thing, and the other goals are subsets of that statement. If Goal 1 were folded into the mission statement, that would be an appropriate place for high-level language. Dr. Skorton also suggested revising the vision statement to specify that NIBIB is where biomedical and physical science research will be brought together. Dr. Ehman countered that Goal 1 as it is currently written is the central mission of NIBIB; if any additional examples are included, they should illustrate Goal 1. Dr. Grimson added that, should Goal 1 remain separate, the interdisciplinary nature of the Institute should be highlighted.

Dr. Jemison added that the Plan could state that NIBIB will work to identify and promote areas of research that are ripe for investment (e.g., point-of-care research). The Plan should also have a place for enhancing health and well-being not specifically related to disease. Dr. Glover agreed; the Plan must describe NIBIB's support of technology development that helps researchers understand the healthy body as well as the diseased one. Dr. Pancake suggested "improving human health through the development of emerging biomedical technologies." Dr. Skorton noted that NIBIB deals with prevention, diagnostics, and therapeutics, based on understanding life processes in health and disease; the Plan should reflect all of those aspects. Dr. Glover noted that the Strategic Plan should be refreshed with new examples as the science evolves.

VII. Adjournment

The open session of the NACBIB meeting was adjourned at 12:10 p.m.

VIII. Closed Session

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 and attachments are accurate and complete.[2]

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Anthony Demsey, Ph.D.
Executive Secretary,
National Advisory Council for Biomedical Imaging and Bioengineering
Director,
Office of Research Administration
National Institute of Biomedical Imaging and Bioengineering

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Roderic I. Pettigrew, Ph.D., M.D.
Chairperson,
National Advisory Council for Biomedical Imaging and Bioengineering
Director,
National Institute of Biomedical Imaging and Bioengineering

[2] These minutes will be approved formally by the Council at the next meeting on May 20, 2011, and corrections or notations will be stated in the minutes of that meeting.