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]
May 16, 2007

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its 14th meeting on May 16, 2007, at the Marriott Suites Bethesda in Bethesda, Maryland. Dr. Roderic I. Pettigrew, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), presided.

In accordance with Public Law 92–463, the meeting was open to the public from 8:30 a.m. to 11:45 a.m. for the review and discussion of program development, needs, and policy. The meeting was closed to the public from 1:00 p.m. to 2:45 p.m. for the discussion and consideration of individual grant applications.

Council members present:
Dr. Ronald L. Arenson
Ms. Rebecca M. Bergman
Dr. David J. Dzielak
Dr. Richard L. Ehman
Dr. Katherine W. Ferrara
Dr. Don Giddens
Dr. Augustus O. Grant
Dr. Robert I. Grossman
Dr. Rebecca R. Richards-Kortum
Dr. David Satcher
Dr. Stephen A. Williams
Dr. Frank C. Yin

Council members absent: None

Ex officio members present:
Dr. Bruce H. Hamilton, National Science Foundation
Dr. P. Hunter Peckham, Veterans Administration
Dr. James G. Smirniotopoulos, Uniformed Services University of the Health Sciences
Dr. Andrew Watkins, Centers for Disease Control and Prevention

Ex officio members absent:
Dr. Anne Plant, National Institute of Standards and Technology

[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 have occurred. This procedure only applies to applications that are discussed individually, not to "en bloc" actions.

Mr. Michael Leavitt, U.S. Department of Health and Human Services
Dr. Elias A. Zerhouni, National Institutes of Health

Executive Secretary:
Dr. Anthony Demsey

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

Dr. John Anderson
Ms. Lillian Ashley
Dr. Prabha Atreya
Mr. Angelos Bacas
Dr. Richard Baird
Ms. Sheila Barrett
Dr. Zohara Cohen
Ms. Nancy Curling
Ms. Angela Eldridge
Ms. Cheryl Fee
Ms. Shirley Finney
Ms. Carol Fitzpatrick
Ms. Rajal Ganatra
Dr. David George
Ms. Pam Glikman
Dr. Valery Gordon
Dr. John Haller
Dr. John Hayes
Dr. William Heetderks
Dr. Lori Henderson
Dr. Rosemarie Hunziker
Dr. Chris Kelley
Ms. Mary Beth Kester
Dr. Dale Kiesewetter
Dr. Brenda Korte
Dr. Lixin Lang
Dr. Richard Leapman
Dr. Albert Lee
Dr. Zheng Li
Mr. Bryan Linares
Dr. Hector Lopez
Dr. Ying Ma
Dr. Alan McLaughlin
Mr. Todd Merchak
Mr. Nicholas Mitrano
Mr. Larry Morton
Mr. Joe Mosimann
Dr. Peter Moy
Mr. Aaron Nicholas
Ms. Donna Pearman
Ms. Allison Peck
Dr. Grace Peng
Dr. Karen Peterson
Dr. Roderic I. Pettigrew
Ms. Patty Runyon
Ms. Katie Serrano
Dr. Belinda P. Seto
Mr. Shaun Sims
Ms. Florence Turska
Ms. Stacy Wallick
Mr. Matt Wise
Ms. Li-Yin Xi
Dr. Yantian Zhang
Dr. Ruixa Zhou

Other Federal employees present:
Dr. Beth Ansel, National Institutes of Health, National Institute of Child Health and Human Development
Dr. David Brown, U.S. Food and Drug Administration
Dr. Kyle Myers, U.S. Food and Drug Administration
Dr. Ralph Nitkin, National Institutes of Health, National Institute of Child Health and Human Development
Dr. Louis Quatrano, National Institutes of Health, National Institute of Child Health and Human Development

Dr. Nancy Shinowara, National Institutes of Health, National Institute of Child Health and Human Development
Dr. Michael Weinrich, National Institutes of Health, National Institute of Child Health and Human Development

Members of the public present for portions of the meeting:
Ms. Jennifer Ayers, American Institute for Medical and Biological Engineering
Ms. Renee Cruea, Academy of Radiology Research
Ms. Stephanie Darby, Biomedical Engineering Society
Dr. John Donoghue, Department of Neuroscience, Brown University
Ms. Mariana González del Riego, Rose Li and Associates, Inc.

I. Call to Order: Dr. Anthony Demsey

Dr. Demsey welcomed attendees and called to order the 14th NACBIB meeting. He reminded Council members that because the morning session of the meeting is open to the public, comments about applications should be reserved for the closed afternoon session. Dr. Demsey introduced Dr. Pettigrew, who formally welcomed all participants.

II. Opening Remarks: Dr. Pettigrew

A. Departing Council Members

Dr. Pettigrew acknowledged the service of several members whose terms on the NACBIB were ending: Dr. Rebecca Richards-Kortum, Dr. Stephen Williams, Dr. Frank Yin, and Dr. Robert Grossman. Dr. Pettigrew thanked the departing Council members for their service, wisdom, and guidance during the formative years of the Institute and indicated that Drs. Williams, Yin, and Grossman served the Council well beyond their initial terms, for which he was particularly appreciative. All retiring NACBIB members were presented with a letter of appreciation from U.S. Department of Health and Human Services Secretary Michael Leavitt. In addition, the four members each received a plaque and a personal note from Dr. Pettigrew.

Dr. Pettigrew also congratulated Dr. Grossman on his recent appointment as the new Dean and Chief Executive Officer of the New York University Medical Center.

B. In Memoriam

Dr. Pettigrew noted that today's Director's Report would be short so that he could attend the funeral of Dr. Stephen Straus, an esteemed colleague. Dr. Straus, the first director of the National Center for Complementary and Alternative Medicine, passed away recently after a courageous, 2-year battle with glioblastoma multiforme. Dr. Pettigrew recalled Dr. Straus's seminal research on the physiological effects and treatment of human papillomavirus, and described him as an exceptionally bright and kind individual. The meeting attendees observed a brief moment of silence in honor of Dr. Straus.

III. Director's Report: Dr. Pettigrew

Dr. Pettigrew discussed the new National Institutes of Health (NIH) budget, new funding mechanisms, the honors received recently by NIBIB-funded investigators, and the NIBIB 5th Anniversary Symposium.

A. New NIH Budget: Impact on the NIBIB

At the last Council meeting, the NIH was operating under a temporary budget provided by a Continuing Resolution of Congress. Since then, a joint Appropriations Act added approximately $600 million to this year's NIH budget, beyond the funding provided by the Continuing Resolution. The additional funds were allocated across nine NIH initiatives as follows:

- NIH Roadmap: $332 million
- Support for Vulnerable Investigators: $91 million
- National Children's Study: $58 million (not funded under the Continuing Resolution; the joint Appropriations Act restored funding)
- NIH Director's New Innovator Award: $40 million
- National Center for Research Resources Shared Instrumentation Program: $34 million
- Pay (Cost of Living) Increase (funded at 50% of total): $18 million
- Support for Authorization Act Activities: $7 million
- National Center for Biotechnology Information: $5 million
- Strengthening National Center on Minority Health and Health Disparities programs: $4 million

With the new NIH budget, the NIBIB received a modest increase of approximately $77,000 to cover 50 percent of the cost of living pay increases provided to employees. However, because the Joint Resolution directly funds the NIH Roadmap initiative, each Institute and Center (IC) is not required to contribute to the initiative as they had in the past. Therefore, the $3.6 million contribution the NIBIB would have made to the Roadmap will instead be available for NIBIB-specific programs. Thus, for fiscal year 2007, the total NIBIB budget will be $297 million.

Dr. Pettigrew also noted a change to the congressional appropriations process. Specifically, in the past, only NIH Director Dr. Elias Zerhouni provided testimony; however, under new leadership, the Appropriations Committee held a series of hearings during which directors of the NIH ICs also testified. The NIBIB testified during the "Frontiers of Science" session, alongside the National Library of Medicine, the National Institute of General Medical Sciences, and the National Human Genome Research Institute. A record of that hearing, held on May 7, 2007, is publicly available.

B. Funding Mechanisms

Dr. Pettigrew highlighted two new NIH initiatives funded by this year's appropriation. The first was the NIH Director's New Innovator Award, which is modeled after the NIH Pioneer Award; however, it targets new investigators with no more than 10 years of experience since their postdoctoral training, and consists of 5-year grants for a maximum of $1.5 million in direct costs.

The receipt date for applications is May 22, 2007, and 14 awards are expected to be made in September 2007.

The second new NIH initiative supports vulnerable investigators and is similar to a program previously developed by the NIBIB. The NIH Director's Bridge Award provides bridge funding to support new and established investigators whose competing renewal grant applications just missed being funded. To qualify, an application must have scored within 10 percentile points of the IC payline, and the investigator must have less than $200,000 in other support. If these criteria are met, the investigator can be nominated by the IC for funding consideration by the NIH Office of the Director. If approved, the applicant will receive funding for 1 additional year at the level of the last year of the current grant, providing time to prepare a resubmission.

The NIBIB policy for bridge funding differs slightly from this new NIH initiative. Specifically, it targets new investigators and is more restrictive than the NIH Director's Bridge Award because only applications within 3 percentile points of the payline are considered. However, the NIBIB policy does not impose a cap on the researcher's additional funds.

C. Honors

NIBIB-funded investigators and staff were acknowledged for their recent accomplishments as follows:

- **Dr. Chunlei Liu**, Stanford University, was nominated for a Rabi Basic Science "Young Investigator Award" from the International Society of Magnetic Resonance in Medicine. Dr. Liu's work focuses on parallel magnetic resonance imaging (MRI), a process that dramatically accelerates the acquisition of magnetic resonance images.
- **Dr. Vladimir Torchilin**, Northeastern University, was awarded the 2007 Lifetime Research Achievement Award at the Pharmaceutical Sciences World Congress. Dr. Torchilin uses nanotechnology to target and deliver medical drugs.
- **Dr. Richard Robb**, Mayo Clinic College of Medicine, was featured in *U.S. News and World Report* for his work on image-guided interventions. Dr. Robb has developed interactive software to aid cardiac electrophysiologists in their attempt to identify electrical sites required for the treatment of atrial fibrillation.
- **Dr. Samuel Achilefu**, Washington University School of Medicine, was recently featured in the Mallinckrodt Institute of Radiology's magazine *Focal Spot* for his work in optical imaging.
- **Ms. Colleen Guay-Broder** and **Ms. Mary Beth Kester**, staff of the Office of Science Policy and Public Liaison, NIBIB, were recognized for their work in developing the NIBIB Web site; they received the NIH Plain Language Award, which honors efforts to improve how the NIH communicates with the general public.
- **Dr. Belinda Seto**, Deputy Director for the NIBIB, was recognized by Purdue University as a Distinguished Science Alumnus.

D. NIBIB 5th Anniversary Symposium

Dr. Pettigrew outlined the program for the NIBIB 5th anniversary celebration, which will be held on May 31 and June 1, 2007. On the evening of May 31, a dinner at the J.W. Marriott Hotel in Washington, DC, will be sponsored jointly by the Academy for Radiology Research, the American Institute of Medical and Biological Engineering, and the Coalition for Imaging and Bioengineering Research. The two speakers featured that evening are Dr. David Satcher, former U.S. Surgeon General, and Dr. Harrison Hagan "Jack" Schmitt, a geologist and former astronaut and U.S. Senator. Additionally, the NIBIB Landmark Achievement Award will be awarded posthumously to Dr. Paul Lauterbur, a 2003 Nobel Laureate, for his seminal work leading to the development of MRI.

The symposium titled "Changing the World's Healthcare through Biomedical Technologies," will take place on June 1, 2007, in the Lister Hill Center Auditorium on the NIH campus and will consist of three parts. The first session, "NIBIB – From Dream to Reality," will begin with opening remarks provided by Dr. Zerhouni and a broad historical overview provided by Dr. Alexander Margulis. During his tenure as Chair of the University of California, San Francisco, Radiology Department, Dr. Margulis was one of the leaders in developing an interdisciplinary imaging program that included radiologists and bioengineers. This lecture will be followed by an overview of the history, milestones, and accomplishments of the Institute as presented by the following NIBIB-funded investigators: Dr. C. Douglas Maynard, Wake Forest University; Dr. Shu Chien, University of California, San Diego; Dr. Stanley Baum, University of Pennsylvania; and Dr. Robert Nerem, Georgia Institute of Technology.

Dr. Pettigrew outlined some of the accomplishments that will be discussed by speakers during this session. He noted the growth of the Institute as an important accomplishment; although it only receives 1 percent of the NIH budget, the NIBIB funds 2 percent of all NIH grantees. New and innovative policies and programs include the Edward C. Nagy New Investigator Award, through which proportionately more new investigators are funded than similar programs at other ICs, the NIBIB bridge funding mechanism, the Quantum Project initiative, and funding scientists whose research is at the interface between the physical and life sciences.

The second session, "Technology in Medicine," will build on these topics and relate them to medicine in the 21st century. Speakers include Dr. Harvey Fineberg, the President of the Institute of Medicine, and Dr. Anthony Atala, a leading expert in the field of regenerative medicine. Dr. Charles H. Townes, a Nobel laureate in physics, will describe his discovery of the laser. Other speakers include Dr. Ralph Weissleder, Director of the Massachusetts General Hospital Center for Molecular Imaging Research, who will give a presentation on molecular imaging, Dr. Shirley Ann Jackson, President of the Rensselaer Polytechnic Institute, who will deliver a talk on interdisciplinary science, and Dr. Waldo Hinshaw, a colleague of Dr. Lauterbur and leader in the biomagnetic imaging technology industry, who will discuss the development of MRI.

The third session, "The Future of Interdisciplinary Science," will include a discussion led by New Investigator Awardees, during which they will recount their formative experiences. Finally, two of the first investigators funded by the NIBIB, Dr. James Duncan and Dr. Dennis Spencer, Yale University, will describe their successes diagnosing and surgically treating epilepsy. With

NIBIB grants, these two researchers have redefined their field with new, state-of-the-art technology. Dr. Pettigrew concluded the Director's Report by encouraging everyone to attend this symposium.

IV. Presentation of the U.S. Food and Drug Administration Commissioner's Special Citation to Dr. Pettigrew

Dr. Demsey gave the floor to Dr. David Brown, representing U.S. Food and Drug Administration (FDA) Commissioner Dr. Andrew von Eschenbach, who presented a special citation to Dr. Pettigrew for his enthusiastic support of the initiation and implementation of the NIBIB-FDA Joint Laboratory for the Assessment of Medical Imaging Systems. Dr. Brown also recognized the contributions of Dr. Seto to this endeavor.

Dr. Pettigrew thanked Drs. Brown and Eschenbach for the honor and spoke about the important contribution of the FDA to the public interest.

V. Scientific Presentation: Advanced Neural Interfaces, Dr. John Donoghue

Dr. Donoghue is the Henry Merritt Wriston Professor and Chair of the Department of Neuroscience at Brown University, and for many years, he chaired the Brain Science Program, an interdisciplinary research collaboration comprising approximately 11 different departments and 80 researchers. His research focuses on how the brain transforms thoughts into actions. Specifically, it addresses how neural activity in the motor cortex is translated into skilled and voluntary movements. This work is presently funded by the prestigious Javits Award of the National Institute of Neurological Disorders and Stroke. Dr. Donoghue has authored more than 100 research articles published in various journals including *Nature* and *Science*. Over his career, while continuing basic science research, Dr. Donoghue has developed a focus on translational research. These efforts have resulted in the formation of a company, Cyberkinetics Neurotechnology Systems, which has developed a new laboratory technology system called BrainGate. BrainGate acts as an interface for a dysfunctional nervous system to provide voluntary control of muscles. Dr. Donoghue received a Breakthrough Award from *Popular Mechanics* magazine in 2005 and a Discover Award for innovation in 2004. The *Reader's Digest* selected BrainGate as a top medical breakthrough for 2005.

Dr. Donoghue began his presentation by explaining that the research he conducts centers on the control of movement by the motor cortex and how it can be artificially restored in paralyzed individuals. Over the years, this work has combined neuroscience, computer science, engineering, medicine, and industry. It has spanned basic research, preclinical work, and recently an ongoing clinical trial. Dr. Donoghue's work applies devices that couple to the nervous system, known as neural interfaces, to paralyzed individuals to restore lost function; however, these technologies may soon treat other disorders like epilepsy and depression.

Dr. Donoghue compared the current state of the art in neurotechnology to cardiac medicine in the 1950's when large, awkward devices were used as the first cardiac pacemakers. Within two decades, these instruments were introduced into the body and coupled with computer chips that

allowed them to make “smart” decisions as they controlled heart rhythm. This is where the field of neurotechnology will be headed.

In general, two categories of technologies are used in the field: those devices that get information into the nervous system and those that take information out. The former requires electrical stimulation and is used for therapy or to restore lost function. The most successful example of this is the cochlear implant, which has partially restored hearing to more than 100,000 people. Similar implants are currently being tested to restore vision, although these only allow visually impaired patients to see dots of light as a simple image. Deep-brain stimulation is another important example of technology that delivers electrical stimuli to the nervous system. Used to treat Parkinson’s patients, the implantation of electrodes into deep brain structures and subsequent electrical stimulation can eliminate disease symptoms. Dr. Donoghue remarked that these technologies are beginning to permeate the health care system, even though the general public remains unaware.

The second type of technology, which takes information out of the nervous system, is much more complicated but has the immense potential of restoring movement or diagnosing disease states in the brain. The systems currently available to translate brain signals (i.e., eye movement boards and electroencephalogram [EEG] caps) are awkward. The developers of these, and similar technologies, have had to wrestle with a number of fundamental questions: where in the brain should signals be obtained, what signals are wanted, how is that signal translated into an action, and finally what actions should be replicated?

Dr. Donoghue’s research focuses on the motor cortex, a region of the brain that is well defined. The motor cortex is topographically organized so that sections of the cortex control, for example, the ability to command arm movements while other sections command face movements. From this region, two kinds of signals are available: Action potentials (electrical signals from single neurons) and field potentials (macro-level signals, the summation of action potentials from a large number of neurons). Action potentials are quickly generated and rich with information, but they are difficult to detect. In contrast, field potentials are generated slowly but are easy to detect (e.g., via an EEG).

To detect multiple action potentials and localize them to particular neurons, Dr. Donoghue and colleagues have developed a multi-electrode array that can be implanted in the brain. This multi-electrode array is a 4x4 mm platform of silicon, which is carved into 100 electrodes that are organized in a 10x10 array. The device also contains a sensor at the top to record field potentials. It now has been tested successfully in 55 monkeys, a subset of which has had the probe removed and replaced periodically. When the electrode array is removed, normal brain tissue returns, and the signal from subsequent implants is normal. Thus, the device has no permanent effect on the brain.

To translate the electrical signal into motor signals, a key is developed by correlating the motor cortex signals to the arm movements of monkeys playing video games. This allows scientists to predict movements based on the patterns of neuron activity in the motor cortex. To do this, fast computers and reliable algorithms are needed, underscoring the interdisciplinary nature of the research. This work led to the development of BrainGate, a system that contains an electrode

array and computer to predict arm movements from motor cortex activity. Currently, four patients have been implanted with this technology as part of two pilot clinical trials. Two patients are tetraplegic from spinal injuries (i.e., without feeling), one is a brainstem stroke patient who cannot move her limbs but can feel them, and one has paralysis caused by a neurodegenerative disease. Together, these patients represent 2,000 days in vivo, with no device-related side effects.

Dr. Donoghue also discussed how the system has been improved compared to early versions, and showed implementations of the technology. In one example, a patient uses the system to communicate by imagining typing keys on a keyboard. In another, the patient changes the channel on a television. Finally, Dr. Donoghue showed examples of patients using the system to replace their lost physical function: One individual controlled a robotic hand while another attempted to operate an electric wheelchair.

In the near future, this technology will become more compact and will include wireless capability. Additionally, BrainGate will interface with functional electrical stimulation (FES) systems so that the signal from the brain would be translated by BrainGate, and sent to an FES system to generate electrical impulses that would be used to control muscle in the paralyzed individual. Finally, Dr. Donoghue also hopes to use the system to predict seizures in epileptics.

Discussion

A meeting participant inquired whether there were other areas of the brain that Dr. Donoghue could investigate more easily given that the motor cortex is relatively hard-wired in its function. If a region that was more prone to learning and adapting were studied, perhaps it could be demonstrated that the brain can conduct some of the computing performed by the BrainGate computers. Dr. Donoghue responded that the original idea was to couple hand function directly to the portion of the brain responsible for movement of the hand. Beyond that, he acknowledged that there are intriguing yet challenging ideas that remain to be explored.

A Council member remarked about the significance of the work given recent disasters and the plight of disabled veterans. Dr. Donoghue was asked to elaborate on how this technology could be used in the setting of depression, an emotional, not motor, disorder. Dr. Donoghue replied that the electrode array detects changes in the brain and that if one assumes that depression is accompanied by localized changes in the brain, the technology might be used as a diagnostic tool. Along these lines, there is functional MRI evidence that certain areas of the brain (e.g., the frontal cortex) change with depression. The technology also may be used therapeutically to guide drug dosages.

VI. Staff Presentation: NIBIB Programs for Modeling, Simulation, Analysis, Robotics and Systems Engineering, Dr. Grace C.Y. Peng

Dr. Peng is a program director at the NIBIB whose portfolio currently has 57 grants and 2 contracts, primarily distributed across the NIBIB program areas for biomechanics; modeling, simulation, and analysis; rehabilitation engineering; telehealth; and surgical tools and techniques. The 59 awards in this portfolio can by categorized in terms of the tools developed: modeling (12), simulation (5), analysis (15), robotics (11), and systems engineering (16)), or categorized by the application areas covered (rehabilitation (15), neuroengineering (20), telehealth (6),

surgical tools (4), and other (14). Of these awards, 7 are co-funded with other institutes at the NIH. Dr. Peng's presentation presented this portfolio in terms of the tools that are being developed in modeling, simulation, analysis, robotics, and systems engineering. The stated goal of this presentation was to show that this portfolio ties together diverse application areas with intelligent tools and methods. Specific points to conclude are the notable thrust in neuroengineering, NIBIB's leadership role in promoting multiscale modeling, and robotics as an emerging focus area at the NIBIB.

NIBIB Modeling Program

The 12 awards in the modeling portfolio support the development of mathematical, statistical, transport, network, population, mechanical, electrical, and electronic models. This program spans the fields of neuroengineering (4), cardiopulmonary systems (5), drug therapy (3), respiratory systems (1), bone (1), renal systems (1), and acquired immune deficiency syndrome (1). Multiple areas may be covered in one award.

As examples of NIBIB-funded work from this portfolio, Dr. Peng described work from the Biomedical Simulations Resource group at the University of Southern California. This group, led by **Dr. Vasilis Marmarelis**, is a P41 national resource center (funded by the NIH for 22 years) that develops nonlinear dynamics methods and models for physiological systems. Within this resource, one core led by **Dr. Theodore Berger** has developed a "memory chip". Multi-array electrode recordings from the behaving rat hippocampus are used to develop models of neuron population dynamics that are encoded onto a chip. When implanted into a rat with a lesion in the CA3 region of the hippocampus, the chip is able to replicate the input and output dynamics of the lesioned region.

Dr. Peng also provided an example of multiscale modeling, which involves the development of mathematical models to predict the interactions of some combination of genes, molecules, tissues, organs, organism, and human health and behavior. More specifically, NIBIB-funded investigators are modeling specific interactions in the cardiome (i.e., a combination of ion channels, cardiac muscle, and the metabolic system).

These and similar efforts are enhanced and supported by the Interagency Modeling and Analysis Group (IMAG), which consists of program officers from seven Federal agencies interested in supporting modeling and analysis programs. This group has been coordinated by Dr. Peng since 2003. In 2004, the IMAG released a special solicitation for multiscale modeling and received more than 400 letters of intent; 200 applications were reviewed of which 24 were funded across 4 agencies. The investigators leading these 24 funded projects form the Multiscale Modeling Consortium which was established to collaborate and share models. This consortium has 10 active working groups around thematic areas. The NIBIB has played a prominent role in this endeavor by hosting a website for the consortium and a wiki-based interface that encourages collaboration.

NIBIB Simulation Program

The 5 awards in the simulation portfolio support the development of technology for training and education as well as simulators for understanding and predicting human systems. This program spans the fields of rehabilitation (1), surgical tools (3), and respiratory systems (1). An example

from this program is the work of **Dr. John Magill**, Physical Sciences, Inc., who has a Phase II Small Business Innovation Research project for the development of a physical simulator for epidural needle insertion. Another grantee, **Dr. Jaydev Desai**, University of Maryland, simulates tissue cutting by developing complex models of tissue deformation and crack growth. **Dr. Survranu De**, Rensselaer Polytechnic Institute, has developed interactive surgical simulations using physics-based models and data from the National Library of Medicine Visible Human.

NIBIB Analysis Program

The 15 awards in the NIBIB analysis program support the development of mathematical analysis tools, statistics, and signal processing. This program spans the fields of rehabilitation (4), neuroengineering (6), telehealth (1), cardiopulmonary systems (1), genomics (2), and proteomics (1). Examples of funded grants include those of NIBIB MERIT Awardee **Dr. Bradley Efron** and his colleague **Dr. Richard Olshen**, Stanford University, who for the last 32 years have developed many of the commonly used statistical tools in biomedical research. In addition, **Dr. Jonathan Dingwell**, University of Texas at Austin, uses nonlinear mathematics to track metrics on how humans develop fatigue when cycling to exhaustion. Finally, a Bioengineering Research Partnership led by **Dr. Carlo de Luca**, Boston University, has developed a wearable-sensor system to measure electromyography at various parts of the body. This system uses artificial intelligence to determine how medication states affect movement disorders of Parkinson's disease patients and ultimately to improve medication management of the disease.

NIBIB Robotics Program

The 11 awards in the NIBIB robotics program support the development, use, and theory of robots. This program spans the fields of rehabilitation (9), neuroengineering (1), and surgical tools (1). Dr. Peng highlighted the strong relationship the NIBIB and the National Institute of Child Health and Human Development (NICHD) share in this field, as evidenced by NIBIB's collaborations with NICHD's National Center for Medical Rehabilitation Research (NCMRR). Dr. Peng acknowledged members of the NCMRR program staff present in the audience (Dr. Michael Weinrich, director of NCMRR, Dr. Louis Quatrano, Dr. Nancy Shinowara, Dr. Ralph Nitkin, and Dr. Beth Ansel). Their collaborative efforts include the co-funding of two contracts developing robots for the rehabilitation of stroke patients with upper arm impairment, conducted by **Dr. David Reinkensmeyer**, University of California Irvine and **Dr. Jiping He**, Arizona State University. The program also has a co-funded grant led by **Dr. William Zev Rymer**, Rehabilitation Institute of Chicago, which serves as a resource for investigators to learn techniques and scientific methods for pilot studies in robotics research. **Dr. Richard Weir**, Rehabilitation Institute of Chicago, is leading a co-funded Bioengineering Research Partnership to develop a prosthetic arm controlled with implanted myoelectric sensors through remote circuitry. A final example in this program was a grant supported through the Collaborative Research in Computational Neuroscience program, sponsored by the NIH and the National Science Foundation. A project led by **Dr. Cynthia Moss**, University of Maryland, focused on the development of computational models correlating neural activity and head movement underlying the echo-locating behavior of bats. A robot using this computational model as a sonar controller was shown to manipulate through a forest of concrete obstacles. This biologically inspired controller may be relevant in the future for individuals with vision impairments.

NIBIB Systems Engineering Program

The 16 NIBIB awards in the systems engineering program support projects that integrate engineering, mathematics, computer science and often early stage testing in humans. This program spans the fields of rehabilitation (1), neuroengineering (10), and telehealth (5). Dr. Peng described several grants that support technology development for electrode arrays similar to the one Dr. Donoghue described. This included work by **Dr. Daryl Kipke**, University of Michigan, who leads the P41 Resource Center for Neural Communication Technology. Dr. Kipke is developing chronic neural interface probes and probes for electrical and chemical sensing. **Dr. Ranu Jung**, Arizona State University, is developing active MEMS neural clamps to record spinal cord activity. **Dr. Alan Litke**, University of California, Santa Cruz, is developing a 512-electrode array system to study cortical networks, potentially for use in retinal prostheses. Dr. Litke was noted as a 'truly' new investigator to the NIBIB and to the NIH, as his background is high energy physics. Dr. Peng noted that NIBIB encourages people with backgrounds similar to Dr. Litke's to apply to the NIBIB for research support. **Dr. Babak Ziaie**, Purdue University, and **Dr. Heiko Jacobs**, University of Minnesota, are developing electronically configurable systems for neural recording. Finally, **Dr. P. Hunter Peckham**, Case Western Reserve University**,** is developing an open architecture neural prosthesis network system that allows actuators and sensors to be developed in module format and customized to the user's needs.

Dr. Peng concluded with a discussion of a brain-computer interface system developed by **Dr. Jonathan Wolpaw**, Wadsworth Center, New York State Department of Health, through a Bioengineering Research Partnership. This system uses a noninvasive skull caps to measure EEGs and translate them into computer signals that allow patients with neurological disorders to communicate. This system is currently in use at 120 sites across the world. Due to the increased usage of this system across sites, software engineer **Dr. Gerwin Schalk**, Wadsworth Center, is making the software for decoding EEG algorithms more available to users through a separate R01 funded through the NIH Continued Development and Maintenance of Software program.

Dr. Peng summarized her talk by reinforcing the importance of intelligent tools and methods, especially computational models in all of these programs. She noted the current thrust in neuroengineering and the emerging importance of robotics in this portfolio. Future activities include promotion of the 10 IMAG working groups and the development of a fiscal year 2008 multiscale modeling initiative.

VII. Review of Council Procedures and Regulations

Prior to the review of Council procedures and regulations, Dr. Demsey noted for the record that there was a quorum for the NACBIB meeting and that ex officio member Dr. Anne Plant was not able to attend.

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 the guidelines with Council regarding conflict of interest, confidentiality, and lobbying.

B. NIH Health Reform Act of 2006

Dr. Demsey addressed the impact of the recent NIH Health Reform Act of 2006 on Council operating procedures. He noted that the Public Health Service Act originally allowed NIH Institutes to make an award of $50,000 or less in direct costs after peer review but without Council review. However, the Reform Act of 2006 requires that all grants now be reviewed by the Council prior to award. Although many NIH Institutes are examining their Council operating procedures and modifying them as a result, the NACBIB Council operating procedures have always stipulated that the Council will review all applications.

C. Future NACBIB Meeting Dates

The next NACBIB meeting is scheduled for September 17, 2007, at the Marriott Suites Bethesda, in Bethesda, Maryland. Dr. Demsey asked Council members to inform him of major conflicts with scheduled upcoming meeting dates.

D. Approval of the January 26, 2007, NACBIB Meeting Minutes

A motion was entertained to approve the minutes of the January 26, 2007, NACBIB meeting. A request was made to correct the spelling of an ex officio Council member's last name. The minutes were approved unanimously with this modification.

E. Other Announcements

Dr. Demsey welcomed members of the community and the science press to the meeting, particularly representatives from scientific societies, including Ms. Renee Cruea, Academy of Radiology Research, Ms. Jennifer Ayers, American Institute for Medical and Biological Engineering, and Ms. Stephanie Darby, Biomedical Engineering Society.

Dr. Demsey also acknowledged Ms. Carol Fitzpatrick and Ms. Pam Glickman, who assist with Council meeting logistics.

VIII. Review of Strategic Plan Implementation

Dr. Grossman reported on the activities of and the issues facing the Strategic Plan Working Group. At its December 1 meeting the group discussed the idea of holding Program Progress Review meetings to evaluate progress and needs in specific program areas. Optical Imaging was identified as an appropriate area to start with. A program review group on optical imaging will be meeting in June 2007 for discussion with experts in the field, implementation, and benchmarking in this programmatic area. The feedback obtained through this process will enable strategic thinking by the Council and Institute. The working group also discussed two areas on which future efforts will focus: High frequency ultrasound and nuclear medicine.

During the working group meeting, Dr. Richard Ehman spoke briefly about the need to evaluate grants for their value (i.e., What is gained for the dollars spent, are the grant funds used efficiently, and how can funding be stretched as much as possible?). He urged the Council to address these questions during these times of budgetary constraints.

Finally, Dr. Grossman emphasized the need to examine the results of the NIH's investments. Benchmarking tools need to be developed and utilized for this purpose. Plans were made to meet with the training group for the September meeting to discuss health disparities.

IX. Review of Training and Career Development

Dr. Williams reviewed the activities of the Training and Career Development Working Group. He began by announcing the election of a new chair, Dr. Don Giddens. Next, Dr. Williams reminded the Council that a full analysis of the training and development portfolio will be presented at the September 2007 Council meeting. He also announced that the F31 predoctoral training grant program was discontinued on April 8, 2007. Finally, in June 2007, diversity supplement awardees will meet to share their experiences.

Dr. Williams then discussed some strategic issues facing the working group and the Council. The primary issue concerns the joint Howard Hughes/NIBIB interdisciplinary training program. This program provides 8 years of support for institutions, with the first 3 funded by the Howard Hughes Medical Institute (HHMI) and the last 5 funded by the NIBIB. Ten institutions currently are in Phase I, the phase funded by HHMI. In fiscal year 2009, these institutions will compete for NIBIB funding in Phase II, and the working group is preparing for that by reviewing the research at these institutions. In Phase II, additional institutions may apply, thereby possibly broadening the scope of the NIBIB financial commitment. At that time, it will be important to ensure that these applicant institutions meet the eligibility and review criteria identified in the Phase I announcement and are not mature research facilities capable of applying for and receiving more traditional training and institutional grants. The second issue is that the NIH Roadmap includes grants for interdisciplinary training that are expiring at the same time as Phase I of the HHMI grants. Thus, the coming years will place great demands on internal resources and budget.
Finally, Dr. Williams addressed the need to improve funding for interdisciplinary research. Because training programs are creating future grantees that may not be appropriate for traditional NIH awards, the working group and the Council will explore new funding mechanisms. The need for greater diversity in the field will also be addressed.

Dr. Seto informed the Council that the high-specificity, high-sensitivity imaging probe Roadmap initiative would also transition to the NIBIB in fiscal year 2009. Although the Institute already is considering how to accommodate optimally the transition of these Roadmap initiatives to the NIBIB, advice from the Council on this matter is being sought.

X. Adjournment

The meeting open session was adjourned at 11:45 a.m.

XI. Closed Session

This portion of the meeting, involving specific grant review, was closed to the public in accordance with the 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 2:45 p.m.

XII. 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 September 17, 2007, and corrections or notations will be stated in the minutes of that meeting.