#### 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> September 13, 2004

The National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) was convened for its sixth meeting on September 13, 2004, in the Neuroscience Center, Bethesda, Maryland. Dr. Roderic I. Pettigrew, Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), served as Chairperson.

In accordance with Public Law 92-463, the meeting was open on September 13, 2004, from 1:00 P.M. until 4:00 P.M. and from 8:30 A.M. until 12:00 P.M. on September 14, 2004, for the review and discussion of program development, needs and policy. The meeting was closed to the public on September 14, 2004, from 1:00 P.M. until 4:30 P.M. for discussion and consideration of individual grant applications.

#### **Council members present:**

Dr. Carlo J. De Luca Dr. Robert I. Grossman Dr. Linda C. Lucas Dr. Shirley A. Jackson Dr. C. Douglas Maynard Dr. Barbara J. McNeil

**Council members not present:** 

Dr. Janie Fouke

#### Ex officio members present:

Dr. Gary Glover Dr. Bruce Hamilton Dr. James G. Smirniotopoulos Dr. Andrew Watkins Dr. Michael Wiener Dr. Vincent L. Vilker Dr. Elias A. Zerhouni, Jr.

Ex officio members absent:

Dr. John Brighton

## **Executive Secretary:**

Dr. Joan T. Harmon

Dr. Norbert J. Pelc Dr. Rebecca R. Richards-Kortum Dr. Stephen A. Williams Dr. Frank C. Yin Dr. James A. Zagzebski

<sup>&</sup>lt;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 real or apparent conflict of interest might occur.

#### Also present:

Dr. Arlene Y. Chiu Dr. John W. Haller Dr. William J. Heetderks Dr. Henry Khachaturian Dr. Belinda Seto Dr. Gary H. Glover Dr. Donald Harrington Dr. Christine A. Kelley Dr. Peter Kirchner

#### NIBIB employees present for portions of the meeting:

Ms. Lillian Ashley	Dr. Albert Lee
Dr. Prabha Atreya	Dr. Alan McLaughlin
Ms. Brenda Borden	Mr. Todd Merchak
Dr. Arlene Chiu	Mr. Nicholas Mitrano
Mr. Lawrence Clark	Dr. Peter Moy
Ms. Nancy Curling	Dr. Grace Peng
Dr. Bonnie Dunn	Dr. Roderic Pettigrew
Ms. Angel Eldridge	Dr. Belinda Seto
Ms. Cheryl Fee	Ms. Theresa Smith
Dr. David George	Dr. Richard Swaja
Ms. Casey Goode	Ms. Carol Torgan
Ms. Colleen Guay-Broder	Ms. Lynda Toussaint
Dr. John Haller	Ms. Florence Turska
Dr. Joan Harmon	Ms. Stacy Wallick
Dr. Bill Heetderks	Dr. Fei Wang
Ms. Christine Hollingsworth	Mr. Elijah Weisberg
Dr. Christine Kelley	Dr. Anthony Wolbarst
Ms. Mary Beth Kester	Dr. Yantian Zhang
Dr. Brenda Korte	
Dr. Peter Kirchner	

## Members of the public present for portions of the open meeting:

- Ms. Vicki Contie, Equals Three
- Mr. Robert Harris, MasiMax Resources Inc.
- Mr. Michael Horn, Biomedical Engineering Society
- Mr. David Leslie, Schmitt & Leslie
- Mr. Ed Nagy, Academy of Radiology Research
- Ms. Chris Peterson, SRI International
- Ms. Gloria Romanelli, American College of Radiology

### **Other Federal Employees Present:**

Dr. Mary S. Pastel, Food and Drug Administration

## I. Call to Order and Opening Remarks:

Dr. Roderic Pettigrew welcomed Council members, guests, and staff to the sixth Council meeting, and announced that the Director of the National Institutes of Health (NIH), Dr. Elias Zerhouni would be addressing the Council members and other attendees. A special welcome was extended to Dr. Bruce Hamilton, a new *ex officio* member of the Council and the Division Director of the Bioengineering and Environmental Systems at the National Science Foundation (NSF), and to Dr. Vincent Vilker for representing the National Institute of Standards and Technology (NIST) on behalf of Dr. Arden Bement. Special thanks were extended to Drs. McNeil and Yin both of whom agreed to extend their terms through the September Council meeting. Dr. Janie Fouke could not be in attendance because of the death of her mother. Dr. Pettigrew extended condolences on behalf of the Institute and Council to Dr. Fouke and her family.

Special mention was made about recent honors received by Council members. Dr. Rebecca Richards-Kortum received the Sharon Kyler Award from the American Society for Engineering Education, for outstanding contributions to engineering education. She received special recognition for her contributions to cancer detection research in optical engineering as well as for her teaching and mentorship of students. Dr. Richards-Kortum was recently appointed Chair of Bioengineering at Rice University.

Dr. Shirley Jackson also received several recognitions since the last Council meeting. She began her term as President of the American Association for the Advancement of Science in February and was selected as a fellow of the Association for Women in Science. In July, she led the Science Coalitions' Breakfast of Champions, an event that honors Congressional champions of science for their support of university-based science research. In early September, Dr. Pettigrew joined Dr. Jackson at the opening of the Rensselaer Polytechnic Institute's Biotechnology and Interdisciplinary Studies Building, a \$100 million project dedicated to interdisciplinary studies in biotechnology. The design of the building was in keeping with a goal of integrating the quantitative and physical science with the life sciences.

Dr. Pettigrew recognized several new NIBIB staff members.

- Dr. Donald Harrington, Chair of Radiology at State University of New York at Stony Brook, recently joined the NIBIB under an Intergovernmental Personnel Act assignment.
- Dr. Arlene Chiu joined the staff from the National Institute of Neurological Disorders and Stroke (NINDS) where she oversaw the stem cell research program. As the Associate Director of Research Administration, Dr. Chiu will also serve as Executive Secretary for future Council meetings.
- Dr. Lawrence Clark has joined the NIBIB staff on a detail for one year from the National Cancer Institute (NCI).
- Dr. Albert Lee has joined the NIBIB for a one year detail from the National Institute of Standards and Technology (NIST).

Dr. Pettigrew recognized Dr. Joan Harmon who is retiring from the NIH. As the first Executive Secretary for the NACBIB, Dr. Harmon was largely responsible for the organization and orchestration of every Council meeting since the inception of the Institute. She was one of the original eight members of the Institute and has demonstrated continued and outstanding dedication to the NIBIB. Dr. Pettigrew highlighted her total and devoted service to the NIH and to NIBIB in particular, and invited everyone to show their appreciation in a round of applause.

Meeting dates for the next six Councils were reviewed. Council members should contact the Executive Secretary with any requests for changes to upcoming Council meeting dates.

January 26-28, 2005 May 25-26, 2005 January 25-26, 2006 May 24-25, 2006 September 13-14, 2006

Dr. Pettigrew then entertained a motion to approve the minutes which was raised by Dr. Norbert Pelc and seconded by Dr. Zagzebski. The minutes were approved unanimously without modification.

The Director presented a draft of the new logo for the institute. Several members of the Advisory Council provided comments on the logo; these will be taken into consideration as additional modifications are planned.

# II. Review of Regulations Operating Procedures - Dr. Joan T. Harmon

Dr. Harmon summarized the requirements under the Government in the Sunshine Act and the Federal Advisory Committee Act. These Acts require the Department of Health and Human Services (DHHS) to open to public observation as many advisory committee meetings as possible, including the meetings of the National Advisory Councils. She announced that the Council meeting would be open to the public observation, but would be closed for the review of grant applications scheduled to begin at 1:30 P.M. on September 14, 2004.

# III. Director's Report – Dr. Roderic I. Pettigrew

Dr. Pettigrew began his remarks by noting the progress made in recent months by the NIBIB staff. The Institute is recognized for its high work to staff ratio, and he wanted to publicly acknowledge the staff's accomplishments.

He reviewed the budget for fiscal year (FY) 2004 which ends on September 30, 2004, and provided an update of legislative activity, recent and upcoming workshops and meetings, the scientific portfolio and new initiatives. Dr. Pettigrew concluded his remarks with a preview of future directions for the NIH and the NIBIB.

### Budget and Legislative Update

The NIBIB received an appropriation of \$289 million in FY2004 which represented approximately a 3 percent increase over FY2003. The President's Budget for FY 2005, which requests close to \$300 million for NIBIB, was passed by the House on September 9, 2004 and is awaiting and action by the Senate. This represents an increase of approximately 3.1 percent over NIBIB's appropriation for FY2004. Dr. Pettigrew highlighted language in the FY2005 House Appropriations Report for the "NIH to develop a five-year professional judgment budget that would enable NIBIB to grow at an appropriate rate." The report is requested to be delivered to the House Appropriations Committee by May 1, 2005.

In July, Dr. William Heetderks, along with other scientists and leaders from the NIH and FDA briefed the Senate Health, Education, Labor and Pensions Committee staff on pediatric device development. In the coming months, Dr. Pettigrew is scheduled to brief the House Medical Technology Caucus.

#### Workshops and Meetings

The NIBIB continues to sponsor workshops to bring together NIBIB grantees and to solicit feedback from the extramural community. Since the Advisory Council meeting in May, the NIBIB has organized or participated in six grantee meetings, workshops, and scientific conferences. Five additional workshops are planned through January 2005. In particular, Dr. Pettigrew noted that Dr. Bruce Alberts, President of the National Academy of Sciences, was a featured speaker at the P41 Principal Investigators' Meeting held on June 23-24, 2004. Dr. Peter Katona, president of the Whitaker Foundation spoke at the Fourth Annual Bioengineering Research Partnership Meeting on July 29-30, 2004. At the same meeting, Dr. Belinda Seto, Deputy Director of NIBIB, and Dr. Norka Ruiz-Bravo, Deputy Director of Extramural Research at the NIH, spoke on the NIH Roadmap for Medical Research. Other meetings relevant to the mission of NIBIB included the annual BECON meeting, held on June 21-22, 2004, and a meeting on image-guided interventions.

In response to a specific request by Congress, NIBIB partnered with the National Science Foundation (NSF) to hold an inter-agency meeting on the interface of life sciences and physical sciences on May 10, 2004. Other participating NIH Institutes included the National Institute of General Medical Sciences (NIGMS) and the National Institute of Dental and Craniofacial Research (NIDCR). Several key recommendations arose from this meeting. The first is to conduct a conference where physical and life scientists will be asked to identify "grand challenges." This meeting entitled "Research at the Interface of the Life and Physical Sciences: Bridging the Sciences," will be held on November 9, 2004, with a welcome by Dr. Zerhouni and Dr. Bement. The objectives of this meeting are to identify specific grand challenges at the interface of the life sciences and the physical sciences that could result in major advances, and to develop recommendations to facilitate research at this interface. Dr. Bruce Hamilton of NSF and Dr. Richard Swaja of NIBIB have taken the lead to organize these two meetings.

## Scientific Portfolios and Initiatives

Investigator-initiated applications continue to increase, with a doubling of the number of applications received in 2004 over 2005. Dr. Pettigrew presented two new training programs of particular interest. The first is a unique partnership between NIBIB and the Howard Hughes Medical Institute (HHMI) to develop a training program focusing on interdisciplinary research. The goal is to develop a cadre of Ph.D. scientists trained to conduct interdisciplinary research bridging the biomedical, physical, computational, and mathematical disciplines. The HHMI will fund Phase I, a 3-year pilot grant; the NIBIB will fund Phase II, a 5-year grant supporting a T32-type mechanism to build on and extend the program developed in Phase I.

Dr. Pettigrew also discussed a new program for clinical residents that will provide research supplements to promote clinical resident research for up to 2 years. These supplements will be awarded to grantees currently supported by the NIBIB. This program dovetails with one of the major areas in the NIH Roadmap – to re-engineer the clinical research enterprise which underscores the need to rethink and retool how we conduct clinical research, and to train clinicians and physicians around the country to participate in the research enterprise on a national scale.

Another initiative based on an NIBIB Workshop held on April 8, 2003, and the BISTIC Symposium of November 6-7, 2003, focuses on multi-scale modeling. Through the leadership of Dr. Grace Peng, the NIBIB has brought together four Federal agencies - the NIH, the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA), and the Department of Energy (DOE) - to participate in this joint initiative.

Dr. Pettigrew noted that the Institute must weigh competing priorities against the availability of funds when considering new initiatives. The NIBIB has recently partnered with the National Institute of Aging (NIA) to support a major initiative for Alzheimer's disease research. This initiative focuses on collecting image-based data from magnetic resonance imaging and positron emission tomography of Alzheimer's patients. Through co-funding this initiative, the NIBIB hopes to stimulate the development of, and to evaluate informatics tools that might be used in clinical-decision making.

#### Research Highlights

Dr. Pettigrew discussed examples of research currently supported by the NIBIB.

- Shape Memory Polymer Devices for Treating Stroke---Dr. Duncan Maitland, Lawrence Livermore National Laboratory: Dr. Maitland is working with shape memory polymers which can be used to remove occlusions in blood vessels.
- Uropathogen Detection Using DNA Biosensors---Dr. Bernard Churchill, University of California, Los Angeles: As part of a BRP grant, Dr. Churchill is developing an electromechanical sensing device that is capable of identifying speciesspecific pathogens based on their DNA and RNA. This technology may have potential use for rapid and accurate evaluation of pathogens that could be used as agents of bioterror.
- High Field MRI: Limitations and Solutions---Dr. Michael Smith, Pennsylvania

**State College of Medicine:** Dr. Smith is leading his research team in both analyzing and devising solutions for difficulties presented in magnetic resonance imaging (MRI) at high magnetic field strength. The purpose of his research is to correct artifacts common in hi-field MRI.

• Multifunction Prosthesis Control using Implanted Sensors---Dr. Richard Weir, Chicago Health Care System and Northwestern University: Dr. Weir and his colleagues are working to improve limitations in current prostheses lacking sufficient independent control sources. They aim to develop a system capable of reading intramuscular electromyographic signals that would increase the number of control sources available for prosthesis control.

# Future Directions

Dr. Pettigrew concluded his report with an update on the Intramural Research Division and intramural research activities. One part of the Intramural Division consists of the PET radiochemistry and imaging physics programs at the NIH which will be officially transferred to NIBIB on October 3, 2004. In addition, the Institute is convening a Blue Ribbon Panel on September 17, 2004, to provide ideas on the scope and direction of the intramural program to the Advisory Council. Co-chaired by Dr. John Linehan, Vice President of the Whitaker Foundation, and Dr. James Thrall, Chair of the Department of Radiology at Massachusetts General Hospital, the blue ribbon panel also includes two Council liaisons, Dr. Barbara McNeil and Dr. Frank Yin.

# **III.** Training and Career Development Report

Dr. Maynard provided a summary of the Training and Career Development Subcommittee meeting held on September 13, 2004, at the Neuroscience Center in Bethesda, Maryland. He acknowledged subcommittee members: Dr. Linda Lucas, Dr. Rebecca Richards-Kortum, Dr. Steve Williams, and Dr. Shirley Jackson. He also thanked Dr. Henry Khachaturian for continuing the work of Dr. Meredith Temple O'Conner in her absence. The subcommittee discussed five major topics: funding; residency supplements; the Howard Hughes-NIBIB initiative, training grant workshops; and the training needs assessment.

# Funding

The number of applications continues to grow along with the number of trainees. Currently the success rate among NIBIB programs is approximately 20 percent compared to 25 percent of other NIH institutes and Centers. He noted a continuing concern about the lack of M.D.s and M.D.-Ph.Ds. in NIBIB training programs. Only seven of 130 NIBIB-supported trainees are M.D.s. The data, however, may be faulty as it does not allow comparison between the number of M.D.s and the number of postdoctoral fellows. Dr. Maynard stressed that while all programs would benefit from continued growth, NIBIB needs to prioritize programs to provide the best trained people to their research fields.

# Resident Supplements

The resident supplement program was recently announced and is the result of two separate workshops for the imaging and bioengineering community. The workshops

focused on ways to attract more clinical researchers, specifically radiology residents to these fields. Limited to residents involved in programs associated with bioengineering and bioimaging, this initiative will provide 1 or 2 years of support to a resident who is already supported by an NIBIB grant within any department. Dr. Maynard noted that subcommittee members felt that this requirement limited the number of eligible applicants because imaging research is being funded by several other Institutes. The subcommittee is working to create a way to widen the applicant pool. Another point of concern is the length of time it takes from submission to receipt of award for residents coming into the training program. NIBIB staff is exploring ways to expedite the approval process either by administrative review or by another fast track method.

There is still a need to attract radiology students by exposing them to research in a shorter time frame. The subcommittee plans to address this in future meetings.

## Howard Hughes-NIBIB Initiative

This initiative is a collaborative program between Howard Hughes and the NIBIB. The objective is to integrate biomedical and computational mathematics disciplines. The initial phase of this initiative will identify approximately ten programs that can facilitate this type of integration. NIBIB support will be provided through the T32 mechanism in the later years of the initiative. There will be a joint press release in the upcoming weeks.

## Training Grant Workshop

Directors of training grants funded by the NIBIB, along with their trainees were invited to a mentorship luncheon. Many trainees were unaware of the range of possible career opportunities in the imaging and bioengineering fields. It was suggested that one or two Council members attend future workshops to observe.

#### Needs Assessment

Dr. Meredith Temple O'Connor has secured a \$50,000 grant to collect data on NIBIB's research programs. The data will be used to determine the needs of the NIBIB community in the areas of biomedical imaging and bioengineering and what data already exists.

The next subcommittee meeting will take place at the January 2005 Council meeting where the intramural training program will be a major discussion topic. Dr. Pettigrew underscored that both the Howard Hughes and Clinical Resident initiatives are groundbreaking in their fields. Council members agreed that both programs were very responsive to needs originally identified by the bioimaging and bioengineering community.

# IV. Strategic Plan Development Report

Dr. Norbert Pelc provided a summary of the Strategic Planning Subcommittee meeting held September 13, 2004, at the Neuroscience Center in Bethesda, Maryland. He first congratulated members of the NIBIB staff, subcommittee, and Council on preparation of the first draft of the report. Dr. William Heetderks' presentation on the status and process of how the plan was drafted was summarized. The draft process began a year and a half ago. During this time period, NIBIB senior staff participated in a number of retreats wherein the plan was drafted. The intent of the strategic plan was to state the mission, vision and goals of the Institute. Although strategies and objectives were provided for each goal, the subcommittee emphasized the need for timetables to achieve these goals. While not in total agreement, subcommittee members concluded that greater detail was needed to ensure that the stated objectives were met.

Concerns were expressed that the language used in the goal statements may unintentionally exclude prospective researchers. Council members were encouraged to send their comments on global questions and detailed editing issues to members of the NIBIB staff by email at <u>nibib\_sp@mail.nih.gov</u> or by contacting Dr. William Heetderks directly.

Dr. Pettigrew congratulated the staff again for efforts in developing a cohesive first draft of the strategic plan.

# V. State of the Science in Brain Imaging and an Update on the International Consortium for Brain Mapping – Dr. John C. Mazziota

John C. Mazziota, M.D., Ph.D., Chairman of the Reed Neurological Research Center, of the David Geffen School of Medicine at UCLA presented an overview of the state of the science in brain imaging, and an update on the International Consortium for Brain Mapping.

In neurology and neurosurgery, the tools to understand brain function are dependent upon existing methodologies and technologies. One hundred and twenty-five years ago, these methods were limited to a clinician observing a patient and assessing their behavior and post-mortem examination of the brain. By comparing the behavioral deficits in thousands of patients and through post-mortem examination of their brains, clinicians developed a rudimentary understanding of the functional systems of the brain.

Modern imaging technologies now enable scientists to look at normal brain functioning. For example, over 25 years ago, Dr. Mazziota and colleagues used positron emission tomography (PET) to measure glucose metabolism in the brain as an indicator of visual information processing. Almost 10 years later, scientists at Massachusetts General Hospital used gadolinium-enhanced magnetic resonance imaging (MRI) to measure blood flow in the brain during visual processing; their results confirmed Dr. Mazziota's earlier work. This advanced technology permits repeated measurements of brain function over time and can be used in children.

Dr. Mazziota reported on the International Consortium for Brain Mapping (<u>http://www.loni.ucla.edu/ICBM/</u>) supported through the Human Brain Project – including support from the NIBIB – for the last 10 years. Began as a North American venture, the ICBM has now become a global activity encompassing eight laboratories in seven countries on four continents. This effort was initiated to develop a functional imaging database of the brain to address variability in brain size, shape, and organization.

Over the last 10 years, the ICBM has studied 7,000 individuals and that number continues to grow. Genotype and phenotype information including: background, education, profession, diet, medical and psychiatric history, and complete medical and neurological exams, has been collected. These data were coupled with structural imaging using MRI and functional imaging using MRI, PET, or electroencephalogram (EEG) studies. DNA samples were also collected from each individual. The core data atlases include "normal" individuals spanning the age spectrum from birth to old age. Atlases for conditions including Alzheimer's disease, multiple sclerosis, trauma, schizophrenia, stroke, and autism have also been developed. More recent studies include examination of brain receptors, vasculature, tissue organization, and neuronal structures. With resolution at the cubic millimeter levels, MRI provides excellent details of deep brain structure and enables reconstruction of the suface anatomy.

Dr. Mazziota showed several video clips depicting the normal growth and aging process in the human brain. Early in life, there is a tremendous burst of growth, particularly in the frontal lobe, followed by little change until about age 65 when both the frontal and the parietal lobes begin to atrophy. Similarly, there is evidence of thinning of the cortex and parietal and temporal lobes later in life. Dr. Mazziota discussed the use of postmortem imaging of the brain to construct templates to correlate MRI images with anatomical landmarks. The ICBM is also using PET imaging *in vivo* to generate maps of ligand binding areas in the brain which mimic the functional organization. MR angiograms and venograms define the relationship between the vascular supply and brain function, and are used to plan operative procedures to avoid injury to the vasculature.

A video clip illustrated the dramatic structural change over time in the brains of individuals with Alzheimer's disease. Dr. Mazziota also demonstrated how the atlas could be used to determine structurally abnormal areas of the brain responsible for seizure activity in epileptic individuals. He then showed an atlas of the brain derived from 1,580 MRI studies conducted in 460 patients with remitting-relapsing multiple sclerosis. The plaques, visualized by gadolinium-enhanced MRI can be used as a surrogate biomarker of the disease to evaluate results of clinical trials testing new therapeutic agents. Development of similar atlases will be critically important for Alzheimer's, Parkinson's, and other degenerative diseases, where many experimental therapies are on the horizon but where testing methods need to be improved, particularly in presymptomatic individuals.

As an example, Dr. Mazziota presented a clinical case of a 29 year-old woman who benefited from these types of imaging studies when she had successful neurosurgery to remove a vascular abnormality in her brain.

In summary, the ICBM began with the concept that scientists could quantify variance in the human brain, both in terms of structure and function. This required the development of a wide range of computational tools within the Consortium to analyze the data from 7,000 normal individuals and apply that to patient populations across the many diseases previously discussed. Ultimately, these data were used to benefit patients like the case mentioned earlier. Although the ICBM began as a program of neuroinformatics, it has

produced many exciting, practical basic science and clinical applications that weren't anticipated at the outset.

# VI. Overview of NIBIB-Supported Research on Image-Guided Interventions – Dr. John Haller

Dr. Haller summarized the NIBIB research portfolio on image-guided interventions (IGI), presented examples of NIBIB-supported work in this area, and reviewed recent workshops and future challenges.

The IGI portfolio includes not only image-guided surgery as discussed by Dr. Mazziota, but also image-guided biopsies, image-guided radiation treatments, and others. Images are acquired either during or immediately before a procedure and are used in a real-time display for navigation during minimally-invasive procedures. Images can also be used to monitor and assess the intervention.

Dr. Haller provided an overview of the IGI grant portfolio which includes approximately 37 grants supporting research in this area; most were received in response to the image-guided interventions RFA released in 2003. IGI requires the expertise of both imagers and bioengineers. For example, engineering technologies used in IGI include robotics, stents, stimulating and recording electrodes, and thermal ablation tools. Bioinformatics tools are used for computer-assisted surgery, image-processing and tissue modeling. In addition, molecular imaging agents and devices have been developed, including: nanotechnology-derived imaging agents, interventional MRI, ultrasound, CT, and optical imaging machines.

Dr. Haller presented examples of IGI research supported by the NIBIB, including:

- Recent studies have suggested the value of MRI breast screening exams for high-risk women as early as 25 years of age. Researchers are working to make MR-guided breast procedures easier to perform by developing improved software to acquire images during open MR breast imaging and improvements in gradient coils in the MR machines.
- Deep brain stimulation has been shown to greatly improve the quality of life in individuals with Parkinson's disease. Researchers are using optical imaging methods with improved resolution of brain structure and vasculature to guide placement of the deep brain electrodes. Researchers are also improving the 3D atlases used to guide electrode placement.
- Researchers are integrating endoscopic images with CT images to control robotic "hands" for minimally-invasive liver surgery.
- Clinicians are more often performing prenatal interventional surgeries to correct congenital heart disease. Previously, these procedures were done late in the second trimester or early in the third trimester using 2D ultrasound for guidance. Researchers are now integrating real-time 3D ultrasound to visualize the very small heart in the fetus with electromagnetic tracking of the cannula. This technology will enable earlier treatment in the fetus and will ultimately be less debilitating to their long-term health.

• Researchers are developing improved intravascular ultrasound technology coupled to catheters to visualize blockages in the cardiac arteries. Ultimately, this may be used to guide a laser-like device to destroy the blockage.

Dr. Haller mentioned two recent workshops. In 2002, the NIH and the National Science Foundation (NSF) sponsored a workshop on image-guided interventions. The recommendations from this workshop included: the development of surgical robots and biopsy devices that locate targets of interest seamlessly across different resolution scales; development of intra-operative, real-time, 3D image-guided navigation for defining moving organs or tissues; and development of "fully-engineered" components of IGI systems that can be seamlessly integrated for a wide range of clinical applications. In response to these recommendations, in 2003 the NIBIB issued an RFA to further research on image-guided interventions. In May 2004, the NIBIB, in conjunction with the NSF and NASA, held a meeting for grantees receiving support through that initiative. The recommendations from the meeting included: further research efforts in robotics, realtime 3D imaging, multi-modality imaging, fusion of multi-modal images, and interchangeable platform technologies; development of a strategic plan for image-guided interventions; and a fostering of inter-agency collaboration. There is currently an interagency IGI group to promote the development and dissemination of image-guided technologies.

Dr. Haller ended his presentation with a discussion of the current gaps and future challenges in IGI. Current gaps include the need for real-time multimodality image fusion and the need to engineer systems to take advantage of new technologies, such as faster computer algorithms, improved imaging modalities like interventional MR, as well as incorporating emerging optical and molecular imaging techniques.

The NIBIB is interested in accelerating the development and translation of minimallyinvasive technologies by encouraging new investigators, and fostering collaborations among investigators, institutions, industry and other Federal agencies.

# VII. Remarks of Dr. Elias Zerhouni, Director, NIH

Dr. Zerhouni began by thanking Dr. Pettigrew for inviting him to attend the Advisory Council meeting. The Director of NIH mentioned current challenges faced by the NIH as a whole, including budgetary issues following the doubling of the NIH budget over the past five years, as well as how to continue the momentum gained in the research enterprise as a result of the doubling.

Dr. Zerhouni discussed the NIH Roadmap for Medical Research and the important role of NIBIB in the Roadmap initiatives. Consistent with its mission, the NIBIB should play a major role in bringing the physical and engineering sciences together with the life sciences to generate new ideas, opportunities, and hypotheses on how biological systems work. In concert with the Roadmap initiatives, the Institute must continue to support interdisciplinary and multidisciplinary research, as well as training for medical residents. The NIBIB has been a key participant in the molecular libraries and the molecular

imaging initiatives. NIBIB can also play a key role in bridging the gap between clinical and translational research.

Dr. Zerhouni and the members of the Advisory Council engaged in a question and answer session. Topics discussed included: the development of partnerships between NIH and other agencies to make tools and user facilities available for investigators; the development of a 5-year professional judgment budget for the NIBIB as requested by the House Appropriations Committee; how the NIBIB can leverage available resources both through the NIH Roadmap and through partnerships with other NIH Institutes and Centers; and role of NIBIB in moving technology advances to the bedside.

# VIII. Closing Remarks-Dr. Roderic Pettigrew

Dr. Pettigrew thanked Dr. Zerhouni for visiting with the Council. The meeting was closed for review of applications at 12:00 P.M.

# IX. 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).

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

Arlene Y. Chiu, Ph.D. Executive Secretary National Advisory Council for Biomedical Imaging and Bioengineering Director, Office of 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

The Council will consider these minutes at its next meeting. Corrections or notations will be incorporated in the minutes of that meeting.