

Roderic I. Pettigrew, Ph.D., M.D., Director
National Institute of Biomedical Imaging and Bioengineering
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Mr. Chairman and Members of the Committee:

I am pleased to present the Fiscal Year (FY) 2008 President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB). [The FY 2008 budget included \$300,463,000.]

BRIDGING THE PHYSICAL AND LIFE SCIENCES

The mission of the NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. A major focus of NIBIB is bridging the physical and life sciences in order to develop new biomedical technologies and methodologies that have a profound, positive impact on human health. Translating these technological breakthroughs from the bench to bedside is also a very important aspect of the NIBIB mission, and is demonstrated in some of the examples given below.

TRANSLATING TECHNOLOGY INTO PRACTICE

A Quantum Project to Treat Stroke

Ultimately, NIBIB seeks to translate technological advances into solutions that improve human health by reducing disease burden and enhancing quality of life. To accomplish this goal, NIBIB must be bold and far-reaching in generating some of its initiatives in order to more rapidly facilitate discoveries and translate them to clinical practice. NIBIB recently launched the Quantum Grants Program, which supports very high impact-high risk, interdisciplinary and transformative research focused on major biomedical problems. The goal of this program is to solve or dramatically improve a major, previously intractable medical problem through the development and application of new and/or emerging technologies. In this program, interdisciplinary teams of scientists will conduct collaborative research resulting in a prototype product, technology or procedure that promises to solve a significant healthcare problem, and that can be translated into clinical practice in an accelerated time frame. The first grant, awarded in September 2006, aims to develop a novel treatment for stroke, based on implantable units

that will lead to neurovascular regeneration of cerebral tissue. This is the first application that has as its target, a treatment for stroke that seeks to *restore functional tissue*.

Seeing and Treating Heart Arrhythmias

Heart arrhythmias are a major health problem. Atrial fibrillation in particular, a disorder found in about 2.2 million Americans, is a significant cause of stroke. This occurs when a blood clot forms in the fibrillating heart chamber and then breaks loose and travels to the brain. Minimally invasive surgery can be used to treat atrial fibrillation. However, the procedure is complicated and lengthy, often lasting many hours. NIBIB investigators are developing new imaging techniques that permit the abnormal electrical activity to be identified and mapped onto a patient specific image of the heart. This potentially permits the procedure to be done in one hour instead of six. Beyond the time saving, this approach could promise lower cost, decreased exposure to x-rays, greater success and fewer complications. The effort involves collaboration between radiologists, computer scientists, bioengineers, and cardiologists.

Addressing heart diseases of a medically underserved population is the central focus of the Jackson Heart Study. Along with the National Heart, Lung and Blood Institute, the National Center for Minority and Health Disparities, the NIBIB co-fund this study to assess risks factors for cardiovascular diseases, including diet, exercise, and co-morbidity factors such as diabetes and obesity.

Help for the Paralyzed

Paralyzed or “locked – in” individuals who retain normal cognitive function but are unable to move parts of their bodies to communicate now have a means of using the computer, based on interface technology developed by NIBIB grantees. Brain waves, detected by a skull cap with electrodes, are decoded and used to communicate with a computer. By simply thinking of the letters, the user can spell words on the computer. No interaction with the keyboard or a mouse is required. Over the past year, a team of neuroscientists has worked intensely to move such a system from the laboratory to home use. For one NIH-funded neuroscientist with late-stage amyotrophic lateral sclerosis (Lou Gehrig’s Disease), this device has enabled him to continue his research. “I couldn’t work

independently without it,” he wrote recently for an article posted on the NIBIB web site entitled “Brain-Computer Interfaces Come Home”.

NANOTECHNOLOGIES TO IMPROVE HEALTH CARE DELIVERY

Point of Care Systems

Empowering clinicians to make decisions at the bedside, or the point-of-care (POC), has the potential to profoundly impact health care delivery and also help address the challenges of health disparities. The success of a potential shift from curative to predictive, personalized and preemptive medicine could rely on the development of portable diagnostic and monitoring devices for near-patient testing. The NIBIB has contributed to advances in this area by funding the development of sensor and platform-based microsystem technologies. These instruments combine multiple analytical functions into self-contained, portable tabletop devices that can be used by non-specialists to rapidly detect and diagnose disease, and can enable the selection of a definitive therapy at the time of the visit to the physician. A prototypic example under development and funded by NIBIB can identify, from a single drop of urine, the DNA of the specific bacteria responsible for a given urinary tract infection. Moreover, this test can be completed in just a few minutes, compared to the 2 days often required by standard culture techniques.

A second example is in the area of improved diabetes control through non-invasive continuous glucose monitoring. Several NIBIB-funded researchers are working to engineer such a device. One has developed a contact lens that changes colors in response to the concentration of glucose in tears. The lens wearer can compare the color of the contact lens to a chart in order to determine his glucose concentration. If indicated, medications to control blood glucose, such as insulin, can then be administered.

NEXT GENERATION MINIMALLY-INVASIVE TECHNOLOGIES

Restoring Touch in Robot-assisted Surgery

Robot-assisted surgery is expanding the applications and reducing the complications of minimally invasive surgery. Nonetheless, this expansion has been inhibited due in part to a significant technical challenge. What’s still missing is a sense of touch. When

surgeons operate on their own, their hands provide important tactile feedback. Although all fields of surgery could benefit from tactile feedback, cardiac surgery is among the fields that have the most to gain. An NIBIB-funded research team is working closely with a cardiac surgeon to create a robotic system that delivers the touch sensitivity required. Because of the large number of sutures used, the delicate tissues involved, and the need for precise work, tactile feedback is essential in cardiac surgery. A robotic surgical system with tactile feedback could mean fewer broken sutures, force that is applied more consistently, and suture knots that hold. Such a system is now in development and could also serve as an important teaching tool. Rather than the current practice of teaching students on live patients, new surgeons could practice in the lab before performing live surgery. Using computer algorithms that recognize motion, a trainee's movements can also be compared to an expert's performance and assessed.

Non-Surgical Biopsy through New Approaches to Optical Imaging

The diagnosis of many conditions such as cancer depends on microscopic evaluation of tissue samples. Typically these samples go through a process of fixation and staining before they are looked at under a microscope in the pathology laboratory. NIBIB researchers have made significant progress in developing techniques to image tissue in place without the need for surgical biopsy, fixing, and staining. This new imaging approach makes use of innate fluorescent characteristics of normal and diseased tissue, and offers the potential for examining the tissue at the point of care, in the operating room or medical office. There are many potential human applications, including imaging tissues that form as a sheet such as the bladder or bowel lining. Physicists, biophysicists, imagers, engineers, biologists and clinicians are working together to advance this technology.

FEEDING AND SUSTAINING THE SCIENTIFIC TALENT PIPELINE

Interdisciplinary Training Programs

An important goal of the NIBIB is to train a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research. The Institute's proactive approach is to develop creative and flexible opportunities that will fill critical

gaps in the career continuum while also enhancing the participation of underrepresented populations. As examples, the NIBIB has a program to co-train basic and clinical investigators, a Residency Supplement Program to provide research experiences to clinical residents and fellows, and post doctoral support programs for interdisciplinary training to individual postdoctoral fellows.

The NIBIB also supports and participates in a number of programs to address gender and diversity issues in biomedical imaging and bioengineering. The NIBIB partners with the NSF in the University of Maryland, Baltimore County, Meyerhoff Scholarship Program alliance. This has been an exceptionally effective diversity honors program. Eighty-five percent of the 511 students who have graduated since 1993 have earned a science, technology, engineering, or math doctoral degree.

The NIBIB has also partnered with the Howard Hughes Medical Institute to support the HHMI-NIBIB Interfaces Initiative, a program to develop new curricula to train Ph.D.-MD level scientists at the interface of the physical and life sciences and give them the knowledge and skills needed to conduct research. Collectively, these programs will help to train a new generation of researchers equipped to better meet the challenges of the 21st Century.

Once trained, it is critical that we encourage those who aspire to be great scientists to pursue research careers. New investigators are the innovators of the future and their entry into the ranks of independent, NIBIB-funded researchers is essential to the health of the research enterprise. In addition, the recent closure of the Whitaker Foundation – a catalyst in the evolution of bioengineering as a forefront discipline – has left many in the scientific community concerned about new and early career investigators. For these reasons, the NIBIB is specifically targeting new investigators for special funding consideration. This policy has proved to be successful; in FY 2006 nearly one-third of the NIBIB-funded traditional research grant investigators were new NIH investigators. The NIBIB also participates in the trans-NIH “Pathways to Independence” program which will support recently trained scientists conducting independent, innovative research.