DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL ADVISORY COUNCIL FOR
BIOMEDICAL IMAGING AND BIOENGINEERING
STRATEGIC PLAN DEVELOPMENT SUBCOMMITTEE

Summary of Meeting
January 14, 2004

The third meeting of the Strategic Plan Development Subcommittee was convened at 9:00 a.m.. on January 14, 2004, in the Bethesda Marriott Hotel, Bethesda Maryland. Dr. Frank Yin, Chairperson presided.

Subcommittee members present:

Dr. Frank C. Yin
Dr. Carlo J. DeLuca
Dr. Norbert J. Pelc

Other Council members present

Dr. C. Douglas Maynard
Dr. Robert I. Grossman

NIBIB staff present:

Dr. Roderic Pettigrew
Dr. Belinda Seto
Dr. Joan Harmon
Dr. Bill Heetderks
Dr. Peter Moy
Dr. Peter Lyster
Dr. Patricia Sokolove
Ms. Colleen Guay-Broder
Dr. Chris Kelley
Dr. John Haller
Dr. Richard Swaja
Ms. Anna Retzke
Ms. Theresa Smith
Ms. Florence Turska
Ms. Sandra Talley
Dr. Yantian Zhang
Dr. Meredith Temple-O'Connor
Ms. Mary Beth Kester
Ms. Cheryl Fee
Ms. Mollie Sourwine
Ms. Nancy Curling

Other attendees:

Mr. David Leslie, Schmitt & Leslie, Inc.
Ms. Michelle Doose, Academy of Radiology Research
Mr. Andrew Hawkins, The Blue Sheet
Mr. Edward Nagy, Academy of Radiology Research

Dr. Roderic Pettigrew welcomed the participants, particularly members of the Council Subcommittee and thanked everyone for their willingness to support the National Institute of Biomedical Imaging and Bioengineering (NIBIB) in defining strategic directions. He expressed the hope that the discussions would result in a plan that will enable the Institute to have an impact on the national health care agenda.

As noted at previous Council meetings, interest in the Institute grows within the extramural community. Dr. Pettigrew stated that he continues to receive an increasing number of requests from organizations to speak on the goals and directions of the NIBIB. A most rewarding outcome of these events has been encounters with young scientists, who credit the establishment of the Institute, with its emphasis on combining technology and health care for their decision to pursue a career in research.

Dr. Pettigrew introduced Dr. Belinda Seto, the new NIBIB Deputy Director. Dr. Seto recently joined the NIBIB after many years in the Office of the Director, Office of Extramural Research (OER). Dr. Seto previously held the positions of Deputy Director and Acting Director, OER.

Dr. Pettigrew introduced Dr. Robert Grossman, the newest member of the National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB). Dr. Grossman is Chairman of Radiology at New York University and past Chairman of the Diagnostic Radiology Study Section at the NIH

Dr. Joan Harmon provided an overview of Federal regulations and policies governing the meeting. She noted that the meeting was organized under the authority of the Federal Advisory Committee Act and the Government in the Sunshine Act and reviewed conflict of interest procedures.

Mr. David Leslie, Schmitt & Leslie, Inc., will be the facilitator for the strategic planning process. Mr. Leslie reiterated that the purpose of the meeting was for the NIBIB Strategic Plan Working Group (SPWG) to receive input from the Council Subcommittee to aid in the development of the Institute's strategic plan. The SPWG is comprised of senior managers of the NIBIB, who will review the results of these discussions at a retreat in February.

Dr. William Heetderks thanked the members of the Subcommittee for coming. He reviewed some of the major goals of the Institute as outlined in the authorizing legislation:

- Advance the development of existing biomedical imaging and bioengineering technologies.
- Develop new techniques and devices.
- Related research in mathematics, physics, computer science, and engineering.
- Technology assessment and outcome studies.
- Research in screening for disease and disorders.
- Develop target-specific agents to enhance images and to identify and delineate diseases.
- Develop advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

- Develop new techniques and devices for more effective interventional procedures.

Dr. Heetderks highlighted recommendations from several earlier workshops.

NIBIB Workshop on Bioengineering and Biomedical Imaging Training (August 2002)

- Provide programs for institutional and individual training support.
- Support undergraduate and graduate programs, junior faculty fellowships, and research awards for untenured faculty.
- Develop a 1 year research training program for radiology residents and radiologists.
- Support "centers of training excellence."
- Support short-term faculty and student training courses.
- Interface the clinical sciences, basic sciences and industry in future NIBIB training initiatives.

NIBIB Workshop on Future Research Directions (December 2002)
Where can NIBIB have an impact on biomedical research in the next 5 to 10 years?

- New imaging modalities and instruments
- Biosensors, devices and probes
- Optical technologies
- Systems approaches, engineering and integration
- Cellular- and molecular-level imaging
- Image-guided interventions
- Prosthetics and artificial organs
- Regenerative medicine (including tissue engineering)
- Computational biology and predictive models
- Minimally invasive technologies

He also described the recently developed web page on the strategic plan as a mechanism for public input and emphasized that the NIBIB is interested in hearing from the scientific community, professional and voluntary organizations, patient organizations, and the general public. Issues on which the NIBIB is seeking broad public input include:

- Current research opportunities, needs and gaps in the NIBIB research portfolio.
- Scientific priorities and concerns of the research community, professional and voluntary organizations, patients and their families, and the general public for the future development of NIBIB programs.
- Emerging trends in science and technology development that may have major implications for future research and should be considered in the planning process.
- New and ongoing multidisciplinary and interdisciplinary collaborations that can be formed to further the NIBIB mission and improve the health of the public.
- Methods that would facilitate obtaining scientific and public input on an ongoing basis.
- Approaches for determining future investigator needs in NIBIB research areas and for ensuring that investigators are adequately trained and appropriately recruited.

- Approaches for enhancing liaisons with Federal agencies, industry, public and private organizations, communities, and investigators that have an interest in NIBIB research and research training and career development.
- Approaches for promoting diversity in NIBIB training and research.

Dr. Heetderks reviewed the outcome of a staff retreat held in February 2003. By 2008, the NIBIB will…

- Be the recognized leader in the development and application of breakthrough technologies and methods from science and engineering to establish a foundation for understanding complex biological processes and for changing the face of healthcare.
- Have established and implemented opportunities that facilitate and support interdisciplinary and interorganizational research collaborations that effectively address global healthcare and biology issues.
- Have developed and implemented interdisciplinary training opportunities that assure the availability of highly trained professionals to conduct the research and to realize the biomedical benefits available from multidisciplinary collaborations.
- Have developed and maintained relevant and effective programs by periodically assessing the performance of our grant portfolio relative to its impact on healthcare and biomedicine

Dr. Yin began the Council presentations. In developing input for today's session, Dr. Yin drew upon salient phrases in the NIH Roadmap:

New Pathways for Discovery

- Building Blocks
  - Develop radical new technologies
- Molecular Libraries
  - Speed development of next generation…
  - Improve detection sensitivity…
- Structural Biology
  - Create a picture of…
  - Find ways to deduce protein structure
- Bioinformatics and Computational Biology
  - Generate software and data development tools…
- Nanomedicine
  - Creation and use of materials and devices at molecular level…applications

Research Teams of the Future

- High Risk Research
  - Accelerate pace of discovery…
- Interdisciplinary Research
  - Training in interdisciplinary strategies…
  - New centers to forge new disciplines
- Public-Private Partnerships
  - Forward-looking conferences

Re-Engineering the Clinical Research Enterprise

- Adopt a systematic infrastructure…
- Increase interactions…
- New technologies for assessing clinical outcomes…

- Multidisciplinary research workforce

He reviewed the structure of the NIBIB and pointed out how the Scientific Divisions – Discovery Science, Applied Science, and Interdisciplinary Training – were well matched to the goals of the Roadmap. In developing the plan, the NIBIB should consider some overarching strategic issues. As a small Institute, the NIBIB should establish areas of research focus that are distinct from other Institutes and leverage the unique mission of supporting technology-centered research that is neither disease-specific nor necessarily hypothesis-driven.

Within this framework, the NIBIB will have to resolve several strategic issues, including: the mix of hypothesis-driven *versus* technology-driven grants; funding processes that will catalyze interdisciplinary research, supporting research teams that may geographically distant, and innovative training mechanisms to develop research teams rather than individuals, possibly using the National Science Foundation Interdisciplinary Graduate Education and Research Training program as a model.

Dr. Yin stated that three major goals of the Discovery Science and Technology Division should be the development of (1) tools for working with complex systems; (2) smart biomaterials to advance the field of regenerative medicine; and (3) biocomputers to function like cells and neurons. Significant priorities for the Applied Science and Technology Division should be support for (1) quantitative high-throughput methods that, for example, would precisely quantify levels of gene and protein expression; (2) improved methods of organizing, transmitting, storing and analyzing large amounts of data and protecting private personal information, such as genetic data; (3) the next generation of imaging modalities to enable the capability to look more deeply and precisely into cellular and molecular atomic processes; and (4) biosensors to accelerate the development of nanorobots and nanomachines.

In the ensuing discussion, it was agreed that NIBIB needed to support longer term projects focused on major innovations, such as those outlined by Dr. Yin, but the Institute also had to balance these needs with support for short-term technology application improvements that could register immediate improvements in health. Dr. Yin encouraged the NIBIB to leverage the unique characteristics of the Institute, such as the focus on technology development. NIBIB should also actively seek collaborations with industry and foundations. Discussion also centered on the best way to maximize the resources of the NIBIB and the initiation of the intramural research program.

Dr. Pettigrew stated that NIBIB aimed to reach the traditional NIH Institute budget distribution that allocates 80 percent of funds to extramural research, 10 percent to intramural research, and 10 percent to administration. He also noted that the Intramural Division would focus on a few areas not currently represented within other intramural labs, such as nanotechnology.

Dr. Carlo De Luca began his presentation by stating that the strategic plan should create an identity for the NIBIB and validate the reasons for the creation of the Institute. NIBIB's identity could center on technologies not heavily supported by other Institutes. Other Subcommittee members agreed on the significance of "identity," possibly to be defined by: (1) a unique research agenda, focused on a few critical areas of technology

development; (2) success in applying these technologies in patient populations; (3) a world-class intramural program recognized as the sole training resource for a few research areas; and (4) the success of the investigators supported by the NIBIB.

Dr. De Luca stated that the NIBIB was established to bring forth new technology. To achieve this goal, the NIIBIB could be distinct from other Institutes in how it funds technology, modifying, for example, the Small Business Innovative Research award to be more responsive to the small business community.

Dr. De Luca defined the second major goal for the NIBIB as facilitating the introduction of technology into society. The Institute could establish a mechanism to support further development of prototype technologies by industry for the benefit of society, possibly through public-private partnerships.

Dr. Norbert Pelc outlined his views on the scientific goals of the Institute. He endorsed the NIBIB's chosen focus on technology development and previous comments on the need to balance support for longer-term projects and those that may have a more immediate impact on human health, possibly within a 3 to 5 year time frame. Projects supported by the NIBIB should have an impact on public health.

Among the strategic issues confronting the NIBIB is the need to demonstrate success to the public in the near term. Dr. Pelc expressed concern that NIBIB's current budget does not provide funding for all highly-rated projects. Thus far, NIBIB has had a major impact, bringing in new investigators and providing support for projects that would not fit within the mission of other Institutes. However, he is concerned that NIBIB will not be able to sustain this momentum with the current budget projected growth rate. Dr. Pelc offered several strategies to manage these limited resources.

In supporting technology development, Dr. Pelc suggested that NIBIB favor the incubation stage of projects over the refinement stage, leaving these latter projects and large clinical trials for disease-oriented Institutes. Through a shared funding strategy, the NIBIB could support small and large companies in moving a device through the early stages of development, when technical hurdles or market assessments must be overcome.

Dr Pelc agreed with the need to establish partnerships with other agencies, nonprofits, and scientific societies to develop training programs. Research could be sponsored in collaboration with other agencies and liaisons with industry would facilitate the introduction of technologies into society.

Dr. Pelc stated that training programs should target pre-doctoral students through early faculty, possibly employing novel mechanism to address interdisciplinary needs. Training programs should be sustainable to have a long-term impact, recognizing that the success of the Institute will be measured in part by the individuals supported through training grants.

To realize the Institute's goals, Dr. Pelc encouraged the NIBIB to publicize its priorities to potential grantees and NIH study sections, thus ensuring that the Institute receives applications consistent with these goals. An Intramural program could adopt priorities not well represented in applications received from the extramural community.

Dr. Douglas Maynard, chairman of the NACBIB Subcommittee on Training and Career Development, presented on the training aspect of the strategic plan. He expressed the view that NIBIB should devote a large percentage of funding to training, because well-trained investigators are the source of new ideas. He noted that there is a vast shortage of clinician scientists, who will be essential to bringing new technologies to the health care system. With the closing of the Whitaker Foundation, there will be a shortage of funds to train the next generation of basic scientists, including biomedical engineers, chemists and computational mathematicians. In keeping with the NIH Roadmap emphasis on interdisciplinary research, the NIBIB must develop investigators ready to work in these environments. The NIBIB should communicate to the extramural community that training is a top priority for the Institute.

Dr. Maynard stated that it is important to have an intramural training program that interfaces with existing programs in other Institutes and agencies. This program could provide opportunities for students and faculty from universities without the capacity to support research training.

Dr. Maynard noted that there is a need to focus on improving infrastructure. For example, industry could partner in creating several animal-imaging facilities around the country for use by researchers from universities and private companies.

Dr Robert Grossman re-iterated the importance of public interest in the mission of the NIBIB. The public is most interested in disease-specific research and the NIBIB must relate the technology developments to improvements in health care.

Dr. Yin summarized the major points of each presentation and the salient points of the ensuing discussion. Subcommittee members agreed that the day had been very productive and that it was very useful to hear the opinions of others. Staff thanked the Subcommittee for the valuable insights and offered comments on the day's discussions.

Dr. Pettigrew concluded the meeting by thanking the group for the high quality of the discussion. He expressed the confidence that the NIBIB will demonstrate its utility to the Nation by supporting research that will have a major impact on health. NIBIB is unique among NIH Institutes in supporting the kind of technological innovation that will drive medical progress. Moving forward, the Institute faces a challenge in balancing the large growth in applications with the limited resources that will likely be available. NIBIB is pursuing partnerships with other agencies

Dr. Pettigrew stated that the staff would review the materials presented today over the next several months and emerge with a strategic plan for Council review.

The meeting adjourned at approximately 3:00 P.M.

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

/s/
Joan T. Harmon, Ph.D.
Executive Secretary
National Advisory Council for Biomedical Imaging and Bioengineering
Director
Office of Extramural Policy
National Institute of Biomedical Imaging and Bioengineering

/s/
Roderic I. Pettigrew, Ph. D., M.D.
Chairperson
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The Council will consider these minutes at its next meeting. Corrections or notations will be incorporated in the minutes of that meeting.