

**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
September 11, 2003**

The second meeting of the Strategic Plan Development Subcommittee was convened at 8:15 A.M. on September 11, 2003, in conference room 6, Building 31, NIH campus. Dr. Frank Yin, chairperson presided.

Committee members present:

Dr. Frank C. Yin
Dr. Janie M. Fouke
Dr. Carlo J. DeLuca
Dr. Barbara J. McNeil
Dr. Norbert J. Pelc

Other Council members present

Dr. James G. Smirniotopoulos
Dr. Michael W. Weiner
Dr. Arden Bement
Dr. Esin Gulari
Dr. John Livengood

NIBIB staff present:

Dr. Roderic Pettigrew
Dr. Joan Harmon
Dr. Bill Heetderks
Ms. Colleen Guay-Broder
Dr. Peter Moy
Dr. Chris Kelley
Dr. Mary Pastel
Dr. Edward Staab
Dr. Peter Kirchner
Ms. Mary Beth Keester
Ms. Cheryl Fee

Other attendees:

Mr. David Leslie, Schmitt & Leslie, Inc.

Dr. Frank Yin opened the meeting with a review of discussions at the May 2003 meeting. The Subcommittee decided, at this meeting, that the roll of the Council Subcommittee on Strategic Plan Development would be to advise the staff on the process and offer feedback on the document prepared by the staff of NIBIB. Dr. Yin announced that this meeting would be devoted to a discussion of the process.

Staff reviewed federal regulations that would guide this meeting, including the Government in the Sunshine Act and the Federal Advisory Committee Act. It was noted

that Subcommittee meetings are announced in the *Federal Register* and are open to the public.

The Subcommittee accepted the minutes from the May 2003 meeting without changes.

Staff provided the Subcommittee with a listing of seventeen broad research areas and subtopics represented in the NIBIB portfolio:

- Mathematical Modeling, Simulation and Analysis
- Drug and Gene Delivery
- Advanced Biomaterials
- Biosensors/Bioinstrumentation
- Tissue Engineering
- Medical Devices
- Image-Guided Therapies and Interventions
- Magnetic Resonance Imaging and Spectroscopy
- Ultrasonics
- X-ray, Electron Microscopy, and Ion Beam Technologies
- Optical Imaging and Spectroscopy
- Nuclear Medicine
- Imaging Agents and Molecular Probes
- Image Processing, Displays, Perception
- Magnetic/Biomagnetic/Bioelectric
- Bioinformatics
- Platform Technologies

Staff noted that the distribution of grants among these categories reflects the recent large transfer of grants from other NIH Institutes into the NIBIB. When applications in response to the ten fiscal year 2003 Requests for Applications are funded following this Council meeting, the distribution will probably change.

As requested by the Subcommittee at the May 2003 meeting, the staff provided an update on the NIH Small Business Innovative Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program. The SBIR program was established in 1982 by the Small Business Innovative Development Act of 1982 and requires all federal agencies with extramural research and development budgets of over \$100 million to set aside 2.5 percent of their budgets for the program. The Small Business Technology Transfer Act of 1992 created the STTR program to be funded by a 0.15 percent budget allocation in Federal agencies with extramural research and development budgets of over \$1 billion. This set-aside will increase to 0.3 percent in fiscal year 2004.

As was communicated to Council at the May 2003 meeting, roughly a third of grant applications received by the NIBIB continue to be for the SBIR program, compared with between 7 and 10 percent for other Institutes at the NIH. The 2.5 percent set-aside is not sufficient to fund a reasonable number of the meritorious applications. Between one third and one half of NIBIB's SBIR applicants identified themselves as new to the NIH. More than half of the applications were unsolicited or not in response to an NIH announcement. Placement at the NIBIB occurred due to applicant preference or to assignment by the NIH Center for Scientific Review. Currently funded SBIR applications are well distributed across the NIBIB portfolio, with a significant number in nuclear medicine,

platform technologies, image processing and image-guided therapies. Although it is anticipated that this distribution will change when applications from fiscal year 2003 initiatives are funded, Council should consider whether SBIR grants fill any significant gaps in the NIBIB portfolio. In response to a request from the Subcommittee for elaboration on how the portfolio would change, staff committed to provide details in January once decisions had been finalized regarding applications in this review round.

In accordance with instructions from the President, the meeting paused at 8:46 AM for a moment of silence in remembrance of the victims of September 11, 2001.

Staff described four strategies to increase support for SBIR applications submitted to the NIBIB:

1. Transfer applications to other Institutes for funding or obtain additional SBIR funds from other Institutes through a fund transfer.
2. Attempt to change the policy on distribution of the total NIH SBIR set-aside among Institutes, providing more funds to Institutes receiving higher volume of applications.
3. Augment SBIR/STTR program with funds from the RPG portion of the NIBIB budget
4. Fund only to the statutory program limit.

Strategy (1), employed in fiscal year 2003, successfully supported only 10 of 27 SBIR grants that merited funding and approach (2) cannot be accomplished in a short time frame. Staff, therefore, requested that Council provide advice on options (3) and (4). During discussion, Council stated that more information was needed, before advice could be offered on either option. Council also suggested that staff may want to focus more on disparate outcomes, as staff has suggested that the likelihood of funding for an individual application varies based on the assigned Institute.

As requested by the Subcommittee in May 2003, the staff reported on progress in establishing an Intramural Division. With initial funding for the Division included in the President's budget for fiscal year 2004, the NIBIB has just begun the planning process, which will be an integral part of the overall Institute strategic plan. Staff envisions that the Division will complement extramural programs and collaborate with other NIH Intramural Divisions and other Federal agencies, such as the National Institute of Standards and Technology.

During this pilot phase, the Institute will seek out seasoned investigators with established programs that already have allocated laboratory space in NIH facilities, as available space is extremely limited on the NIH campus. Consistent with this approach, the staff is working on the administrative transfer of a highly productive PET research group from the NIH Clinical Center to the NIBIB. Staff also just completed a workshop on tissue engineering to determine potential priority areas. The NIBIB has established a Council working Group on Intramural to advise throughout the planning process.

Turning to the strategic planning process, the staff described current expectations, expected results, and some general ideas on the scope of the plan.

The planning process has seven phases:

- I. Getting Organized – Hire an outside consultant to lead the process and develop internal staff structure to carry out the planning.
- II. Data Gathering – Obtain input from extramural community and sort and analyze data.
- III. Develop draft plan – The NIBIB working group will draft the plan.
- IV. Solicit feedback – Through letters to stakeholders, web page, presentations to advisory groups.
- V. Refine the plan based on the feedback.
- VI. Last Round of Feedback – repeat of phase IV
- VII. Publish and Implement – Develop a standard document or consider one that includes information on science and technology advances and how technology has improved health.

Staff suggested a timetable for the above activities that would produce a final document in January 2005.

Dr. Yin provided a summary of steps taken by five other NIH Institutes to develop a strategic plan. The National Institute on Deafness and Communication Disorders organized one meeting involving stakeholders and produced a draft plan within less than a year. The National Center for Research Resources published a draft plan for public comment, organized a meeting of stakeholders to review the materials, and completed several focused workshops to feed into a final document. The National Institute of Diabetes and Digestive and Kidney Diseases established four working groups of scientists, staff and the public to provide input for its plan. The National Human Genome Research Institute brought together a large number of stakeholders to kick off and conclude its process, with a series of focused workshops in the intervening months. The National Heart, Lung, and Blood Institute devoted two years to a multi-phase process involving meetings and input from scientists, staff, the Institute's advisory bodies, and other stakeholders before producing a five-year plan.

Dr. Yin requested that members offer feedback on these sample processes, as well as suggestions on the process outlined by staff. He also asked that members consider the balance of targeted versus unsolicited in the NIBIB portfolio and the proportion of budget funds that the NIBIB should allocate to SBIR grants in light of material presented at the meeting today.

A brief discussion followed. Council offered that the process of engaging various stakeholders in developing the plan would be more important than the final document because of the additional awareness and support for the Institute that may flow from such an exchange. It was emphasized that the process should be iterative accommodating ongoing feedback from the extramural community. Staff provided Council additional information on how other NIH Institutes use the strategic plan to bring together a broad range of constituents and to guide the development of initiatives. Council noted that this first plan would, in many ways, define the Institute.

In response to the process outlined by staff, Council strongly suggested that Subcommittee members have input much earlier than the phase proposed by staff. For example, staff could organize a retreat for Council, staff, and previous workshop

participants to focus effort on the development of the first draft document. Council could also assist staff in identifying stakeholders.

Subcommittee members ultimately endorsed the process, but voiced concerns about not having sufficient time to thoughtfully consider the proposal, as none of the materials presented were provided to Council prior to the meeting.

The meeting adjourned at approximately 9:45 A.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
Office of Science Administration
National Institute of Biomedical
Imaging and Bioengineering

/s/

Roderic I. Pettigrew, Ph. D., M.D.
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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.