

MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman

Welcome to the second issue of the PPP Advisor. The focus in this second issue is a bit more general than in the first—The BIO 2008 meeting has come and gone, with a robust showing by The Biomarkers Consortium and lots of new interest in the FNIH and the NIH PPP Program; our first AAAS Fellow has completed a year learning about PPPs and has moved on to her next stage; and we continue to develop new ideas for partnerships that respond to NIH interests as well as to those of potential outside partners. In this issue you will read about our efforts to help focus a new “Science of Health” and to fashion a broadly based partnership around this notion. We are also closing out what proved to be a summer of wonderful weather and many activities. We have been busy fielding questions and reviewing documents and agreements



Dr. Barbara B. Mittleman

from many NIH ICs about specific partnerships. We have begun a series of visits to the Directors of all of the ICs to see what the ICs need and want, as well as to introduce ourselves and the PPP Program resources. We also used the summer to totally revamp the PPP Program Web site as well as to develop some nifty new materials, including

a brochure and a folder with informational inserts (to be published very soon), and we have put the new logo on every paper object we can think of.

As the summer ends and we move into September, PPP Coordinating Committee (PPPCC) meetings resume with a visit from a U.S. Department of State representative to discuss international partnerships. Future discussions will include the SBIR program and how to write an RFA so that future PPPs can be anticipated while meeting the ICs’ goals, and there will

SPOTLIGHT

Did you know? The PPP Program Web site (<http://ppp.od.nih.gov>) has been totally revamped! We are pleased to announce that we have a new look as well as updated and new information. Some of the new features include:

The banner has been changed to show our new PPP “branding” for the PPP Program, with the new PPP logo using dark and light blue colors. Detailed information has been added about the Program and its resources and capabilities. All of the pages have been rewritten, and we have added many new Web pages.

The PPP Information section gives an overview of the NIH Public-Private Partnerships Program including the new *PPP Program Focus Areas* Web page, which describes the resources and services provided to potential partners to facilitate relationships to develop partnerships as well as provide general practical assistance.

The new *Value Proposition* page addresses the advantages and challenges of a PPP design and implementation and describes the value proposition for potential partners, each according to the organization’s own missions and goals. Also on this page we introduce basic PPP principles and requirements, partner roles and responsibilities, the flow of resources, and definition of policies relevant to PPPs.

The new *PPP Authorities* page reaffirms that the basis on which NIH engages in PPPs is the same as the basis for all the other NIH activities: There is no new PPP Authority! Also described here are the authorities relevant to PPPs and how the Foundation for the NIH or another foundation can serve as a helpful partner in appropriate situations.

The new *Steps to Developing a PPP with NIH* page describes the processes necessary to start and develop a PPP and how the PPP Program staff can help you through every action.

Please visit us at <http://ppp.od.nih.gov>!

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be visits from representatives of several companies. We are also hoping for presentations from representatives of other Federal Government agencies on their new offices of innovative programs and partnerships. As presenters come to NIH to speak to the PPPCC, we also try to arrange individual meetings with the ICs to promote the development of tailored partnerships that meet IC scientific goals. We are always on the lookout for informative and engaging speakers to bring to the PPPCC. We also are welcoming some new members to the PPPCC, as ICs identify how best to make use of the information shared at these meetings or as staff turnover takes its toll.

We continue to take the PPP “show” “on the road,” making presentations to the Advisory Council to the NIH Director and the NIH Office of Portfolio Analysis and Strategic Initiatives’ Council of Councils and in discussions with Merck, GE, the Semiconductor Research Corporation Board, the Montgomery County Council President, Johns Hopkins University at Shady Grove, and the Institute of Medicine Drug Forum. More presentations by all of the PPP program staff are scheduled for the months to come, and we will keep you posted about what develops as a result of initiating such conversations and contacts.

As always, we are here to serve as a resource to the NIH community and to potential outside partners, so please do not hesitate to let us know what you need or to call for information or advice. We are always open to suggestions about how we can meet your needs more effectively. ❖

PPP PROGRAM STAFF

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EXPERIENCES OF AN AAAS SCIENCE AND TECHNOLOGY POLICY FELLOW AT THE NIH PPP PROGRAM

Dr. Eliane Schnirman Lessner

There are two questions an American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellow is asked for the duration of his/her fellowship: Where are you located, and how do you like it? After a few instances, one goes on autopilot and answers the first question in the long format (to avoid having to spell what the Office initials stand for—and it did take me a long time to say “NIH Public-Private Partnerships (PPP) Program” without stumbling) and the second question in the enthusiastic “I am enjoying it very much” format. I am now at the end of the fellowship year and felt this to be the proper time to give the second question serious final consideration.

I am a theoretical physicist and spent 20 years at two national laboratories. I first worked at Fermi National Laboratory and then at Argonne National Laboratory (ANL). During those years, I worked in a broad range of areas, from modeling complex nonlinear phenomena, to beam dynamics and simulations of large systems, to engineering applications

of technical developments. Examples of my work include a major risk assessment project for a state-of-the-art heavy-ion accelerator, from conceptual phase to recommendations for design options to achieve high machine availability; the establishment of the best beam-capture and acceleration parameters for a high-intensity high-frequency synchrotron; and development of methods to mitigate high-current effects in the Advanced Photon Source accelerator complex, the world’s most brilliant source of x-rays.

Throughout my career, I have been involved in scientific organizations addressing policy issues, in outreach programs and events promoting science to young students, and in extensive contributions to the development of new or expanded opportunities to advance scientific and technical women and members of diversity groups. As a spokesperson for the scientific and technical women staff

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EXPERIENCES OF AN AAAS SCIENCE AND TECHNOLOGY POLICY FELLOW AT THE NIH PPP PROGRAM (CONTINUED FROM PAGE 2)

members at ANL, I facilitated effective communication among the scientific women on staff and between women and laboratory management. I have played a leadership role in issues pertaining to scientific integrity and in promoting networking among the ANL staff and am a member elected to the Committee on the Status of Women in Physics, whose function is to encourage the recruitment, retention, and career development of women physicists at all levels.

A long-term interest in policy issues led me to apply for the AAAS fellowship. My interest, background, and strength in multidisciplinary subjects led me to accept a position in the PPP Program, where, among other functions, I would work to develop and implement a PPP centered on nanotechnology and biomedical sciences.

My fellowship experience has been remarkable: I have enjoyed my time at NIH and came to admire the sense of mission that distinguishes the institution in general but particularly the mission of the PPP Program. The challenges have been manifold: My background is not in biomedical sciences, and, last but not least, I always worked with an overwhelming majority of men, never in an all-women group (the male/female ratio for physicists is about 15%, compared with almost 50% for biological scientists). There is definitely a different dynamic in a predominantly female work group that is quite pleasant without sacrificing efficiency.

My activities and responsibilities included, but were not limited to, acquiring knowledge of policies, procedures, laws, and scientific priorities relevant to PPPs and developing skills relevant to PPP organization, development, and implementation. As part of the Program's general activities, I helped redesign and update the PPP Program Web site and initialize the form and contents of the PPP Program newsletter and brochure and served as the Executive Secretary of the PPP Coordinating Committee (PPPCC). The PPPCC is a trans-NIH group comprising representatives from all Institutes and Centers plus the Office of the Director offices. Its agenda is to broadly educate the NIH community about PPP policy and practice, identify new opportunities, and share best practices. I also sought to engage partners within and outside the Federal Government to participate in NIH nano activities. By reaching out to former associates, combined with the strong network provided by the AAAS fellowship, I was able to establish contacts with several government agencies to explore partnership possibilities with NIH in bionanotechnology.

It was an intense year, during which I developed communication, negotiation, and leadership skills through activities involving teamwork and professional collaborations. I can perhaps best describe the evolution of my PPP knowledge by the amount of information I am able to take away from meetings attended. Whereas in the beginning I spent a lot of effort trying to understand the meeting purpose, I am now able to follow the meeting's general flow, its currents and undercurrents, the role assumed by each participant, and the outcomes, which may be quite different from the initial goal. I am also much more aware of my supervisor's abilities to direct the meeting trajectory: That is what I want to be able to do when I grow up.

Finally, as a scientist who spent a long time studying the evolution of physical systems, I cannot avoid the comparison



Dr. Eliane Schnirman Lessner

between the chaos theory that essentially describes nonlinear phenomena and the dynamics of partnerships. The behavior of both nonlinear physical systems and partnerships as a whole cannot be described by the simple decomposition of its parts (i.e., the total is not the sum of its components). The later performance of the system/partnership is dependent on the initial conditions: for the former, for instance, on the initial energy state; for the latter, on the parameters the participants bring to the partnership, defined by their history and experiences. Both are deterministic, following prescribed trajectories, but are not stable: The final state or outcome may be far from the initial assumptions, and the trajectory may wander a lot from the initial goal. It takes a great deal of work/energy to maintain the system in a stable condition.

I could not end this article without thanking PPP Program staff members for their support, especially Dr. Barbara Mittleman, whose guidance, humor, and knowledge of basins of attraction helped me to thoroughly enjoy my fellowship tenure. ❖

THE BIOMARKERS CONSORTIUM: "SPOTLIGHT AT BIO 2008"

Dr. Shawnmarie Mayrand-Chung

In an effort to increase visibility and participation, The Biomarkers Consortium (BC) was highlighted at the Foundation for the NIH (FNIH)-sponsored two-part supersession at the recent 2008 BIO International Convention in San Diego, June 17-20. Geared toward industry and academic leaders, this supersession explored new collaborative research models, transformation of the biomarker research paradigm, and acceleration in solving the critical health challenges of the 21st century.

The supersession featured two panel presentations: "Accelerating the Identification and Development of Biomarkers for Human Health Through Public-Private Partnerships" and "The Promise and Progress of The



Biomarkers Consortium Exhibit at BIO 2008, San Diego, CA, June 2008. Photo courtesy of FNIH.

Biomarkers Consortium." Both sessions were well attended, with over 200 attendees at each session. David Wholley, M.A. (Director, The Biomarkers Consortium, Foundation for the National Institutes of Health), moderated the

first session, which described public-private partnerships in biomarkers under way in the United States and Europe and provided research, development, and regulatory perspectives on the challenges involved. Panel participants included:

- Thomas Insel, M.D., Director, National Institute of Mental Health
- Garry Neil, M.D., Corporate Vice President, Corporate Office of Science and Technology, Johnson & Johnson
- Irene Norstedt, M.Sc., Head of Sector Innovative Medicines, European Commission, Directorate General for Research
- ShaAvhree Buckman, M.D., Ph.D., Acting Director, Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

The BC also used this supersession to unveil a new proactive approach for the identification of High-Impact Biomarker Opportunities (HIBOs) in an effort to identify biomarker projects that are crosscutting and overarch multiple therapeutic areas.

The second supersession presentation focused on the specific strategies and progress of the BC in addressing cancer biomarkers. Several significant projects that promise to develop, improve, and standardize both biochemical and imaging biomarkers in different cancers and to integrate biomarkers into innovative trial designs were presented and discussed. Dr. Anna Barker, Deputy Director, Strategic Scientific Initiatives, National Cancer Institute (NCI), moderated this session. Speakers included:

- Jeff Evelhoch, Ph.D., Executive Director, Medical Sciences, Imaging Sciences, Amgen
- Joe Gray, Ph.D., Professor of Laboratory Medicine and Radiation Oncology, University of California, San Francisco, and Director, Division of Life Sciences, Lawrence Berkeley National Laboratory
- Gary Kelloff, M.D., Special Advisor, Cancer Imaging Program, NCI

FNIH also hosted a booth in the Exhibit Hall where BC staff members, including Shawnmarie Mayrand-Chung (who serves both from the NIH side as the NIH Program Director from the BC as well as working part time with FNIH as Senior Advisor to the Consortium), were available to discuss the BC with BIO meeting participants.

The FNIH and NIH presence at the BIO meeting, both in the biomarkers supersession and at the exhibit booth, generated tremendous excitement about the BC. The BC's potential for creating fundamental change in how health care research and medical product developments are conducted is enhanced by bringing together leaders from the biotechnology and pharmaceutical industries, government, academia, and nonprofit organizations to work together to accelerate the identification, development, and regulatory acceptance of biomarkers. ❖

"The FNIH and NIH presence at the BIO meeting, both in the biomarkers supersession and at the exhibit booth, generated tremendous excitement about the BC."

NEWS FROM CLINICAL RESEARCH PARTNERSHIPS

Dr. Wendy B. Smith

As we continue to explore common interests in many of the emerging areas, we will share news as these develop. In this issue: an update on the Science of Health.

As modern medicine has evolved, the treatment of chronic illness has become a primary focus. State-of-the-art care provision will require an expansion of our health care system to address not only disease management but also prevention. An additional shift to include the importance of maintaining health and wellness takes this approach one step further—not just avoiding illness but also enhancing well-being, with or without the presence of disease. Although the word “health” is commonly bandied about in many contexts and for many purposes, there is no universally shared definition; a knowledge base describing various health states in ways that can be compared is lacking, and methodologies to study health lag far behind those directed toward the study of illness.

Research on how people’s individual, community, and world environments shape and influence not only their risks for illness but also their resilience to disease is critical to understanding how to best provide both preventive and treatment-oriented health care. An

individual’s intrinsic risks, strengths, and propensities (e.g., genetics, genomics) as well as previous experiences, exposures, and history all contribute to the likelihood of maintaining wellness. These factors include physical behaviors (nutrition, exercise, diet, etc.), psychological characteristics (resilience, coping strategies), and personality characteristics—any of which may affect one’s health status. Community factors, including relationships between individuals and others (social support, families, communication and relationships with health care providers) all may impact the ability to stay well and, when illness does occur, to experience that illness in as “healthy” a way as possible. Political and economic factors such as access to care, quality of care, and socioeconomic factors also impact the individual’s ability to maintain wellness. Technologies and infrastructure to enhance the ability to work in coordinated teams and include hard-to-reach populations in a wellness system are also critical for the health of the public. The relationships between the individual and the physical world (i.e., one’s immediate natural and built-in environment, including local and larger community and the world) may influence health status as well.

These include such factors as pollution, climate, etc. Research to gain a rigorous and nuanced understanding of these complex and interacting factors to inform health care decision-making is a critical need so that we can ultimately enhance our ability to maintain wellness, promote health, and, when ill, receive both medical treatment and medical care.

The movement from a perspective of prevention of illness to preservation of wellness/promotion of health and the recognition of the need for clear definitions, a robust scientific knowledge base, and the development of appropriate methodological approaches provide the underlying basis for building a science of health.

We are currently exploring interest in these areas and look forward to continuing to develop topics of shared interest with our NIH colleagues and the private sector. Current ideas under discussion are to hold a scientific meeting to address the challenges and approaches that would help develop the science of health, along with a strategic plan for implementation and/or working with outside entities whose missions dovetail with the research mission of the NIH. ❖

THE PPPCC: TWO YEARS IN REVIEW

Dr. Eliane Schnirman Lessner, Marjorie A. Bonorden, Dr. Barbara B. Mittleman

The Public-Private Partnership Coordinating Committee (PPPCC) is a trans-NIH committee with representation from all 27 Institutes and Centers (ICs) as well as a number of representatives from the NIH Office of the Director. The goals of the PPPCC are to:

- Serve as a bidirectional communication venue between the PPP Program and the ICs
- Bring in and disseminate new and relevant information and models for PPPs
- Provide focused guidance for the NIH staff regarding development and implementation of public-private partnerships (PPP)

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THE PPPCC: TWO YEARS IN REVIEW (CONTINUED FROM PAGE 5)

The group meets monthly, and speakers from within and outside NIH have represented a wide range of organizations and topics. Following are highlights of PPPCC meetings during the first 2 years of its existence:

At the PPPCC **June 2006** inaugural meeting, members summarized their experiences with PPPs and what they wanted to learn from one another as well as from outside speakers.

At the **September 2006** meeting, Ms. Annette Levey, NIH Office of the General Counsel (OGC), provided an overview of the laws, regulations, and statutes underlying NIH's ability to engage in PPPs and guidance about when and how to involve OGC in setting up the agreements necessary to implement a PPP. Dr. Anna Barker, NIH National Cancer Institute (NCI), gave a presentation on NCI partnership activities and experiences. Dr. Bonny Harbinger, NIH Office of Technology Transfer (OTT) (representing the PPP Manual Chapter Working Group), led a discussion on the draft PPP Manual Chapter.

In **October 2006**, Dr. John McGowan, NIH National Institute of Allergy and Infectious Diseases (NIAID), gave an overview of partnership models engaged by NIAID, and Dr. Barbara Mittleman, Director of the Public-Private Partnerships Program (PPPP), discussed The (then brand-new) Biomarkers Consortium (BC), a PPP involving the U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Pharmaceutical Research and Manufacturers of America (PhRMA), and Biotechnology Industry Organization (BIO). The goal of the BC is to promote the discovery, development, and qualification of biomarkers. Dr. Stacy Carrington-Lawrence (PPPP) and Mr. Richard Barnes, NIH Center for Information Technology, presented the PPP Intranet site, which was created to serve as a resource for accessing documents such as meeting minutes and materials and the calendar and dates of interest to the PPPCC.

At the **December 2006** meeting, Ms. Janis Mullaney, Foundation for the National Institutes of Health (FNIH) liaison to NIH, and other FNIH staff members provided a description of the Foundation and described how FNIH approaches and implements PPPs.

In **January 2007** Dr. Gayle Lester, NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, gave a presentation on the Osteoarthritis Initiative (OAI). The OAI is a PPP between NIH and industry in which FNIH raises funds and manages donor relations, leading to the funding of a multisite NIH contract to create a resource to hasten the discovery of biological markers for osteoarthritis.

In **March 2007** Darrick Fu, M.B.A., Associate Vice President of Scientific and Regulatory Affairs, PhRMA, gave an overview of the PhRMA PPP program. PhRMA is a trade association whose primary role is to serve industry members, including pursuing collaborative approaches to implementing ideas and resolving issues. Involving PhRMA (as an organization) to identify potential partners among the individual companies that make up its membership allows efficiency and precludes NIH ICs avoiding "playing favorites" among companies.

At the **April 2007** meeting, Dr. Flora Katz, NIH Fogarty International Center (FIC), talked about the International Cooperative Biodiversity Groups (ICBG) partnership models. ICBG comprises groups addressing bioexploration and discovery, scientific and economic development, biodiversity, and conservation issues. FIC is an important component of NIH activities on the international level, and ICs can benefit from understanding how FIC works and how they can be involved when international partnerships are contemplated.

The **February and May 2007** meetings included a two-part discussion by Dr. Laura Rodriguez, NIH National Human Genome Research Institute (NHGRI), and Ms. Annette Levey (OGC) about the Genetic Association Information Network (GAIN). GAIN is a PPP among NIH, FNIH, and Pfizer, Affymetrix, Perlegen, and other companies, which was formed to provide genotyping for common diseases such as schizophrenia, diabetic nephropathy, ADHD, bipolar illness, psoriasis, and depression. GAIN illustrates how parallel activities by an outside partnership (sequencing) can complement NIH activities (formation of a database for whole-genome scan data and phenotype data), with NIH oversight of the ethical aspects of the project.

During the **June 2007** meeting, Mr. Ken Davidian, National Aeronautics and Space Administration (NASA), discussed the prizes awarded by NASA to solve specific engineering challenges, including the collection of lunar regolith, plans for improvement in the gloves worn by astronauts as part of their spacesuits, and other specific needs. Although NIH does not

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THE PPPCC: TWO YEARS IN REVIEW (CONTINUED FROM PAGE 6)

currently have prize authority, this is an interesting model to spur innovative work to solve specific scientific problems or address needs.

The **September 2007** meeting focused on the discussion by Mr. Joe Ellis, NIH Office of Policy for Extramural Research Administration (OPERA), “Non-Federal Support of Extramural Grant Initiatives,” with emphasis on defining the roles and rights of outside entities providing support for NIH extramural funding initiatives or leveraging the NIH peer review system to support decision-making for the outside organization’s independent awards. This policy is undergoing clearance for publication as a Manual of Issuance Chapter.

At the **October 2007** meeting, Dr. Shawnmarie Mayrand-Chung (PPPP) provided an update on the BC, pointing out its many new activities, among them a newly convened Infection and Immunity Steering Committee. Dr. William Martin, NIH National Institute of Environmental Health Sciences (NIEHS), presented an overview of the Head-off Environmental Asthma in Louisiana (HEAL) Project, a collaborative research project conducted by Tulane University and the New Orleans Department of Health to learn about the effects of mold and other indoor allergens on children with asthma in post-Katrina New Orleans. He also commented briefly on the NIEHS-sponsored “GEH Forum: How Partnerships Overcome Barriers to Improve Global Environmental Health” held on September 28, 2007 at the Cloisters.

The **November 2007** meeting featured two presentations. Dr. Bonny Harbinger (OTT) talked about “Technology Transfer—The NIH Experience,” and Dr. Shawnmarie Mayrand-Chung (PPPP) gave an “Update on The Biomarkers Consortium.”

At the **December 2007** meeting, JoAnne Goodnight, NIH Office of Extramural Research, talked about a proposal for a database for unfunded grant research whose goal is to increase and expand health research to improve public health.

At the **January 2008** meeting, Ms. Annette Levey (OGC) discussed the fundamentals and importance of Memorandums of Understanding (MOUs), with attention to language that is binding, the need to cite NIH authorities, and the importance of identifying the appropriate signatories for each partner. This is relevant to PPPs in that they are memorialized in MOUs.

At the **February 2008** meeting, Ms. Elaine Ayres, PPP Coordinator for the NIH Clinical Center (CC), discussed a PPP between CC and the Bravewell Collaborative that supports a fellowship program in integrative medicine. Dr. Anthony Suffredini, CC Critical Care Medicine Department, discussed a proposal for a PPP to distribute endotoxin as a tool for clinical investigation. This is an opportunity for NIH to leverage its ability to develop and produce resources for scientific research beyond its walls.

Dr. Altaf Carim, Office of Basic Sciences, U.S. Department of Energy (DOE), and Co-Chair of the Nanoscale Science and Technology Subcommittee of the National Nanoscale Initiative, presented information at the **March 2008** meeting about DOE’s user facilities, in particular those dedicated to nanoscale research. One of the aims of the meeting was to introduce DOE’s facilities to NIH, so that NIH researchers can get to know those facilities and use them to their best advantage.

At the **May 2008** meeting, Dr. Michael Hehenberger, Global Solutions Executive, IBM Corporation, discussed his company’s perspectives on partnerships and other issues of interest to NIH. In particular, he talked about the impact of PPPs on biomarker-based pharmaceutical research and development.

The final meeting before the summer break was held on **June 19, 2008**. Dr. Dan Herr, Semiconductor Research Corporation, talked about opportunities for PPPs with the semiconductor industry, and Dr. Piotr Grodzinski, NCI Alliance for Nanotechnology in Cancer, gave an update on nanoscience activities at NIH. Dr. Barbara Mittleman (PPPP) distributed the brand-new PPP Program brochure, highlighting the Program’s mission, focus areas, and staff. She also presented the first edition of the PPP Advisor, the PPP Program’s newsletter featuring articles about the Program’s activities as well as articles relevant to partnership issues.

The next meeting will take place on **September 18, 2008**, when Dr. Jay L. Benforado, U.S. Department of State (DOS), will talk about the DOS Sustainable Development Program and its mission, current partnerships, and collaboration with the United Nations Commission on Sustainable Development. ❖

Visit us at <http://ppp.od.nih.gov>

LOOKING FOR PPP INFORMATION?

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for future *PPP Advisor* articles/
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CALENDAR

DATE	MEETING	TIME	LOCATION	SPEAKER	SUBJECT
9.18.08	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 31/ Rm 6C6	Jay L. Benforado, U.S. Department of State	Sustainable Development Partnerships
10.16.08	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 31/ Rm 6C6	JoAnne Goodnight, NIH SBIR/ STTR Program Coordinator, OD/OER/OEP	SBIR/STTR Changes

Please check the PPP Web site for updates and additions.

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NIH PUBLICATIONS
No. 08-6531
PRINTED SEPTEMBER 2008