PUBLIC-PRIVATE PARTNERSHIPS PROGRAM

PPP ADVISOR

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WELCOME *to NIH's newsletter on public-private partnerships. The mission of the NIH Program on Public-Private Partnerships (PPPs) is to facilitate collaborations to improve public health through biomedical research.*

MESSAGE FROM THE DIRECTOR

INTRODUCING PUBLIC-PRIVATE PARTNERSHIPS

Dr. Barbara B. Mittleman

Collaboration between and among scientists is not new and is one of the great joys in doing science. By working together, we can share knowledge, skills, reagents, data, and more. Sometimes these collaborations cross institutional or organizational lines and require specific legal agreements to allow them to proceed. This can be straightforward, for example, when a Materials Transfer Agreement (MTA) is sufficient. More complex relationships for clinical trials are defined within Clinical Trials Agreements (CTAs), and agreements permitting specific terms and conditions for intellectual property disposition are Cooperative Research and Development Agreements (CRADAs). MTAs, CTAs, and CRADAs are technology transfer instruments, with law and policy defining how and when they can be used and under what circumstances, and can be utilized with help from the Technology Development Coordinators in each Institute and Center (IC). What to do when technology transfer does not apply to your relationship or plan? That's when a public-private partnership (PPP) may be the way to go!

PPPs vary a great deal in format and focus and can include a variety of partners. A PPP can have a single outside partner or many. A PPP can be about a single well-defined project or activity or include a way to do many related projects over a long time. Partners can be from the for-profit private sector but can also include academics and academic institutions, professional societies, trade organizations, philanthropic foundations and individuals, and advocacy organizations. Other Federal agencies can participate and the U.S. Food and Drug Administration is a frequent partner in NIH PPPs.

Partners can contribute a lot to helping NIH and NIH ICs meet our missions. Partners can be very smart, have useful knowledge and perspective, provide access to reagents and technologies and analytics to which NIH does not otherwise have access, provide access to patient populations or samples or data, provide financial contributions, and more. NIH contributes smart people, unique technologies and reagents, and platforms and analytics, and access to unique patient populations or samples or data. The aim in working together within a PPP is to achieve a synergy that allows the work to be accomplished better and/or faster and/or cheaper than it would if any one partner engaged in it alone. To meet NIH's goals, PPP work must always be driven by the science and by the public health benefit.

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The NIH Program on Public-Private Partnerships (PPP) is pleased to announce the first issue of its quarterly newsletter. The PPP Program represents an important aspect of the NIH Roadmap and resides within the Office of the NIH Director, in the Office of Science Policy, as a reflection of its overarching potential relevance to all NIH ICs and scientific programs and of the expectation that cross-disciplinary and cross-sector science will be of increasing interest and importance over time. This edition of the PPP newsletter provides a special focus on The Biomarkers Consortium (BC).

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Introducing PPPs (continued from page 1)

With any project, the devil is in the details, and there are a great many details in making a PPP. From the start, it is critically important to define the roles of each partner and what that partner will contribute. How intellectual property will be handled, what will happen to data and samples brought into the project as well as those developed during the conduct of the project, policies for publication or permitting public access to data and samples, policies covering antitrust issues when relevant, how conflicts of interest among the organizations and individuals participating in the PPP are handled, and so on, must all be defined at the outset of the PPP. These issues are complex, require knowledge and skills not usual among scientists, and represent the possibility of making some important mistakes. The role of the Public-Private Partnership Program is to help make partnerships possible by helping to identify the right partners both inside and outside NIH; by developing and implementing useful policies relevant to PPPs; and by working with the NIH IC staff to work out the details of specific individual partnerships. We also develop resources for NIH staff to reference and coordinate the engagement of other NIH resources such as the Office of the General Counsel to make partnerships happen.

Call us, we're friendly! We'll help you think through what you need to make your partnerships succeed, and we'll help you make it happen!❖

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The Biomarkers Consortium

Introducing Dr. Shawnmarie Mayrand-Chung

The Public-Private Partnership (PPP) Program provides resources that allow NIH investigators to leverage Federal resources through the formation of partnerships. One such partnership is The Biomarkers Consortium (BC), a unique partnership among FDA, NIH, and industry serving the individual missions of each organization while focusing on biomarkers, an area of alignment of the interests of all the Consortium's participants.

The NIH contact for The Biomarkers Consortium is Shawnmarie Mayrand-Chung, Ph.D., J.D., who is trained and experienced as both an immunologist and a patent attorney. She serves as the NIH Program Director for the BC and works within the PPP Program. This position provides a unique vantage point to work with both NIH investigators on biomarker-related projects and with the Foundation for the NIH (the managing partner of the BC). Dr. Mayrand-Chung can serve as an effective bridge to move NIH-related biomarkers research forward via cross-sector, precompetitive, and synergistic efforts involving a variety of resources not available within the NIH alone.

With so many partners and covering biomarker discovery, development, and qualification across the entire field of biomedical research, the BC is complex in its structure. Current activities span the fields of neuroscience, oncology, inflammation and immunity, and metabolic diseases, although projects outside these areas are also open for consideration and support. Questions are often raised about just how to participate in the BC. In Dr. Mayrand-Chung's role as its NIH Program Director, *she can help NIH-ers navigate the BC!*

Dr. Mayrand-Chung is always available to answer questions about the BC or to review a potential project submission. As the coordinator for the NIH's BC-related efforts, she can provide information and help you decide whether your research may be a good match for the BC. *So…bring your ideas for biomarkers research and come see her!*❖

Clinical Research Partnerships

Introducing Dr. Wendy B. Smith

As the Public-Private Partnership (PPP) Program recognizes the importance of bringing basic scientific discovery to clinical translation, the newest focus of the program is on clinical research topics. In Dr. Wendy Smith's role as the NIH Program Director for Clinical Research Partnerships, she will focus on the development, design, and implementation of partnerships for translational and clinical research and clinical trials. Since this effort is in its infancy, we will use this space to introduce Dr. Smith, but in future months you will hear directly from Dr. Smith as she reports on clinical research PPPs as the clinical partnership effort coalesces.

Dr. Smith joined the PPP Program in early 2008 from the Director's Office of the National Cancer Institute (NCI), where she led the exploration of public-private partnerships in integrative medicine. She is a licensed experimental psychologist and came to the NIH in 1990 to conduct clinical research on pain. She then joined the NCI in 2000 as the first Deputy Director of its Office of Cancer Complementary and Alternative Medicine, where she also served as Director of the Research Development and Support Program.

Having been at NIH for almost 20 years, Dr. Smith has gone from conducting clinical research and patient care to leading the creation of many new scientific programs. She also witnessed firsthand the promise and potential benefits of partnering with other government and nongovernment groups to further our scientific mission. She is excited to be a part of the PPP Program and is here to help others navigate the sometimes complex system in order to reach their goals. As part of the PPP Program, she will work with any and all of the NIH Institutes and Centers, NIH and extramural scientists, academic medical centers, industry, and philanthropy, among others, on partnerships relevant to patient care. The common goal is to improve public health through rigorous science. Some of the specific partnerships under exploration and development include partnerships focused on the science of health and wellness, integrative medicine, patient-reported outcomes, and the use of technology to improve health.

"Some of the specific partnerships under exploration and development include partnerships focused on the science of health and wellness, integrative medicine, patient-reported outcomes, and the use of technology to improve health."

She looks forward to hearing your ideas and sharing news of the clinical partnerships as they develop in the future. For further information or to explore the development of new clinical partnerships, please contact Dr. Smith at (301) 443-YPPP (9777).❖

Emergent Partnerships: *The Nexus of Biomedical Science and Nanotechnology*

Dr. Eliane Schnirman Lessner

Richard Feynman in his famous "there is plenty of room at the bottom"[1] speech in 1959, talked about the possibilities and problems of manipulating and controlling things on a small scale. It took almost 30 years for the "nanotechnology revolution" to happen, when the development of high-precision tools such as the scanning tunnel microscope and the atomic force microscope made the control of matter at the nanometer scale possible. Considered the translational technology of the 21st century, nanotechnology can create new materials or produce faster, lighter, better performing versions of existing materials. It is precisely the combination of appropriate tools and the proper exploration of the "unusual" properties of materials at the nanoscale that allow the wealth of innovations in chemistry, materials science, biology, and medicine.

At the nanoscale, the large ratio of an object's surface area to its volume becomes dominant, leading to different properties of matter, thereby increasing, for example, the ability of "silver nanoparticles" to fight infection. The intersection of nanoscience, nanotechnology, and biology is enabling the development of methods and devices that can lead to better drug-delivery systems, better and faster

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Emergent Partnerships: The Nexus of Biomedical Science and Nanotechnology (continued from page 3)

determination of the molecular signature of diseases, and better understanding of biological processes. Together, these can transform biomedical research and health care delivery with novel developments in prevention, diagnostics, and therapeutics.

NIH has the research tools and human capital that make us uniquely positioned to lead the bionanoscience and bionanotechnology enterprises. Some current NIH-supported efforts include targeted drug delivery, detection, imaging, and surveillance at the nanoscale in living cells; imaging in real time; organ-tissue nanoengineering; and tissue regeneration. Research leading to the understanding of interactions of nanoparticles with living systems and the corresponding risk assessment of potential human and environmental harmful effects of nanomaterials are of critical importance and reflect the unique mission and strengths of the NIH.

Nanoscience is intrinsically multidisciplinary, and understanding and exploiting nano-associated tools and technologies are broadly interesting to many sectors and parties, including industries such as aerospace, semiconductors, chemicals and coating, pharmaceuticals, and others; policy and public advocacy groups; government agencies such as the U.S. Environmental Protection Agency (EPA), U.S. Department of Defense, National Institute for Occupational Safety and Health, U.S. Food and Drug Administration (FDA), and others; and many NIH ICs. A public-private partnership (PPP) offers an ideal vehicle to further advance nanoscience and nano-related risk assessment programs focusing on safety and toxicology. The National Institute of Environmental Health Sciences and National Institute of Biomedical Imaging and Bioengineering are spearheading a developing NIH PPP, the NanoHealth and Safety Enterprise. Two of its strategic goals are to promote rapid, safe, and targeted development of nanomaterials and to facilitate risk assessment. Possible partners are the FDA, EPA, public advocates, and industry.

"The Program on Public-Private Partnerships is ready and able to help with identifying possible partners and developing nano-related PPP structure(s) and policies."

Other of the multifaceted aspects of bionanoscience and bionanotechnology, such as dedicated nano delivery systems, medical nanodevices, and tools to accelerate the development of molecular technologies, are also areas of strategic interest to NIH.[2] The Public-Private Partnership Program is ready and able to help with identifying possible partners and developing nano-related PPP structure(s) and policies.❖

[1]*http://www.zyvex.com/nanotech/feynman.html*
[2]*Reference: Report of the Trans-NIH Nanotechnology Task Force (TF) to the Director, NIH*

Up and Running: The Biomarkers Consortium

Dr. Shawnmarie Mayrand-Chung

Now that The Biomarkers Consortium (BC) is nearly 2 years old, it is time for an interim report on this unique effort in which industry, government, academia, and public/patients advocates can work together. We all know that biomarkers have the potential to streamline and even revolutionize research of pathobiology, conduct of clinical trials, and regulatory decision-making for drugs and therapeutics. This promise serves as the foundation and impetus for the BC, a novel public-private partnership initiated in October 2006.

The idea for the BC began with PhRMA, the trade organization for the pharmaceutical industry. The need for robust and meaningful biomarkers, well characterized for use and widely available to all, was self-evident and was shared with regulators (FDA) and scientists (NIH). The BC capitalizes on the strengths of the individual partner organizations and brings everyone together in an effort to discover, develop, and qualify biomarkers to support new drug development, preventive medicine, and medical diagnostics.

NIH, FDA, and industry (PhRMA) are founding members working together to develop and execute biomarkers research. Each organization has a distinct mission and therefore a

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Up and Running: *The Biomarkers Consortium*

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distinct need for biomarkers, but the need is acute for each of the partners.

The value proposition for NIH lies within the agency's mission to improve the public health through biomedical research. The scope of the research undertaken within the NIH's 27 Institutes and Centers ranges from basic mechanistic work to late-phase clinical trials and includes everything between. Biomarkers serve as indicators of biological mechanisms and probes for pathobiological processes and may also serve to bridge animal models of disease with human disease and provide tools for translational research. Biomarkers in the setting of clinical research allow for the detailed characterization of patients and stratification of subjects on clinical trials, and can demonstrate evidence of the effect of study interventions. And finally, biomarkers will provide useful and novel tools for clinical decision-making.

Currently four approved projects are under way by the BC, including two projects being conducted by the National Cancer Institute (NCI) that involve studying the use of FDG-PET as a biomarker for clinical trials conducted in non-Hodgkin's lymphoma and non-small cell lung cancer; an evaluative study looking at the utility of adiponectin as a biomarker predictive of glycemic efficacy – by pooling existing clinical trial data from previously conducted studies carried out by four pharmaceutical companies; and a carotid MRI reproducibility study – being conducted as a substudy to the AIMHIGH (Atherothrombosis Intervention in Metabolic Syndrome with Low HDL-Cholesterol/High Triglyceride and Impact on Global Health Outcomes) study ongoing through the National Heart, Lung, and Blood Institute.

"This is an invaluable opportunity to have scientific experts from industry, government, academia, and public/patients advocacy groups working together to design and carry out cutting-edge biomarkers research."

In addition to the BC projects under way, there are also approved project concepts in the areas of circulating tumor cells (prostate cancer), Alzheimer's disease, Parkinson's disease, depression, and rheumatoid arthritis and breast cancer, just to name a few.

For all involved in the BC, this multisector initiative provides the benefit of access to resources, both financial and in-kind, that may not otherwise be possible. This is an invaluable opportunity to have scientific experts from industry, government, academia, and public/patients advocacy groups working together to design and carry out cutting-edge biomarkers research.❖

NIH Perspective: *The Biomarkers Consortium*

Dr. Shawnmarie Mayrand-Chung

As you have read above in the articles about The Biomarkers Consortium (BC) and about my role as the NIH Program Director for the NIH BC, the BC is a complex partnership with a diverse set of partners, so what is the unique role of the NIH in the BC? The Consortium's founding partners are the National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), and Pharmaceutical Research and Manufacturers of America (PhRMA).

Founding partners have a special place in the BC, with a responsibility and right to be represented on every Steering Committee and Project Team as well as in the governing Executive Committee.

Additional partners represent the Centers for Medicare & Medicaid Services, biopharmaceutical companies and trade organizations, patient and professional groups, and the public, and partners in all categories share a common goal, using biomarkers to hasten the development and implementation of effective interventions for health and fighting disease.

Operations of the BC are managed by the Foundation for the NIH (FNIH), a free-standing charitable foundation with a congressionally mandated mission to support the research mission of the NIH. As managing partner, the FNIH is responsible for coordinating both the funding and administrative aspects of the BC and staffs the Executive Committee, Steering Committee, and Project Team members with respect to BC operations.

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NIH Perspective: *The Biomarkers Consortium*

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The BC is structured in three tiers: an Executive Committee represents both founding partners and stakeholders, sets BC policy, and makes decisions regarding operations and projects of the BC. Subject matter Steering Committees oversee the development and implementation of projects that, in turn, are implemented by dedicated Project Teams, which always include NIH participation. Finding the right NIH participants, briefing them regarding relevant NIH policy and practice, and coordinating IC awareness of the BC are jobs of the NIH PPP Program.

BC policies have been developed through a multisector process of discussion and negotiation and apply to all BC activities. Policies address BC behavior regarding intellectual property, conflicts of interest, grants and contracts (that are awarded by the BC, i.e., not government grants and contracts), data sharing and data access, and so on. Briefing NIH participants in the BC regarding BC policy is primarily the role of FNIH, but the PPP Program helps to apprise NIH participants of how BC policy and government policy dovetail.

The NIH PPP Program worked closely with FNIH and the other founding partners to draft the governing policies and procedures for the BC and continues to play an integral role in the development of the BC as well as the implementation and execution of BC projects through regular staff level meetings, by supporting scientific participation in the Steering Committees and Project Teams as well as supporting the three IC Directors who represent NIH on the Executive Committee.

The BC accommodates a number of varied and discrete projects, each devoted to biomarker discovery, qualification, and/or use in targeted areas of disease-related biomedical and clinical science. Projects can be proposed by anyone—members of the BC, academics, patient advocates, and the public—and are developed and implemented according to their scientific merit, public health need and opportunity, and availability of support and funding. Soliciting and coordinating NIH proposals to the BC for new project concepts and for new project plans is also a job of the NIH PPP Program. As projects are developed into highly specific project plans, the PPP Program also coordinates input from NIH's Office of the General Counsel and Office of Technology Transfer, as well as, when needed, the Ethics Counsel, Human Subjects Protections input, and so on to ensure that the details of each project comport with NIH policies and Federal law.

Should any of the founding partners perceive a project concept or plan to be outside their own mission or outside the mission of the BC, founding members can exert a veto on the project's inclusion in the BC. This ensures that the needs and interests of founding members are well represented in all BC activities. No vetoes have occurred to date, but this assurance is built into BC policies.

The NIH is committed to the growth and success of the BC. To promote the success of the BC, Dr. Shawnmarie Mayrand-Chung has joined NIH's PPP Program staff to serve as NIH Program Director for the BC. In this role, she works closely with NIH Institute and Center staff involved in or interested in the BC and serves as an interface between BC staff at the FNIH and NIH representatives to the BC's Executive Committee, Steering Committee, and Project Team members. To better facilitate communication and coordination with FNIH BC staff, Dr. Mayrand-Chung has recently begun a part-time detail to the FNIH as Senior Advisor to the BC, further cementing the intimate relationship between NIH and FNIH around the BC.

To date, the Executive Committee of the BC has approved about a dozen project concepts for development. Two projects are already under way to examine the role of the imaging modality FDG-PET in lung cancer and in lymphoma and are conducted as supplements to ongoing NIH-sponsored trials. Images from both trials will be put into an NCI image bank and are broadly available for research use. A third project, managed by FNIH and initiated in April 2008, focuses on the role of adiponectin in assessing treatment responsiveness in Type II diabetes. This project is novel because it provides a means for several companies to pool and jointly analyze datasets to answer a question of more general interest. Upcoming is a fourth project, also supplementing an ongoing NIH trial, AIMHIGH, assessing the utility of carotid MRI as a biomarker in cardiovascular disease. Project Teams for the remainder of the approved project concepts are working to develop detailed project plans for future funding and implementation.

The past year has been exciting for the development of the BC and has brought about some changes as well. In January of this year, the Executive Committee decided to adopt a proactive approach to identify projects characterized as "high-impact biomarker initiatives" (HIBOs), which will be rapidly feasible and a productive use of biomarker information. Through this

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NIH Perspective: *The Biomarkers Consortium*

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effort, the Executive Committee is in the process of selecting and implementing three to five HIBOs for the BC. This new focused approach will be highlighted at the BIO International Meeting in San Diego in June 2008, a comprehensive meeting of the biotechnology industry during which the BC will be spotlighted as the focus of a daylong Super Session.

So, in summary, the BC is moving into a new phase of implementation and growth, accepting project ideas via the original process; initiating new, highly focused projects; and collecting and synthesizing data from ongoing projects. The BC is evidence of a new culture of cross-sector collaboration and partnership that will rapidly, economically, and collaboratively accomplish the partners' shared goals to increase the availability and utility of biomarkers in all areas of biomedical science. The NIH's commitment to leveraging resources to provide synergy via PPPs; the PPP Program's focus on effective PPP development and management from the NIH standpoint; and the dedicated efforts of Dr. Mayrand-Chung will all serve to support the progress of biomarker discovery, development, and qualification through the FNIH-managed Biomarkers Consortium.

For further information or to develop new biomarker projects within the NIH ICs, please contact Dr. Shawnmarie Mayrand-Chung at (301) 443-YPPP (9777).❖

The PPP Program Purpose and Value Proposition

Dr. Barbara B. Mittleman

A public-private partnership (PPP) is a partnership between the public and private sectors to perform a specific project or task that takes advantage of what each sector does best. PPPs offer many advantages but can be challenging to design and implement. It is necessary to find the basis for alignment in missions and business or operating principles among the partners.

The NIH PPP Program is the coordinating body between NIH Institutes and non-NIH sectors. The program provides mechanisms to conduct collaborative tasks with other government agencies, non-government organizations, or industry, by acting as a centralized source of policies, procedures, and information, and by providing guidance. The PPP Program creates a framework for a comprehensive program by helping to establish shared goals, priorities, and strategies, and provides the opportunity for each individual partner to leverage the resources of all participating partners. The program can help to form and to structure partnerships that maximize leverage of resources, respond to scientific needs, and ensure NIH's public mission. It can provide a variety of partnership models, identify potential partners, and coordinate the information and resources necessary to the implementation and development of partnerships. The program also offers synergistic, leverage NIH resources and ensures that partnership agreements are compliant with Federal law, regulations, and policies. In addition, it strives to ensure that the principles of benefit to the public health, open access to data, and inclusiveness and fairness are observed.

An NIH PPP offers an array of advantages:

- For the public—better, safer, more effective, cheaper and more rapid prevention, diagnosis, treatment, or cure.
- For the Federal government—leverage resources to accomplish its mission in a better, faster, and cheaper manner.
- For the academic—availability of more resources to do science; and availability of better tools to provide patient care.
- For industry—access to the best resources of the Federal government and other sectors, and the opportunity for partial investment for total outcome.

The program helps to identify areas of overlap and alignment of goals and objectives and to reconcile diverse practices and modus operandi to minimize significant cultural and operational differences among partners while maintaining NIH's guidelines of development of public resources, promotion of the principles of inclusivity and fair access, protection of human subjects, and promotion of public dissemination of NIH discoveries and intellectual property (IP).❖

Visit us at **http://ppp.od.nih.gov**

Looking for PPP information?

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Calendar

Date	Meeting	Time	Location	Speaker	Subject
6.19.08	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 1/Rm 151	Piotr Grodzinski	Nano at NIH: Update
				Daniel Herr, Semiconductor Research Corporation	Synergistic PPP Research Opportunities
9.18.08	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 1/Rm 151	Jay L. Benforado, U.S. Department of State	Sustainable Development Partnerships

**Please note: There are no scheduled meetings for July and August, but they will resume on September 18, 2008.*

PPPs for Synergy and the Public Health

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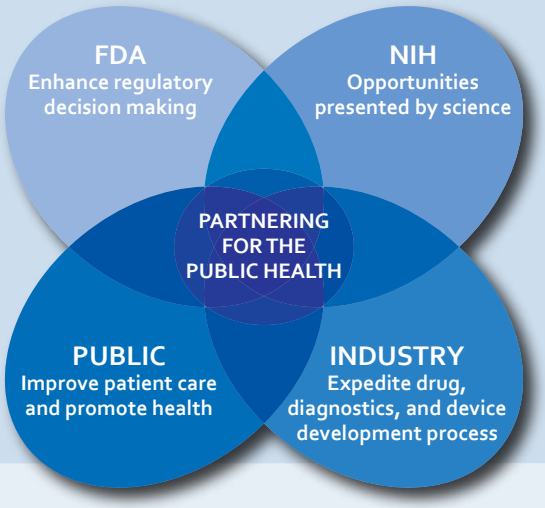

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