October 6, 2003

sent via electronic mail to

Office of Science and Technology Policy 1650 Pennsylvania Avenue, N.W. Washington, D.C. 20502

ATTENTION: Michael J. Holland

SUBJECT: NSTC Research Business Models Comments

Dear Mike:

I am pleased to provide Stanford University's response to the August 6, 2003 Federal Register notice requesting input for the OSTP Subcommittee on Research Business Models. We understand that this new subcommittee will review the policies, procedures and plans related to the business relationship between federal agencies and research performers with the goal of improving performance and management of federally funded sponsored basic and applied scientific and engineering research.

In preparation of our response, Stanford solicited comments from approximately 60 key members of our research enterprise, including research deans, principal investigators, and research administrators. Input was provided via written comment, individual interview, and through two facilitated campus sessions. The latter were designed to permit researchers and research administrators to jointly articulate a desired future state of research and to identify strategies to help us move closer to that desired state. Major barriers impeding federally funded research were also catalogued.

Overall, much of the feedback provided by the Stanford Research community echo recommendations found in the Presidential Review Directive – 4 report. While some recommendations from that report have already been implemented, many remain to be fully achieved. We suggest that the PRD-4 serve as a key resource for the Subcommittee to identify those principles and action items of critical importance to the university research community. We also suggest that the subcommittee take advantage of the work of the Federal Demonstration Partnership (FDP) and, in particular, the FDP Initiative to Reduce Administrative Burden (IRAB) Task Force.

The areas of opportunity identified by Stanford as most critical to address include the following:

(1) Create Articulated Principles for Research Partnership

While recognizing the value of a diverse funding community, we nonetheless see the lack of underlying business principles as a significant obstacle to an effective partnership. At the present time, no common underlying agreement exists among federal agencies, the audit community, and the university research community defining the acceptable principles and business standards for the conduct of research. This deficiency is reflected in such areas as the lack of an overarching principle governing the overall reimbursement of costs for research; in the lack of agreement as to the standards or norms against which an institution is audited; in the extraordinary diversity among federal agencies in proposal, peer review, and award business practices, terms and conditions and interpretation of requirements; complexities surrounding F&A rate negotiations; varying interpretations concerning the dual roles of students; and in the disagreements about what constitutes acceptable mechanisms to allocate costs, to name just a few.

This lack of agreement results both in tremendous effort for investigators, program officers and grant and contract officials to track and enforce the myriad of requirements, and results in uncertainty on the part of researchers and university administrative officials about what constitutes an appropriate level of compliance. Faculty can feel they are personally at risk as they try to decide the appropriate level of compliance, which results in their spending significant time on identifying (often small) alternative fund sources to cover less routine research costs, or in moving their research portfolio to the private sector as a way to avoid perceived financial or other risk. The lack of clarity makes it profoundly difficult for an institution to accurately analyze and correct areas of deficiency, and to foster an appropriate balance between meaningful and material compliance and a responsive, flexible research enterprise.

To address this core issue, we recommend:

- A. The federal government, working in close collaboration with the University research community, should formalize the key underlying principles governing the federal government/university research partnership (e.g, in a new OMB Circular, "A1-The Principles of Research Partnership.) This document should leverage the excellent work contained in the PRD-4 and its successor clarifications to OMB A-21.
- B. Federal and inter-university research policies, practices, and standards should be aligned with these principles. New federal policies or standards should be reviewed before they are adopted to ensure that they are in conformance with these principles. Existing federal circulars, policies and practices should be reviewed and adjusted within a reasonable period of time. This effort should leverage the work of the FDP, particularly its "Initiative to Reduce Administrative Burden" Task Force, COGR, and as the national research professional organizations (NCURA, SRA, NPMA, etc.), who are well positioned to provide leadership in the area of development and assessment of inter-organizational standards.
- C. Agency and institutional best practices, norms and standard interpretations built on these principles should be developed by federal agencies, university business partners, national research administration organizations (e.g., FDP, COGR, NCURA, SRA) and the audit community, and broadly disseminated.
- (2) Refine Approach to Research Facility, Instrumentation and Infrastructure Support In the performance of research, scientists are increasingly dependent on complex, multimillion dollar instrumentation that is smaller than the neutron, synchrotron radiation or high energy facilities. This instrumentation is usually shared by many investigators from a broad range of scientific fields who are supported by several different federal agencies. They are aided by scientists and/or technicians who are dedicated to maintaining and improving these experimental systems in an effort to assure that they are used well, well maintained, constantly at the state-of-the art. This is a highly efficient way of using such instrumentation that federal policies and practices should encourage. Unfortunately, funding to support such research infrastructure is limited, particularly at this mid-range level. Existing research business models for such major instrumentation, joint-use facilities, and laboratory renewal are limited and, at times, serve as a deterrent for collaboration and sharing of vital research resources. "Service Center" models for major facilities do not allow for adequate fiscal planning for stability, evolution or replacement, and audit-worthy business models for allocating acquisition, use, and ongoing maintenance costs among multiple investigators have proven to be impractical in all but the most simple sorts of cases. As multi-investigator and cross-organizational research increase, this issue is expected to become of even greater concern.

Our recommendations are as follows:

A. Federal funding agencies, and university business partners should work together to create new policies, practices and business arrangements that will foster the development, use and continuous improvement of shared facilities/equipment (rather than focusing on accounting for their use). Federal funding agencies and universities should recognize the importance of their joint role in maintaining stable, accessible, state-of-the-art research infrastructures in the university community, (including facilities, equipment, and core technical personnel) and should evaluate whether their business practices can be modified to better support this need (e.g., development and ongoing maintenance/infrastructure support for regional large scale instrumentation or core facilities; allocation of core funding for shared facility costs and corresponding decrease in the precision of cost allocation to individual research projects; change in service center requirements; stable funding for students during their graduate tenure; university policies that encourage outside academic use of government funded instrumentation; development of attractive career ladders and stable funding for key technical personnel, etc.) The business arrangements should be piloted through the FDP and, if successful, should be broadly implemented.

(3) Administrative Support for Researchers

The cap on recovery of indirect administrative costs, coupled with the prohibition on direct charging of administrative costs that are directly related to the research, is causing faculty and other researchers to spend considerable time on administrative tasks. Most of these tasks could be performed better by administrative assistants trained to perform them. This would leave the researchers more time for research and enhance the productivity of the research enterprise.

Our recommendations are as follows:

A. OMB Circular A-21 should be modified to allow the direct charging of administrative services directly linked to the performance of the research. The research enterprise is best served when researchers are conducting research, and administrators are providing skilled project oversight support for their researchers. A reasonable and allocable amount of administrative support should be able to be direct charged to federal projects. The best way for the federal government to limit administrative costs and to provide a stable, competent research enterprise is not to prevent administrative costs from being direct charged to projects, nor or to cap their reimbursement as indirect cost items, but rather to simplify and streamline requirements so that the oversight of research can be conducted more efficiently.

(4) Research at the Borders of Disciplines and Agencies

Some of the most important and exciting modern research is at the borders of the disciplines and of the individual agencies' responsibilities. Investigators seeking to acquire federal funding for such endeavors must be knowledgeable about a host of different individual agency missions and business practices, peer review preferences, and funding parameters (often tied to single-investigator/single-project and "big science" projects.) They find, in addition, that the sophistication of the peer review process varies among agencies tremendously, as well. Both the federal government and the universities must continue to refine their methods of dealing with this, while recognizing the importance of keeping the disciplines strong and that some agencies funding research have specific missions.

Consequently, we recommend that:

A. Federal agencies should re-examine and eliminate existing barriers (political and practical) for projects that transcend disciplines and specific agency missions. Business models should be developed that would facilitate cross-agency support and minimize the amount of time that researchers are required to devote to administrative activities (e.g., implementation of common

- proposal submission requirements across agencies, development of common expectations about co-PIs, implementation of a single set of terms and conditions governing a portfolio of awards, common reporting requirements, etc.)
- B. Federal agencies and universities should work together to become more sophisticated and science-focused in their research administration practices. A "stable" of administrative mechanisms and expectations should be developed and deployed based on the unique needs present in each type of project (e.g., individual investigator-led project; individual investigator with a portfolio of projects; multiple investigators working on a single project, joint funding of a project by multiple funding sources (including non-federal) funding a single initiative, or "big-science").
- C. Federal agencies and universities should consider whether "mid-size" science (usually multi-investigator) is adequately supported. Funding for mid-size projects (\$500K \$1M/year) either involving several investigators in a single area or cross-disciplines, or projects involving two or several investigators in complementary but connected areas is difficult to find, and agency personnel seem hesitant to engage in funding allocations that cross directorates, institutes, or agencies. In addition, these projects are administrative burdensome for both the agency and the institution(s) involved, since requirements of different agencies are often involved. These projects often require considerable coordination to be successful, but existing business models for sharing resources are limited, and administrative support is typically not able to be directly charged to facilitate the process.
- D. Federal agencies should improve peer review oversight and inter-agency communication about project funding. The degree to which peer review is utilized varies tremendously among federal agencies, as well as there being a significant variance in the degree of sophistication and rigor in peer review systems. It would be extremely helpful if peer review was extended more broadly, utilizing well-understood and articulated review criteria and processes, and identifying and deploying the best practices of the leading peer review agencies, NIH and NSF. A common approach to peer review will be essential to the success of inter-disciplinary and cross-agency funding.
- E. Federal agencies should work to eliminate barriers caused by artificial distinctions between research and education (and public service). In the current research environment, a student receiving a stipend on a fellowship may perform identical work to the salaried student sitting at the bench next to her, but receive very different levels of compensation (including benefits and eligibility for tuition remission) and be treated differently for tax purposes, VISA eligibility, and health care benefits. It is essential that the "dual role" of research and education for graduate students and postdoctoral scholars be recognized and artificial barriers removed.
- (5) Revise Agency/University Business Relationship to Recognize Accountability and Trust Despite a plethora of experience working with one another, current business models between the federal funding agencies and universities remain almost entirely "transaction" based (e.g., proposals, awards, reports, etc.). This business model is expensive, labor-intensive (of particular concern given the administrative cap on F&A), and takes little account of the technological advantages that are now available. We recommend that:
- A. Federal agencies and universities should consider the viability of "business-to-business" models for working together. For example, if common standards for conducting business are adopted and best business practices implemented, institutional research oversight systems deploying these standards and practices could potentially be accredited to do business with the federal government, allowing

business to be conducted on a "business-to-business" basis rather than on a per-transaction basis. Accreditation could result in the removal of project-specific requirements and rules, and compliance and stewardship verified via exception reporting or periodic system audits or even remote access by federal officials to on-line real-time information of common interest.

B. Federal agencies should promote the use of business models that limit data collection to information that is critical and timely to decision-making, and that recognizes existing roles and responsibilities in the research enterprise. Excellent examples of this model are NIH's Modular Grant and Just-in-Time mechanisms, both of which warrant extension to other agencies. The modular grant mechanism simplifies proposal preparation by focusing attention on those data elements that are critical to the peer review process, and provides up-front recognition that extremely detailed budgetary information is irrelevant given the post-award authority of principal investigators to make judicious budgetary adjustments as their projects are under way. The Just-in-Time mechanism eliminates the need for an institution to perform protocol reviews for projects not likely to be funded, resulting in significant labor and cost savings.

(6) The Funding of Institutional Review Boards

Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs) play critical and demanding roles in modern biomedical and social science research. They are central to the nation's efforts towards protecting human and animal subjects while ensuring that the research moves forward. Yet, there is considerable evidence that they are under-funded and over-worked. Because the federal reimbursement for administrative expenses is capped and insufficient to cover university administrative expenses associated with federally-funded research, IRB and IACUC members carry on their responsibilities on top of those for which they are paid. Such a situation necessarily limits, on average, the attention that can be devoted to the important IRB and IACUC responsibilities

To alleviate this problem, we recommend that:

A. The federal government recognize the importance of the IRBs and IACUCs by fully funding that portion of their endeavors that is attributable to federally-funded research. The funding should be sufficiently large so that it compensates all those who participate in, and staff, these compliance committees. Such funding would free up time for the committee members to focus on their compliance responsibilities.

We appreciate the opportunity to provide input into the agenda for the OSTP Subcommittee on Research Business Models, and would welcome the opportunity to work with the Subcommittee to articulate the key principles, to prioritize the overall agenda, and to identify and implement solutions to the problems outlined here and by others.

Sincerely,

Arthur Bienenstock Vice Provost and Dean of Research and Graduate Policy