

October 6, 2003

Michael J. Holland
Office of Science & Technology Policy
1650 Pennsylvania Avenue, NW
Washington, DC 20502

RE: National Science and Technology Council (NSTC) Research Business Models Comments; Response to Office of Science and Technology Policy's Federal Register notice of August 6, 2003 [Volume 68, No. 151, Page 46631].

Dear Dr. Holland:

I am writing on behalf of the University of California (UC) system to respond to the Office of Science and Technology Policy's (OSTP) request for information on "Research Business Models," to be used by the National Science and Technology Council/Committee on Science/Subcommittee on Research Business Models. The University of California is proud to have one of the largest and most successful academic research enterprises in the country, spread amongst its campuses at Berkeley, Davis, Irvine, Los Angeles, Riverside, Santa Barbara, Santa Cruz, San Diego, and San Francisco (with a tenth campus opening soon in Merced) as well as the three U.S. Department of Energy national laboratories managed by UC. There is considerable breadth and diversity in the kinds of basic and applied research undertaken at the University of California, with research conducted in over 600 research centers, institutes and programs, as well as by individual faculty in academic departments spanning all the disciplines.

We are pleased that OSTP is seeking public input regarding how to improve the management and performance of federally sponsored basic and applied scientific and engineering research. Federal sponsorship of research has been critical to fostering advances in knowledge that have brought countless tangible benefits to this country's health, economic well-being, security and overall standard of living. We believe it is important not only to ensure robust future federal support for research, but also to ensure that such support is administered in a way that ensures accountability and risk management while minimizing or eliminating unwarranted administrative burdens that deflect critical resources away from research. This perspective is at the heart of many of the comments and technical suggestions provided in the attached appendix, which respond to a number of the questions posed in OSTP's Federal Register Notice.

The comments in our appendix are by no means exhaustive. Many of the questions posed in OSTP's Federal Register notice are extremely broad and not susceptible to simple, easy answers. Even within the academic community, there are a variety of viewpoints from researchers in different disciplines. Recognizing that OSTP's notice was published during the summer when many academic researchers were away from campus, our hope is that OSTP will continue its efforts throughout the coming year to engage the research community in substantive discussion about these issues. We also hope that OSTP will consider suggestions regarding improving the management of the federally-funded research process that have been made in recent years through related federal projects – e.g., the Federal Demonstration

Project, responses to the last Presidential Review Directive, and responses to federal grants streamlining activities related to Public Law (P.L.) 106-107, the Federal Financial Assistance Management Improvement Act

Finally, I want to echo the caution expressed by the Council on Governmental Relations (COGR) about the application of the term "business model" to the relationship between universities and federal funding agencies. The University of California has a tripartite mission of teaching, research, and public service; our goal is to create and disseminate knowledge, to train students (and the next generation of researchers), and to translate scientific discoveries into practical knowledge and technical innovations that benefit California and the nation. While we agree that it is useful to examine the adequacy of existing research funding mechanisms, we believe it is important to recognize that universities serve a unique role and that it is not necessarily appropriate to apply to universities models and assumptions taken from the for-profit business world.

The attached appendix provides specific comments on some of the questions raised in OSTP's Request For Information. We appreciate the opportunity to provide input into the important work of the Subcommittee.

Sincerely,

Lawrence B. Coleman
Vice Provost for Research

Enclosure

cc: Provost King
Vice Chancellors for Research
AVP Sudduth
AVP Huttner
Executive Director Bennett
Director Mears
Director Auriti

University of California response to OSTP notice
October 6, 2003 - Page 3

Office of Research: OSTP_comments_Univ_of_CA_10.6.03.doc

UNIVERSITY OF CALIFORNIA
October 6, 2003
Response to OSTP's Request for Information

APPENDIX

A. Accountability

We recognize that the University-federal government research partnership is based in part on the premise that federal investment in research will result in significant public returns. Indeed, our society enjoys substantial economic and intangible benefits from federally funded research and from the education and training that are interwoven with it. The advances in knowledge produced by federally funded research have led to economic growth (with jobs and even whole new sectors of the economy growing out of advances in areas like biotechnology and information technology), improved health, agriculture, security, and overall standard of living.

It would be a mistake, however, to equate the appropriate measures of such public returns with those used in the private sector to measure commercial "returns on investment." For the most part, universities are not vendors and university support for research is not a procurement activity. Much federally funded research is basic research for which there are no pre-determined results or measurable "deliverables." Basic research (experimental or theoretical work undertaken primarily to acquire new knowledge) creates the foundation upon which more applied research relies. The benefits of basic research are real and significant, if sometimes less susceptible to easy measurement than the "returns" realized on more applied research. Many of the benefits of more fundamental research accrue incrementally through subsequent developments and through uses of the results by those who did not invest directly in the research.

Thus, it is a challenge to develop relevant and meaningful quantitative measures of the return on the public investment in research. The University of California is engaged actively in an effort to develop some such measures through the Economic Research Unit of its Industry-University Cooperative Research Program. This program has piloted studies that have yielded valuable insights into the direct economic contributions stemming from federally funded basic research, and has defined several specific measures, which include creation of new businesses and production of R&D leaders, among others, that may be broadly applicable to federal investments in university science and engineering research activities. The pilot studies, however, have required access to information that is not readily available and that requires considerable investment of time and resources. Additional research is needed to determine how and whether it is possible to make these analyses practicable at a federal level.

With respect to mechanisms for ensuring "accountability," we point to the effectiveness of the current system of merit-based peer review in the allocation of federal funds for scientific research. It is widely understood that the unwavering emphasis on expert peer review at the National Science Foundation and the National Institutes of Health has enabled the United States to build a scientific and engineering knowledge base that is the envy of the rest of the world. Peer review administered by federal agencies is an essential part of the accountability for public investments in research, and the University of California strongly supports participation by its faculty in the peer review process. Competitive merit-based peer review ensures selection of well-qualified investigators engaged in research examining worthwhile scientific questions.

In addition, the myriad of federal compliance rules such as those for human subjects, animal welfare, conflict of interest, and costing and administrative rules, and restrictions found in Office of Management and Budget (OMB) Circulars, audits, Cost Accounting Standards, agency-specific requirements, and

indirect cost rate proposals provide significant financial and compliance accountability measurements and restrictions within which the research enterprise must operate. Universities take seriously their obligation to comply with these measures. Compliance is audited annually as well as in some cases, on a project basis. Such audits provide the federal government with continuous “accountability for the Federally-supported research enterprise.”

B. Inconsistency of policies and practices among Federal agencies

The implementation of more common policies, practices and administrative systems across all federal agencies would improve the efficiency and the cost effectiveness of recipients’ research administration. Among the many federal requirements of which recipients must be knowledgeable and capable of administering multiple systems and rules are:

- Invoicing and payment systems: Currently, our institution is required to use over 15 different federal invoicing and payment procedures/systems, despite the federal Treasury Department rule to require government agencies to use only one of two or three payment systems.
- Indirect cost rate and base exceptions: Federal agencies limit the proper use of federally negotiated indirect cost rates on hundreds of individual programs, continually making exceptions to standard approved rates and well as creating a variety of bases against which these restrictive rates must be charged.
- Cost Principles: Federal agencies do not uniformly implement the federal cost principals set forth in OMB Circular A-21. Agencies disallow a variety of allowable costs such as tuition, benefits, or travel in individual programs.
- Inconsistent definitions for cost sharing: Some agencies restrict what is allowable cost sharing, such as unrecovered indirect costs.
- Multiple electronic proposal submission, award administration and reporting systems: Universities are required to have the expertise, software, and hardware to use more than ten different federal electronic proposal, award, and reporting systems. The continuous development of these systems adds to the university’s research infrastructure expense burden.
- Inconsistent terms regarding treatment of data. Federal agreement terms applying to the treatment of data are becoming increasingly inconsistent with and contradictory to the essential federal premise that research is either classified or unclassified. We are concerned about some federal agencies’ insertion of publication restrictions into grants and contracts for unclassified fundamental research deemed to be “sensitive.” Agencies should adopt a consistent approach, whereby the products of fundamental research remain unrestricted and whereby classification is the mechanism used for exerting controls required by national security. We also are concerned about the application of information technology security clearance requirements for databases that are supposed to be open and available for all researchers under an agency’s data sharing requirements. Adding to this problem is the improper application of export control regulations to basic research.
- Inconsistent terms regarding treatment of inventions. Federal agreement terms applying to the treatment of inventions are becoming increasingly inconsistent with and contradictory to the tenets of the federal Bayh-Dole Act (35 U.S.C. 200-212). As discussed in Section J, below, we are concerned that

certain Federal agencies are starting to issue awards that are inconsistent with the standard Bayh-Dole provisions, and about the alteration of terms in the middle of multi-year awards. Please see Section J for more comments relating to the Bayh-Dole Act.

- Lack of government-wide adoption of common rules as applied to such compliance requirements as misconduct in science and disclosure of financial conflict of interest adds unnecessary complexity and cost to recipients.

Recommendations:

-- We recommend that electronic proposal and progress report submission systems continue to be developed and, most importantly, standardized as much as possible. The NSF FastLane system is a prime example of an efficient electronic submission system; it is accessible to principal investigators, staff support personnel, and administrators. We caution against the development of numerous, competing electronic submissions systems that may create significant confusion and jeopardize timely submission.

- Examine best practices, where agencies have adopted consistent approaches, such as:
 - Department of Health and Human Services (DHHS) Human Subjects regulations, which have been adopted by all agencies as a common rule.
 - Adherence to standardized invention terms under the Bayh-Dole Act across all agencies for all Federal awards to universities at the prime and subrecipient levels.

C. Inconsistency of policies and practices among universities

- Use of model subagreements and subcontracts: The Federal Demonstration Partnership has produced model subagreements and subcontracts for educational institutions and nonprofit organizations to use when subawarding federal funds to one another. Wide-spread adoption and use of these models would streamline the subaward process for these recipients.
- Consistent application of federal indirect cost rates on federally funded subawards: Too often, prime recipients of federal awards refuse to allow their subrecipients to charge their applicable federal indirect cost rates.
- Subrecipient monitoring: The A-133 Audit Compliance Guide needs to make clear that subrecipients are not required to provide a copy of their A-133 audits to prime institutions. What is required is that the prime recipient verify on the Federal Audit Clearinghouse website that there are no audit findings in relation to a specific subaward. Clarifying this procedure would help reduce the need for the subrecipient to produce additional and unnecessary paperwork.

D. State and Institutional requirements

- States do not consistently “flow down” federal regulations and OMB Circulars with federal funds. Rather, they often apply more restrictive and in some cases contradictory state rules to federal funds. Recipients of federal funds via state awards are thus forced to apply an entire different set of requirements to these flow-through federal funds. Specific examples include: Restrictions on overhead recovery; restrictions on use of data, copyrights, and publications; additional audit requirements; lower equipment definition thresholds; re-budgeting restrictions; and invoicing documentation.

- Many state invoicing and payment systems require additional university administrative staffing for manual implementation. California state agencies, for example, do not have electronic invoicing/payment systems; require extensive detail and documentation; and are not consistent with OMB Circular A-21 in a number of areas such as: hourly rates rather than effort; equipment definitions; cost per task rather than per project; and application of indirect cost rates.

Recommendation: Require states to “flow down” applicable federal rules in their federally funded subawards.

E. Regulatory requirements

There are a number of opportunities for revising and streamlining the regulatory process to ease the administrative burden on universities. Some examples include:

- Eliminate limit on cost recovery that threatens the research enterprise: Because the Office of Management and Budget has placed a cap on the administrative costs for which universities can be reimbursed, institutions have no way to recover the rising costs of new and increasing unfunded federal mandates such as:
 - The rising cost of annual A-133 audits due to increasing scope and requirements;
 - Implementation of the requirements of the new federal Health Insurance Portability and Accountability Act (HIPAA);
 - Training requirements for investigators engaged in research projects involving human subjects;
 - CDC and APHIS select agent record-keeping and screening rules.

Recommendation: Remove the cap on the administrative component of the negotiated indirect cost rate to permit institutions to recover the funds required to pay for proper and timely implementation of federal mandates.

- Agency Program Audits: Federal agency program staff and their auditors should coordinate to make final closeout reports available internally within the agency so that the reports are not requested several more times from the grantees by different parts of the agency.
- Single Audit Clearinghouse: OMB Circular A-133 should state clearly that all federal agencies should obtain institutions’ A-133 audits through the Single Audit Clearinghouse and *not* request them from the grantee institution.
- Subrecipient Monitoring: The single audit process leaves prime grantees vulnerable to any problems found in subsequent audits of their subrecipients. While a subrecipient’s A-133 audit may provide the prime grantee with some level of assurance about the subrecipient’s general financial and administrative systems, the subrecipient monitoring requirements do not protect the prime grantee from claims by the federal agency for any improper subrecipient charges found *after* the subaward is closed out and the subrecipient’s A-133 audit for that subaward period is completed. As such, the administrative burden posed by this inappropriate subrecipient monitoring requirement outweighs the costs of any real value such a monitoring system could provide. No matter how responsible the prime is, the subrecipient’s A-133 audit results will always be published long after the subaward is closed out.

Recommendations:

- Limit prime grantee responsibility for subrecipient monitoring to information provided by progress reports and invoices available during the period of performance of the project. Disallowed costs found in subsequent audits should be addressed directly by the federal agency to the subrecipient.
- Revise subrecipient monitoring guidance to require subrecipient to report any audit disclosure issues related to a specific subaward to the prime grantee, with any disallowances to be worked out directly with the federal agency, rather than inefficiently requiring the prime recipient to find the audit finding and collect a disallowance from a subrecipient whose subaward was closed out a year earlier.

- Cost Accounting Standards: It is very costly to implement and maintain the Cost Accounting Standards Disclosure (CAS) Statements. Much of the Disclosure Statement (DS-2) is duplicative of the requirements for developing an indirect cost rate proposal. The CAS Disclosure Statement adds nothing to the information provided to our federal cognizant agency in our indirect cost rate agreement proposals. Educational institutions are already required to comply with the costing standards set forth in OMB Circular A-21. The cost incurred to establish and maintain the Disclosure Statement is expensive, duplicative, unnecessary, and is another *unfunded* federal requirement burdening educational institutions whose ability to pay for such unfounded mandates is limited by the administrative cap applicable to indirect cost recovery.

Recommendation: Eliminate the DS-2 requirement for educational institutions.

F. Research support

- Increase size and duration of federal awards: The dollar amount and duration of many federal awards is too small and too short to allow for efficient development of a research idea, direction and program. Under the current system, Principal Investigators must spend too much of their time constantly seeking new and additional funding which detracts from the time they can spend on their research programs. For a more detailed explanation of this issue, see the National Science Foundation Report on Efficiency of Grant Size and Duration at: http://www.nsf.gov/od/gpra/grantsize/mathematica_NSFRptFinal6.htm#S5HEAD

Recommendation: Federal support for research should incorporate the concept of funding of large, basic assistance awards, that provide funding for general research programs (program/project grants) rather than continuing to require investigators to seek additional funding for multiple, project-specific awards. The general program/project grant would allow an investigator more time and support to develop various aspects of the research focus as one whole program, rather than splitting each part of it into separately funded, separately administered and separately accounted for pieces. It could provide sufficient funding to encourage more multidisciplinary research. It would provide an efficiency of scale as well.

- Fund administrative support: The combination of the cap on the administrative component of the indirect cost recovery rate and the restriction on federal support for departmental administration in OMB Circular A-21, section F. 6. J., means that federal agencies are not permitted to reimburse recipient institutions for the administrative support costs borne by those institutions. As a result, investigators are forced to spend more and more of their time on administrative details. This is a costly and inefficient use of the investigator's time that negatively affects research. To the extent that an investigator's time is diverted from research to administration, the research capacity is diminished.

The purpose of federal research funds is to provide financial support to investigators and their institutions to conduct research programs. As the funds for the institutional administrative support of the research

enterprise are reduced and stressed with more new mandates, the institution's ability to support its researchers is also diminished.

Recommendation: Revise OMB Circular A-21 section F. 6. J. to permit agencies to support administrative needs of researchers and pooled support in their departments.

- Expand Federal Demonstration Partnership: We recommend that the Federal Demonstration Partnership (FDP) continue to be expanded and enhanced to enroll more institutions and heighten the visibility of this valuable initiative. FDP is both a policy tool and delivery mechanism that has streamlined the efficiency of sponsored research delivery by standardizing terms and conditions across Federal agencies, simplifying the prior approval process, and streamlining the award distribution process. FDP has made federally sponsored research more accessible to the researcher and easier to manage for the administrator.
- Expand mechanisms for encouraging support of a broad mix of investigators: The FDP and electronic submissions systems have encouraged researchers from various fields, backgrounds and institutions to pursue collaborative sponsored research because these systems make the administrative aspect of research uniform.

Recommendations:

-- Expand successful electronic submission systems (e.g., NSF FastLane) to other sponsoring agencies;
-- Improve and expand centralized repositories that list available funding opportunities. Heightened visibility of Requests for Proposals and Applications would encourage those without an established relationship with agency program officers to apply for additional funding opportunities. On some campuses, research funding is skewed toward those researchers in the physical and biological sciences with a long history of extramurally funded projects. Creating a highly visible, centralized repository of funding opportunities may encourage investigators in the social sciences, as well as the less experienced researchers, to apply for federal funds.

- Support for cross-disciplinary research: Though care should be taken to ensure a balance between funding for individual and multidisciplinary projects (with neither type being funded to the exclusion of the other), we applaud the Subcommittee's focus on exploring ways to encourage multidisciplinary research. Contemporary complex research efforts in, for example, nanotechnology, biotechnology, and biomedical engineering require scientists in different disciplines to work together. As we move into the 21st century, cross-disciplinary research will be the standard mode for advancement in many areas of scientific inquiry in science and engineering fields.

Recommendation:

-- Consider expanding collaborative Center-based research: Explore expanded funding for Research Center-based efforts as one way of encouraging cross-disciplinary and collaborative research. Examples of existing Center-based efforts include the NSF Science and Technology Center (STC) and Engineering Research Center (ERC) programs, which are centered on the idea of conducting research (and complementary educational efforts) in a collaborative Center setting. Typically, diverse faculty teams and collaborators from industry and national laboratories from multiple disciplines work jointly with graduate students, post-docs, and researchers to investigate inherently complicated problems. Research Center environments emphasize co-supervision of students and researchers, active visitors and exchange programs and, typically, application-driven research. Center-based efforts are becoming increasingly important components of the research and education focuses of science and engineering departments.

-- Support related infrastructure needs. In considering how best to expand Center-based research, consideration should be given to providing expanded federal support for related infrastructure needs. Infrastructure is critical to ensuring that researchers have the cutting-edge tools and facilities they need to advance the frontiers of scientific knowledge. For example, large-scale computing resources are critical to many science and engineering fields. Large-scale university-based computing-centered research requires substantial investment in basic supporting infrastructure, including costs for maintenance and administrative staff. Such a “cyber infrastructure” is important in 1) supporting campus-wide, cross-disciplinary, multi-investigator collaborations; 2) supporting complex data management that includes access to appropriate data analysis tools to utilize on multiple data sets describing highly complex phenomena; and 3) supporting rapid data sharing among scientists over high-speed networks. This last need arose, in part, from advances in ultra-high-resolution imaging, sensor-network technology, and increasing supercomputing simulation power. In many cases, data sets are now so large that individual scientists are no longer able to fully mine the generated data, making it increasingly important to be able to share massive data sets with the scientific community at large using advanced high-speed networks.

We suggest more federal funding mechanisms and programs be made available to provide more academic institutions with access to funding dedicated to supporting infrastructure needs of such large-scale efforts. Funding could also play a valuable role in fostering communication and collaboration across disciplines and institutions (as well as between academia and industry), for the purpose of helping ensure adequate integration of multiple hardware and software system development efforts.

- Review agency research funding priorities: Agencies and researchers need to work together to continually review and adjust federal research funding priorities. Due to the nature of the federal budget process, designated funding priorities may lag behind current research needs. Researchers in new areas may have difficulty finding funding if their research areas are not yet named within any agency budget. Federal government should work with research universities to determine how to identify and fund new areas related to societal goals where we are currently under investing. Agencies need more flexibility in their budgets to fund new, unexplored research areas, to respond ahead of a crisis to emerging societal issues.

Recommendation: Provide for an undesignated fund in agency budgets to address new research areas. Establish mechanisms to encourage continuous exchanges between federal agencies and researchers from various disciplines to help agencies select new funding directions.

G. Multidisciplinary/collaborative research

Please see our comments in Section F, above, regarding encouragement of cross-disciplinary and collaborative work. Additional comments are provided below:

- Explore funding mechanisms that encourage collaborative work: Examples worth considering include:

-- NSF Collaborative Proposal Mechanisms – NSF’s collaborative research opportunities and FastLane system make the collaborative submission process simple. Prior to linking proposals from various institutions for a collaborative project, NSF requires that the approval of the relevant program officer be secured. Once such approval is granted, the collaborating institutions are allowed to submit their respective proposals, which are electronically linked through the FastLane system. The collaborating institutions each receive separate research funds, i.e., no subcontracting is involving. However the

projects remain programmatically linked. Under this system, the administrative burden is significantly lighter for the participating institutions, while the investigators/institutions clearly benefit from the collaboration.

-- University of California's Industry-University Collaborative Research Program – This is an example of a successful funding mechanism that encourages university-industry collaboration. This University of California program awards hundreds of UC Discovery Grants each year in five fields of science and engineering, in addition to offering a Microelectronics grants. This competitive matching-grant program nurtures university-industry collaborations by inviting researchers to find industry partners to sponsor a research project. If selected, the program, using State of California funds, will match (1:2) the industry partner's contribution to the direct costs of the project. The goal is for the university to partner with industry to facilitate research and potentially commercialize any technology that may arise from the research results. More information about this program can be found at the following url:
<http://uc-industry.berkeley.edu/welcome.asp>

-- University of California's MEXUS Program – This is an example of a successful funding mechanism that encourages international collaboration. The University of California Institute for Mexico and the United States (UC MEXUS) and Mexico's El Consejo Nacional de Ciencia y Tecnologia (CONACYT) partner to fund collaborative research between U.S. and Mexican researchers. The program funds collaborative projects co-directed by UC investigators and investigators from a Mexican institution, and encourages proposals that include participants from multiple institutions. The program funds projects expected to lead to the development of major, long-term collaborations, and favors projects that enhance institutional infrastructure in terms of graduate student training and researcher exchange. If a project is selected, the MEXUS program issues an award to the Mexican and UC institution, separately, with common and uncomplicated terms and conditions. Similar to the NSF Collaborative projects, the MEXUS program provides administrative ease and straightforward terms and conditions, and facilitates collaboration.

- Concern: Restrictive terms and lack of support for administrative workload: One of the few troublesome issues encountered with large multidisciplinary and collaborative awards has been restrictive federal agency terms inserted in RFAs for cooperative projects or in amendments to grants and cooperative agreements for collaborations which conflict with university and federal agency policies. These include: requirements to delay publications or restrict use and distribution of data; split indirect cost rates; and terms providing collaborative steering committees with authority to approve or prevent actions that are rightfully the domain only of the recipient institutions.

A secondary concern is that federal agencies are transferring the workload without providing the financial support for the administrative staff needed for large collaborative or multidisciplinary programs. This problem occurs in cases where prime recipients write and administer multiple subawards rather than having the federal agency provide multiple prime awards. In addition, some prime recipients do not use appropriate subaward models and terms such as the FDP model and others limit the indirect cost rate that subrecipients can use.

Recommendation: These matters can be addressed with guidance, training and infrastructure support. They do not detract from maintaining the system for funding large program, multiple awards currently is place. Inserting an independent administrative prime recipient between the federal agency and the collaborating institutions only creates more bureaucracy, expense, and improper application of federal regulations. Particularly where the prime recipient is a non-profit or for-profit organization administering

awards to educational institutions, there are more issues created with inappropriate terms and conditions and indirect cost restrictions than when educational institutions manage these collaborations themselves.

H. Research Infrastructure

Please see our comments in Section F, above, pertaining to funding of infrastructure needs.

Also, in addition to facilities and equipment needs, administrative support is an important component of the research support infrastructure. One significant issue for universities related to funding of research infrastructure is the cap OMB Circular A-21 places on administrative costs. With the rising costs of complying with new and increasing federal regulatory mandates, the inability of universities to recover legitimate administrative costs has become a serious issue. Please see our comments in Sections E and F, above.

I. Information Technology

While research institutions can control their internal selection and development of information technology systems, they are forced to respond to a growing number of external systems that require costly multiple platforms, staff training and technical expertise. In the worst case scenario, these various agency systems are not responsive to the internal needs of recipient institutions' procedures and requirements. Within a given research institution or agency, the thoughtful development of appropriate information technology is reducing paper and increasing efficiency. However, the uncontrolled growth of systems and platforms among agencies is making complicating implementation of these changes. Also see comments in Section B, above.

J. Technology transfer optimization.

The University of California does not have data in addition to that provided by the Council on Governmental Relations in its response to OSTP, but would like to provide some observations in the technology transfer area.

The Bayh-Dole Act (35 U.S.C. 200-212) created a new business model for federally funded research results that supported the transfer of technology to commercial partners so that research results can be further developed and made available to the general public. In so doing, it led to the development of a technology transfer infrastructure within research universities across the nation that is now showing significant results. At the University of California alone, more than 180 companies have been founded on the basis of technology licensing agreements, and in the last decade, campuses reported more than 6,000 inventions, including many that led to new technologies and products.

The Bayh-Dole model was forward-thinking in standardizing patent rights clauses across Federal agencies, thus eliminating inconsistencies across Federal agencies and time-consuming negotiations for each Federal award. The Bayh-Dole Act also provided universities the ability to retain control over its intellectual property thereby providing universities the flexibility to promote commercialization of its research results and the further development of ongoing basic research programs that serve as the foundation for future technology development.

Even as the government-university-industry relationship becomes increasingly complex, Bayh-Dole continues to serve this multi-faceted relationship well. We have noticed and are concerned, however, that

certain Federal agencies are starting to issue awards that are inconsistent with the standard Bayh-Dole provisions, through more frequent use of Determinations of Exceptional Circumstances without accommodating the special circumstances as required under 37 CFR 401.3(b) or consulting with the university community on more appropriate approaches. There are also concerns about expanding use of the Other Transaction Authority by the new Department of Homeland Security and other Federal agencies. Please also see comments under Section B, above.

With respect to the increasing complexity of the university technology transfer enterprise, we refer you to hearing testimony delivered by Associate Vice Chancellor Andrew Neighbour from UC's Los Angeles campus to the House Energy and Commerce Subcommittee on Health at its July 10, 2003 hearing on "NIH: Moving Research from the Bench to the Bedside." The testimony is available at the following url: <http://energycommerce.house.gov/108/Hearings/07102003hearing990/Neighbour1580.htm>