October 6, 2003

Dr. Michael Holland Office of Science and Technology Policy 1650 Pennsylvania Avenue, N.W. Washington, DC 20502

Dear Dr. Holland:

The Office of the Vice President for Research and faculty and staff at the University of Iowa who are actively engaged in research activities appreciate the opportunity to comment on the Office of Science and Technology Policy's National Science and Technology Council Subcommittee on Research Business Models.

While we support the stated goals of the Subcommittee to improve efficiency, effectiveness and accountability, we believe that utilizing business models in the research enterprise must be accomplished within the compelling public policy goal of research: the creation of new knowledge that serves the public at large. For this reason, not all practices appropriate to a for-profit industry can be applied to a not-for-profit organization dedicated to basic and applied scholarship. At the same time, some effects of these models can be applied to improve efficiency and effectiveness.

Specifically, we would like to address the questions as outlined by the Subcommittee:

A. <u>Accountability</u> – Accountability must be accomplished not only by the researchers and their institutions but also must have a comparable federal component. There are many measures currently in place that require institutions to provide a myriad of reports, for example: annual, progress; financial; and equipment accountability. However, we feel there should be more effort on the part of federal offices to ensure that these reports are being utilized within the agency and that the research results are being disseminated widely. It is also important that accountability be defined appropriately. For instance, accountability for a contract will vary widely from accountability in a grant.

In general, however, certain board guidelines should be considered for research accountability. They are: 1) did the project research its goals as originally outlined; 2) were there tangible intellectual property benefits (publications, patents etc.) 3) did students benefit through participation in the project; and finally 4) were there benefits to the public as a whole?

B. <u>Inconsistency of policies and practices among federal agencies</u> For university researchers, administrators and others it is increasingly difficult to try to understand and comply with the wide number of federal guidelines, rules and procedures. Even within NIH, each institute varies. In many instances, each agency acts independently. We believe that there should be consideration of general guidelines and procedures that would be consistent across all federal agencies. These guidelines and procedures should

focus more on outcomes than on the process. Even in situations such as scientific misconduct where there is a common rule, many agencies have implemented it differently. In the long-term, such uniformity could result in cost savings both at the federal and institutional level.

C. <u>Inconsistency of policies and practices among universities</u>. We agree that there needs to be an improvement across research institutions on internal policies and procedures. However, there are some models such as the NSF Shared Instrumentation Program and the NCI model for a central Institutional Review Board that could be considered as examples for these activities. Likewise, using the guidelines as set out by the Federal Demonstration Project for contracts might be another useful model for interuniversity activities. It can be found at: http://www.nsf.gov/home/grants/grants_fdp.htm

In response to more interest at the federal level in interdisciplinary research, institutions of higher education must continue to foster dialogues among universities, most likely through relevant research/academic organizations, and with federal agencies to ensure that interdisciplinary research prospers. This dialogue can only work if each institution and each federal agency, no matter how it is organized, ensures that internally. Barriers are not put in the way of this important research.

D. <u>State and institutional requirements</u>. At the University of Iowa, we have been ly fortunate that, for the most part, the state of Iowa has not significantly intruded in our administrative or regulatory activities as they relate to research. However, there are issues such as intellectual property, sovereign immunity and privacy which continue to present obstacles to our research efforts. Likewise, the Iowa General Assembly recently passed a law that could further restrict stem cell research even within overriding federal dictates.

E. <u>Regulatory requirements</u>. We would encourage federal agencies to continue their long-standing methods of receiving comments from interested parties through announcements in the <u>Federal Register</u>. We believe the ability to comment and to learn of other viewpoints is helpful to higher educations institutions as well as to the federal government. In addition, we believe it s helpful for agencies to have continuous communications with our research organizations such as the Association of American Universities (AAU), National Association of State Universities and Land-Grant Colleges (NASULGC), the American Council on Education (ACE), the Association of American Medical Colleges (AAMC), and the Council on Governmental Relations (COGR) among many others. Through these organizations, individual universities can collectively state their views on a wide variety of regulatory issues that can have profound effects on the conduct of research. At the federal level, there are several publications under the auspices of the NIH Extramural Office that have systematically studied this issue. They can be found at the following sites.

• <u>NIH Initiative To Reduce Regulatory Burden Report</u>, March 1999

• <u>Near-term Efforts to Reduce Regulatory Burden</u>: 3 Month Plan, September-November 1999

• <u>Regulatory Burden Update</u>, June 2000

One model to consider in attempting to work toward a long-term reduction in the regulatory burden could be accreditation. Recently, the University of Iowa became one of the first in the nation to be accredited by the Association for the Accreditation of Human Research Programs. (AAHRP). While this accreditation does not reduce our regulatory burden it could be considered as a model whereby accreditations such as this might ultimately reduce the need for the current level of federal oversight.

F. <u>Research support</u>. We believe it is of paramount importance for the federal government to continue to identify strategic research interests for the nation. One recent example is the federal efforts in the area of nanotechnology. We believe these interdisciplinary, interagency efforts are vital to the national scientific enterprise. However, the success of such efforts will rest on the ability of agencies to agree on how funding can be mutually shared and how each can contribute to these interdisciplinary and interagency goals without sacrificing their central missions.

Especially in the area of basic research, we feel it can be best accomplished through allowing researchers a sufficient length of time to work toward these goals. In many instances, the current model gives researchers three years. We believe that five years would be optimal and would help ensure those goals are met. A good model for funding grants can be found at this website:

<u>http://www.nsf.gov/od/gpra/grantsize/contents.htm?gpraplan97</u> It addresses this issue along with many others of relevance.

We also believe it is important that agencies effectively promote interagency and intraagency communication. Many researchers encounter inconsistencies between agencies and even within separate divisions of an agency. An example of a successful interagency effort was the effort to promulgate regulations on scientific misconduct common rule. Both the NIH and NSF cooperated in developing the final rules.

G. <u>Multidisciplinary/collaborative research</u>. There are funding mechanisms, such as the NIH P series of grants, which force institutions to do multidisciplinary work. Although it is in its infancy, awards relating to homeland security (which often focus on a region of the U.S.) must be interdisciplinary and collaborative if they are to be effective. Likewise, many non-profit foundations have had a historical interest in assuring their major projects were multidisciplinary and included collaborations with not only other institutions of higher education, but others in the public and private sectors.

H. <u>Research Infrastructure</u>. The Council on Governmental Relations reports on Facility and Administrative costs and has a wide variety of data available. These costs, however, only recover existing costs, not new ones. Therefore, if an institution decides to internally devote some of this funding to new construction it can only be at the expense of maintenance on other facilities. We support efforts on the federal level to fund new construction and/or remodeling of existing structures. Such funding is necessary for universities to continue to be responsive to new and emerging initiatives.

I. <u>Information Technology</u>. We believe that efforts such as FastLane and electronic submissions have been highly successful and such models should be encouraged. However, there needs to be a substantial and coordinated effort by the federal government to promote high performance computing.

J. <u>Technology Transfer Optimization</u>. We continue to support the provisions of Bayh-Dole and believe that its provisions have been instrumental in sustaining the progress to date in technology transfer. The Association of University Transfer Managers is an important resource for those who are interested in the transfer of academic intellectual property. It has made data available to the general public at: <u>http://www.autm.net/index_ie.html</u>

We look forward to hearing more about the work of the Subcommittee and would welcome additional dialogue on these topics. If you have any questions or wish to receive more detailed information on any of these issues, please contact me at 319-335-2119 or by e-mail: <u>bill-decker@uiowa.edu</u>

Sincerely,

William Decker Interim Vice President for Research

cc: Ad Hoc Group