University of California Office of the President April 29, 2010

GUIDELINES FOR DISCLOSURE AND REVIEW OF PRINCIPAL INVESTIGATOR'S FINANCIAL INTEREST IN PRIVATE SPONSORS OF RESEARCH

These Guidelines Implement the University Policy on Disclosure of Financial Interest in Private Sponsors of Research

I. Rationale

University research is currently reviewed according to the principles specified below and according to other well-established policies guiding the conduct of sponsored research, including the principle that researchers must be free to pursue knowledge and that this freedom, which is essential to the research process, must not lightly be abridged. The proposed review is supplemental to this process and takes advantage of the expertise and structure of the existing system. While it is normally the case that a principal investigator takes responsibility for the central issues raised in these guidelines, when a principal investigator has a financial interest of the sort defined in the University Conflict of Interest Code requiring disclosure, it is possible that his or her judgment may appear to be affected by potential financial gain rather than by the pursuit of knowledge. Therefore, it is proper that the principal investigator, the University community, and the public be assured that the principles central to the research process are followed.

II. Principles

A. Traditional conflict of interest situations should continue to be avoided

In the conventional sense, conflict of interest refers to situations in which employees may have the opportunity to influence the University's business decisions in ways that could lead to personal gain or give advantage to associates or entities in which employees have an interest. Principal investigators, like all UC employees, are expected to continue to separate their University and private interests in accordance with existing University policies and State law.

B. Research is appropriate to the University

The research must be appropriate to the mission of the University, i.e., promising significant contributions to scholarship and knowledge and, when possible, providing appropriate opportunities for students. The suitability of the research would be judged according to the standards of the discipline and should be guided by the principles and policies of University Regulation 4, Special Services to Individuals and Organizations (APM - 020).

C. The teaching and research environment is open

The teaching and research environment should continue to promote the free exchange of ideas, information, and materials among students and faculty in all of their forumsCclassrooms, laboratories, meetings, and anywhere in the University. Selection of students for participation in the research project should not be inappropriately influenced by the interest of the sponsoring entity.

D. Freedom to publish and to disseminate research results is preserved

Consistent with current University policies, there should be no limits placed on the freedom to publish, except for short periods of delay that permit a sponsor to comment or to permit filing of patent applications.

E. Licensing agreements require thorough review

If the principal investigator has a financial interest in the sponsoring entity, justification for granting of an exclusive license to the sponsoring entity will require careful review to ensure that the best interests of the public and the University are served. This review should be coordinated with the Patent Administrator for consideration in negotiations concerning patent rights.

F. University facilities and resources are used appropriately

As is currently the policy, University resourcesCsupplies, equipment, and facilities, as well as staff timeCmust not be used for the benefit of the outside entity without proper compensation.

III. Procedures for conduct of committee review

Review committees should be guided by the following practices and apply them as appropriate.

A. Assure adherence to relevant University policies, guidelines, and regulations

These policies are identified; summarized, and paraphrased in the Business & Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest.

B. Consider, to the extent possible, the nature and extent of the financial interest in the relationship of the principal investigator to the sponsoring entity

In addition, to the extent possible, the potential financial effects of the research both on the sponsor and on the principal investigator should be considered.

C. Give special consideration to:

- 1. Conditions of research agreements which involve:
 - a. The testing of a sponsor's products or inventions;
 - b. Research conducted in the sponsor's facilities;
 - c. Research performed jointly with an employee or agent of the sponsor; or
 - d. Research involving the provision of proprietary information from the sponsor.
- 2. The relationship between the principal investigator and the sponsor when the principal investigator has:
 - a. A significant ownership interest in the sponsor;
 - b. The opportunity to receive substantial financial benefits from the sponsor (e.g. bonuses, stock options); or
 - c. A long term or ongoing consulting relationship with the sponsor.

D. Obtain additional information from the Principal Investigator when necessary

Since committees may find it useful to get more information from the principal investigator than is covered in the Statement of Economic Interests, Form 700-U, a sample form is provided (entitled the Principal Investigator's Addendum to Statement of Economic Interest) which includes possible questions and also advice to the principal investigator about the purpose of the request and its legal status.

In the event that such a sample form, or the like, is utilized, it must contain a privacy statement.

E. Apply the principles set forth in II above:

Some questions which might be considered when appropriate are:

- 1. Do the facts and circumstances suggest that the principal investigator's financial involvement with the sponsoring entity will in any way affect or impair the conduct of the research in accordance with the applicable University policies and the highest professional standards?
- 2. How will the interests of the University be maintained in consideration of the principal investigator's interest in the sponsor?
- 3. Will the research project lead to the advancement of knowledge rather than to routine testing of primary benefit to the sponsor?
- 4. How will this research project contribute to the University's mission of teaching, research, and public service?
- 5. Do the potential public benefits to be gained from undertaking this research outweigh any potential erosion of academic freedom, collegiality, or public trust?
- 6. Are the best interests of the University and the public served by granting an exclusive license to the sponsor?

F. Make a recommendation providing the necessary documentation and indicating:

- Acceptance of the gift or grant.
- Non-acceptance of the gift or grant.
- Modification, specifying what modifications need to be made, or what conditions need to be imposed.

The UC Presidential Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research can be found at [insert link].