General University Policy Regarding Academic Appointees: APM - 028 - Guidelines for Disclosure and Review of Financial Interest in Private Sponsors of Research

028-10 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

In conducting a review of a researcher's financial interests in sponsors of privately sponsored research, pursuant to the <u>UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in</u> <u>Private Sponsors of Research</u>, the following provides additional guidance.

I. Rationale

University sponsored-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 limited. 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 the principal investigator's 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 must continue to be avoided

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.

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B. Research appropriate to the University

Review of the suitability of the research when a principal investigator has a financial interest in the sponsor is judged according to the standards of the relevant academic discipline and should be guided by the principles and policies of University Regulation 4, Special Services to Individuals and Organizations (<u>APM - 020</u>).

C. The teaching and research environment is open

The teaching and research environment should continue to promote the free exchange of ideas, information, and data among students and faculty in all of their classrooms, laboratories, colloquia, and the like. Selection of students for participation in a research project should not be inappropriately influenced by the interest of the sponsoring entity. In addition, student participation in a research project covered by this policy should be consistent with the educational mission of the University and an appropriate use of the student's time.

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 develop research questions, or the freedom to publish, except for short periods of delay that permit a sponsor to comment or to permit filing of patent applications. Sponsors may not require pre-publication review of research. When publishing, faculty should identify the sponsors of research.

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 resources, supplies, equipment, facilities, and staff time must not be used for the benefit of the outside entity without proper compensation.

III. Procedures for conduct of committee review

The review process and the role of the Independent Substantive Review Committee are described in the <u>UC Policy on Disclosure of Financial Interests and Management of</u>

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<u>Conflicts of Interest in Private Sponsors of Research</u>. The Independent Substantive Review Committee, as described in the Presidential Policy, 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 <u>University</u> <u>Compendium of Conflict of Interest and Integrity Policies - Guidance (formerly</u> Business & Finance Bulletin G-39).

B. Consider the nature and extent of the financial interest of the principal investigator in the sponsoring entity

Where information is available, the potential financial effects of the research both on the sponsor and on the principal investigator should also be considered.

C. Give special consideration to:

- 1. Research agreements that 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 includes possible additional questions and also advice to the principal investigator

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about the purpose of the request and its legal status. For information on Form 700-U see the UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest In Private Sponsors of Research.

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

E. Apply the principles set forth in II above:

Some questions that 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 given the principal investigator's interest in the sponsor?
- 3. Will the research project advance knowledge beyond routine testing that is of primary benefit to the sponsor?
- 4. Will this research project contribute to the University's mission of teaching, research, and public service?
- 5. Do the perceived 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, along with the necessary documentation, indicating:

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

Revision History

September 23, 2020:

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• Technical revision to remove gendered language and to correct minor grammatical errors.

February 1, 2019:

• Substantive revisions to rescind the policy language contained in APM - 028. The Substantive policy language of APM - 028 is replaced by the <u>UC Policy on Disclosure of Financial Interests</u> and <u>Management of Conflicts of Interest in Private Sponsors of Research</u>. Still in effect are the Guidelines for Disclosure and Review of Principal Investigators Financial Interest in Private Sponsors of Research (APM - 028-10).

For details on prior revisions, please visit the Academic Personnel and Programs website.