

NOTE: The below *University Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects* remains in effect, but is currently under review and has not been revised to reflect the new federal requirements set forth in the August 25, 2011 Department of Health and Human Services Final Rule (76 Fed. Reg. 5356 - 53293), that will become effective no later than August 24, 2012, or upon noticed revision of the below policy, whichever first occurs.

**University of California
Office of the President**

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Revised October 15, 1997;
Technical Revisions February 1, 2009;
Technical Revisions March 4, 2010*

**UNIVERSITY OF CALIFORNIA POLICY ON DISCLOSURE
OF FINANCIAL INTERESTS AND MANAGEMENT OF CONFLICTS OF INTEREST
RELATED TO SPONSORED PROJECTS**

I. Policy and General Principles

The University has published high standards for Faculty conduct, including the conduct of research, in the University of California [Faculty Handbook](#) and the [Academic Personnel Policy Manual](#). All University of California Investigators are expected to carry out research consistent with these standards.

Even when these high standards have been met, however, conflicts of interest or perceptions of conflicts may still occur when there is a convergence of an Investigator's private interests with his or her research interests, such that an independent observer might reasonably question whether the Investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain. Such conflicts are common in modern research universities and do not necessarily impugn the character or actions of any individual.

Although the University does not require Investigators to disclose their personal financial interests as a matter of routine, the University is sometimes obligated by external requirements, or may establish such requirements on a program by program basis, to require disclosure processes under circumstances specified in Section II of this Policy. Such disclosure processes are the most widely accepted method for identifying and managing actual or potential conflicts of interest related to sponsored projects in public institutions.

Therefore, it is the policy of the University of California that any Investigator (that is, any University employee responsible for the design, conduct, or reporting of a sponsored project at the University) may be required to disclose significant personal financial interests related to that project, pursuant to circumstances specified by this Policy. When the University determines that such an interest

might reasonably appear to be directly and significantly affected by the sponsored project, the University will take steps either to manage or to eliminate the conflict.

As noted in Section IIB(1), State Disclosure Requirements, this Policy supplements, but does not supplant, the University Policy on [Disclosure of Financial Interest in Private Sponsors of Research](#) (issued April 26, 1984) and published as [Academic Personnel Manual Policy 028](#), and the [Guidelines for Disclosure and Review of Private Investigator's Financial Interest in Private Sponsors of Research](#) (issued April 27, 1984).

II. Purpose and Scope of Policy

A. Purpose

When required by Section IIB, Scope, this Policy establishes a process of disclosure and independent review when an Investigator has significant personal financial interest(s) related to a sponsored project that might reasonably appear to be directly and significantly affected by the sponsored project.

The process is intended to identify and manage such potential conflicts to assure the objectivity with which projects are designed, conducted or reported. This Policy is not directed toward the disclosure of financial interests of the Investigator in an individual sponsor; rather this Policy is directed toward disclosure of any significant personal financial interests which exceed the threshold for disclosure and that would reasonably appear to be directly and significantly affected by the work performed under a sponsored project.

B. Scope

This Policy shall apply automatically only to research projects sponsored by the U.S. Public Health Service, including the National Institutes of Health, and the National Science Foundation. As described below, the University may elect to apply the disclosure requirements of this Policy to certain University-managed programs, if those programs so request, and if their requests are subsequently granted by the Vice Provost for Research. Application of this Policy will be expanded to other extramural sponsors only if necessary to comply with official requirements subsequently imposed by those sponsors.

- 1. Federal Disclosure Requirements.** This Policy implements federal requirements pertaining to "Objectivity in Research" promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 and 45 CFR Part 94. This Policy also implements federal requirements contained in the National Science Foundation's "Investigator Financial Disclosure Policy." Both

agencies require the University to maintain an appropriate written policy on conflict of interest disclosure as a condition for receiving federal grants. These federal requirements, as implemented in this Policy, are applicable to all proposals for extramural awards submitted to these two federal agencies. Application of this Policy will be expanded if necessary to comply with official requirements imposed by other federal agencies or other extramural sponsors.

2. **State Disclosure Requirements.** The California Administrative Code, Title 2, Section 18755, requires disclosure of financial interest in private sponsors of research by all principal investigators on sponsored projects administered by the University. The University has implemented the State requirement by the University Policy on Disclosure of Financial Interest in Private Sponsors of Research issued April 27, 1984, published as [Academic Personnel Manual Policy 028](#) and utilizing University Form 700-U. Principal Investigators must continue to file Form 700-U pursuant to state law when research proposed for funding to PHS or NSF will also be sponsored in part by a non-governmental entity. In such cases, campuses and laboratories are encouraged to alert principal investigators to the separate reporting thresholds for 700-U purposes and the need to also file a 700-U form.
3. **University Managed Programs.** The State of California has assigned responsibility to the University for the management of certain programs that involve the submission of proposals and the making of awards to University campuses and non-University of California entities. The University may elect to apply the disclosure requirements of this Policy to such programs. The applicability of this Policy to such programs requires the approval of the Vice Provost for Research.
4. **Voluntary Disclosure.** On occasion, Investigators may have questions about whether certain financial arrangements or relationships whose disclosure is not required under the terms of this Policy may nevertheless appear to constitute an actual or potential conflict of interest with respect to a sponsored project. In such cases, Investigators may exercise an option voluntarily to apply the disclosure requirements of this Policy to the sponsored project in question. Should the University subsequently determine that the voluntarily disclosed interest might reasonably appear to be directly and significantly affected by the sponsored project, the University may take steps either to manage or to eliminate the conflict.

III. **Disclosure of Financial Interests**

When an Investigator has a significant financial interest that is related to the sponsored project, as those terms are defined below, a written disclosure form

detailing that interest is required. When an Investigator does not have a financial interest that is significant and related to the sponsored project, a simple negative statement, in some documented form, may be substituted for the full written disclosure. This reporting responsibility is separate from an Investigator's ongoing duty to *update* financial disclosures either annually or as new significant and related financial interests are obtained throughout the period of the award (see Section IV, Part F of this Policy). Each campus and Laboratory may design its own forms of documentation as long as they meet minimum requirements established in this Policy.

IV. Definitions

A. University Reviewing Official

An official designated by the campus or Laboratory to review completed Disclosure of Financial Interest forms and to determine whether any reported financial interest would reasonably appear to be directly and significantly affected by the sponsored project.

B. Investigator

Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project. This includes the Principal Investigator, Co-Investigators, and any other individual who has independent responsibility for designing, conducting, or reporting the results of the sponsored project. Consistent with current federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), reporting requirements pertaining to financial interests as defined below require the Investigator to aggregate his or her financial interests with those of his or her spouse and dependent children.

C. Independent Substantive Review Committee (ISRC)

A Committee appointed by the Chancellor or Laboratory Director (or designee) to review disclosures and relevant features of the sponsored project(s) and, on the basis of the review, to recommend to the Chancellor or Laboratory Director (or designee) whether funding for the project(s) should be accepted and, if so, whether any modifications or conditions are needed.

D. Significant Financial Interest

A financial interest must be reported when required by the above-referenced federal regulations. The requirement that an Investigator must report a significant financial interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential conflict of interest. The existence of a conflict of interest is determined subsequently by a designated University Reviewing Official or an Independent Substantive Review Committee (ISRC). If a conflict is identified, the Official or the ISRC may require additional steps to manage or eliminate

the conflict (see Section VIII of this Policy).

This reporting responsibility is separate from an Investigator's ongoing duty to *update* financial disclosures either annually or as new significant financial interests are obtained throughout the period of the award (see Section IV, Part F of this Policy).

In determining whether salary, royalties or other payments constitute significant financial interests, federal regulations require institutions to ensure that their Investigators make their best reasonable estimates of expected income, from a single entity, over the next twelve months (45 CFR Part 94.3). It is the policy of the University of California that the best reasonable estimate of expected income from an entity over the *next* twelve months is the amount of income the Investigator received from the entity, exceeding \$10,000, during the *previous* twelve months. A designated University Review Official or Independent Substantive Review Committee may request more detailed financial information at a later point in the review process if they deem such detail necessary to assess and manage a potential conflict of interest.

Therefore, consistent with current federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), this Policy defines significant financial interests as anything of monetary value, including, but not limited to:

1. Income from a single business entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans, exceeding \$10,000 during the prior twelve months when aggregated for an Investigator *and the Investigator's spouse and dependent children* (pursuant to federal regulation 42 CFR Part 50.603 and 45 CFR Part 94.3);
2. Income from a single public or nonprofit entity, including salary, consulting payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans, exceeding \$10,000 during the prior twelve months when aggregated for an Investigator and the Investigator's spouse and dependent children, excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for public or nonprofit entities;
3. An equity interest, in the form of stock, stock options, real estate, or any other investment or ownership interest, a 5% ownership interest, or a loan to the entity, exceeding \$10,000 in value (current market value if publicly traded; internal estimate of value if not publicly traded; otherwise, amount of investment), for any one

enterprise when aggregated for an Investigator and the Investigator's spouse and dependent children;

4. A management position such as board member, director, officer, partner, or trustee, held by the Investigator; or
5. Intellectual property interest held by the Investigator, or Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than The Regents. .A financial interest does not include payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration.

E. Related Financial Interest

When the work to be performed under the sponsored project and the results of the undertaking would reasonably appear to affect the Investigator's significant financial interest (42 CFR Part 50.604 and 45 CFR Part 94.4), the interest is regarded as related to the sponsored project and must be disclosed. The designation of an Investigator's financial interest as being related to the sponsored project, under the terms of this Policy, does not in and of itself imply the existence of an actual or potential conflict of interest. Again, the existence of a conflict of interest is determined subsequently by a designated University Reviewing Official or an Independent Substantive Review Committee (ISRC). If a conflict is identified, the Official or the ISRC may require additional steps to manage or eliminate the conflict (See Section VIII of this Policy).

Consistent with current federal regulations, the following are significant financial interests which are considered "related" to a sponsored project:

1. The Investigator is carrying out a project and the results of that project would be relevant to the development, manufacturing, or improvement of the products or services of the entity in which there is a financial interest;
2. The Investigator has a financial interest in an entity which might manufacture or commercialize a drug, device, procedure, or any other product used in the project, or that will predictably result from the project;
3. The Investigator has consulting income from a single entity that exceeded \$10,000 during the prior twelve months, and the financial interests of that entity, or the Investigator's financial interests related to consulting for that entity, would reasonably appear to be affected by the research.

An assessment of which, if any, of the Investigator's financial

interests related to consulting (or which, if any, of the financial interests of the entity to which the Investigator consults) would reasonably appear to be affected by the proposed research may be made by the Investigator based on his or her academic expertise in his or her professional field; those interests are to be reported if they exceed the reporting threshold of \$10,000 from a single entity during the prior twelve months. *Investigators who are members of the faculty are reminded of their separate obligation, pursuant to the University Policy on Outside Professional Activities of Faculty Members, published as [Academic Personnel Manual Policy 025](#), to provide descriptive information, through annual reports to department chairpersons or equivalent unit heads, regarding time and effort devoted to all outside professional activities related to their academic specialty.*

Alternatively, campuses and Laboratories may elect to require Investigators to report all consulting income in the Investigator's professional field (provided it exceeds \$10,000 from a single entity during the previous twelve months) to a University Reviewing Official, to the ISRC, or to a panel of experts in the Investigator's academic specialty, for an independent assessment as to whether any of that entity's financial interests, or the Investigator's financial interests related to consulting for that entity, would reasonably appear to be affected by the proposed research.

4. The Investigator has a financial interest in an entity and the sponsored project proposes to subcontract a portion of the work, or lease property, or to make referral of participants to, or make purchases from the entity; or
5. The Investigator has a financial interest in an entity that is part of a consortium or that will otherwise participate in the sponsored project.

Financial interests which are not related to the sponsored project do not need to be disclosed.

F. Update of Disclosure of Financial Interests

Consistent with current federal regulations, a written form or statement is to be completed by Investigators either annually or whenever they acquire new significant financial interests that are related to their projects but were not listed in the original Disclosure of Financial Interest form.

V. Disclosure Requirement

For each sponsored project application covered under the terms of this Policy, Investigators must fully disclose all Related Financial Interests. It is the responsibility of the local Sponsored Projects office to alert the Principal

Investigator if any of the Investigators on the project who are required to disclose financial interests under the terms of this Policy have not yet submitted the required Disclosure (or a negative declaration, in some documented form) to a designated University Reviewing Official. Either the Principal Investigator or the Sponsored Projects office should then contact that Investigator to remind him or her that all required Disclosures must be submitted prior to University acceptance of the award.

All Investigators must also file an updated Disclosure of Financial Interests either when they acquire new financial interests related to active projects, or on an annual basis, as determined by the campus or Laboratory. Alternatively, campuses and Laboratories have the option of requiring a single, annual Disclosure from an Investigator in lieu of a separate Disclosure with each award, provided that a designated University Reviewing Official and, if necessary, an Independent Substantive Review Committee, can assure that each specific sponsored project and the related financial interests were examined in the scope of the annual review.

Disclosure and Update forms are open to public inspection, under state law.

VI. Disclosure and Update Form(s)

When an Investigator has a significant financial interest that is related to the sponsored project, as those terms are defined above, a written disclosure form detailing that interest is required. When an Investigator does not have a significant personal financial interest, a simple negative statement, in some documented form, may be substituted for the full written disclosure. This reporting responsibility is separate from an Investigator's ongoing duty to update financial disclosures either annually or as new significant and related financial interests are obtained throughout the period of the award. Each campus and Laboratory may design its own Disclosure and Update form(s) and may determine the appropriate level of detail necessary for review, as long as the following minimum standards are incorporated into the procedure. The Disclosure and Update form(s) must:

- a. Indicate whether the Investigator has any significant financial interests related to the work to be conducted under the sponsored project(s);
- b. Provide the name of each entity in which the Investigator has a significant and related financial interest and the type of the financial interest (income, equity, management position, or intellectual property);
- c. Indicate, for income interests in each entity, whether the aggregate value exceeds \$10,000;
- d. Indicate, for equity interests in each entity, whether the current value exceeds \$10,000;
- e. Indicate, for equity interests in each entity, whether the current percentage

of ownership exceeds 5%;

- f. Indicate whether the entity in which the Investigator has a significant financial interest is a proposed subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the sponsored project(s);
- g. Indicate whether the entity in which the Investigator has a significant financial interest might manufacture or commercialize any drug, vaccine, device, procedure or any other product involved in or that will predictably result from the sponsored project(s); and
- h. Provide notice to the Investigator that the disclosure will be open to public inspection and include a Privacy Act Notice substantially as follows: The principal purpose for requesting the information on this form is to comply with University policy and federal regulations regarding disclosure of any financial interests that would reasonably appear to be affected by the conduct of a sponsored project. Provision of the information is mandatory if you want to submit a proposal for support of a project covered by the terms of this Policy. This information will be used to implement the University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects. The information may be released or transmitted to the sponsor, including federal agency representatives, and, according to state law, may also be released to the public upon request. For further information about the Policy and use of the information, you may contact: *(provide name and telephone number of campus or laboratory contact)*. At the Office of the President, you may contact the Director of Research Policy and Development at (510) 987-9428.

Finally, the Disclosure and Update form(s) may provide the Investigator with a direct opportunity to indicate whether or not he or she believes the project(s) could directly and significantly affect the Related Financial Interest(s) he or she is reporting.

VII. Review of Disclosures

The Disclosure shall be reviewed by a University Reviewing Official or the ISRC to determine whether any related financial interest is one which would reasonably appear to be directly and significantly affected by the proposed sponsored project.

A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest, or when the organization is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one which will materially affect the value of the organization, its earnings, or the sales of its products, or the organization is a proposed subcontractor or participant in the project.

Based on information provided in the Disclosure, the University Reviewing Official or the ISRC may determine that there is no reasonable basis on which to conclude that a project could directly and significantly affect the financial interest and that the financial interest is not likely to affect the design, conduct, or reporting of the project. In this case, a record should be made of the Reviewing Official's or ISRC's action and the project can proceed without further review.

In the event that either the Investigator or the University Reviewing Official concludes that a project might have a direct and significant impact on the financial interest and that the financial interest could affect the design, conduct or reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the campus or Laboratory ISRC for consideration. (At the Department of Energy Laboratories, this requirement can be delegated to the Reviewing Official working in concert with Laboratory management and Ad Hoc Review Committees, where appropriate). The ISRC (or Laboratory equivalent) makes a final recommendation to the Chancellor or Laboratory Director (or designee) about whether the project should proceed and whether any conditions or restrictions should be placed on the project to manage the conflict of interest. The same review process takes place when an Investigator files an Update form reporting a new, related financial interest.

VIII. Management or Elimination of Conflicts of Interest

When an Investigator has financial interests that would reasonably appear to be directly and significantly affected by the sponsored project, the designated University Reviewing Official or the ISRC (or Laboratory equivalent) may recommend to the Chancellor or Laboratory Director (or designee) that the project may not proceed. Alternatively, the Official or the ISRC (or Laboratory equivalent) may recommend that the campus or Laboratory impose special conditions or restrictions to manage the conflict of interest to minimize the effect of the Related Financial Interest(s) on the design, conduct, or reporting of the sponsored project(s). Investigators may also be asked to make recommendations about how to manage the conflict of interest. Examples of conditions or restrictions that may be imposed to manage or eliminate conflicts of interest include:

- a. Public disclosure of the Related Financial Interest(s), including notice of the interest as an addendum to all publications arising from the project;
- b. Monitoring of the project by independent reviewers;
- c. Modification of the research or project plan;
- d. Disqualification from participation in all or a portion of the project;
- e. Divestiture of the Related Financial Interest(s); or
- f. Severance of relationships that create actual or potential conflicts.

The review of the Disclosure(s) and adoption of conditions or restrictions to manage or eliminate the conflict of interest must be completed within 90 days of receipt of the award, unless the sponsor requires action by an earlier date. Some sponsors may also require a report of the existence of a conflict of interest and assurance that it has been managed, reduced, or eliminated.

IX. Sanctions

Failure to file a complete Disclosure of Financial Interest or Update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds for discipline pursuant to the University Policy on Faculty Conduct and the Administration of Discipline or other applicable employee disciplinary policies. In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of University policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.

X. Responsibilities and Administration

Chancellors, Laboratory Directors, the Executive Vice President, Business Operations, the Senior Vice President--Business and Finance, and the Vice President--Agriculture and Natural Resources, within their respective areas of responsibility, shall implement this Policy. In addition, they are authorized to issue local guidelines, implementing procedures, and supplementary forms, as appropriate, consistent with this Policy and applicable sponsor regulations. Universitywide implementation shall be monitored by the Vice Provost for Research or designee, in consultation with the Provost and Senior Vice President--Academic Affairs.

Records regarding Disclosures, Reviewing Official's determinations, ISRC recommendations, and University actions regarding management of a conflict of interest must be retained by each campus or Laboratory for three years beyond the termination or completion of an award, or until resolution of any action by the sponsor involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

Implementation of this Policy shall include compliance with applicable sponsor regulations governing institutional responsibilities, certification of compliance, reporting requirements, and other duties required under the specific sponsor's regulations.

Department of Energy Laboratory implementation of this Policy will be integrated with the requirements of each prime contract and other legal constraints. Each Laboratory will examine local conditions and obligations to determine what additional actions and procedures need to be implemented to bring local practices into conformance with this Policy.

