

**UNIVERSITY OF CALIFORNIA, SANTA BARBARA
OFFICE OF RESEARCH**

SPONSORED PROJECTS POLICY

RESEARCH CIRCULAR D.1.

**POLICY ON DISCLOSURE OF FINANCIAL INTERESTS
UNDER FEDERAL DISCLOSURE POLICIES**

I. References

- A. University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects (effective October 1, 1995, revised October 15, 1997).
- B. Public Health Service (PHS) regulations, *Objectivity in Research*, 42 CFR Part 50 and 45 CFR Part 94.
- C. National Institutes of Health Grants Policy Statement (version at issue of policy: March, 2001).
- D. National Science Foundation (NSF) Grant Policy Manual, Section 510 (version at issue of policy: August 1, 2002).

II. Policy

A. General Statement

Any Investigator who has responsibility for the design, conduct, or reporting of a project sponsored by the National Science Foundation (NSF), Public Health Service (including NIH) and certain other agencies must disclose all Significant Financial Interests (see definition below) of the Investigator and his or her spouse and dependent children that may be related to or affected by the sponsored project. If the University determines that such an interest might reasonably appear to directly and significantly affect the sponsored project, then the Significant Financial Interest has created a conflict of interest. Under federal regulations, the University must take steps to either manage or eliminate conflicts of interest.

Additionally, proposals submitted to PHS, NSF and certain other agencies require an authorized institutional official to certify that financial interest disclosure requirements set forth in this policy have been met and that any conflict of interest will be satisfactorily managed or eliminated prior to the institution's expenditure of funds under the award. Certain agency regulations also require that all required financial disclosures under this policy are provided at the time that the proposal is submitted to the agency. Therefore, the University will not submit proposals to PHS, NSF or any other sponsor requiring adherence to the federal regulations or the 800-U disclosure process (which implements the federal regulations) unless all investigator(s) of the proposed project have signed a Disclosure of Financial Interests Under Federal Policies (Form 800-U) and submitted a Statement of Economic Interests: Addendum (Form 800-UA), if required. The University shall not release award funds until the 800-U forms, including any addenda (Form 800-UA) in the cases where a significant financial interest is identified, have been reviewed and any conflicts of interest have been managed or eliminated.

The identification of financial interests under federal regulations is broader than the State of California Conflict of Interest Policy. While the state disclosure laws require disclosure of financial interest in the *individual sponsor*, the Federal regulations require disclosure of any financial interest that *may be affected by the work* performed under a sponsored project.

B. Definitions.

1. Investigator. An “investigator” includes any individual who has responsibility for the design, conduct, or reporting of the sponsored project (i.e., any University individual, including students).

2. Significant Financial Interest. A “Significant Financial Interest” is anything of monetary value including, but not limited to:

- (a) Income exceeding \$10,000 when aggregated for an Investigator and the Investigator’s spouse and dependent children from a single Entity (business, public or non-profit) including salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value, including payments during the past 12 months and income expected to be received in the next 12 months. Income from a Public or Non-profit Entity for seminars, lectures, teaching engagement or service on advisory committees or review panels is exempt.
- (b) Equity in the form of stock, stock options, real estate, loan to, or any other investments or ownership interest exceeding \$10,000 (current market value) or a 5% ownership interest, for any one enterprise when aggregated for an Investigator, the Investigator’s spouse and dependent children.
- (c) A management position such as board member, director, officer, partner or trustee held by the Investigator, the Investigator’s spouse and/or dependent children; or,
- (d) 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 Significant Financial Interest does not include: (1) payments made by the Regents; (2) income from seminars, lectures or teaching engagements sponsored by a public or non-profit entity; or (3) income from service on advisory committees or review panels for public or non-profit entities.

3. “Related” Significant Financial Interest. A Significant Financial Interest is “related” to the sponsored project if:

- (a) The Investigator is conducting a project where the results could be relevant to the development, manufacturing or improvement of the products or services of the entity in which there is a financial interest;
- (b) 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;
- (c) The Investigator has consulting income from a single entity that exceeds \$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.

- (d) 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,
- (e) The Investigator has a financial interest that is part of a consortium or that will otherwise participate in the sponsored project.

C. The Disclosure Process.

1. Initial Disclosure Documentation. All Investigators must complete and sign the Form 800-U (Disclosure of Financial Interests Under Federal Policies) before the University will submit the project proposal to the sponsoring agency. The Lead Principal Investigator is responsible for assuring that all Investigators are properly identified, and for assuring that each Investigator complete and submit the Form 800-U and any other required documentation to the Sponsored Projects Office for review. The Form 800-U should be submitted to the Sponsored Projects Office with the initial proposal review package.

2. Supplemental Disclosure Documentation. If a Significant Financial Interest is identified by any Investigator, that Investigator must also complete the Statement of Economic Interests: Addendum (Form 800-UA) and attach any supporting documentation requested by the Form. The Lead Principal Investigator is responsible for assuring that all Investigators who identify a Significant Financial Interest properly complete and submit Form 800-UA. The Form 800-UA should be submitted to the Sponsored Projects Office.

3. Review of Significant Financial Interests. All Significant Financial Interests must be subject to an independent substantive review prior to the acceptance of the funding at issue. The reviews shall be performed by the Conflict of Interest Committee, which recommends to the Vice Chancellor for Research whether the disclosed Significant Financial Interest might reasonably appear to directly and significantly affect the sponsored project and if so, whether the conflict of interest created by that Significant Financial Interest can be effectively managed or eliminated. The Vice Chancellor for Research must approve the acceptance of funds, and any conditions to be attached, before the funds can be accepted by the University. The Conflict of Interest Committee is appointed pursuant to Section III.A.2. of the Policy on Acceptance of Private Funds for Research. The Conflict of Interest Committee may require the submission of additional documents or information, or require the Investigator to appear before the Committee, if needed to make it's determination.

If the Conflict of Interest Committee determines that the conflict of interest cannot be satisfactorily managed or eliminated, the Vice Chancellor for Research shall notify the agency in accordance with the agency's policies and guidelines.

4. Management or Elimination of Conflict of Interest. The Conflict of Interest Committee may recommend that special conditions or restrictions be imposed to manage or eliminate an existing or potential conflict of interest. The goal in managing conflicts of interest is to minimize the effect of that interest on the design, conduct, or reporting of the sponsored project. Examples of conditions or restrictions that may be imposed include:

- 1. Public disclosure of the related financial interest
- 2. Monitoring of the project by independent reviewers.

3. Modification of the research or project plan
4. Disqualification of the Investigator from all or a portion of the project.
5. Divestiture of the financial interest
6. Severance of the relationship(s) that create actual or potential conflicts.

6. Updating Disclosure Information Disclosure information shall be updated whenever new or substantially increased Significant Financial Interests related to a project are acquired by an Investigator for which a prior disclosure form has been submitted--it is the responsibility of the individual Investigator to assure that a new form is completed promptly when a new or substantially increased Significant Financial Interest is created. Disclosures may also need to be updated when the Principal Investigator receives notification of a pending award. It is the responsibility of the Principal Investigator to assure that each Investigator of the project submits updates at this time. Reviews of updated disclosures will be completed by the Conflict of Interest Committee within sixty (60) days of receipt of the updated disclosure forms.

D. Sanctions Failure to file complete or updated disclosure forms, when applicable, or failure to comply with any conditions or restrictions imposed on the conduct of a sponsored project under this Policy, will be grounds for discipline pursuant to the Policy on Faculty Conduct and the Administration of Discipline or other applicable employee policies. In addition, Federal regulations may require reports to the Federal sponsor of any violations of University policy. Sponsors may suspend or terminate the award and/or debar an investigator from receiving future awards.

E. Record Retention Records regarding disclosures--, including the disclosure forms, COIC recommendations, and University actions--must be retained for three years beyond the termination or completion of an award for a sponsored project, or until resolution of any action by the sponsor involving the records, whichever is longer. Records related to unfunded projects need not be retained.

IV. Attachments

- A. Disclosure of Financial Interests Under Federal Policies (Form 800-U)
- B. Statement of Economic Interests: Addendum (Form 800-UA)

First Issued: September 15, 1995

Last Revised: February 1, 2003, effective: February 15, 2003

Steven Gaines
Acting Vice Chancellor for Research

cc: Meta Clow, Administrative Services