

Procedures for Reporting, Reviewing, and Managing Conflicts of Interest in Research

This document describes the process for reporting, reviewing and managing potential conflicts of interest in sponsored research and educational activities, including the process for disclosing financial interests, the referral of positive disclosures to the Conflict of Interest Committee, the process for reviewing positive disclosures, and the establishment of management plans for managing, reducing or eliminating conflicts of interest in sponsored research and educational programs, including research programs involving human subjects.

All Principal Investigator and other Investigators must disclose their financial interests and the financial interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s) (as indicated below) whenever submitting a proposal for a sponsored project.

With regard to proposals for sponsored research to the National Science Foundation and Public Health Service agencies (including the National Institutes of Health), Principal Investigator and other Investigators must disclose project-related financial interests for themselves and the financial interests of their spouses/domestic partners and dependent children at the proposal submission stage on the appropriate form(s) (as indicated below). This requirement also applies to subrecipients of contracts from PHS/NIH or NSF or from other agencies that have adopted the federal requirements (e.g., the American Heart Association, the American Cancer Society, the California Institute for Regenerative Medicine, the International Vaccine Institute, UC Discovery Grants, and the UCOP Special Research Programs).

I. Initial Disclosure by Principal Investigators

A. Principal investigators shall complete California State Form 700-U when:

1. A new, renewal, or continuation proposal is prepared for submission to a nongovernmental sponsor or the University of California for a UC Discovery Grant.
2. There is a request to receive material from or provide material to a nongovernmental sponsor pursuant to a Material Transfer Agreement.
3. A gift is received from a nongovernmental entity, which is earmarked for research or educational activities for which the principal investigator is responsible.

No disclosure is required if the nongovernmental funding agency is listed in Title 2, Division 6 of the California Code of Regulations § 18755 (d)(1).

- #### B. Principal Investigators shall submit [Form 800](#) (Statement of Economic Interests Related to Government Sponsored Programs and Other Projects Involving Human Subjects Research) when a new, renewal, or continuation proposal is prepared for submission to any of the agencies listed at <http://research.ucdavis.edu/home.cfm?id=OVC,10,1754,1152>, or when the Principal investigator seeks or receives funds from a nongovernmental sponsor for research involving human subjects.

II. Initial Disclosure by Principal Investigator and other Investigators

Principal Investigator and other Investigators shall complete [Form 800](#) (Statement of Economic Interests Related to Government Sponsored Programs and Other Projects Involving Human Subjects Research) (a) when a new, renewal, or continuation proposal is prepared for submission to any of the agencies listed at <http://research.ucdavis.edu/home.cfm?id=OVC,10,1754,1152>, (b) when Principal Investigator or other Investigators will work on a project involving human subjects funded by a nongovernmental sponsor, or (c) when a project described in subsections (a) or (b) above is transferred to UC Davis from another entity, in which case completion of the transfer will be subject to completion of the Form 800.

III. Supplemental Disclosure by Principal Investigators and other Investigators

- A. Principal Investigator and other Investigators who make a positive disclosure on one of the forms described above must also submit a Supplemental Form--Statement of Economic Interest to describe the nature of the financial interest related to the sponsored project. A positive disclosure is made when the Principal Investigator or another Investigators reports a financial interest in or related to the research.
- B. When completing the Supplemental Form for a project sponsored by the federal government or other agency for which Form 800 is required, Principal Investigator and other Investigators shall consider all significant financial interests to determine if any are related to the sponsored project. Examples include but are not limited to the following:
 - 1. Financial interest in a business entity that develops, manufactures, or improves a product or offers services related to the research project.
 - 2. Financial interest in a business entity that might manufacture or market a drug, device, procedure, or any other product used in the project or that will predictably result from the research project.
 - 3. Consulting income from a business entity where the consulting activity could reasonably appear to be related to the research project.
 - 4. Financial interest in a business entity that will act as a vendor, subcontractor, lessor, or other participant on the research project.
 - 5. Financial interest in a business entity that is related to intellectual property in which the investigator is named as an inventor if the research project could reasonably appear to be affected by the interest.
- C. All disclosure forms must be submitted when submitting the proposal. Funding will not be accepted until the forms are received and the Conflict of Interest Committee completes any necessary review.
- D. All Principal Investigator and other Investigators involved in projects sponsored by the federal government must file an updated Form 800 (Statement of Economic Interests Related to Government Sponsored Programs and Other Projects Involving Human Subjects Research) when they (or their spouse/domestic partner or dependent children) acquire a new financial interest related to a project while the project is receiving financial support from federal government.
- E. When making a positive financial disclosure, a Principal Investigator or other Investigators may, at his or her option, include a proposed management plan. A proposed management plan shall include the elements set forth in section V, below.

IV. Review by the Conflict of Interest (COI) Committee

- A. The COI Committee will review each positive disclosure to determine whether an actual or potential conflict of interest exists. The COI Committee may consider the following in determining whether a conflict of interest exists: the amount of the financial interest, the role of the reporting individual with respect to the relevant entity, how closely the financial interest is related to the subject of the research, whether the research involves human subjects, whether and to what extent students are involved in the research, and any other factors that may be relevant. The factors and documents relied upon by the COI Committee will be addressed in the meeting minutes.
- B. If the Committee determines that a potential or actual conflict of interest exists, the Committee

will consider:

1. Whether the nature of the conflict could potentially influence or bias the outcome of the research,
 2. Whether any harm could come to research subjects if a conflict biased the design, conduct or results of the research,
 3. Whether the potential conflict should be managed, reduced, or eliminated. If none of these options is viable, the Committee will consider whether the research should proceed.
- C. If the Committee determines there is a potential or actual conflict, the Committee will transmit its recommendation as follows:
1. When the case involves research with human subjects, the Committee will transmit its recommendation to the Institutional Review Board. The IRB will review the recommendation to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program. After receiving input from the IRB, the Committee will transmit its recommendation to the Vice Chancellor--Research, who will issue a decision regarding the Committee's recommendation.
 2. In all other cases, the Committee will transmit its recommendations directly to the Vice Chancellor--Research for decision.
- D. If the Vice Chancellor--Research decides that a potential or actual conflict of interest exists, the reporting individual will be notified and may be asked to submit a proposed management plan (see section V, below).
- E. If the Vice Chancellor--Research determines that a conflict of interest exists, he/she will determine (upon review of recommendations by the Conflict of Interest Committee and/or Institutional Review Board) what actions should be taken by the campus to manage, reduce, or eliminate the conflict. If a conflict of interest is found by the Vice Chancellor--Research involving PHS funding, he/she shall report to the PHS awarding agency the existence of a conflicting interest (but not the nature of the interest or other details) and provide assurances that the interest has been managed, reduced or eliminated. With regard to conflicting interests identified after the University's initial report under a PHS agency award, the Vice Chancellor--Research shall provide the same report and assurances to the PHS awarding agency within 60 days of the identification.

V. Management Plan

- A. The proposed management plan should include:
1. Name and role of the Principal Investigator and other Investigators on the project;
 2. Title of the research and a short abstract of the project;
 3. Name of the business entity with which the Principal Investigator or any other Investigator has a conflict;
 4. Nature of the conflict;
 5. Names of potential person(s) who could serve as a monitor or as part of a management sub-committee;
 6. Declaration of how research will be conducted to reduce the potential for bias in the research;

7. Plan for reporting the financial status of the project and on-going compensation from the business entity;
8. Appropriate level and timing of reporting to the monitor or management sub-committee;
9. Documents that would be appropriate for the monitor or management sub-committee to review.

B. Management and Oversight

1. Some actions that may be taken to manage a conflict of interest include:
 - a. Disclosure of the conflict to the public, human subjects, publishers and/or conference organizers,
 - b. In the case of human subjects research, requiring an independent investigator to obtain informed consent or conduct all or part of the research,
 - c. In the case of human subjects research, requiring independent safety monitoring,
 - d. Requiring that the financial interest be divested, restructured or placed in a blind trust,
 - e. Modification or severance of the financial relationship,
 - f. Requiring additional disclosures to relevant University committees,
 - g. Non-participation of the Principal Investigator or the other Investigators in any business transactions between the Principal Investigator/other Investigators and the business entity/entities,
 - h. Disclosure and/or review of relevant publications prior to submission,
 - i. Review of financial report on a regular basis by a monitor or management sub-committee,
 - j. Submission of reports on a pre-determined basis to a monitor or management sub-committee,
 - k. Annual (or other pre-determined timeline) meeting with a monitor or members of a sub-committee.
2. If the Vice Chancellor--Research deems it necessary, he will appoint a monitor or management sub-committee to oversee implementation of the management plan and management of the conflict of interest. The members of the management sub-committee may include individuals from outside of the University where the Vice Chancellor--Research determines that outside expertise is required to manage the conflict.
3. In these cases, the monitor or sub-committee will meet with the Principal Investigator/other Investigators and review and approve the management plan. The plan will be signed by the monitor or chair of the management sub-committee and the Principal Investigator/other Investigators. Any dispute between the Principal Investigator/other Investigators and the monitor or sub-committee will be referred to the COI Committee for a recommended resolution and the Vice Chancellor--Research for decision.
4. The monitor/sub-committee and the Principal Investigator/other Investigators will agree upon a timeline for reporting and reviewing documentation relevant to the oversight responsibility of the monitor/sub-committee. Documentation will vary depending upon the nature of the research and the conflict.

5. The monitor/sub-committee will review the report and relay the report and any additional relevant information to the Conflict of Interest Committee. Any revision of the plan or apparent deviation from or non-compliance with the plan will be relayed to the Conflict of Interest Committee. If the issues cannot be resolved within a reasonable time frame, the Committee will subsequently refer the matter to the Director--Research Compliance and Vice Chancellor--Research for action consistent with PPM 230-05.