

UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES

Conflict of Interest

Section 481-3: Conflicts of Interest in Human Subjects Research

Responsible Office: Office of Research Administration

Issued: January 1, 2000

Revised: June 1, 2001 (to apply to all research personnel); October 2006

References / Resources

Federal Regulations

- 21 CFR Part 54, Food and Drug Administration, Financial Disclosure by Clinical Investigators
- 42 CFR Part 50, Public Health Service, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- 45 CFR Part 94, Public Welfare, Responsible Prospective Contractors, National Science Foundation, Grants Policy Manual, Section 510, Conflict of Interest Policies

University of California, Office of the President: UC Policies

- UC Office of Research Contract and Grant Memo, Operating Requirement No. 95-5, Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects, dated February 15, 1995.

University of California, Irvine Policies

- UCI Research Policy Protection of Human Subjects in Research, dated December 16, 1983, and as subsequently revised.

A. Background

The Institutional Review Board (IRB) is the University of California, Irvine's body authorized to review research protocols to protect the rights and welfare of human subject participants and to ensure that human research activities conform to the federal and state statutes and regulations, and to UC policies. The informed consent document is considered the principal means by which to advise potential subjects of any risks associated with their participation in a research project.

In 1998, the Vice Chancellor for Research (VCR) approved a recommendation of the Research Conduct Policy Committee that all investigators should disclose for review outside financial interests, and that such interests were to be disclosed to the human participants through the informed consent document. The VCR charged the campus Conflict of Interest Oversight Committee (COIOC) with the review of financial disclosures associated with human research protocols in coordination with the IRB.

B. Policy

As of January 1, 2000, Lead Researchers (LR) are required to disclose financial interests as part of the Application for IRB Review. This requirement was expanded on June 1, 2001, to require financial disclosures from all study team members listed on the Application.

This policy establishes a process of disclosure and independent review to identify harmful conflicts of interest and to reduce, manage or eliminate such conflicts in order to preserve objectivity in the design, conduct, or reporting of research.

Investigators shall report for themselves, their spouses and dependent children the following disclosable financial interests:

- Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:
 - Less than \$10,000 when aggregated for the immediate family and
 - Publicly traded on a stock exchange and
 - Value will not be affected by the outcome of the research and
 - Less than 5% interest in any one single entity.
- Compensation related to the research, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value, including payments made to the University Health Sciences Compensation Plan, unless it meets both of the following tests:
 - Less than \$10,000 in the past year when aggregated for the immediate family and the
 - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.

Related financial interests occur when the investigator, their spouse or dependent children have a disclosable financial interest that would reasonably appear to be affected by the research or when the entity in which the financial interests are held would reasonably appear to be affected by the research. To assist in the disclosure process, the following examples are provided:

- The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the Investigator has a financial interest.
- The investigator has a financial interest in an entity that might manufacture, commercialize or license a drug, device, procedure or any other product used in the project or that will predictably result from the project;
- The investigator received compensation from activities in his/her professional field during the prior twelve months, where the financial interest of the entity or the investigator would reasonably appear to be affected by the project;
- The investigator has a financial interest in an entity and the project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity; or

- The investigator has a financial interest in an entity that is part of a consortium or that will otherwise participate in the project.

On occasion, financial arrangements or relationships that would not require disclosure under the terms of this Policy, but that could appear to constitute an actual or potential conflict of interest with respect to a project, may be disclosed voluntarily by study team members. Should the University subsequently determine that the voluntarily disclosed interest would reasonably appear to be affected by the research or the interests of the entity would reasonably appear to be affected, the University may take steps to manage or to eliminate the conflict.

In addition, the informed consent document must advise potential subjects whether or not anyone involved with the research has a financial interest that is related to the study. Disclosure language is included in the consent template for [medical studies](#) and for [social and behavioral studies](#).

Final approval of the IRB protocol and informed consent by the IRB is postponed until the COIOC assesses the disclosure and the potential conflict of interest.

C. Definitions

1. **Lead Researcher:** The investigator with primary responsibility for meeting all ethical, scientific, and regulatory requirements for conduct of a UCI study human subjects protocol, whether or not acting as the Principal Investigator for the award that funds the study.
2. **Conflict of Interest Oversight Committee (COIOC):** The faculty advisory committee appointed by the Vice Chancellor for Research to review financial disclosures where there is the possibility of a conflict of interest. This group is also referred to as the Independent Substantive Review Committee in UC policies.
3. **Investigator:** Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the protocol or sponsored project. Investigator includes the Principal Investigator, co-investigators, and any other individual (including personnel from other institutions). For purposes of this policy, investigators must disclose interests of their spouse and dependent children.

Note: Reporting includes authorship on publications resulting from the research. Thus, if authors, graduate and undergraduate students may be required to disclose, even if they are not paid from the project.

D. Procedures

1. In the Application for IRB Review, the Disclosure of Investigators' Financial Interests form asks each study team member listed on the protocol to indicate whether or not they have any disclosable financial interests for themselves, their spouse and dependent children (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research. Lead Researchers (LR)

are responsible for obtaining financial disclosures, if any, from all study team members listed on their IRB Application. This requirement applies to all studies, sponsored and unsponsored.

2. Upon receipt of the Application, the IRB staff forward information regarding disclosures of financial interests to the Office of Research Administration Conflict of Interest Administrator.

3. The Conflict of Interest Administrator will evaluate whether the individual has disclosed or will disclose financial interests for the same project under the policy implemented for federal disclosures on grants and contracts. If no current disclosure is pending, the COIOC administrator will contact the named individual and ask them to complete a full Addendum regarding the specifics of the financial interest.

4. The LR is responsible for the inclusion of appropriate information in the informed consent document advising potential research participants whether or not anyone involved with the research has a disclosable financial interest related to the protocol. Suggested language is included in the consent template for [medical studies](#) and for [social and behavioral studies](#).

a. For use in a study involving human subjects when the Lead Researcher and other study team members do not have financial interests that exceed the applicable thresholds.

“No one on the study team has a disclosable financial interest related to this research project.”

b. For use in a study involving human subjects when the Lead Researcher or another study team member has financial interests that are disclosable.

“[a member of the study team or their spouse or dependent child(ren) - list people here] has a disclosable financial interest in [the Sponsor company or other related entity - list here]. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee, and this committee has determined that the investigator’s financial interests will not compromise the quality or reliability of the study. Furthermore, the UCI Institutional Review Board has determined that the investigator’s financial interests will not adversely affect your safety and welfare.”

5. The disclosure and Addendum will be reviewed by the Conflict of Interest Oversight Committee at its next meeting. The materials are considered by the COIOC as outlined in Section E of this policy. The COIOC makes a recommendation on each disclosure to the Vice Chancellor for Research, who decides whether the financial interests are acceptable or should be reduced, managed or eliminated. The COIOC Administrator enters the decision into the COI database.

6. The COIOC Administrator forwards the decision of the Vice Chancellor for Research, along with an explanation and suggested consent language, to the

IRB Administrator for review to determine whether the COIOC has adequately considered the effect of the disclosed financial interests on the rights and welfare of the human subject participants. The IRB makes the final decision related to the project's acceptability and may impose additional requirements in order to protect human subjects. If additional protections are required, the IRB Administrator informs the COIOC Administrator in order to document the change.

E. Deliberations of the COIOC

1. The Disclosure, Addendum, and other appropriate documentation are forwarded to the COIOC for review at its monthly meeting. The COIOC considers whether the project could affect the financial interests of the entity or the investigator's financial interests could affect the design, conduct, or reporting of the project.

2. The COIOC considers the research project according to traditionally held principles of ethical conduct and academic freedom. The COIOC evaluates whether: the financial interest will adversely affect the integrity of the research; there is sufficient separation of University and private interests; the proposed research is appropriate to the University; the teaching and research environment is open; freedom to publish and to disseminate research results is preserved; the University's intellectual property rights are protected; the University's facilities and resources are used appropriately and that the University receives proper compensation for their use.

3. The COIOC also considers the effects of the disclosed financial interests on the rights and welfare of the human subject participants. The COIOC considers whether the rights of the participants would be better protected by reduction or elimination of a financial interest, separation of responsibilities for financial and research decisions, additional oversight, implementation of an independent data and monitoring committee, or any other mechanism that would mitigate the effects of the financial interest.

F. Authority and Responsibility

1. **Lead Researcher** is responsible for:
 - a. answering questions on the Application for IRB Review regarding the cumulative financial interests of themselves, their spouse and dependent children;
 - b. informing the study's research personnel of the conflict of interest policy and including the names of research personnel who have disclosable interests on their Application for IRB Review;
 - c. including the appropriate statement in informed consent documents regarding the financial interests of research personnel;

- d. answering questions from the IRB regarding the financial interests of the research personnel listed on the Application for IRB Review; and
 - e. answering questions posed by research subjects during the consent process regarding the financial interests of any research personnel disclosed in the consent.
2. **Institutional Review Board (IRB)** is responsible for:
- a. forwarding financial disclosures accompanying the protocol application to the COIOC;
 - b. approving, disapproving, or requiring modification in all informed consent language and the consenting process; and
 - c. reviewing COIOC findings to determine whether the COIOC has adequately considered the effect of the disclosed financial interests on the rights and welfare of the human subjects participants.
3. **Conflict of Interest Oversight Committee (COIOC)** is responsible for:
- a. reviewing financial disclosures from research personnel and evaluating the impact on research participants and the research environment;
 - b. forwarding recommendations for acceptance, disapproval or management of a financial interest to the VCR for input prior to the IRB's review; and
 - c. communicating the decision of the VCR to the disclosing individual and the IRB staff and maintaining a record of the decision in accordance with applicable record retention requirements.
4. **Vice Chancellor for Research (VCR)** is responsible for:
- a. considering recommendations of the COIOC for conflict of interest concerns;
 - b. endorsing the recommendations of the COIOC or developing other management responses that serve to protect the integrity of the research and minimize the effects on human subjects;
 - c. informing the campus community of policies, procedures, principles and other information sources related to conflict of interest; and
 - d. convening oversight committees, as needed, to manage conflicts of interest related to research.