UC IRVINE RESEARCH POLICIES, GUIDELINES & PROCEDURES

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

Responsible Administrator: Vice Chancellor for Research – Office of Research
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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, Award and Administration Guide, Chapter IV-Grantee Standards, 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

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A. Background and Purpose

UCI's Institutional Review Board (IRB) is responsible for reviewing and approving research protocols to ensure that they protect the rights and welfare of human subject participants and that human research activities conform to the federal and state statutes and regulations, and to UC policies. UCI's Conflict of Interest Oversight Committee (COIOC) is responsible for reviewing financial disclosures related to UCI's research programs, including human subject research.

Since the outside financial interests of UCI's Researchers may pose potential or real risks with regard to the rights and welfare of human subject participants, UCI has established a process of disclosure and independent review to:

- Identify and reduce, manage or eliminate harmful conflicts of interest;

- Protect the rights and welfare of human subject participants; and
- Preserve objectivity in the design, conduct, or reporting of human subject research.

B. Applicability

This policy applies to all researchers engaged in human subjects research, including non-UCI collaborators listed on the IRB protocol narrative.

C. Policy

As part of the Application for IRB Review, all Researchers engaged (or will be engaged in human subjects research) shall report for themselves, their spouses/registered domestic partners and dependent children the following disclosable financial interests (if any) related to the human subject research:

- Income greater than $10,000 received from a single entity over the twelve months prior to disclosure. Income includes salary, consultant payments, honoraria, royalty payments, dividends, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans.

- Equity in a publicly-traded entity greater than $10,000 (current market value) or greater than a 5% ownership interest. Equity includes stock or stock options, real estate, or any other investment or ownership interest. Equity does not include investments in a mutual fund, pension fund or other investment fund over which the Researcher or his/her immediate family member do not exercise any control.

- Any equity in a non-publicly-traded entity, including stock or stock options, or any other investment or ownership interest.

- Any management position, such as Board of Directors, director, officer, partner or trustee.

- Intellectual property interest in a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the UC Regents held by the Researcher, their spouse/registered domestic partner and/or dependent children.

Related financial interests occur when the Researcher, their spouse/registered domestic partner and/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. The following are examples (which are not all inclusive) of related financial interests:

- The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the Researcher has a financial interest.

- The Researcher has a financial interest in an entity that might license (for commercial purposes) an invention, technology, drug, device, procedure or any other product used in the project or that will predictably result from the project.

- The Researcher 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 Researcher has a financial interest in an entity and the project proposes to subcontract a portion of the work, or lease property, or refer participants to, or make purchases from the entity.

- The Researcher has a financial interest in an entity that will participate in the project, including as part of a consortium.

In those cases where the University determines that:

- The research could reasonably appear to affect the disclosed interests; or

- The disclosed interests could reasonably appear to affect objectivity in the design, conduct, or reporting of the research.

The University shall take steps to manage, reduce or eliminate the conflict of interest, including but not limited to requiring that the informed consent document advise potential subjects that one or more Researchers has a financial interest related to the research/study.

Final approval of the human research protocol and informed consent by the IRB shall not occur until after the COIOC review and approval process is complete.

D. <u>Procedures</u>

1. In the electronic IRB application, researchers are required to disclose whether or not they have any disclosable financial interests for themselves, their spouse/registered domestic partner and/or 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 inquiring with all Researchers listed on the IRB Application if they have a related disclosable financial interest.
    a. New IRB applications and continuing protocol applications require disclosure from all researchers listed on the protocol as research personnel.
    b. Modifications that change the Lead Researcher and/or add new research personnel require disclosure only from the new Lead Researcher and/or the new research personnel.

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 Conflict of Interest staff.

3. The Conflict of Interest staff will contact the named individual and ask them to complete a full Addendum regarding the specifics of the financial interest.

4. The disclosure and Addendum will be reviewed by the Conflict of Interest Oversight Committee at its next meeting. The COIOC makes a recommendation on each disclosure to the Vice Chancellor for Research or designee, who decides whether the financial interests are acceptable or should be reduced, managed or eliminated.

5. The COI staff forwards the decision of the Vice Chancellor for Research or designee, 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.

6. 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 Researchers 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 Researcher 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 (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare."

E. Deliberations of the COIOC

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.

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) or designee** 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.

F. Definitions

1. **Researcher:** Any individual engaged in human subjects research (including non-UCI collaborators) listed in the protocol narrative of the UCI IRB approved research protocol.

2. **Lead Researcher:** The Researcher listed in the IRB approved protocol as the Lead Researcher. Section 480-2.1 of the UCI Research Policies, Guidelines and Procedures provides a comprehensive definition of Lead Researcher and describes the duties and general responsibilities of individuals designated as such.

3. **Conflict of Interest Oversight Committee (COIOC):** The faculty advisory committee appointed by the Vice Chancellor for Research to review financial disclosures of Researchers. This group is also referred to as the Independent Substantive Review Committee in UC policies.