

## UCI Administrative Policies and Procedures

### OFFICE OF RESEARCH

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

**Responsible Office:** Office of Research

**Issued:** January 1, 2000

**Revised:** June 1, 2001; October 2006; June 2014; April 2022

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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 IX-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](#)
- [UC Protection of Human Subjects in Research Policy, dated 11/6/2020](#)

#### University of California, Irvine Policies

- [UCI Research Policy Protection of Human Subjects in Research, dated December 16, 1983, and as subsequently revised](#)

**Contacts:** Office of Research – Associate Vice Chancellor for Research Administration at (949) 824-5677, Conflict of Interest Administrator at (949) 824-0012, or Director of Human Research Protections at (949) 824-5746.

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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 mitigate, manage or eliminate harmful conflicts of interest;

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

This policy applies to all researchers engaged in human subjects research, including non-UCI collaborators.

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## **C. Definitions**

**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.

**Disclosable financial interest:** An outside financial interest that needs to be disclosed and reviewed by the COIOC includes one or more of the following for the researcher, their spouse/registered domestic partner and/or dependent children:

- Income greater than \$10,000 received from a single entity (excluding UC Regents) 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.

**Engaged in human subjects research:** An individual that is or will be doing one or more of the following in a human subjects research project:

- Intervenes with subjects by performing research procedures, or by manipulating the environment for research purposes;
- Participates in the recruitment and/or selection of subjects;
- Participates in the informed consent process;
- Collects or reports subject identifiable data; and/or
- Have access to subject identifiable study data or identifiable specimens.

**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.

**New disclosable financial interest:** A newly discovered or acquired and not previously reviewed by the Conflict of Interest Oversight Committee disclosable financial interest related to an active IRB protocol. This also includes acquiring or discovering a new type of disclosable financial interest (income, equity, management position, or intellectual property rights) in an entity that was previously disclosed and approved for the related IRB protocol. For example, a Researcher receiving equity interests in a company after having previously disclosed receiving income from that company is considered a new disclosable financial interest that needs to be reviewed if it relates to an active IRB protocol.

**Related:** 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.

**Researcher:** An individual engaged in human subjects research (including non-UCI collaborators).

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#### **D. Policy**

All Researchers engaged (or will be engaged) in human subjects research shall report for themselves, their spouses/registered domestic partners and dependent children their disclosable financial interests (if any) related to the human subject research at the following times for sponsored and unsponsored IRB protocols:

- With new IRB applications from all Researchers listed on the protocol, including research personnel;
- When adding new research personnel, only the new Researchers must disclose; and
- When a Researcher has acquired or discovered a new disclosable financial interest that relates to their active IRB protocol(s).

This policy establishes a process of disclosure and independent review by the Conflict of Interest Oversight Committee to identify and address potentially harmful conflicts of interest created by a Researcher's financial interests and the human subjects research in which they are engaged. The COIOC may recommend or require additional steps to mitigate, manage, or eliminate such conflicts, as necessary, to preserve the objectivity of the research. For human subjects research projects without any extramural funding, the

COIOC considers whether the study is an appropriate use of University resources that aligns with the University's mission and does not provide an unfair advantage to one entity over others in light of the related disclosable financial interest. In some cases, the COIOC may require extramural funding from the outside entity benefiting from the study to address these concerns and comply with University policies.

The COIOC provides recommended language for the consent form to the IRB describing the disclosable financial interest reviewed by the COIOC, which the IRB can choose to include if they determined the protocol required a consent form. The IRB has the final authority on the consent form language.

The University requires public disclosures of related disclosable financial interests in publications, presentations, and consent language (if applicable) related to the reviewed human subjects research project.

Final approval of the human research protocol and informed consent language by the IRB shall not occur until after the COIOC has reviewed the financial disclosure, made a recommendation to the Vice Chancellor for Research (or designee), and the Vice Chancellor (or designee) has approved the recommendation.

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#### **E. Authority and Responsibility**

**Lead Researcher** is responsible for:

- Answering questions on the Application for IRB Review regarding the disclosable financial interests of themselves, their spouse/registered domestic partner and dependent children;
- 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;
- Including the appropriate statement in informed consent documents (if applicable) regarding the financial interests of research personnel;
- Answering questions from the IRB regarding the financial interests of the research personnel listed on the Application for IRB Review; and
- Answering questions posed by research subjects during the consent process regarding the financial interests of any research personnel disclosed in the consent.

**The IRB is responsible for:**

- Reviewing the research protocol along with the COIOC report to either accept the management plan or revise the management plan to ensure the rights and welfare of the participants are adequately protected; and
- Deciding whether an investigator's financial interest and the COIOC management plan, if any, allow the research to be approved.

**Conflict of Interest Oversight Committee (COIOC)** is responsible for:

- Reviewing related disclosable financial disclosures from research personnel and

evaluating the impact on research participants and the research environment;  
and

- Recommending to the VCR (or designee) whether a financial disclosure should be approved, including the mitigation steps or management plans necessary to safeguard research objectivity.

**Vice Chancellor for Research (VCR) or designee** is responsible for:

- Considering COIOC recommendations and concerns;
- Approving financial disclosures, including requiring mitigation steps or management plans in addition to, or in lieu of, those recommended by the COIOC;
- Informing the campus community about policies, procedures, principles and information sources related to conflict of interest; and
- Convening oversight committees, as needed, to manage conflicts of interest related to research.