

UC Santa Barbara

OFFICE OF RESEARCH

Conflicts of Interest in Human Subjects Research

Responsible Office: Office of Research

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Revised:

References / Resources

Federal Regulations

- [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 & Guidance

- [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](#)
- [Financial Interest Disclosure in Research Consent Form](#)

University of California, Santa Barbara Policies

- [UCSB Policy on the Use of Human Subjects](#)

Contacts: Office of Research –

Conflict of Interest Administrator at coi@research.ucsb.edu

Human Research Protections at hsc@research.ucsb.edu

A. **Background and Purpose**

UCSB'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. UCSB's Conflict of Interest Committee (COIC) is responsible for reviewing financial disclosures related to UCSB's research programs, including human subject research.

Since the outside financial interests of UCSB's Researchers may pose potential or real risks with regard to the rights and welfare of human subject participants, UCSB has established a process of disclosure and independent review to identify and reduce, manage or eliminate conflicts of interest with the goals of

- Protecting the rights and welfare of human subject participants; and
 - Preserving objectivity in the design, conduct, or reporting of human subject research.
 - Ensuring the appropriate use of university resources.
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B. Applicability

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

C. Definitions

Collaborator: A non-UCSB individual “engaged” in the human subjects research, who will be relying on UCSB’s IRB review of the research activities.

Conflict of Interest Committee (COIC): 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: A financial interest that needs to be disclosed and reviewed by the COIC includes one or more of the following for the researcher, their spouse/registered domestic partner and/or dependent children:

- Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:
 - Less than \$5,000 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 non-UC salary, consultant payments, honoraria, non-UC royalty payments, dividends, gifts, loans, or any other payments or consideration with value, unless it meets both of the following tests:
 - Less than \$5,000 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.

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 biospecimens.

Researcher: The individual assigned as the “researcher” role in the IRB approved protocol.

This individual assumes overall responsibility for research involving human subjects and their data or specimens.

New disclosable financial interest: A disclosable financial interest related to an active IRB protocol that was newly discovered or acquired and not previously reviewed by the Conflict of Interest Committee. This also includes acquiring or discovering a new type of disclosable financial interest in an entity that was previously disclosed and approved for the related IRB protocol. For example, a Researcher disclosed income in a company related to the IRB study and has now received equity interests in that same company, which is considered a new disclosable financial interest that needs to be reviewed.

ORahs: Office of Research Application for the use of Human Subjects; the electronic web-based IRB protocol submission system for distribution, review, and approval for human subjects research projects.

ORCOI: Office of Research Conflict of Interest online disclosure system; the online disclosure system for conflict of interest statement submissions required by the Public Health Services, National Science Foundation, State of California and for human subjects research projects.

Related interest: 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 Researcher has a financial interest in an entity where the project results appear relevant to the development, manufacturing, or improvement of products or services of that entity.
- 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.

D. **Disclosure Requirement**

As part of the electronic applications 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 their disclosable financial interests (if any) related to the human subject research. This includes the following regardless of whether or not the study is extramurally funded:

- New IRB applications and continuing protocol applications that undergo annual IRB review require disclosures from all researchers listed on the protocol, including research personnel.
- Continuing protocol applications for research that do not undergo an annual IRB review require all research personnel to notify Conflict of Interest (COI) staff when there is a new disclosable financial interest related to the study.
 - Researchers are required to submit a protocol modification to notify the IRB within 30 days of acquiring a new disclosable financial interest that relates to their human subjects research project. This would include a disclosable financial interest in a new entity or a new type (income, equity, management position, or intellectual property rights) of disclosable financial interest that was not previously disclosed.
- 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 document establishes a process of disclosure and independent review by the Conflict of Interest 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 COIC may recommend or require additional steps to reduce, manage, or eliminate such conflicts as are necessary to preserve the objectivity of the research.

The COIC will communicate with the IRB on the nature of the conflict of interest and the proposed management conditions. The IRB will evaluate the proposed management conditions and determine whether additional safeguards are necessary. Any changes to the proposed management conditions will be communicated to the COIC.

As a matter of best practice, the University recommends disclosures of related disclosable financial interests in consent language related to the associated human subjects research project.

Final approval of the human research protocol and informed consent language by the IRB shall not occur until after the COIC review has been conducted and agreed upon by the Vice Chancellor for Research or designee.

E. Procedures

1. Researchers disclose all related disclosable financial interests or report a new related disclosable financial interest in their ORahs protocol application including when UCSB is the IRB of record/reviewing IRB for IRB Reliance studies. See below for some variations to this process:
 - When UCSB is relying on another IRB, researchers will complete the HSC COI Checklist as part of the reliance application request. If any of the questions on the COI Checklist are marked as a "yes", HS staff will notify COI staff of the disclosable interest. The COI staff will create a COI disclosure in ORCOI and send a request out to the researcher to complete the COI disclosure. Researchers with disclosable financial interest(s) will complete a 600U for each related entity. The HSC will not complete the IRB reliance agreement until the COI review is complete. If the

reviewing IRB's institution conducts their own COI review, the researcher is responsible for sharing the results of that review with UCSB's HS staff and the COI administrator.

- When UCSB is the IRB of record, researchers with a new related disclosable financial interest will be asked to disclose related financial interests of the research team (including collaborators relying on UCSB's IRB review) via the ORahs protocol application. If any of the questions on the disclosable financial interests are marked as "yes", ORahs will notify the COI staff, HS team and copy the researcher. The COI staff will create a COI disclosure in ORCOI and send a request out to the researcher to complete the COI disclosure. Researchers with disclosable financial interest(s) will complete a 600U for each related entity. The HSC will not complete the IRB review until the COI review is complete.
2. Upon receipt of the ORahs protocol application that includes a disclosable financial interest, the online system will generate an automated email notification to the COI Administrator, Human Subjects Office, and Researcher with the disclosable interest.
 3. The COI staff will contact the disclosing individual and ask them to complete a 600U form regarding the specifics of the financial interest in ORCOI. Researchers with disclosable financial interest(s) will complete a 600U for each related entity.
 4. The form will be reviewed by the Conflict of Interest Committee at its next meeting. The COIC makes a recommendation on each disclosure to the Vice Chancellor for Research or designee, who decides where 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 to the IRB, which makes the final decision related to the project's acceptability, the informed consent language (if applicable), and may impose additional requirements in order to protect the human subjects. If additional protections are required, the IRB Administrator informs the COI Administrator in order to document the change.
 6. The Researcher is responsible for the inclusion of appropriate information in the informed consent document (if applicable) advising potential research participants whether or not anyone involved with the research has a disclosable financial interest related to the protocol.

F. Deliberations of the COIC

The COIC considers the research project according to traditionally held principles of responsible conduct and academic freedom. The COIC evaluates whether: the financial interest has the potential to adversely affect the integrity of the research; there is sufficient separation of University and private interests; 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 COIC also considers the effects of the disclosed financial interests on the rights of the human subject participants to be fully informed of financial interests that could impact their willingness to participate in the research. The COIC also considers whether the integrity of the research 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.

G. Authority and Responsibility

Lead Researcher is responsible for:

- Answering questions on the ORahs protocol application for IRB Review regarding the cumulative 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 ORahs protocol 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 or COIC regarding the financial interests of the research personnel listed on the ORahs protocol application for IRB Review;
- Answering questions posed by research subjects during the consent process regarding the financial interests of any research personnel disclosed in the consent; and
- Notifying the reviewing IRB, if not UCSB, of any COI determinations related to the project/protocol.

The IRB is responsible for:

- Supporting the COIC by providing the protocol application to the COIC, if requested;
- Reviewing the research protocol along with the COIC report and either accepting the management plan, or revising the management plan to ensure the rights and welfare of the participants are adequately protected; and
- Having the final authority to decide whether an investigator's financial interest and the COIC management plan, if any, allow the research to be approved.

Conflict of Interest Committee (COIC) is responsible for:

- Reviewing financial disclosures from research personnel and evaluating the impact on research participants and the research environment;
- Forwarding recommendations for acceptance, disapproval or management of a financial interest to the VCR for input prior to the IRB's review; and
- 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.

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

- Considering recommendations of the COIC for conflict of interest concerns;
- Endorsing the recommendations of the COIC or developing other management responses that serve to protect the integrity of the research and minimize the effects on human subjects;
- Informing the campus community of policies, procedures, principles and other information sources related to conflict of interest; and
- Convening oversight committees, as needed, to manage conflicts of interest related to research.

Office of Research Integrity staff are responsible for:

- Maintaining records in accordance with the retention schedule and sponsor requirements (if applicable).
- Monitoring compliance with any management conditions imposed by the COIC.
- Notifying the Lead Researcher about their responsibilities for coordinating with other IRBs, when UCSB is not the reviewing IRB. The reviewing IRB is responsible for ensuring appropriate notification to research subjects, and may have their own COI disclosure and review requirements.