

Policy Number: 25

Title: Investigator and Research Personnel Conflicts of Interest

Date of Last Revision: 07/28/06, 10/03/10, 08/08/11

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all disclosable financial interests be captured as part of the IRB application for review by the COIOC and the IRB to assure protection of the rights and welfare of participants in human subjects research.

Disclosable Financial Interests are any of the following financial interests of any key research personnel (Lead Researcher and all individuals responsible for the design or conduct of the study), or his or her immediate family (spouse, domestic partner, and child), in aggregate:

1. Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:
 - a. Less than \$10,000 when aggregated for the immediate family and
 - b. Publicly traded on a stock exchange and
 - c. Value will not be affected by the outcome of the research and
 - d. Less than 5% interest in any one single entity.
2. 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:
 - a. Less than \$10,000 in the past year when aggregated for the immediate family and the
 - b. Amount will not be affected by the outcome of the research.
3. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
4. Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.

References:

University Policy on Disclosure of Financial Interest in Private Sponsors of Research (APM-028), dated April 26, 1984

University Guidelines for Disclosure and Review of Principal Investigator's Financial Interest in Private Sponsors of Research, dated April 27, 1984

UCI Policy on Disclosure of Principal Investigator's Financial Interests in Nongovernmental Sponsors of Research, revised December 15, 1999

UCI Research Policy for Conflict of Interest in Human Subjects Research

42 CFR 50.603

21 CFR 54.1

Procedure Number: 25.A

Title: Procedure for Investigator and Research Personnel Disclosure of Conflicts of Interest

Procedure:

This procedure outlines the process for reporting and disclosing any conflicts of interest in human subjects research.

I. Lead Researcher (LR) Responsibilities

- A. A LR who is conducting human subjects research at UCI or utilizing UCI resources or facilities is required to disclose all disclosable financial interests:
 - 1. That would reasonably appear to be affected by the research; or
 - 2. In entities whose financial interests would reasonably appear to be affected by the research.
 - 3. This requirement applies to all studies, sponsored or non-sponsored.
- B. The LR is responsible for submitting financial disclosures, if any, from all research personnel listed on the application and protocol.
- C. Disclosures must be submitted:
 - 1. At initial IRB submission using the "Disclosure of Investigator's Financial Interests" form;
 - 2. When adding research personnel through a modification request;
 - 3. At each continuing review of the study using the electronic continuing protocol application; and
 - 4. Within 30 days of becoming aware of any previously undisclosed financial interest using the "Disclosure of Investigator's Financial Interests" form.
- D. The Investigator must comply with the recommendations of the Conflict of Interest Oversight Committee (COIOC) and IRB to minimize the conflict.

II. IRB Committee Responsibilities

- A. The IRB will have final authority to decide whether an investigator's financial interest and the COIOC management plan, if any, allow the research to be approved.
- B. The IRB will review the research protocol along with the COIOC report and will either accept the management plan, or revise the management plan to ensure the rights and welfare of the participants are adequately protected.

III. IRB Analyst or Higher Responsibilities

- A. When the IRB receives a IRB application where a researcher has disclosed a financial interest:
 - 1. In an effort to facilitate the regulatory review process, FOR NEW STUDIES ONLY, IRB review may run concurrent with COIOC review.
 - 2. If a positive financial conflict of interest has been noted, HRP Staff will send an email to the Lead Researcher & Administrative Contact, notifying them that IRB review will be concurrent with COIOC review however, the study may not be granted a conditional approval until the IRB has reviewed the COIOC report and suggested text language for the consent form as accepted by the Associate Vice Chancellor for Research. This notification is sent out utilizing current email template language.
 - a. The COIOC Administrator is sent a copy of the email notification by HRP Staff.
 - b. HRP Staff will forward a hard copy of the IRB Application to the COIOC Administrator.

- B. When the IRB receives a modification, or continuing review application where a researcher has disclosed a financial interest:
 - 1. If a positive financial conflict of interest has been noted, HRP Staff will send an email to the Lead Researcher & Administrative Contact, notifying them that IRB review will be on hold pending COIOC review and acceptance of the COIOC recommendations by the Associate Vice Chancellor for Research, utilizing the current email template language.
 - a. The COIOC Administrator is sent a copy of the email notification by HRP Staff.
 - b. HRP Staff will forward a hard copy of the IRB Application to the COIOC Administrator.
 - 2. Additionally, HRP Staff must consider the list of researchers that should be disclosing a positive financial conflict of interest for each study that they are involved in (regardless of whether they indicate a positive financial conflict of interest or not). This list is routinely circulated by the COIOC Administrator via email to all HRP staff. When a submission with one of these names is noted an email is sent to the COIOC Administrator.
 - a. The COIOC Administrator will send a follow up email to the applicable parties.

IV. IRB Administrator or Designee

- A. Once the COIOC Administrator provides the final COIOC report, informing the IRBs of the results of the COIOC evaluation and management plan, the modification, or continuing review application can be placed on an upcoming IRB agenda (research involves greater than minimal risk) or reviewed by an IRB subcommittee (research involves minimal risk).
- B. In the case of an IRB Application, IRB review is concurrent with the COIOC review, as noted above. If the final COIOC report, informing the IRBs of the results of the COIOC evaluation and management plan is not available at the time IRB review, the IRB must "T" the new study pending this information. Once the report is available, the new study must return to the IRB for final review and approval.
- C. If the IRB determines that additional protections are required, the IRB Administrator informs the LR and the COIOC Administrator.

V. Conflict of Interest Oversight Committee (COIOC) Responsibilities

- A. 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 the University receives proper compensation for their use.
- B. 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.
- C. The COIOC makes a recommendation on each disclosure to the Associate Vice Chancellor for Research, who decides whether the financial interests are acceptable or should be reduced, managed or eliminated.

VI. **COIOC Administrator Responsibilities**

- A. The COIOC Administrator pre-reviews the Disclosure of Investigator's Financial Interests form to assure that the information is complete and meets the requirements under COIOC policies and procedures.
- B. The COIOC Administrator will prepare reports including, but not limited to, information obtained from a COIOC questionnaire completed by the Investigator and a copy of the protocol, for consideration by the COIOC.
- C. If additional information regarding an Investigator's financial interests is required, the Administrator will contact the Investigator and request the additional information.
- D. The COIOC Administrator enters the decision of the Committee into the COI database.
- E. The COIOC Administrator forwards the decision of the Associate Vice Chancellor for Research
- F. Once the Associate Vice Chancellor for Research accepts the financial disclosures, the COIOC Administrator prepares the COIOC report to inform the IRBs of the results of the COIOC evaluation and management plan. The report includes the:
 - 1. IRB Protocol number and study title;
 - 2. Disclosing Individual's name;
 - 3. Lead Investigator's name;
 - 4. Study Sponsor and Award Type;
 - 5. Description of the disclosable financial interest;
 - 6. Scientific rationale for the research;
 - 7. The COIOC determination;
 - 8. An explanation for the determination; and
 - 9. Suggested informed consent language, if any.
- G. The COIOC Administrator sends a memo to the Investigator via e-mail of the outcome of the COIOC review.