

**Policy Number: 9**

**Title: IRB Committee Member and Consultant Conflicting Interest**

**Date of Last Revision: 07/28/06, 10/04/10, 01/21/11**

**Policy:**

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all conflicting interests of an IRB committee member and consultant be declared before review of any research under IRB jurisdiction. IRB Committee Members and consultants with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must absent themselves from the meeting during the IRB's deliberative discussion and vote on the affected research.

A conflict of interest is a situation where an IRB Committee Member's outside financial interest(s) or obligation(s) bias or has the potential to bias the deliberative discussion and vote of the affected research protocol. IRB committee members are those individuals serving as members including Chairs, the IRB, alternates or expert consultants regardless of voting privileges.

IRB committee members and consultants are considered to have a conflicting interest if they or their immediate family member (spouse, domestic partner, or child) have any disclosable financial interest; role in the conduct of or participation in the research; or other individual conflict of interest.

**Disclosable Financial Interests are:**

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:**

38 CFR 16.107(e)

21 CFR 46.103, 107

21 CFR 56.107

21 CFR 54 (as reference)

42 CFR 50 Subpart F

45 CFR Part 94

UCI Policy on Conflicts of Interest in Human Subjects Research

OHRP May 2004 Financial Relationships and Interests in Research Involving Human Subjects Guidance for Human Subjects Protection

UCOP Academic Conflicts of Interest or Commitment Related to Sponsored Research  
UC Irvine Administrative Policies & Procedures Sec. 700-09: Policies on Gifts, Gratuities, and Conflict of Interest

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**Procedure Number: 9.A**

**Title: Procedure for IRB Committee Member and Consultant Conflicting Interest**

**Procedure:**

This procedure outlines the IRB committee member and consultant responsibilities regarding required disclosure of conflicts of interest when reviewing human subjects research.

**I. Individual with Conflict Responsibilities**

- A. Each committee member must review this Procedure and corresponding Policy and sign the “UCI IRB Members Standards” document at the initial IRB committee member orientation and annually thereafter.
- B. Each committee member must review and sign a “Conflict of Interest (COI) Disclosure Form for IRB Members” at the initial IRB committee member orientation and annually thereafter.
- C. Each consultant must read this Procedure and corresponding Policy and sign the “UCI IRB Members Standards for Consultants” before reviewing a research protocol and disclose any conflicting interest.
- D. Each committee member must indicate on the IRB Reviewer checklist whether or not they have a conflicting interest. Also, those members who have a conflict of interest must inform the IRB Administrator before the Committee meeting or at the beginning of the meeting. At the beginning of each convened IRB meeting the IRB Chair or designee will ask the members if anyone has a conflicting interest with any of the research protocols on the agenda. IRB members are encouraged to review the IRB Members Conflict of Interest Standards provided at each meeting.
- E. IRB committee members with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must absent themselves from the meeting during the IRB’s deliberative discussion and vote on the affected research.
  - 1. This includes the review of unanticipated problems involving risks to participants or others, as well as the review of potential non-compliance matters.
- F. IRB committee members may absent themselves from the discussion and vote for any reason, if they feel it is necessary to avoid any appearance of a conflicting interest.
- G. IRB members who review Expedited level research in subcommittee must also absent themselves from the review and any deliberative discussion and vote on the affected research.
  - 1. This includes the review of unanticipated problems involving risks to participants or others, as well as the review of potential non-compliance matters.
- H. IRB committee members may absent themselves from the discussion and vote for any reason, if they feel any member of the research team or others has exerted undue influence. Such situations should be reported to the Vice Chancellor for Research or to the designated officials named in the UCI Whistleblower Policy and Procedures.

**II. The Human Research Protections (HRP) Team Responsibilities**

- A. The HRP team (Administrator, Senior Analyst, and Analyst) and other HRP staff under the direction of the Administrator, identify IRB members with COIs (e.g., IRB members or their immediate family member listed as a study team member) in preparing the agenda for a convened meeting, as well as in preparing for subcommittee. Members with an identified COI are not assigned as study reviewers. The HRP team lists COI recusals on the IRB agenda to remind members to leave the room, when applicable. HRP staff monitors COI recusals during the meeting.

- B. The HRP team and other HRP staff under the direction of the Administrator, evaluates the annual IRB Member's disclosures of financial interest. Administrators maintains a spreadsheet titled, "Member Standards and COI Log" which confirms that the "UCI IRB Members Standards" document, as well as the "Conflict of Interest (COI) Disclosure Form for IRB Members" has been completed and reflects any positive disclosures to be considered per member. Members with a financial COI are not assigned as study reviewers. The HRP team lists COI recusals on the IRB agenda to remind members to leave the room, when applicable. HRP staff monitors COI recusals during the meeting.
- C. For a convened meeting, the HRP team records in the minutes each time a member is absent from the Committee discussion and vote due to a COI.