

Policy Number: 9

Title: IRB Committee Member and Consultant Conflicting Interest

Date of Last Revision: 07/28/06, 10/04/10, 01/21/11, 03/04/22

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