

P&P: GA 104 Version No: 1.2 Effective Date: 1/31/14	IRB MEMBER CONFLICT OF INTEREST	Supersedes: CPHS Policies and Procedures 9/1/2007
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1. POLICY

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

Specific Policies

1.1 Definition of a Conflict of Interest (COI) for IRB Members

An IRB member is said to have a conflicting interest whenever that IRB member, or his/her spouse, domestic partner or first degree relative (e.g. child, sibling, or parent):

- is an investigator or key personnel on the protocol under consideration;
- acts as an officer or a director of the sponsor or an agent of the sponsor;
- is involved in the research as a coordinator, protocol consultant and/or primary advisor;
- has received any of the following from an entity whose financial interests would reasonably appear to be affected by the outcome of the research:
 - non-university salary or other payments for services (e.g., consulting fees or honoraria) exceeding \$10,000 over a 12-month period;
 - equity interests (e.g., stocks, stock options or other ownership interests) exceeding \$10,000 or 5% of the equity of the entity; or
 - intellectual property rights (e.g., patents, copyrights, royalties from such rights); or
- has identified him/herself for any other reason as having a conflicting interest (e.g., having a close personal or professional association with the submitting investigator, serving as co-investigator and/or the primary mentor for a student or post doc investigator).

1.2 Disclosure and Documentation of Financial Interest and COI

It is the responsibility of each member of the IRB to disclose any COI in a study submitted to the IRB and recuse him/herself from the review of that protocol. No member may participate in the discussion for initial or continuing review of any research project in which the member has a conflict of interest, *except* to provide information or answer questions from the IRB as requested.

Members with a COI for a protocol may not be present during IRB voting on that protocol. The procedures for recusal of IRB members, including the IRB Chair, from deliberating and voting on all protocols for which there is a potential or actual conflict of interest are detailed in FO 303 - IRB Meeting Administration.

The Institutional Official has the authority to determine when COI exists as defined by institutional policy and to enforce the requirements of the policy.

1.3 OPHS Employees

OPHS staff whose job status or compensation is affected by research that is reviewed by the IRB must recuse themselves from any meeting during the time at which such a protocol is reviewed, discussed, and voted on.

2. SCOPE

These policies and procedures apply to all IRB members and OPHS staff of UC Berkeley.

3. RESPONSIBILITY

The Vice Chancellor for Research is responsible for articulating and enforcing the conflict of interest policy at UCB.

The IRB Chair is responsible for identifying COI disclosures at IRB meetings before each protocol review and discussion.

The Director serves as the liaison between UCB's COI Committee Chair and/or COI Coordinator and the IRB

OPHS staff are responsible for documenting all COI disclosures and recusals in the IRB meeting minutes.

IRB members and OPHS staff are required to be knowledgeable about conflict of interest issues and institutional policies pertaining to COI.

IRB Members and/or staff must disclose any personal existing COI to the IRB Chair and/or the OPHS Director prior to the IRB beginning the review of the pertinent protocol.

4. PROCESS OVERVIEW

IRB members will declare to the IRB Chair and recuse themselves from voting where a COI exists or may appear to exist. They may be present for the discussion to provide information or answer questions if the IRB determines that they may have information that is beneficial to the deliberations.

OPHS staff will declare to the OPHS Director any such personal existing COI and will refrain from being involved in the administrative review processes of the protocol under consideration and not be present when the IRB reviews the protocol.

The OPHS staff documents COI disclosures and recusal in IRB meeting minutes.

The IRB Chair and Director ensure that IRB members with a COI do not participate in the IRB voting subject to their COI disclosures.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

OHRP's "Financial Relationships and Interests in Research Involving Human Subjects:
Guidance for Human Subject Protection" (5/12/2004)