



Policy: IRB Member Conflict of Interest (last updated August 4, 2016)

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Policy

IRB Members with a conflicting interest cannot participate in review of the research activities except to provide information requested by the committee and must leave the room during the IRB deliberations and vote. These conflicts may take the form of financial interests (defined below), or be conflicts that are based on the IRB Member's responsibilities or relationships.

IRB Members are expected to inform the IRB Chair or Administrator of any conflict of interest that may arise in the review of research for the IRB that may compromise objectivity.

Guiding Principles

Members of the IRB, including alternate members, or expert consultants participating in the review of a protocol, regardless of voting privilege, should not have or appear to have a conflict of interest, including a disclosable interest, related to any of the studies in which they participate in the review process. In this context, the term "conflict of interest in research" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an IRB member's professional judgment or objectivity in reviewing or evaluating a research project.

The goal in adhering to this principle is to prevent conflicting interests from interfering with the review process either by competing with an IRB member's or consultant's obligation to protect participants or by compromising the credibility of the review process. A conflict of interest depends on the situation, and not on the character or actions of the individual member.

For purposes of this document, the term "IRB Member" will be used to refer to Regular and Alternate Members as well as IRB Consultants.

Disclosable Financial Interests

The following financial interests of the IRB member or his or her immediate family* that are related to the research being reviewed should be disclosed:

* "Immediate family member" includes an IRB Member's spouse, registered domestic partner, and dependent children.

- **Remuneration and/or Equity interests:**

- With regard to any publicly traded entity, the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated exceeds \$5,000. Remuneration includes salary (e.g., consulting fees, honoraria, paid authorship). Equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value.
- With regard to any non-publicly traded entity, if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000 or if any equity interest is held (e.g., stock, stock options, or other ownership interest).

- **Anticipated Income or other payment for services** if the amount of anticipated income could reasonably appear to be affected by 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 whether compensated or not.

- **Other types of financial interests** including financial interests in an entity to which a portion of the research might be subcontracted, from which space will be leased, to which participants will be referred or from which purchases may be made.

Other Considerations

An IRB member should also consider the following potential conflicts of interest and determine whether a particular role or relationship could affect his or her objectivity before reviewing, participating in the IRB committee discussion or deliberation, and voting on a protocol:

- An affirmative answer to any of the following questions indicates **a conflict of interest requiring recusal** by the Member from reviewing or voting on a particular protocol.

- **Participation in the research:** Is the IRB Member, or member of his/her immediate family, listed as the investigator on the study, or as a member of the research team?
- **Supervision of the research:** Is the IRB Member or member of his /her immediate family, the Faculty Sponsor of the Investigator, or supervisor of the investigator on the conduct of the study under review? (Example: The faculty chair of a graduate student's thesis or dissertation committee)

- An affirmative answer to any of the following questions **does not automatically disqualify a Member from reviewing and voting, but does require careful consideration**. If the Member believes the situation poses a conflict of interest, he or she should follow the policy on recusal from deliberations and voting on the research.

- **Potential conflicting relationship with research sponsor or investigator:** Do any of the following apply to the IRB Member or member(s) of his/her immediate family:
 - A financial interest in an entity, as defined above, which may reasonably be considered to have a competitive interest in the study under review by the IRB?

- Conducting research which may reasonably be considered to be competing with the study under review?
 - A competitive relationship with the investigator, including but not limited to being in direct competition for limited resources (e.g., funding, equipment, space, research participants)?
- **Other:** Does the IRB Member have other concerns that warrant abstaining from review, deliberation and voting on a protocol? Examples may include a commitment to a particular research approach or objections to a particular type of research.

Procedures

• **Assignments for Review**

IRB Members will not knowingly be assigned studies for review for which they have an actual or potential conflict of interest. In the event this happens, it is the responsibility of the IRB member to disclose the conflict of interest to the attention of the IRB Staff. The study will be reassigned to another IRB Member for review.

• **IRB Meeting**

- Every agenda includes a printed reminder that any member with a conflict of interest must leave the room during the deliberation and voting on the study.
- The agenda also indicates the names of any IRB members known to have a conflict of interest associated with a particular study.
- Any member with a conflict of interest must leave the meeting room before the IRB deliberation and vote on the agenda item. Prior to leaving the room, however, the IRB member may answer questions from the IRB about the project.
- The IRB Staff will record the recusal of the Member(s) from the IRB deliberation and vote in the meeting minutes. The minutes will indicate that a conflicting interest was the reason for the recusal.
- The recused IRB Member will not be counted as part of the quorum for that agenda item. If a quorum is not present as a result of this absence, then the IRB cannot take further action or vote on the protocol. The protocol will have to be rescheduled for a meeting for which there will be a quorum.

• **Expedited Review**

- If the IRB staff knows that a particular IRB Chair or designee has a conflict of interest with a study which will be reviewed using the expedited procedure, the IRB staff member will route the study to another Chair or designee without the conflict.
- If a Chair or designee reviewing an expedited study discloses a conflict of interest previously unknown to the staff member assigning the review, the study will be rerouted to an IRB Chair or designee who does not have a conflict of interest.

• **Unanticipated Problems and Non-Compliance**

Procedures for management of IRB member conflicts of interest also apply to full committee and expedited review of unanticipated problems involving risks to participants and others and non-compliance with regulations or laws or the requirements of the UCLA IRB.

- ***Principal Investigators***

If a Principal Investigator or other investigator on a study believes that a particular IRB member may have a potential conflict of interest he or she should bring this to the attention of the IRB Chair or Administrator. The Chair, in consultation if needed, will make the final decision as to whether the IRB member should recuse him or herself from IRB deliberations and voting on the study in question.

References

[OHRP Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection](#),” May 2004

UCLA Research Policy & Compliance, [Conflict of Interest in Research](#) website.

Change history:

6/9/2016: Updates to links and references, formatting

8/4/2016: Modification to disclosure requirements regarding remuneration and equity interests; replaced references with link to UCLA Research Compliance & Policy website.