

Avoiding IRB Members' Conflicts of Interest

SOP 106.3
Approved: December 18, 2015

Purpose and Scope

This Standard Operating Procedure (SOP) sets forth the requirements by the University of Hawai'i (UH) human research protection program (HRPP) to ensure objectivity in UH institutional review board (IRB)'s review and oversight of research involving human subjects.

This SOP demonstrates compliance with applicable federal regulations, which state, "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."¹

These policies and procedures apply to regular and alternate members of all UH IRBs, Human Studies Program staff, and consultants requested by IRB to provide information during protocol review.²

Definitions

Immediate Family Member means spouses, domestic partners, reciprocal beneficiaries, and dependent children.³

Conflict of Interest (COI)⁴: A conflict of interest exists when there is a separation between an individual's private interests and his/her professional obligations to the University and/or research projects such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal financial gain. A conflict of interest depends on the situation, and not on the character or actions of the individual.⁵

An IRB member has a conflicting interest in a proposed or active research project when the IRB member or the member's immediate family member:

1. Is an investigator or involved in the performance of the study under review by the IRB;
2. Is an officer, director, or other agent of the study sponsor;
3. Has a significant financial interest, as defined below, in the research;

¹ DHHS, 45 C.F.R. § 46.107(e) (2013); FDA, 21 C.F.R. § 56.107(e) (2013).

² For purposes of this SOP, IRB members will also include HSP staff and consultants who are also involved in reviewing or providing information during protocol review.

³ A5.000 Academic Affairs, UH, 3 (July 11, 2012), <http://www.hawaii.edu/svpa/apm/a500/a5504.pdf>.

⁴ Executive Policy – Academic Affairs, E5.214, UH (Jul. 11, 2012), <http://www.hawaii.edu/apis/ep/e5/e5214.pdf>.

⁵ Stanford University. 4.4 Conflict of Commitment and Interest for Academic Staff and Other Teach Staff (accessed Feb. 11, 2015). Retrieved, with permission, from: <http://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/conflict-commitment-and-interest-academic-staff-and-other-teaching-staff>

4. Is involved in the research as a coordinator, consultant, or advisor;
5. Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
6. Has any other financial or non-financial interest that conflicts or appears to conflict with the member's ability to objectively review a study, e.g., the member has a close personal or professional association with the investigator, serves as a thesis or dissertation advisor or committee member, is the author of a grant application that supports a student investigator's research, or serves as a mentor for a student or post-doctoral investigator.

Significant Financial Interest⁶: significant financial interest exists when the IRB member or the member's immediate family member receives any of the following from an entity such that the IRB member's or the family member's financial interests would reasonably appear to be affected by the outcome of the research:

1. Non-UH salary or other payments for services, e.g., consulting fees or honoraria, exceeding \$5,000 over a 12-month period;
2. Equity interests, e.g., stocks, stock options, or other ownership interests, exceeding \$5,000 or 5% of the equity of the entity; or
3. Intellectual property rights, e.g., patents, copyrights, or royalties from such rights.

Significant financial interest does not include income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.⁷

Procedures

Assurance

IRB Meetings:

1. No IRB member may participate in the initial or continuing review of any study in which the member has a conflicting interest except to provide information requested by the IRB.
2. **Disclosure.** Each IRB member (and consultant) must disclose to the IRB Chair any conflicting interest in a study submitted to the IRB for review and approval.
 - a. Consultants with a conflict of interest in a study may still provide information at the IRB's request. They are not allowed to participate in the discussion of the study.
3. **Notification.** Members with a conflicting interest should notify the IRB staff prior to the meeting to avoid loss of a quorum.
4. **Primary Reviewer.** If an IRB member is assigned as the primary reviewer for a study with which the member has a conflicting interest, the member should immediately notify the HSP staff so that the staff can assign another primary reviewer.
5. **Discussion and Voting.** No IRB member with a conflicting interest in a study may participate in the discussion except to provide information at the IRB's request. No IRB member with a conflicting interest in a study may vote on that study.

⁶ Conflict of Interest Policies, Nat'l Sci. Found., http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510 (last visited Oct. 24, 2013).

⁷ APM A5.54: Procedures for Disclosing and Addressing Conflicts of Interest and Commitment, UH, 7 (Jul. 11, 2012), <http://www.hawaii.edu/apis/apm/a500/a5504.pdf>.

6. **Quorum.** When an IRB member is absent from the room during the vote on a study due to a conflicting interest, that member does not count toward the quorum for the vote of the study.
7. **Minutes.** When an IRB member is absent from the room during the vote on a study due to a conflicting interest, this is recorded in the meeting minutes as a recusal. The minutes will reflect the name of the recusing IRB member.
 - a. Minutes will also document any conflicts of interests of any consultants used.

IRB Chairs:

If the IRB Chair has a conflicting interest with a study under review by the IRB, the person may not chair the meeting during the discussion and may not vote on the study.

1. The IRB Chair must be absent from the room during the discussion and vote on the study with which the chair has a conflicting interest.
2. If the IRB Chair recuses from participation in the review and vote on a study, the chair will appoint a temporary IRB Chair from among the participating members of the IRB.
3. The meeting minutes will reflect the IRB Chair did not chair the meeting or participate in the discussion and vote for the study due to a conflict of interest. The minutes will record the name of the temporary Chair.

Expedited Review:

1. The IRB coordinator will route the study to a member without a conflict.
2. If a member reviewing an expedited study discloses a conflict of interest previously unknown to the coordinator assigning the review, the coordinator will reroute the study to a member without a conflict.

Exempt Review:

Since HSP staff are primarily responsible for the review of research that qualify for exempt status, an HSP staff that has a conflict of interest with a proposal or protocol under review will re-route the application to a staff without a conflict.

Unanticipated Problems and Non-Compliance:

The procedures described above also apply to the review of unanticipated problems involving risks to participants and others, and non-compliance with regulations, laws, or the requirements of the UH IRBs.

Questions Regarding Conflicts of Interest:

If an IRB member has a question about whether a conflict of interest exists with a study, the member should consult with the Director, the IRB Chair, or the UH Conflict of Interest Committee. If the Chair has a question about whether a conflict of interest exists with a study, the chair should consult with the UH Conflict of Interest Committee.

Training:

1. Each IRB member will sign an “IRB Member Conflict of Interest Agreement” upon appointment, and renewal of the appointment, to the IRB.

2. IRB Chairs will at least annually remind IRB members of the procedures documented in this SOP.

Materials

- DOC 701: IRB Member Conflict of Interest Agreement

References

- The IRB has and follows written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB (**AAHRPP Element II.1.D.**).