



**University of La Verne Institutional Review Board
Policy and Procedure on Conflicts of Interest
Approved February 10, 2017**

IRB Members, IRB Administration, IRB Consultants, and the Office of Research and Sponsored Programs (ORSP) will not engage in pre-reviews, reviews, making determinations, and voting if a conflict of interest exists. IRB Members must leave the IRB meeting prior to the vote on the item with which they have a conflict of interest. Their exit will be recorded as recused and will be removed from the member count for quorum. They may return after the vote and be added back to the member count for quorum.

I. Types of conflict of interest:

- a. ***Significant involvement in the preparation of materials submitted to the IRB for review or determination.*** IRB members can be drawn upon to be significantly involved in the preparation and writing of materials submitted to the IRB in a variety of contexts. It is considered a conflict of interest when this has occurred for: 1) an Initial Application for IRB approval, 2) continuing review application (i.e., extension), 3) an amendment that increases risk, decreases benefits, or has a significant change in protocol procedures, and 4) determination requests for not human subjects research, exempt status, and engagement status.
- b. Participation on the research team: Any IRB member that is listed as an investigator on the IRB application, or is otherwise a member of the research team.
- c. Supervision of the investigator: This refers to any situation in which the investigator is currently under the professional supervision of the IRB member. This extends to employment and similar situations outside of academic departments. For example, the faculty chair of a graduate student's thesis or dissertation committee.
- d. Supervision of the IRB member by a member of the research team: This means that the investigator on the IRB application has a supervisory or other official authority role with regard to the IRB member. For example, the investigator is the chair of the IRB member's department; the IRB member is a student, and the investigator is the student's mentor or faculty advisor; the IRB member is a paid member of the investigator's research team.
- e. Financial conflict of interest in the research: Financial conflict of interest is defined for IRB members in the same way as it is defined for investigators in the La Verne Conflict of Interest Policy.
- f. Other potentially conflicting relationship with the research sponsor: Examples include serving on a non-governmental sponsor's board of directors, advisory board, scientific board, or safety board.
- g. Personal relationship with the investigator: This is defined as having an immediate family relationship (e.g., romantic partner, sibling, child, parent, household member) or other close personal relationship with the investigator, or with co-investigators who have a significant role in the research.

- h. Competitive or contentious relationship with the investigator: This means the IRB member is in direct competition with the investigator for limited resources (e.g., funding, sponsorship, space, equipment, research subjects), or the IRB member is considered a personal or professional adversary of the investigator for reasons not related to the IRB. Whether this situation creates a conflict of interest for the IRB member should be determined by the IRB Chair.
 - i. Other: The IRB member may have other interests that the IRB member believes conflicts with his or her ability to objectively review the research, including individuals whose other positions at La Verne are dependent on whether a specific project gets funded and thereby has a vested interest in the application being approved. For example, the IRB member may be a participant in a study and such participation may be a conflict of interest for participating in the review of an amendment, adverse event form, or extension.
- II. Identification – A conflict is most likely to be identified when incoming materials are assigned to an IRB member for pre-review, determinations (e.g., exempt status), expedited review, reviewing materials for a convened IRB meeting, and serving as a consultant to the IRB.
- a. Disclosure
 - i. Voluntary disclosure – It is the responsibility of the IRB member to disclose all certain or potential conflicts of interest prior to engaging in any IRB review or determination activities. An email should be sent to the IRB Chair as soon as the conflict of interest is realized.
 - ii. IRB meetings – The conflict of interest should be disclosed prior to application review in the meeting. During the meeting, any conflicted IRB member will disclose the existence of the conflict just before the review of the relevant item begins and then will recuse themselves and leave the room.
 - iii. IRB consultants – Consultants will be provided with a copy of this policy and asked whether they have a conflict of interest with the research when they are asked to provide consultation. The consultant will disclose the conflicts of interest at that time.
- III. Determination when it is not clear – When it is not clear whether a conflict of interest exists, the individuals listed below make a determination. The determination is based on gathering as much information as necessary from relevant sources and it is the position of the La Verne IRB that decisions should err on the side of caution.
- a. Conflicted IRB member: IRB Chair
 - b. Conflicted IRB Chair: IRB Chair and/or Director of Research and Sponsored Projects (DRSP) and/or Vice Provost
 - c. ORSP staff: IRB Chair
 - d. DRSP: IRB Chair and/or Vice Provost
- IV. Management of conflict of interest
- a. ORSP staff – Will not participate in review activities, pre-review, or regulatory determinations. These activities are assigned by the IRB Chair to another IRB member with similar qualifications. They will also recuse themselves during discussions of standard review applications during IRB meetings.
 - b. IRB members:

- i. As reviewers – Will not serve as primary or expedited reviewers. If the conflict is disclosed after review assignment, the review is re-assigned to another IRB member. If the review is already completed, the application will be re-reviewed by another reviewer.
- ii. At IRB meetings – The conflict is disclosed via email to the Chair prior to the IRB meeting (as soon as the conflict is realized) and just prior to the review of the relevant item at the IRB meeting. Although La Verne IRB policy does not require the IRB member to leave the room during the IRB’s discussion, s/he does not participate in the discussion except to provide information at the IRB’s request.
 - a. The IRB member is recused before the vote as discussed in II(a)(ii).
- iii. Consultants – In most cases, a possible consultant who discloses a conflict of interest does not provide consultation to the IRB. However, a conflicted consultant may still be asked to provide consultation when the IRB lacks specific expertise that is important to the review and an alternate consultant cannot be located. For example, this situation might arise if the research involves highly specialized technology, procedures, or subject matter.
 - 1. Procedures
 - a. The will be consultant asked specific questions that are focused and objective. For example, the consultant may be asked, “What are the risks associated with this research – specifically, their nature, magnitude, duration, and likelihood?” rather than open-ended questions such as “Do you think this research is too risky to perform?” The board will make a final determination using the answers provided.
 - b. IRB Administration documents the nature of the conflict in an Add Note within the application on the Chair Approval screens in IRBManager.
 - c. If the consultant’s information has a negative effect on the IRB’s assessment of the research, in particular in cases where the consultant is a rival to the applicant, the investigator is provided with an opportunity to respond.

V. REFERENCES

- a. This document is adapted from: University of Washington, Human Subjects Division “IRB Member Conflict of Interest”
- b. 45 CFR 46.107(e) and 21 CFR 56.107(e)