



IRB Standard Operating Procedures		
SOP#: 02 Revision#: 01	Title: IRB Member Conflict of Interest	Effective Date: March 18, 2019
Approved By:	Institutional Review Board	Approval Date: March 18, 2019

PURPOSE

To prevent any conflict of interest (COI) from influencing the review process either by competing with an IRB member's or consultant's obligation to protect human subjects or by compromising the credibility of the review process.

DEFINITIONS

Conflict of interest (COI) - a situation in which financial or other personal or professional circumstances may compromise, or have the appearance of compromising, an IRB member's professional judgment or objectivity in reviewing or evaluating a research study.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

IRB members - regular members as well as IRB consultants participating in the review of a research study.

WHO IS AFFECTED BY THIS POLICY

IRB members, the IRB chair, and the IRB vice chair.

POLICY

Members of the IRB or expert consultants participating in the review of a protocol should not have or appear to have a conflict of interest related to any of the studies for which they participate in the review process.

The conflict may take the form of financial interests or be based on the IRB member's responsibilities or relationships.

An IRB member should consider all actual and 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.

IRB members are expected to inform the IRB chair or staff of any COI for self and/or others that may compromise the objectivity of the review process.

IRB members with a COI may not participate in review of the research activities, except to provide information requested by the committee, and must recuse themselves from deliberations pertaining to the review.

Types of COI

The following circumstances are indicative of a COI for anyone participating in the review of a research study by the IRB:

Financial COI

- Any current or anticipated financial interest, remuneration, and/or other types of personal gain, in the research that is being reviewed.

Nonfinancial COI

- Participation in the research, if the IRB Member or member of his/her immediate family, or anyone with whom they have a close relationship is listed as the investigator on the study, or as a member of the research team.
- Supervision of a project (IRB member is an academic sponsor of the Principal Investigator, or a situation in which any investigator must report to or is under the professional supervision of the IRB member).
- Other nonfinancial interests that may be conflicting interests, such as if the IRB member has an interest that he/she believes conflicts with their ability to review a project objectively; or the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or the IRB member is considered a personal or professional adversary of the investigators.

RESPONSIBILITIES

IRB Staff

- Provides all IRB members with a copy of the COI policy.
- Indicates known COI on the pre-review form.
- Assigns a study for review to the IRB member without the conflict.

IRB Members

- Disclose a COI during convened meetings and/or exempt and expedited review processes. Include the disclosure of COI as a first comment in the review document for exempt and expedited studies.

PROCEDURES

Full Review by the Convened IRB

- IRB members should alert the IRB staff and the chair about any COI that may be previously unknown. The IRB chair will give an opportunity to the IRB member with

COI to recuse. If the member with COI is reluctant to recuse themselves, the decision will be made by the IRB through a confidential vote prior to the 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.
- The member may provide information requested by the committee.
- 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 at which there will be a quorum.

Expedited Review

- If the IRB chair or designee reviewing an expedited study discloses a COI previously unknown to the staff member assigning the review, the study will be rerouted to a member who does not have a COI.
- **Other**
Same procedures apply to review of unanticipated problems and other instances of noncompliance.

REGULATIONS

[45 CFR 46.107\(d\)](#)

[21 CFR 56.107\(d\)](#)

[Financial Conflict of Interest: HHS Guidance](#) (2004)

AUTHOR REFERENCE

NEIU IRB

[UCLA IRB SOP "IRB Member Conflict of Interest"](#)

Contact Information

Please direct questions or concerns about this policy to:

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Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.