

SOP: IRB MEMBER CONFLICT OF INTEREST

1. PURPOSE

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

2. GUIDANCE

- 3.1. Members of the IRB 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.
- 3.2. 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.
- 3.3. A conflict is most likely to be identified when incoming materials are assigned to an IRB member for review. 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.
- 3.4. IRB members with a COI may not participate in review of the research protocol, except to provide information requested by the committee, and must recuse themselves from deliberations pertaining to the review.

3.5. Types of COI

The following circumstances are indicative of a COI:

3.6. Financial COI:

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

3.7. Nonfinancial COI:

- 3.7.1. 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.
- 3.7.2. 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).
- 3.7.3. Other nonfinancial interests, for example:

- 3.7.3.1. The IRB member has an interest that he/she believes conflicts with their ability to review a project objectively; or
- 3.7.3.2. The IRB member is in direct competition with the investigator for limited resources, funding, and sponsorship, or
- 3.7.3.3. The IRB member is considered a personal or professional adversary of the investigator(s).

4. RESPONSIBILITIES

4.1. IRB Staff:

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

4.2. IRB Members:

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

5. PROCEDURES

5.1. Full Review by the Convened IRB

- 5.1.1. Every agenda includes a 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.
- 5.1.2. At the beginning of each meeting, the IRB Chair asks the members to disclose any conflict of interest concerning any of the items on the agenda. During the meeting, a conflicted IRB member discloses the existence of a conflict and recuses themselves before the review of the relevant item begins.
- 5.1.3. As a practical matter, an IRB member may provide information requested by the committee, but should recuse themselves and leave the room before deliberations begin.
- 5.1.4. 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.
- 5.1.5. 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.

5.2. Other Types of Review

- 5.2.1. If the IRB chair or designee reviewing an expedited or exempt 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.

REGULATIONS

45 CFR 46.107(d)
21 CFR 56.107 (e)

AUTHOR REFERENCE

Northeastern Illinois University, IRB SOP “IRB Member Conflict of Interest”
University of Washington, IRB SOP “IRB Member Conflict of Interest”
Governors State University Policy 53

CONTACT INFORMATION

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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. Requests for exception to any portion of this SOP must be presented in writing to the Institutional Official.