

Guidance -

IRB Members on Conflicting Interests

Any IRB member must disclose a conflicting interest in a project that is under review to the IRB Chair, Director, IRB Operations and HRPP, IRB Specialist, or IRB Analyst and must leave the meeting room during the voting on a project, except if the IRB member is providing information at the IRB's request.

Definition of Conflicting Interest

IRB member, alternate IRB member, or consultants are defined when they have a conflicting interest as follows:

Definitions

- “**Immediate Family**” means spouse and dependent children.
- “**Financial Interest Related to the Research**” means financial interest in the sponsor, product or service being tested
- Involvement of the IRB member, consultant, or their immediate family in the design, conduct, or reporting of the research.

The following conflicts are considered:

- 1) Participation in a project (IRB member is listed as an investigator on the project or is a member of the research team);
- 2) Supervision of a project (IRB member is Principal Investigator, or a situation in which any investigator must report to or is under the professional supervision of the IRB member);
- 3) Financial Interest when it reaches the level of a Financial Conflict of Interest (FCOI);
- 4) Personal relationship with investigator (IRB member has an immediate family relationship or other close personal relationship with the investigator);
- 5) Fiduciary relationship to sponsor (IRB member serves as an executive to a company sponsoring the research or serves on the company's board of directors);
- 6) Other nonfinancial interests that may be conflicting interests, such as if
 - a. The IRB member has an interest that he/she believes conflicts with the member's ability to review a project objectively; or
 - b. The IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or research subjects, or the IRB member is considered a personal or professional adversary of the investigators. The IRB member must disclose the circumstances to the IRB Chair or Director, IRB Operations and HRPP for a determination of whether a conflicting interest exists.
- 7) Any other reason for which the IRB member believes he or she has a conflicting interest with the research.

Procedures for Protocol Review and Attendance at the IRB Meeting

- 1) IRB members should review the list of projects for an upcoming meeting with the conflicts issue in mind and should disclose a conflicting interest as soon as possible to the IRB Specialist or Analyst, IRB Chair, or Director, IRB Operations and HRPP. An IRB member with a conflicting interest in a project should not accept that project for review, and it should be reassigned to another IRB reviewer.
- 2) If an IRB member recognizes a conflicting interest in a project at the IRB meeting, the IRB member must inform the IRB Chair of the conflicting interest and leave the room during the discussion of and vote on the project.

- 3) If other IRB members need to request information about the project from the IRB member with the conflicting interest, the IRB member may remain in the room during the presentation of the project. The IRB member must then leave the room during the IRB's discussion and vote.
- 4) IRB staff will record in the minutes a recusal based on a conflicting interest. The IRB member will not be counted as part of the quorum for the project. (Should the quorum fail, the IRB may not take further action or vote on the project.)

Note: *An abstention may be acknowledged at any time when an IRB member has any other concerns that in his or her own judgment warrant abstaining from review, deliberation, and voting on a project.*