

The University of Mississippi

Conflict of Interest and IRB Protocol Review

Summary/Purpose: Defining conflicts of interest involving IRB members, alternates, staff, and consultants.

Policy: Federal regulations prohibit a member of the Institutional Review Board (IRB) from participating in the initial or continuing review of any protocol in which the member has a conflict of interest (COI), except to provide information at the IRB's request ([45 CFR 46107\(e\)](#)). This policy: (1) extends exclusion of individuals with COIs to review of revisions, unanticipated problems involving risk to subjects or others, non-compliance investigations, or suspension/termination decisions, (2) extends exclusion coverage to consultants (*ad hoc* reviewers who are not IRB members but sometimes are asked to review a project because of their expertise), and (3) defines and gives examples of COIs.

Because the Director is paid from funded project indirect costs in the Office of Research and Sponsored Programs budget, the Director cannot review funded projects, even if exempt. Reviews for funded research must be conducted by the Research Compliance Specialist (RCS), chair, an alternate chair, or another member.

IRB Committee Members, alternate members, consultants, and IRB staff are considered to have a COI if they have any: (a) significant financial interest as defined below; (b) significant role in the conduct of the research; or (c) other COI including having an immediate family member as an investigator on an IRB protocol.

Definitions:

Conflict of Interest is any situation which involves a financial interest, other opportunity for tangible personal benefit, or a personal relationship that could affect the reviewer's impartiality.

Significant Financial Interest: Anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, board member, executive relationship, or other ownership interests); and intellectual property rights (e.g., patents, trademark, licensing agreements, copyrights and royalties from such rights).

Immediate Family Member: Immediate family includes spouse or domestic partner, all dependent children (stepchildren, biological children, wards), siblings, parents, and guardians.

Significant Role in the Conduct of Research: Service as a Principal or Co-Investigator, a supervisory role over the Principal Investigator, chair of a thesis or dissertation committee, and member of a thesis or dissertation committee where a significant benefit is likely (e.g., publication authorship).

Examples of COIs:

- An application includes an investigator or research staff who is a spouse or relative of the reviewer
- A thesis or dissertation application for which the reviewer is a member of the thesis or dissertation committee if publication or presentation authorship is likely
- An IRB member is an investigator on a project
- An IRB member (or immediate family) has or will receive from the sponsor of the research financial or other forms of compensation
- An IRB member (or immediate family) has a significant financial interest in the company/agency/firm that is sponsoring the research
- An IRB member (or immediate family) discloses a conflict of interest to the FDA or other agency.

Full Board Review Procedures:

1. Chair asks if anyone has a COI to declare.
2. Any member with a COI must leave the room during the discussion of the protocol and the related vote. However, they may provide information at the IRB's request.
3. While recused, the member will not count towards the quorum, and the meeting minutes will document the temporary recusal.
4. Consultants who declare a COI will be excused from the review of the protocol and the IRB will identify another consultant with the relevant expertise.

Expedited or Exempt Review Procedures:

1. The RCS, Director, or Chair declares a COI.
2. The protocol is assigned to another board member for review.
3. Consultants who declare a COI will be excused from the review of the protocol and the IRB will identify another consultant with the relevant expertise.