



Conflicting Interests of IRB Members and Consultants

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1. PURPOSE

- 1.1. Federal regulations prohibit an **IRB member** from participating in the review of any **human research** project in which this individual has a **conflicting interest**, except to provide information that is requested by the IRB. This is to ensure that financial or other interests do not compromise the rights and welfare of human research participants.
- 1.2. This **policy** describes when IRB members or **consultants** are considered to have conflicting interests and the **procedures** that must be followed for disclosure and IRB review of research when such conflicts exist.

2. DEFINITIONS

- 2.1. **Conflicting Interest**: a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. Also: *Conflict of Interest*.
- 2.2. **Consultant**: a **scientist** or **non-scientist** from within or external to University of Georgia who has special expertise to assist in the review of a research project at the request of the IRB.
- 2.3. **Financial Conflict of Interest (FCOI)**: is a significant financial interest (SFI) related to research that could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University. See *Policy on Conflicts of Interest in Sponsored Programs*.
- 2.4. **Immediate Family**: spouse, domestic partner and dependent children.

3. POLICY

- 3.1. An individual involved in research review is automatically considered to have conflicting interest when the individual or the individual's immediate family have any of the following:
 - 3.1.1. Involvement in the design, conduct, or reporting of the research (such as when the individual is a member of the research team);
 - 3.1.2. Supervision of a project (IRB member is an academic mentor or a member of the advisory committee of a study team member) or a situation in which any investigator must report to or is under the professional supervision of the IRB member;
 - 3.1.3. Ownership interest, stock options, or other ownership interest related to the research of any value exclusive of interests in publicly-traded, diversified mutual funds;
 - 3.1.4. Compensation related to the research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research;
 - 3.1.5. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreements including royalty from such rights;



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- 3.1.6.A specific financial interest in the research or the product or service being tested;
- 3.1.7.Has received or will receive compensation with value that may be affected by the outcome of the study;
- 3.1.8.A general financial conflict of interest related to the sponsor such as: ownership interest, stock options, or other ownership interest, exclusive of interests in publicly-traded, diversified mutual funds, which, when aggregated, exceeds \$5,000 in the past year; has received compensation in the past year, including compensation for costs directly related to conducting research which, when aggregated, exceeds \$5,000;
- 3.1.9.Is an executive or director of the agency or company sponsoring the research;
- 3.1.10. Any other interest for which the individual believes conflicts with his/her ability to objectively conduct a review.
- 3.2. It is the responsibility of an IRB member or consultant to determine what qualifies as a conflicting interest, and to disclose any conflicting interest when conducting a review.
- 3.3. No IRB member or consultant with a conflicting interest may participate in any type of IRB review of a project (i.e., initial, continuing review, modification, noncompliance, incident report, unanticipated problem/adverse event, protocol violation or deviation), except to provide information requested by the IRB. When attending a convened meeting, these individuals are not counted toward quorum.

4. PROCEDURES

- 4.1. IRB Staff will review the list of study team members and will not assign reviews to any IRB member or consultant listed on the submission.
 - 4.2. Upon receiving a review assignment, the IRB member or consultant must determine whether he/she has a conflicting interest with the research by reviewing the list of study team members and the funding information provided in the submission and then reviewing this policy.
 - 4.3. If an IRB member (or consultant) has a conflicting interest with a **non-committee review** assignment, he/she must notify the IRB staff as soon as possible to allow the submission to be re-assigned. Disclosure of the presence or absence of conflict of interest is documented on the reviewer checklist.
 - 4.4. If an IRB member (or consultant) assigned as a primary or secondary reviewer for a study that requires committee review has a conflicting interest, he/she must notify the IRB staff by e-mail to disclose the conflicting interest as soon as possible to allow the submission to be re-assigned.
 - 4.4.1.At a convened meeting, the individual with a conflicting interest must notify the IRB Chair and **recuse** him/herself (i.e., leave the room). This individual can only answer questions
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pertaining to the research, but cannot be present during the discussion and vote on the research. The recusal will be noted in the meeting minutes.

5. MATERIALS

- 5.1. CHECKLIST: Exemption Determination
- 5.2. CHECKLIST: Expedited Review
- 5.3. CHECKLIST: Subject Matter Review

6. REFERENCES

- 6.1. 45 CFR §46.107(e).
- 6.2. 21 CFR §56.107(e).
- 6.3. Policy and Procedure: Non-Committee Review Preparation and Conduct
- 6.4. Policy and Procedure: Pre-Review of IRB Submissions
- 6.5. Policy on Conflicts of Interest in Sponsored Programs