

## SOP 1.1.3      **Conflicts of Interest**

### **General Description:**

Potential conflicts of interest in research are important to manage and especially so when projects involve human subjects. This SOP describes the policies and procedures related to conflicts of interest for investigators, research team members, IRB members and consultants to the IRB.

### **Policy:**

1. Conflicts of Interest may exist whenever an individual has a stake in the outcome of research and/or review of projects. Federal and Commonwealth requirements for disclosure and management of conflicts of interest have been addressed at Mason through [Policy 4001](#). This SOP provides additional procedures for investigator and team members' conflicts related to human subjects projects. Additionally, 45 CFR 46.107(e) states that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." This SOP addresses this requirement.
2. In order to effectively manage conflicts of interest, all potential conflicts must be disclosed, reviewed, and acted upon.

### **Procedures:**

1. Conflicts of Interest for Researchers
  - a. The IRB Application Form asks whether any investigators or team members have Conflicts of Interest. All investigators' and team members' Conflicts of Interest must be disclosed on the application form.
  - b. When the "Yes" box is checked, these listed interests will be referred to the Chair of the Conflict of Interest committee to confirm that the university has reviewed the interest. In cases where the interest has not been reviewed, the involved investigator will be asked to provide a full conflict of interest disclosure to be reviewed prior to IRB review of the project. If the interest has been reviewed and found to not pose a Conflict of Interest this information will be provided to the IRB and maintained with the protocol file.
  - c. In cases where the interest does pose a Conflict of Interest, the management plan will be provided to the IRB for consideration during review.
  - d. After review, should the IRB recommend any additional management strategies, this information will be reported back to the Conflict of Interest Committee for consideration of inclusion in the management plan.
  - e. If the Conflict of Interest Committee rejects the additional management strategies, the IRB will be notified and the reasons for rejection will be provided. If the Conflict of Interest Committee accepts the additional management strategies, a final updated management plan will be provided back to the IRB for inclusion in the protocol file.
2. Conflicts of Interest for IRB Members and Consultants
  - a. IRB members and consultants reviewing research are responsible for identifying all potential conflicts of interest prior to deliberations and review of a protocol. An individual involved in research review is automatically considered to have a conflict of interest when the individual or the individual's immediate family have any of the following:
    - i. Involvement in the design, conduct, or reporting of the research.

- ii. Ownership interest, stock options, or other ownership interest related to the research of any value exclusive of interests in publicly-traded, diversified mutual funds.
  - iii. 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.
  - iv. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
  - v. Any other reason for which the individual believes that he or she cannot be independent.
- b. When an IRB member or consultant determines that they have a conflict of interest, they must recuse themselves from expedited review by notifying the IRB office so that the application can be reassigned. For protocols assigned to full board review, they must report this information to the IRB Chairperson at least 24 hours prior to full board meetings so that the Chairperson can appropriately manage the meeting.
  - c. During the full board meeting, any conflicted board members or consultants must exit the room during deliberations and voting. They may be asked to join the meeting to provide information but then must immediately exit prior to additional deliberations and voting.
  - d. This exit from the room will be documented in the meeting minutes.

**Related Forms, Guidance, and SOPs:**

- Institutional Review Board Application Form
- University Policy 4001
- SOP 1.6.1 Full Board Meetings
- SOP 1.6.2 IRB Minute taking and storage of minutes

**Responsibility:**

Principal Investigators  
 Research Team Members  
 IRB staff  
 Institutional Review Board

**Approval and Version History:**

Please contact [irb@gmu.edu](mailto:irb@gmu.edu) if you have any questions about this policy or the version and approval history.

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<b>Approved By</b>	<b>Title and Division</b>	<b>Date Approved</b>
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