	UNIVERSITY RESEARCH POLICY: IRB Conflict of Interest Responsible Office: Research Integrity			
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Policy Statement

This policy describes the policy and procedures for disclosure and IRB review of conflicts of interest related to human subjects research conduct or IRB committee membership.

Conflicts of Interest

Conflicts of interest (COI) in research may arise when financial, professional, or other personal considerations compromise, or have the appearance of compromising an individual's judgement in the review, design, conduct, or reporting of research. IRB committee members, and faculty and staff engaged in human subjects research at Lehigh University, are subject to the University-wide Conflict of Interest Policy administered by the [Internal Audit](#) department. As appropriate, faculty and staff are also subject to the Conflicts of Interest in Sponsored Programs policy and related Addendum to Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects for Research and Funded by the United States Public Health Service and sponsors requiring adherence to PHS Rules, administered by the [Research Integrity](#) department.

IRB Committee Members

IRB members are prohibited from participating in the review of a research protocol in which they have a COI, except to provide information requested by the IRB. IRB members who are unaffiliated with Lehigh University are not required to complete standard COI disclosures per university policy. These members are required to sign a statement at the time of appointment to the board that certifies the University-wide Conflict of Interest Policy was provided to them. The IRB Conflict of Interest policy will be reviewed annually with all committee members to ensure that they are aware of acceptable COI thresholds.

Immediate family includes spouse, spousal equivalents, (including domestic partners), dependents, and all members of the employee's household.


An IRB committee member or consultant has a potential conflicts of interest (COI) if any of the following are true for the member/consultant or a member of their immediately family:

- Being listed as an investigator or involved in the design, conduct, or reporting of the research.
- Having equity interest related to the research, exclusive of interests through mutual funds.
- Having a financial interest in the sponsor of the research or the technology being evaluated.
- Having a proprietary interest (or having an immediate family member with such an interest) in the research, such as a patent, trademark, copyright, or licensing agreement.
- Being an executive, director, or officer at the agency or company sponsoring the research.
- Having received compensation related to the research in the preceding 12 months or anticipated compensation related to the research.
- Having a financial interest in the research that either cannot be readily determined, or exceeds \$5,000.
- Having any other conflict that may be perceived to inhibit a fair and unbiased review of the research.

Faculty appointment or employment within the same academic department do not constitute COIs.

Consultants

Consultants to the IRB will be asked, at the time they are contacted to review a research study, if they (or a member of their immediate family) have a conflict with the study on which they are being asked to consult. Consultants are prohibited from participating in the review of a research protocol in which they have a COI.

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Review Assignment, Conduct, and Documentation

IRB committee reviewers and consultants are prohibited from participating in the review of a research study in which he or she has a COI or an active role as study personnel. When reviewing research at full board meetings, IRB members and consultants with a COI with the research being reviewed are required to disclose the conflict to the IRB Chair and/or Research Integrity staff prior to the meeting. When reviewing research through expedited review, IRB committee members and consultants with a COI with the research being reviewed are required to disclose the conflict to Research Integrity staff and will the review will be re-assigned to another member. COI disclosures related to expedited review assignments will be documented in IRBNet. Members or consultants with a COI are required to leave the room during full committee IRB deliberations and voting related to the study with which they (or an immediate family member) have a conflict. Absence of members or consultants due to a conflict (i.e. listed as an investigator, financial, or other conflict) during the full committee discussion of the research protocol and the vote will be documented in the minutes of the full board meeting to include the reason for their absence. Members or consultants with a COI are allowed into the meeting room at the request of the Chair if specific information is requested by the IRB committee.