

IRB MEMBER AND CONSULTANT CONFLICT OF INTEREST

1. Overview

Federal regulations do not permit an IRB member to participate in the review of research in which he/she has a conflicting interest, except to provide information requested by the IRB. This requirement helps to ensure that financial or other interests do not compromise the rights and welfare of human research subjects.

This policy describes when IRB members or consultants are considered to have conflicts of interest and the procedures that must be followed for disclosure and IRB review of research when such conflicts exist.

2. Definitions

Conflict of Interest: A financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual's professional judgment in exercising any University duty or responsibility, including the review of research. *Note: For IRB members and consultants, financial and non-financial interests/opportunities are included.*

Financial Conflict of Interest: An interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual's interest in any entity whose financial interests would reasonably appear to be affected by the research. *Note: Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).*

Non-Financial Conflict of Interest: An interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially compromises the objectivity and credibility of the research review process.

Immediate Family: For purposes of OSU HRPP policy, an IRB member or consultant's spouse and dependent children.

3. General Information

A. Conflicts of interest must not compromise the rights and welfare of research participants or the integrity of the research review process. The regulations do not provide flexibility in the management of an IRB member's (or consultant's)

conflicting interest. Specifically, the regulations require that IRB members must not participate in the review of research in which they have a conflicting interest, except to provide information requested by the IRB.

- B. Financial relationships with entities involved in research and the financial interests these relationships create (e.g., equity interests, payments for services, etc.) may lead to financial conflicts of interest. Such conflicts of interest may affect the rights and welfare of human subjects. However, financial interests are not prohibited and not all financial interests cause conflicts of interest. For more information on financial conflicts of interest, see OSU's [Financial Conflict of Interest Policy](#) and [Financial Conflict of Interest Policy Implementation Procedures](#).
- C. Conflicts of interest may also be non-financial, such as when an IRB member or consultant is asked to review research in which he/she is also participating as a member of the research team. Other "personal or professional" conflicting interests are described below. An individual may opt out of a review for any reason, including a conflicting interest not specifically described by this policy.
- D. When a conflict of interest is identified, an IRB member or consultant may not participate in any type of review of the research conducted by the IRB, including initial or continuing reviews, review of amendments, or other reviews (e.g., event reports, potential noncompliance, etc.). This requirement applies to reviews conducted by the convened IRB and those performed by expedited procedures.

4. Financial Conflict of Interest

- A. An IRB member or consultant to the IRB is considered to have a conflicting financial interest when he/she (or a member of his/her immediate family) is receiving compensation for services or has financial interests or intellectual property rights that would reasonably appear to be affected by the research, including the following:
 - Ownership interest, equity or stock options, or other financial interest whose value (when aggregated for the immediate family) is:
 - \$10,000 or greater when referenced to publicly traded prices or other measure of fair market value
 - Any amount when the value of the interest cannot be referenced to publicly traded prices or other measure of fair market value
 - Any amount when the value of the interest would be affected by the outcome of the research
 - 5% or more interest in any one single entity
 - Compensation whose value (when aggregated for the immediate family) is:
 - \$10,000 or greater in the past year

- Any amount when the compensation would be affected by the outcome of the research.
 - Proprietary interest related to the research of any value, including (but not limited to) a patent, trademark, copyright, or licensing agreement
 - Board or executive position (regardless of compensation) related to the research.
- B. The financial interests that are considered conflicting interests for IRB members and consultants are the same as those for investigators and key personnel involved in research. For additional information on financial conflict of interest for faculty and research personnel, see OSU's [Financial Conflict of Interest Policy](#) and [Financial Conflict of Interest Policy Implementation Procedures](#).

5. Non-Financial Conflict of Interest

An IRB member or consultant to the IRB is considered to have conflicting interest (other than monetary) in any of the following circumstances:

- IRB member/consultant (or member of his/her immediate family) is a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
- IRB member/consultant (or member of his/her immediate family) is related to a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
- Principal investigator of the research is the IRB member's/consultant's immediate supervisor or the supervisor of the member's/consultant's immediate family member
- IRB member/consultant (or member of his/her immediate family) has an interest in competing research or is competing directly for resources such as funding or sponsorship
- Other conflicting interest that appears to preclude objective assessment, at the IRB Chair's discretion.

Note: Departmental affiliation is not automatically considered to be a conflicting interest, except as described above.

6. IRB Member Disclosure

- A. IRB members are asked to complete a *Financial Conflict of Interest Screening/Disclosure* form when they are appointed to the Board if a current disclosure form is not already on file. Members are required to update the disclosure form annually and whenever there are changes in their (or their immediate family members') financial interests. IRB members will refer to the

OSU HRPP policy for information about financial and non-financial conflicts of interest.

- B. IRB Protocol Analysts utilize Board members' CVs and financial disclosure forms when making reviewer assignments to avoid assigning research review to an IRB member with an identified financial or non-financial conflict of interest. IRB Protocol Analysts will select IRB members without apparent conflicting interests as primary or secondary reviewers; however, IRB members are ultimately responsible for final identification of conflicts.
- C. IRB members will examine the materials assigned to them upon receipt to identify any financial and/or non-financial conflicts of interest. If a conflict exists, the member should immediately contact the appropriate IRB Protocol Analyst so that the review can be reassigned to another IRB member. IRB Protocol Analysts will document a conflict of interest as the reason for reassignment.
- D. IRB members may contact the Conflict of Interest Administrator or appropriate IRB Chair for information or assistance with conflict of interest questions. The IRB Chair or Vice-Chair will make the final determination about whether a conflict of interest as defined by OSU HRPP policy exists.

7. Identification of Conflicts – IRB Review

- A. At the start of each convened meeting, the IRB Chair (or acting Chair) reminds all IRB members that anyone with a conflict of interest must excuse himself/herself before the discussion of the research begins, unless asked to be present to answer questions or provide information to the IRB.
- B. IRB members are asked to self-identify research in which they have a conflicting interest, inform the IRB Chair (or acting Chair), and excuse themselves before convened discussion begins. Although IRB members are asked to self-identify conflicts, the Chair has the final authority to determine when there is a conflict as defined by OSU HRPP policy and to ask a member to leave the room as necessary.
- C. If questions arise during the discussion, the IRB Chair may invite the IRB member with the conflicting interest back into the room to provide information but will excuse him/her again before final deliberation and voting.
- D. For IRB review conducted by expedited procedures, IRB members will be asked to document (in writing or electronically) that they have reviewed the policy, have considered any potential conflict of interest, and have either found no conflict or disclosed the potential conflicting interest. In the event that a conflict is identified, another reviewer will be selected.

8. Consultant Conflict of Interest

- A. When a consultant is identified, an ORRP staff member will ask the consultant to complete a *Financial Conflict of Interest Screening/Disclosure* form to identify any potential financial conflict of interest. Consultants will be referred to the OSU HRPP policy for information about financial and non-financial conflicts of interest. Consultants will also be provided preliminary information about the research, sponsor, investigator, and study staff to assist in their determinations.
- B. Prior to assisting in IRB review, consultants will be asked to document (in writing or electronically) that they have reviewed the policy, considered any potential conflict of interest, and have either found no conflict or disclosed the potential conflicting interest. The IRB Chair or Vice-Chair has the final authority to determine whether a conflict of interest as defined by OSU HRPP policy exists.
- C. In the event that a conflict is identified, another consultant will be selected. Consultants who have financial or non-financial conflicts of interest will not assist in the IRB review of research.

9. Documentation of Conflicts of Interest

ORRP staff are responsible for documenting that an IRB member did not participate in the convened review of research in which the member had a conflicting interest. IRB minutes will record when the member left the room, with the reason noted as being because of a “conflict of interest.” IRB members out of the room due to a conflict of interest are not counted toward the meeting quorum. ORRP staff are responsible for monitoring IRB meeting attendance to ensure that quorum is maintained.

10. Applicable Regulations/Guidance

21 CFR 56.107, 45 CFR 46.107, DHHS “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection” (05/05/04), NIH “Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F, Grants and 45 CFR Part 94, Contracts)” (10/28/08)