

**IRB Member, Ad Hoc Consultant,
and OPRS Staff Conflicting Interest
Policy**

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DEFINITIONS:

- I. IMMEDIATE FAMILY: means spouse and dependent children.
- II. FINANCIAL INTEREST RELATED TO THE RESEARCH: means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

POLICY:

- I. An IRB member with a conflicting interest will not be counted towards quorum.
- II. An IRB member, consultant, or OPRS staff member is automatically considered to have a conflicting interest when the member/consultant or the member's or *ad hoc* consultant's immediate family has any of the following:
 - A. Involvement in the design, conduct, or reporting of the research.
 - B. Ownership interest (equity or stock options) or other financial interest related to the research unless it meets four tests:
 1. The value of the interest does not exceed \$10,000 when aggregated for the immediate family.
 2. The interest is publicly traded on a stock exchange.
 3. The value of the interest does not exceed 5% interest in any one single entity when aggregated for the immediate family.
 4. No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
 - C. Compensation related to the research unless it meets two tests:
 1. The value of the compensation does not exceed \$10,000 in the past year when aggregated for the immediate family.
 2. No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
 - D. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- III. "Financial Interest Related to the Research" does not include:
 - A. Salary or other remuneration from the University;

- B. Income from seminars, lectures, or other teaching engagements sponsored by public or nonprofit entities;
- C. Income from service on advisory committees or review panels for public or non-profit entities; and/or
- D. Holdings in mutual funds or pension accounts over which the IRB member or his/her immediate family does not exercise control.

IV. "Other Interest" includes but is not limited to:

- A. Supervision of a project (i.e., an IRB member is the investigator's Faculty Sponsor, or a situation exists in which any investigator must report to or is under the professional supervision of the IRB member);
- B. Personal relationship with investigator (IRB member has an immediate family relationship or other close personal relationship with the investigator);
- C. Other personal interests that may be conflicting interests, such as if (a) the IRB member has an interest that he/she believes conflicts with the member's ability to review a project objectively; or (b) the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or research subjects, (c) the IRB member is considered a personal or professional adversary of the investigators, or (d) the IRB member is a subordinate to the investigator. For (b), (c), and (d), the IRB member should disclose the circumstances to the IRB Chair or OPRS Director for a determination of whether a conflicting interest exists; and/or
- D. Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

PROCEDURES:

I. IRB Member Conflict of Interest.

- A. IRB members with a conflicting interest must absent themselves from the meeting room for the review of research including the discussion and voting except to provide information requested by the IRB. IRB members are responsible for the self-identification of their conflicting interests in advance of both convened IRB review and review using the expedited procedure.
- B. When an IRB member has a conflicting interest at a meeting the chair will ask the remaining IRB members whether they have any questions regarding the conflict of interest for the IRB member with a conflicting interest. Then the IRB chair will ask the IRB member with a conflicting interest to leave the room until the discussion and voting is complete.

II. Ad Hoc Consultant Conflict of Interest.

- A. When the IRB uses an ad hoc consultant to aid in the review of a particular research protocol, the consultant must not have a real or perceived conflict of interest with the research. When an ad hoc consultant is identified, OPRS staff informs them of this policy and determines whether the consultant has a

conflicting interest. Ad hoc consultants with a conflicting interest may not serve as a consultant.

III. OPRS Staff Conflict of Interest.

- A. OPRS staff are expected to self-identify when they have a conflicting interest with a protocol and to not be involved in any protocol in which they have a conflicting interest.

REFERENCES:

[21 CFR 56.107\(e\)](#)

[38 CFR 16.107\(e\)](#)

[45 CFR 46.107\(e\)](#)

[Department of Health and Human Services Final Guidance Document, *Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subjects Protection*](#)

[Office for Protection from Research Risks, *Institutional Review Board Guidebook*, Chapter I, Institutional Administration](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 10/01/08	1.0, 04/18/07	Reformatted to fit new policy template.
1.2, 8/12/09	1.1, 10/01/08	Included a statement that IRB members with a conflicting interest will not be counted towards quorum.