



IRB Consideration of Conflict of Interest: Member, Guest Reviewer and Investigator

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Associational Interest

- An IRB member or guest reviewer's formal or informal relationship or involvement with a sponsor of the research (e.g., positions on advisory boards, boards of directors, service on a board of a venture capital fund, etc.)
- An IRB member or guest reviewer is an immediate family member of the researcher.
- An IRB member or guest reviewer who has a professional reporting relationship to an investigator

2.2. Significant Financial Interest

- Any of the following financial interests of an Institutional Review Board (IRB) member, guest reviewer or their immediate family member that are reasonably related to the research under review by the IRB:

◇ Intellectual Property Rights and Interests:

- IP owned by an IRB member or guest reviewer when that IP is being utilized in the research

◇ Reimbursed or Sponsored Travel:

- Travel expenses incurred and reimbursed directly to an IRB member or guest reviewer or travel that is paid for by a research sponsor on behalf of an IRB member or guest reviewer.

Threshold: \$5,000 aggregated from one entity over 12 months.

◇ **Remuneration:** Payments made directly to an IRB member from the research sponsor (e.g., consulting fees, honoraria, paid authorship)

- Threshold: \$5K aggregated from 1 entity over 12 months

◇ **Equity:** includes any stock, stock option, or other ownership interest: in a non-publicly traded (private) entity

- Threshold: Any ownership (even \$0)

◇ **Equity (and remuneration):** in a publicly traded entity

- Threshold: \$5K in aggregate (stock + payment)
- Exclusions: Income from investment vehicles (e.g., mutual funds, retirement accounts) as long as the IRB member does not control the investment decisions.

2.3. Immediate Family Member

- Spouse, parent, or dependent child

3. PROCEDURE BODY

The purpose of this document is to detail circumstances under which Marshfield Clinic Research Foundation IRB (MCRF IRB) members will be determined to have a conflict of interest, and how such situations will be handled, and to discuss how MCRF IRB will proceed with review when an investigator has disclosed a significant financial interest. The same definitions of significant financial interest and associational interests are applied to investigators and IRB members alike.

3.1. Background

- a. Federal regulations (45 CFR 46.107(e) and 21 CFR 56.107(e)) state that no IRB may have a member participate in the initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.
- b. Federal grant and contract regulations and institutional policy require that significant financial interests and associational interests of investigators be disclosed, considered, and managed by an institutional official or committee. MCRF internal policy requires that the IRB not review research in which the Principal Investigator (PI) or any Key Personnel has a conflict of interest until the Research Conflict of Interest Committee (RCOIC) determines whether the significant financial or associational interest creates a conflict of interest, and if so, determines how this conflict will be managed or eliminated. The findings and rulings of the RCOIC must be passed on to the IRB to consider during its review of the project. (See MCRF policy, ["Investigator Conflicts of Interest in Research."](#))

3.2. IRB Member Conflict

- a. Conflicts may be financial or associational (see definitions above). For each item being reviewed, each IRB member or guest reviewer is responsible for identifying, based upon the definitions above, as to whether a conflict exists. Upon review of the IRB agenda or any IRB distributed materials, a member or guest reviewer who is unsure whether an existing circumstance represents a conflict of interest related to reviewing a research project shall contact the Office of Research Integrity & Protections (ORIP) for guidance in making that determination. Members and guest reviewers will be asked about existing conflicts each time they complete a reviewer guide or evaluation form. At each convened IRB meeting, the IRB chairperson will also poll the IRB members who are present regarding any existing conflicts of interest with items on the IRB agenda.
- b. It will be assumed that a conflict of interest exists for any IRB member or guest reviewer if:
 - He or she is listed on the IRB application and/or protocol being reviewed as a PI or Key Personnel ; or

- He or she has a financial or associational interest in any aspect of the research study in question, which meets the definitions of Significant Financial Interest or Associational Interest noted above.
- c. In circumstances where a conflict of interest does exist, the member or guest reviewer must declare that conflict. The member or guest reviewer may give information to the IRB prior to or during the meeting. They may not, however, participate in the final discussion at the convened meeting, and may not vote on the item in question. During the recusal, such a member will not be counted toward quorum. The IRB minutes will document that the member was absent due to conflict of interest.

3.3. IRB Consideration of Investigator or Key Personnel Conflicts

- a. If a significant financial interest or associational interest exists for an investigator, the IRB must hold review of the project until the Research Conflict of Interest Committee (RCOIC) makes a determination as to whether the interest creates a conflict for the investigator.
- b. If a person named as Key Personnel has a significant financial interest or associational interest, IRB review may be conducted only if the person is not a PI and is removed from consideration for approval. The PI may later request inclusion of this person as Key Personnel once the RCOIC has met. If the RCOIC determines that the significant financial interest or associational interest creates a conflict for the person, the IRB must consider whether the measures taken by the RCOIC are adequate to protect potential research participants. Additional provisions or restrictions may be imposed by the IRB. At a minimum, if the RCOIC determines that a conflict exists, the informed consent document will include this information. The IRB will make the final decision regarding what detail about the conflict and how it is being managed should be provided to subjects.

4. ADDITIONAL RESOURCES

- 4.1. References:
 - [Procedure - Investigator Conflicts of Interest in Research](#)
- 4.2. Supporting documents available:
 - None.

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #777.8 Revisions to (sect 2.1 – 2 nd bullet to read: An IRB member or guest reviewer is an immediate family member of the researcher. Section 2.3 revised to say: Spouse, parent, child

PROCEDURE

2.0	Add hyperlink to other applicable policy referenced in this document
-----	--

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A

Co-Author(s):

Approver(s): This document has been electronically signed and approved by: Ziembra, Steven J PHD on: 12/1/2015 4:14:03 PM

Live

PROCEDURE