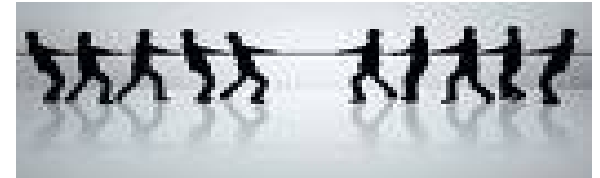


Collaborative IRB Member Conflict of Interest



University of Illinois at Chicago
Office for the Protection of Research Subjects
Charles Hoehne
Assistant Director, Education and Training
(Version 1.1, 08/31/2009)

Training Goal- Help IRB members to:

- **Identify and properly address their own conflicts of interest in their capacity as IRB members.**

- **Become familiar with:**
 - what types of activities trigger a COI;
 - the key definitions related to COI;
 - the procedures to follow once they have determined that they have a COI;
 - identify the responsibilities of each institution;
 - where to find the IRB member COI policy and procedure; and
 - practical application of COI.

Special Considerations for the Collaborative IRB

- The Collaborative IRB is made up of three institutions:
 - Northwestern University,
 - the University of Illinois at Chicago, and
 - the Jesse Brown Veterans Administration Medical Center
- *The reporting and resolution of conflicts of interest for IRB members, regardless of their institutional affiliation/s, is centralized in the Collaborative IRB and OPRS office.
- *Please note that a different process as to conflict of interest exists for investigators and research staff.

Where to find the Collaborative IRB Member COI policy and procedure

- Regardless of institutional affiliation/s, the UIC OPRS policy and procedure as to IRB Member conflict of interest applies to all Collaborative IRB members when they are acting in their capacity as IRB members.
- OPRS Web-Site:
<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0271.pdf>
- Note: Copy of policy attached to handout.

Key Definitions

IRB members are automatically considered to have a COI when they or their immediate family has any of the following (4):

1. Involvement in the design, conduct, or reporting of the research.
2. Ownership interest (equity or stock options) or other financial interest related to the research unless it meets four tests:
 - a. The value of the interest does not exceed \$10,000 when aggregated for the immediate family.
 - b. The interest is publicly traded on a stock exchange.
 - c. The value of the interest does not exceed 5% interest in any one single entity when aggregated for the immediate family.
 - d. No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.

Key Definitions

3. Compensation related to the research unless it meets two tests:
 - a. The value of the compensation does not exceed \$10,000 in the past year when aggregated for the immediate family.
 - b. No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.

4. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.



Key Definitions

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

“Financial Interest Related to the Research”

- “Financial Interest Related to the Research” does not include:
 - Salary or other remuneration from the University;
 - Income from seminars, lectures, or other teaching engagements sponsored by public or nonprofit entities;
 - Income from service on advisory committees or review panels for public or non-profit entities; and/or
 - Holdings in mutual funds or pension accounts over which the IRB member or his/her immediate family does not exercise control.

“Other Interest” (Slide 1 of 2)

“Other Interest” includes but is not limited to (4):

1. 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);
2. Personal relationship with investigator (IRB member has an immediate family relationship or other close personal relationship with the investigator);

Cont. next slide

“Other Interest” (Slide 2 of 2)

3. 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.
 - e) 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

4. Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

Procedures for IRB Members with Conflicts of Interest

- IRB members with a COI 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 COIs in advance of both convened IRB review and review using the expedited procedure.

Best Practices for Convened IRB Meetings

- The Chair may ask at the beginning of the IRB meeting whether any IRB members would like to discuss or declare potential or actual conflicts with any of the protocols being discussed at the meeting;

and/or

- An IRB Coordinator or IRB Assistant Director may ask the IRB members before each protocol is review whether any IRB members would like to discuss or declare potential or actual conflicts with any of the protocols being discussed at the meeting.

Best Practices for Convened IRB Meetings

- An IRB member may announce a potential conflict of interest to the IRB before protocols are reviewed and have the members of the IRB decide whether or not that individual has a conflicting interest.
- This IRB deliberation must be documented in the meeting minutes, including the reasoning behind the outcome.

Procedures for IRB Members with Conflicts of Interest

- When an IRB member has a COI at a meeting:
 - The chair will ask the remaining IRB members whether they have any questions regarding the COI for the IRB member with a conflicting interest.
 - Then the IRB chair will ask the IRB member with a COI to leave the room until the discussion and voting is complete.

All IRB Members – Regardless of Institutional Affiliation

- For convened IRB review:
 - As a best practice, all IRB Members should:
 - review the convened agenda beforehand;
 - identify whether or not they have a possible or actual conflict;
 - disclose the potential or actual conflict in advance of the meeting to the IRB Chair and/or IRB Assistant Director;
 - disclose the potential or actual conflict either at the beginning of the meeting or before the affected protocol is to be discussed; and
 - be prepared to discuss and answer questions about the conflict at the convened IRB meeting.

All IRB Members – Regardless of Institutional Affiliation

- For expedited review:
 - As a best practice, IRB members should:
 - Carefully consider whether a conflict of interest exists per the UIC policy for IRB Members for each protocol they review
 - Please consult with the IRB Chair or an IRB Assistant Director if you are unsure whether a conflict of interest exists before making any determination as to a protocol.
 - Please speak with an Assistant Director to be reassigned a different protocol if you are sure that a conflict of interest exists.

Case Studies

Farcus

by David Waisglass
Gordon Coulthart



**“What conflict of interest?!
I work here in my spare time.”**

Case Study A: Biomedical Research

Assume an IRB member is a consultant with a drug company, where he or she receives a consulting fee for designing a drug trial. The IRB member is not the principal investigator.

- \$11,000 per year in consulting fees;
- The IRB member's father also receives \$2,000 in consulting fees for the same; and
- Compensation does not increase based on drug approval or study results.

Question 1:

Does this IRB member have a conflicting interest in reviewing and voting on a protocol related to the same drug company and drug?

Answer Key: Question 1

Question 1: Does this IRB member have a conflicting interest in reviewing and voting on a protocol related to the same drug company and drug?

Yes, for two reasons.

1. First, the IRB member is involved in the design of the research.
1. Second, although no arrangement was entered into where the amount of compensation is affected by the outcome of the research, the IRB member received compensation exceeding \$10,000 in the past year.

*Note that the IRB member's father does not meet the definition of "immediate family."