



# MCW IRB Committee Procedures

## CONFLICTS OF INTEREST – IRB COMMITTEE MEMBERS

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Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

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### **PURPOSE:**

*Medical College of Wisconsin (MCW) Corporate Policies: Conflicts of Interest - General (AD.CC.030) and Financial Conflicts of Interest in Research (RS.GN.020) mandates that MCW faculty and staff and IRB Committee Members must report all conflicts of interest to the institution for review and determination.*

The HRPP Office promotes objectivity in research by establishing standards to ensure that the design, conduct or reporting of research funded under a covered award are not biased by conflicting interests of the Institutional Review Board (IRB) Committee Members.

If an IRB member has an actual or perceived conflict of interest with an IRB submission being reviewed, the member should recuse themselves from the discussion and voting on the agenda item and submission. This policy applies to consultants who are called upon by the IRB Committee to provide specific expertise for review of a project.

### **DEFINITIONS:**

**Covered Award:** sponsored award for research funded by a PHS Awarding Component, by a Non-Profit Sponsor, by the NSF, by any other federal funding agency as required per agency policy or award terms and conditions, or by an Industry Sponsor.

**Covered Person:** any Faculty, Exempt Staff or other individual employed by MCW or Emeritus faculty who is responsible for the design, conduct or reporting of research sponsored by a Covered Award. Covered Persons include but are not limited to Principal Investigators, Co-Investigators and other Key Personnel as identified by MCW in the grant application and others who influence or are responsible for the design, conduct or reporting of research funded by a Covered Award as determined by MCW (e.g. other employees, collaborators or consultants). For sponsored awards funded by an Industry Sponsor, only the PI is considered a Covered Person

**Covered Person's Professional Responsibilities:** activities performed on behalf of the institution (MCW). These responsibilities may include but are not limited to activities such as research, research consultation, teaching professional practice, institutional committee membership and service on panels such as institutional review boards or data safety monitoring boards.

**Key Personnel:** The Principal Investigator and those project staff as identified by MCW in the grant application, progress report or any other report submitted to the PHS, and other employees who influence or are responsible for design, conduct or reporting of PHS funded research, whether or not they receive salaries or compensation, such that they might qualify for co-authorship on publications. Individuals who only provide clinical

care or support to subjects in a research project do not need to be considered Key Personnel.

**Industry Sponsor:** The publicly traded or non-publicly traded entity that granted the award/contract and provided the funding

**Immediate Family Member:** defined by *MCW Corporate Policy: Conflicts of Interest - General (AD.CC.030)* as a staff member's spouse and any person who receives more than one-half of their support from a staff member or from whom the staff member receives more than one-half of their support.

**Non-Profit Sponsor:** The non-federal / non-industry sponsor following federal PHS FCOI-R requirements (e.g. American Heart Association, American Cancer Society).

**Significant Financial Interest (SFI):** as defined by *MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*

1. **Financial Interests** include but may not be limited to one or more of the following interests of the Covered Person (and those of the Covered Person's spouse and dependent children) that reasonably appears to be related to a Covered Person's professional responsibilities at MCW.
  - a. Compensation – if the aggregated amount of income exceeds \$5,000 in the previous 12 months (prior to the Covered Person's disclosure) from the entity. Income includes salary and payment for services (e.g., consulting fees, honoraria, paid authorship).
  - b. Equity – any amount of interest (equity) in an outside entity in the previous 12 months (prior to the Covered Person's disclosure). Equity Interest includes stocks, stock options not yet exercised and/or other ownership.
  - c. Intellectual Property Rights and Interests with Entity – upon receipt of any income related to such rights and interests from the entity.
2. **Reimbursed or Sponsored Travel:** paid on behalf of the Covered Person engaged in research funded by a PHS Awarding component or by a Non-Profit Sponsor that is related to their professional responsibilities at MCW. This disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure does not apply to travel that is reimburses or sponsored by:
  - a. A US-based federal state or local government agency;
  - b. An institution of higher education (as defined at 20 USC 1001(a)); or
  - c. An academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education.

## **PROCEDURE:**

### **Conflicts of Financial Interest**

1. IRB Members upon invitation to join an Institutional Review Board (IRB) Committee, and on a continuing annual basis, must complete the financial disclosure form, *IRB Member Form: Annual Conflict of Interest Form* and disclose any financial conflicts of interest in accordance with *MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*.
2. As IRB members are in a position to review projects funded by a broad range of companies and businesses, they must disclose all possible financial conflicts with industry sponsors and maintain an up-to-date disclosure statement in accordance with MCW institutional policies.
3. Any IRB member holding a significant financial interest in regards to an IRB submission, as defined by *MCW Corporate Policy: Financial Conflicts of Interest in*

*Research (RS.GN.020)* and in accordance with this procedure will not be permitted to participate in an IRB review of that submission.

4. Individuals who hold positions that are responsible for the business development of the organization, the review and approval of grants, contracts or sponsored programs at MCW, Froedtert Health, or Versiti are not eligible to serve as IRB Members or as ex-officio members on the Committee.

#### **Conflicts of Professional Interest**

1. MCW HRPP does not permit any IRB members in any of the following roles to participate in the review of an IRB submission:
  - a. Key Personnel of the project
  - b. For federally funded projects, all persons identified as “key personnel”;
  - c. Members of the immediate family of, or those having close personal relationship with, the principal investigator.
2. Froedtert Investigational Pharmacy staff serving as IRB members are not in positions of potential conflict of professional interest, in the context of this policy, when their involvement with a given project is limited to:
  - a. Arranging for the investigational pharmacy to dispense project medications, or
  - b. Dispensing project medications as pharmacists
3. If an IRB member is assigned to review a research project and identifies that they have a conflict, either financial or professional, the matter should be reported to the IRB Coordinator II (C2) as soon as possible and not continue with the review.

#### **Conflicts of Interest – Other Activities**

1. MCW HRPP does not permit any IRB members in any of the following roles to participate in the review of an IRB submission:
  - a. Participating in or had participated in the research project, unless
    1. The IRB member is an oncologist with only a peripheral clinical role in the project under the exception defined by the OHRP Letter to NCI Describing OHRP’s Viewpoint on Conflicting Interests of PedCIRB Members, August 31, 2005.
  - b. Members of the immediate family of, or those having close personal relationship with, the Principal Investigator.
  - c. Led a routine review or for-cause audit of the project within the past 12 months.
2. If an IRB member is assigned to review a research project and identifies that they have a conflict, either financial, professional or otherwise, the matter should be reported to the IRB C2 as soon as possible and not continue with the review.

#### **IRB Meetings**

1. The agenda of every IRB meeting includes a reminder to IRB members to identify and declare any actual or perceived conflicts of interest.
2. At the start of each meeting, the IRB Chair will ask whether any members have a conflict of interest with any of the agenda items to be reviewed. Members should identify which items they have a conflict with to ensure it is entered in the IRB meeting minutes.
3. IRB members with a conflict of interest for a specific agenda item must recuse themselves from the discussion and vote and will leave the meeting room/space.
  - a. Recused IRB members may return to the meeting once the vote has occurred.
4. The IRB Chair may ask IRB members if they have any questions for the member with the conflict of interest when the project comes up for review if appropriate.
  - a. Questions about facts may be answered, but no discussion should occur until that member leaves the meeting room/space.

- b. If questions arise during the project discussion that the recused member might be in a good position to answer, the IRB Chair should collect all questions, allow the recused member to return briefly to answer questions about facts (without any discussion), and then excuse the recused member before any discussion resumes.
5. IRB members who recuse themselves are not counted towards the quorum requirement. Therefore, if quorum is lost when a recused member leaves the meeting, review and action on that project is deferred automatically to a subsequent meeting.

**REFERENCES:**

OHRP Letter to NCI Describing OHRP's Viewpoint on Conflicting Interests of PedCIRB Members

**SUPPORTING DOCUMENTS:**

*MCW Corporate Policy: Conflicts of Interest – General (AD.CC.030)*

*MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*

*IRB Member Form: Annual Conflict of Interest Form*

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