



MCW IRB Committee Procedures

CONFLICTS OF INTEREST – IRB COMMITTEE MEMBERS

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

Applies to: Institutional Review Board Committees

PURPOSE:

Medical College of Wisconsin (MCW) Corporate Policies: Conflicts of Interest, Outside Professional Activities and Consulting (AD.CR.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 PHS grants or cooperative agreements or PHS contracts 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 him/herself from the discussion and voting on the agenda item and/or submission item. This policy applies to consultants who are called upon by the IRB Committee to provide specific expertise for review of a protocol.

DEFINITIONS:

Covered Person: any Faculty or Exempt Staff employed by MCW who is responsible for the design, conduct or reporting of research sponsored by any federal agency, including the NIH. 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 PHS funded research as determined by MCW (e.g. other employees, collaborators or consultants).

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.

Immediate Family Member: defined by *MCW Corporate Policy: Conflicts of Interest, Outside Professional Activities and Consulting (AD.CR.030)* as a staff member's spouse and any person who receives more than one-half of his/her support from a staff member or from whom the staff member receives more than one-half of his/her support.

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

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.

- **Publicly Traded Entity:** if the aggregated amount of income or interest exceed \$5000 in the previous 12 months (prior to the Covered Person's disclosure) from the entity.
 - Income includes salary, payment for services (e.g. consulting fees, honoraria, paid authorship)
 - Interest includes equity interests (stocks, stock options and/or other ownership)
- **Non-Publicly Traded Entity:** if the aggregated amount of income exceeds \$5000 in the previous 12 months (prior to the Covered Person's own disclosure) from the entity, or any amount of interest.
 - Income includes salary, payment for services (e.g. consulting fees, honoraria, paid authorship)
 - Interest includes equity interests (stocks, stock options and/or other ownership)
- **Intellectual Property Rights and Interest with Entity:** upon receipt of any income related to such rights and interests from the entity.

Reimbursed or Sponsored Travel: paid on behalf of the Covered Person that is related to their professional responsibilities at MCW. This disclosure does not apply to travel that is reimbursed or sponsored by 1) a federal state or local government agency; b) an institution of higher education (as defined at 20 USC 1001(a); or 3) 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: *Financial Interests and Arrangements of Institutional Review Board Members of the Medical College of Wisconsin*, 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 studies 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 policy.
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 or Froedtert Hospital 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 s/he has a conflict, either financial or professional, the matter should be reported to the IRB Coordinator 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 (under the exception defined by the OHRP Letter to NCI Describing OHRP’s Viewpoint on Conflicting Interests of PedCIRB Members, August 31, 2005(the IRB member is an oncologist with only a peripheral clinical role in the project.
 - 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 s/he has a conflict, either financial, professional or otherwise, the matter should be reported to the IRB Coordinator as soon as possible and not continue with the review.

IRB Meetings

1. The agenda of every IRB meeting includes a reminder to members to identify and declare any actual or perceived conflicts of interest. At the start of each meeting, the 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.
2. IRB members with a conflict of interest for a specific agenda item must recuse themselves from the discussion and vote, and physically leave the meeting room. They may return to the meeting once the vote has occurred.
3. The 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 room and closes the room door. If questions arise during the project discussion that the recused member might be in a good position to answer, the Chair should collect all questions, allow the member to return briefly to answer questions about facts (without any discussion), and then excuse the conflicted member before any discussion resumes.

4. IRB members who recuse themselves are not counted towards the quorum requirement. Therefore, if quorum is lost when a recused member leaves the meeting, action on that project is deferred automatically to a subsequent meeting.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

MCW Corporate Policy: Conflicts of Interest, Outside Professional Activities and Consulting (AD.CR.030)

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

Financial Conflict of Interest Verification Form for Institutional Review Board Members of the Medical College of Wisconsin

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

Effective Date: 06/15/2018
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Approved By

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