

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 - 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 Investigator or other Key Personnel as defined by the Institutional Review Board (IRB) and responsible for the design, conduct

Covered Award as determined by MCW (e.g. other
collaborator or sponsored awards (funded by an institution) 5.4 (strategy)] TJ 0 -1.153 TD .0011 Tc -.0002 Tw [Sponsors

Covered Personnel Responsibilities:

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

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”;

- 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.