

21. Conflicts of Interest and Commitment in Research

It is medical school policy to preserve public trust in the integrity and quality of research by reducing actual or perceived conflicts of interest and commitment in the conduct of research.

Conflicts of interest and commitment in research can be broadly described as any interest that competes with an organization's or individual's obligation to protect the rights and welfare of research subjects, the integrity of a research study, or the credibility of the research program. Conflicts of interest and commitment can be financial or non-financial.

In the environment of research, openness and honesty are indicators of integrity and responsibility, which are characteristics that promote quality research and strengthen the research process. Therefore, conflicts of interest and commitment should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

21.1 Disclosure of Researcher Conflicts of Interest and Commitment

Pursuant to medical school policy GEN04, *Conflicts of Interest and Commitment*, which serves as the IRB research conflict of interest policy, the medical school IRB collaborates with the Research Integrity Officer to ensure that conflicts of investigators and research staff are identified and managed before the IRB completes its review of any research application.

For IRB purposes, review of researcher conflicts occurs at the time of new study submission, continuing review, with the addition of a new researcher, and whenever a researcher updates their medical school conflicts disclosure indicating a new or changed interest. For FDA studies, the clinical investigator(s) shall supply to the sponsor the completed DHHS forms 3454 and 3455 one year following the completion of the study. For the medical school IRB, the completed medical school *Conflict of Interest – Significant Financial Interests Disclosure* form must be completed. HRPP/IRB staff notify the Research Integrity Officer whenever a submission requiring conflict review is received. The Research Integrity Officer reviews the researcher's disclosures and notifies the researcher and HRPP/IRB staff that no researcher conflict was identified or that one or more researchers has an interest that requires further review. In the event a conflict that requires disclosure or management is identified, the Research Integrity Officer provides to the IRB in writing a summary of the conflict, and also the conflict management plan approved by the associate dean for research and the Research Integrity Officer. If the associate dean for research, associate dean for finance administration, and the Research Integrity Officer have not completed the review, the IRB defers the research study review or prohibit participation by the researcher with a potential conflict until the review process is completed and the results are made available to the IRB.

21.2 Evaluation of Conflicts of Interest and Commitment

The IRB reviews conflicts of interest and conflict management plans to determine:

- Whether the conflict affects the rights or welfare of research subjects.
- Whether the conflict might adversely affect the integrity or credibility of the research or the research program.
- Whether the conflict management plan effectively protects research subjects and the integrity and credibility of the research and the research program.

The IRB considers:

- The support and financing of the research.
- The nature and extent of the conflict.
- The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research.
- The ability of the conflicted individual to influence the outcome of the research.

21.3 Management of Conflicts of Interest and Commitment

The IRB has final authority to determine whether the research, the conflicts of interest and commitment, and the conflict management plan, if any, allow the research to be approved. With regard to the conflict management plan issued by the medical school or another organization, the IRB may either affirm or add additional stipulations. The IRB can require additional measures to manage a conflict of interest so that the research may be approved. However, the IRB must adhere to, at a minimum, the conflict management plan approved by the medical school or a relying organization. If additional conflict management is required by the IRB, the IRB shall provide the management plan to the researcher and Research Integrity Officer. This management plan then constitutes the medical school conflict management plan for the research, and remains subject to additional stipulations, as appropriate, by either the Research Integrity Officer or IRB. If the conflict lessens or resolves, the Research Integrity Officer and IRB adjust the management plan accordingly.

For example, in addition to the conflict management plan, the IRB may require:

- Disclosure of the conflict of interest to subjects through the consent process.
- Modification of the protocol/research plan or safety monitoring plan.
- Monitoring of research by a third party.
- Disqualification of the conflicted party from participation in all or a portion of the research.
- Appointment of a non-conflicted PI.
- Divestiture of significant financial interests or conflicts of commitment.
- Severance of relationships that create actual or potential conflicts.

In the event the conflict cannot be effectively managed, the IRB may disapprove the research.

21.4 IRB Member Conflicts of Interest

No IRB member or alternate may participate in the review of any research project in which the member has a conflict of interest or commitment, except to provide information as requested. It is the responsibility of each IRB member to disclose any conflict of interest or commitment related to a study submitted for review in a timely manner, and recuse himself/herself from both the discussion and vote by leaving the room.

IRB members and alternate members of the IRB complete an *IRB Member Research Conflict of Interest Assessment Form* when first appointed and annually thereafter, or sooner if there is a change in their conflicts. These forms may be submitted via mail, email, or in person and reviewed by the HRPP director, who determines if a conflict of interest exists. HRPP/IRB staff are notified when a conflict of interest exists and will not assign members or alternates to review studies for which the member or alternate has a conflict. HRPP/IRB staff may consult with the IRB chair to clarify whether a specific study poses a member conflict.

IRB members, alternates, and consultants *may* be considered to have a conflicting interest requiring recusal when they, or an immediate member of their family, have any of the following:

- Involvement in the design, conduct, and reporting of the research.
- Significant financial interests. Medical school policy GEN04, *Conflicts of Interest and Commitment*, defines significant financial interests related to research, including research being reviewed by the IRB.
- A reporting relationship with the Principal Investigator.
- Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a study.

The IRB chair must ask IRB members at the beginning of each convened meeting if any members have a conflict of interest regarding any of the items to be reviewed and reminds members that they must recuse themselves by leaving the room during the discussion and vote of the specific research study. If a conflicted member is participating by conference call, videoconference or web meeting, the member's participation concludes and the call disconnected for both the discussion and vote. If the IRB requests, the conflicted member may remain or return in order to provide information or answer questions, but will leave or disconnect before final IRB deliberations and vote.

IRB members with a conflicting interest are excluded from being counted towards quorum during the review of the item for which they have a conflict. Recusals of members with conflicts of interest are recorded in the minutes.

21.5 Institutional Conflict of Interest

The medical school has established principles and procedures to ensure that research involving human subjects under the auspices of the medical school is conducted without untoward influence resulting from either medical school financial investments or holdings or the personal financial interests or holdings of key institutional leaders.

Endowment funds that financially support the medical school are independently held and managed by the Western Michigan University Foundation. The medical school does not control the investment strategies or holdings of the endowment funds.

21.6 Recruitment Incentives

Payment arrangements among sponsors, organizations, investigators, and those referring research participants present a conflict of interest and may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective study participants (“finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of study enrollment (“bonus payments”) also are not permitted.