

Bridgewater State University

IRB Member and IRB Consultant Conflicting Interests

No IRB member or consultant/ad hoc reviewer may participate in the IRB initial or continuing review of any project in which the member/consultant has a conflict of interest, except to provide information requested by the IRB. Reviewers must declare conflict of interest so that the study application can be assigned to another reviewer. The member will be asked to recuse themselves from committee discussions and voting. Minutes should reflect that a conflict of interest was disclosed and document recusals required to manage the disclosed conflict. The type of conflict should be identified in the meeting minutes.

When the chair submits an IRB application, another reviewer will be assigned. An exempt or expedited decision will be forwarded to IRB administrative staff. Formal correspondence concerning a chair's submission will come from a designee of the university president.

When a member (including the IRB chair) has a protocol for review before the IRB (investigator-member), the member may be present at IRB meetings, like any investigator, only to provide information requested by the IRB. The investigator-member must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not vote (e.g., abstain, approve, defer, disapprove) on the study. The absent member is not counted towards a quorum when the vote on the study in question is taken.

The following defines the circumstances under which an IRB member, consultant or reviewer is considered to have a conflicting interest:

“Conflict of interest” refers to a divergence between an individual's personal financial, relational, or other interests and his/her professional obligations to the University – whether through teaching, involvement in research, contracting, purchasing, or performing other administrative duties -- such that an independent observer might reasonably determine that the individual's professional actions or decisions are, or potentially could be adversely affected, distorted or otherwise compromised by the individual's personal interest.

The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research, defined below.

“Financial conflict of interest in research” is the existence of a significant financial interest that an independent observer might reasonably determine affects or compromises, or appears to affect or compromise, the design, conduct, reporting or management of research.

Interests of IRB members, consultants, reviewers and their immediate families (whether by blood, law or marriage) with the same financial interest as an investigator would cause the IRB to consider this a conflict of interest.

Financial and non-financial criteria for conflict may include but are not limited to:

- a. Serving as a co-investigator or other member of the research team;
- b. Having a financial interest in the research with value that cannot be readily determined;
- c. Having a financial interest in the research with value that exceeds a specified monetary threshold (\$10,000);
- d. Having received or expecting to receive compensation with value that may be affected by the outcome of the study;
- e. Having a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
- f. Having received payments from the sponsor that exceed a specified monetary threshold (\$10,000) in the past year;
- g. Having ownership interest (equity or stock options) of any amount when the value of the interest would be affected by the outcome of the research;
- h. Having compensation of any amount when the value of the interest would be affected by the outcome of the research;
- i. Holding a position as director, officer, partner, trustee, employee, or any other position of management of the agency or company sponsoring the research;
- j. Holding patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving the University
- k. Has an interest that the IRB or the IRB member believes conflicts with his or her ability to objectively review a protocol;
- l. Has an interest that the IRB, IRB member, or others perceive may conflict with his or her ability to objectively review a protocol.

It is the responsibility of the member, consultant or reviewer to declare any real or perceived conflicts of interest (as previously described) at least annually or within 30 days of a change in status, and to declare any real or perceived conflicts of interest (as previously described) he/she may have prior to initiating any requested review.

Actions taken when a conflict of interest is declared

An IRB member with a conflicting interest may be in the meeting room only to provide information requested by the IRB. An IRB member with a conflicting interest will be asked to leave the meeting room before voting and/or discussion unless asked specifically to remain for providing information. In any case, the IRB member must leave the room prior to the vote.

If an IRB member declares a conflicting interest, that interest is documented in the minutes indicating the nature of the conflict. The minutes will note that the member declared the conflict and left the room prior to vote and/or discussion. If the member is asked specifically to remain for providing information, the minutes will note that the member remained during discussion at the request of the IRB for the purpose of providing information requested and then left the room before the vote.

A consultant or outside reviewer with a conflicting interest may not provide information to the IRB.

Other requirements:

The name of the person with a conflicting interest must be recorded in the IRB meeting minutes for each applicable vote. IRB members with conflicting interests cannot count towards quorum. An IRB member may not vote on a project, and is not counted towards a quorum, when s/he or an immediate family member has a conflict of interest with a project being reviewed.