Bridgewater State University Meeting Procedures

The IRB meeting is called to order when a quorum of members is in attendance. A quorum consists of more than half of the members. Approval of an action requires a majority vote of the members when a quorum is present. IRB members with conflicting interests cannot count towards quorum (see IRB member conflict of interest for more details). The meeting ends when business is finished or is suspended whenever a quorum of members is no longer present for deliberations.

IRB meetings are conducted by the IRB chair, and the meeting agenda should be arranged to place less controversial issues at the beginning of the meeting. Education or informational items should be distributed with adequate time to review prior to the meeting and sufficient time should be allotted to discuss issues concerning this information. More comprehensive or complex issues, including initial, continuing review and amendments that may require significant committee discussion are placed at the end of the agenda.

Each reviewer is asked to organize and present the item within ten minutes, after which adequate discussion and the IRB action follows. If the reviewer requires additional time for presentation, the chair and committee should be notified in advance. Reviewers should contact the investigator to resolve questions prior to presentation. If a reviewer believes that issues related to the protocol cannot be resolved in a reasonable amount of time, the reviewer may recommend that the protocol be deferred and the reviewer will continue to work directly with the investigator to resolve any outstanding issues.

At the discretion of the chair and/or other reviewer, the investigator(s) may be invited to attend the meeting for the purpose of additional clarification or discussion. The investigator(s) is (are) required to leave the meeting for subsequent discussion and voting.

At the discretion of the chair, voting may be by written ballot, a show of hands, or voice vote. The official meeting minutes record, without individual identification, the numbers of votes to approve, disapprove, defer, or abstain. If vote(s) to disapprove is cast, the minutes should reflect the reason(s) for the disapproving vote(s). In the event a member of the IRB elects to abstain, or is asked to recuse themselves, the minutes record such and identify the individual who did not vote. A majority vote of the members present at the meeting is required for approval. Proxy votes, written, electronic, or telephone, are not allowed.

Investigators may be notified electronically and/or by formal letter of the decision of the IRB and any changes required. If minor specific changes are required by the IRB, the changes may be reviewed and approved by the chair or designee, once returned. Minor specific changes (e.g., address change, addition or deletion of study personnel, change in number of subjects to be recruited, substitution of specific words and/or phrases etc.) may be approved by the IRB chair or his/her designee without return to the full board for review.

The IRB shall notify investigators and the institution in writing of its decision to disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond/appeal in person or in writing. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the University President or designee, and the appropriate federal department or agency head.

The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

The IRB through its administrative staff shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed and any associated documentation or materials, including: scientific evaluations that accompany the proposals, sample consent documents, progress reports, amendments or extensions submitted by investigators, reports of incidents or injuries to subjects, and copies of all correspondence between the IRB and the investigators.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the name of any person with a conflict of interest and reason for conflict; the basis for requiring changes in disapproved research proposals; and a written summary of the discussion of controversial issues and their resolution.

3. Listing of continuing review activities and of research proposals that have been approved under the expedited and exempt review procedures.

4. A list of IRB members, written procedures for the IRB.

The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher, except for purposes of audit or inspection by federal agencies to assure compliance.