PURPOSE

The purpose of the Bridgewater State University IRB is to protect the rights, dignity, welfare, and privacy of human research subjects at the University by adhering to the principles of the *Belmont Report* and the regulations of the Department of Health and Human Services (DHHS) and its subordinate agencies and offices in reviewing all human subject protocols. The IRB is committed to advancing responsible conduct in research, ethical treatment of human research subjects, and ensuring that the right of every human being to voluntary, informed consent to research is respected.

This purpose includes:

1. Reviewing all research involving human research subjects before it is initiated to approve, modify (to secure approval), or disapprove the human research conducted by the organization;
2. Suspend or terminate research not conducted in accordance with the regulations, statutes and principles or IRB's requirements mentioned above or when unanticipated problems occur;
3. Working to protect the rights and welfare of human research subjects by fostering and advancing the ethical and professional conduct of persons and organizations that engage in research with human participants;
4. Providing education to researchers, research staff and the public;
5. Conducting periodic reviews of research involving human subjects.

THE AUTHORITY OF THE IRB

All human subjects research carried out at the University or under its auspices must be reviewed and approved by an IRB prior to the start of the research. The IRB chair, vice-chairs, President or designee handle requests for confirmation that activities do not constitute human subject research. They use the criteria listed in the *Belmont Report* and the regulations of DHHS and its subordinate agencies and offices to make this determination.

The IRB reviews human subjects research projects when:

1. the research is sponsored by the institution or one of its affiliated institutions,
2. the research is conducted by or under the direction of any employee or agent of the institution in connection with his or her institutional responsibilities,
3. the research is conducted by or under the direction of any employee or agent of the institution using any property or facility of the institution,
4. the research involves the use of the University’s non-public information to identify or contact human subjects, or
5. any research referred by an institutional official.

The authority conveyed to the IRB includes the following:

1. Review, approve, and ratify all non-exempt human subject research covered by the Federal-wide assurance in which it is determined that the risks to participants are reasonable in relation to potential benefits to participants and society;
2. Approve pending receipt of specific required modifications. The IRB will draft correspondence to investigators requesting specific modifications to the protocol or the informed consent form. The requested modification must be specific

enough to allow the IRB chair to determine whether the responsive materials provided by the investigator match the modifications required by the IRB. The IRB will be informed of these approvals at the next regularly scheduled meeting. When the convened IRB requests clarifications, requests for additional information, or modifications that cannot be described specifically, the protocol will be tabled, pending subsequent review by the convened IRB of responsive material;

3. Review and determine the status (exempt, expedited or requiring full review) of new research projects;
4. Defer (pending further communication between the investigator and the IRB) studies that have substantive concerns or significant requests for clarification.
5. Review and disapprove the initiation of new research projects in which it is determined that the risks to participants are not reasonable in relation to potential benefits to participants and society;
6. Require from investigators revisions in research protocols and informed consent documents as a condition for initial or continuing approval;
7. Monitor the activities in approved projects including regularly scheduled continuing review at least annually, and verification of compliance with approved research protocols and informed consent procedures;
8. Develop mechanisms for prompt reporting to the IRB of any planned changes in approved projects prior to the implementation of those changes;
9. Develop mechanisms for prompt reporting to the IRB of any adverse experiences occurring in approved projects, or reporting of unanticipated problems involving risks to subjects or others (UPIRTSO), in other projects related in context to the approved projects;
10. Suspend or terminate previously approved research;
11. Restrict aspects of research for the purposes of human subjects protection;
12. Review and monitor the use of test materials or devices for the purpose of treatment;
13. Recommend sanctions to the Office of the President for cases of non-compliance investigated and found actionable by the IRBs;
14. Report human research guidelines violations to the appropriate state or federal agency.

Referral to an External IRB

If an apparent or real institutional conflict of interest is identified that may affect or may appear to affect a proposed research project, the project may be referred to an external IRB for review and oversight. If new institutional conflicts are identified, the transfer of existing approved projects to an external IRB may also be recommended. In these cases, the IRB will facilitate the efficient transfer of all documentation to prevent an interruption of research procedures. If a study is referred to an external IRB for review or if the study is reviewed by any other IRB, the Bridgewater State University Institutional Review Board may consider signing an IRB Authorization Agreement with the external IRB.

Authority of Institutional Officials
The President has the authority to review decisions of the IRB. In the case of an approval decision, should the President conclude that a project does not fully comply with policies or obligations of the Bridgewater State University, the project may be disapproved, suspended, or terminated on behalf of the institution.

In the case of a decision by the IRB to disapprove, suspend, or terminate a project, the President or any other officer or agency of Bridgewater State University, state government, or federal government may not reverse the decision.

In the case where an institutional conflict of interest has been identified, the President or designee may refer the study to an external IRB for review and oversight. Affiliated institutional officials retain the same authority as the University's institutional official for their respective organizations. Affiliated institutions will utilize their own internal policies and procedures to manage conflicts of interest unique to their institution.

If a project does not fully comply with policies or obligations of the University, the project may be disapproved, suspended, or terminated on behalf of the institution.