Membership
The IRB shall be comprised of no fewer than seven members:

1. At least one faculty member from each college or school of the University, chosen to assure representation by both scientific and nonscientific personnel,
2. At least one person qualified to assess each of the following risks: physical (medical), psychological, social,
3. At least one person qualified to assess the validity of experimental design so the benefits of the research may be adequately addressed,
4. At least one member from the community at large not otherwise affiliated with Bridgewater State University,
5. The Director of Grants and Sponsored Projects, who serves as Executive Secretary,
6. Additional members as necessary to provide special expertise for adequate attention to the risks of certain research subject populations.

Membership shall include a balanced representation of ethnicity and gender. New members will be selected by the Chair of the IRB in consultation with past and present members of the IRB, college or school deans and appropriate vice presidents. Members shall be appointed by the University President or designee to serve overlapping five-year terms.

The length of service for an appointed IRB member will be five years and can be renewed President or designee. No more than one quarter of membership may be considered for renewal or for replacement each year. If a member resigns prior to the end of their term, a nominee may be appointed to complete the original term.
The All College Committee will be informed of any changes in IRB membership.

Appointment of Members
IRB members will be appointed utilizing the following criteria:

In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the reviewing IRB will include of one or more individuals who are knowledgeable about and experienced in working with these subjects.

No IRB will consist entirely of men or entirely of women. Qualified persons of both sexes will be considered so long as no selection is made to the IRB only on the basis of gender.

No IRB will consist entirely of members of one profession.

Each IRB will consist of members of various professions including at least one scientist, one nonscientist, and one member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution (community member).7

No IRB member will be knowingly appointed whose institutional responsibilities conflict or appear to conflict, with the primary goals of the IRB. This includes, but is not limited to: University Counsel, Office of Grants and Sponsored Programs, or as a voting member of a similar compliance related committee (IACUC, etc.).

During the first year of the IRB member's initial term, the IRB chair may assign a Executive committee member to serve as a mentor for the new appointee. This mentor will assist the new member, when requested, in preparing for committee meetings, contacting investigators for additional information, and working through any problems noted with the IRB submission, before the IRB meeting is held.

If the IRB member chooses to continue to serve on the IRB at the end of the five year term, the IRB member will submit a request to remain on the committee. The IRB chair, in consultation with the President or designee, may extend an invitation for a committee member to remain.

Alternates, if appointed, are designated for a specific member. If both the alternate and the member attend a meeting, only one of these two may vote. In these cases, the minutes reflect who is in attendance as a voting member.

At the discretion of the President or designee, non-voting (*ex officio*) members from among the academic or administrative staff of BSU, whose presence at the meetings of the IRB would aid the IRB in conducting its duties, may take part in meetings or discussions, and make recommendations, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the presence of non-voting members, Human Subjects Protection Program Office (HSPPO) staff and visitors.

Members of the IRB may be removed before the end of their term if their participation in IRB activities is deemed to be inadequate, inappropriate, or damaging to the reputation of the University and its research activities. Removal may be initiated by the President or designee, at the recommendation of the chair of the IRB on which the member participates, or the chair of the member's department or dean of the college or school the member represents.

IRB chair
The President or designee appoints the chair (and if needed a vice chair), for the IRB. These individuals are respected, active members of the University community who are well informed in regulations relevant to the use of human subjects in research. The term of service is three years. Whenever the chair or vice chair is not available to conduct IRB business, the chair or vice chair may designate a board member to assume his/her responsibilities during the period of his/her absence.

IRB chairs and vice chairs should have experience in conducting human subjects research, have thorough knowledge of federal regulations and state statutes concerning human subjects research, and understanding of BSU research policies, conflict of interest policies and knowledge of ethical guidelines governing research.

Responsibilities of the chair, vice chair, or their designee, include:

1. Determining the type of review (exempt, expedited, full board),
2. Assigning primary reviewers, running full board meetings, reviewing minutes,
3. Reviewing specific revisions to protocols/consent documents that are required as conditions of approval,
4. Reviewing local serious adverse event reports and any reports of unanticipated problems involving risks to subjects or others.

In addition, the chair and vice chair serve as a resource for investigators and IRB members regarding issues related to University, state and federal policies on human subjects research. IRB chairs must disclose any conflicts of interest at least annually and notify the President or designee of any changes that occur between annual disclosures.

The chair votes only to break a tie vote or for the purpose of ensuring that a sufficient number of members eligible to vote are available to have a properly constituted quorum. IRB minutes will reflect when the chair is required to vote.

IRB chairs and appropriate staff should meet at least quarterly basis with the President or designee to discuss any items of concern. IRB chairs serve at the discretion of the President and the President or designee will evaluate performance each year.

IRB Chair Designee
Experienced IRB designees are IRB members with sufficient time served with the IRB and experienced in reviewing submitted research to act in lieu of the chair in reviewing, determining the status of research, or approving exempt or expedited research. A chair determines that a member qualifies as an experienced designee by evaluating one or more of the following: a) their qualifications as a researcher, b) IRB service, and c) member knowledge of the regulations and guidance concerning human subjects in research. An IRB designee may, on occasion, act for the chair in situations that require the absence of the chair (i.e., conflict of interest, business emergencies, etc).

Administrative Designee
A chair may designate a staff member to serve as their designee in the following types of situations:

1. triage received applications to the chairs for exempt and expedited review;
2. make assignment of protocols, in consultation with the IRB Chair, to primary reviewers for IRB meetings;
3. review HIPAA authorizations; and
4. other tasks as assigned by the chair(s) and approved by the board.

A chair determines that a HSPPO staff member qualifies as an experienced designee by evaluating their knowledge of IRB policies, procedures, regulations, and guidance.

Consultants/Ad hoc Reviewers
At its discretion, the IRB may invite scientists or non-scientists from within or outside BSU, who have special expertise, to function as consultants and ad hoc reviewers of a project application. Any individual asked to participate, as a consultant/ad hoc reviewer, will be required to sign a confidentiality agreement and declare in writing that they have no conflict of interest or financial conflict of interest in research for each consultation that relates to the protocol that they are asked to review. These individuals have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but may not vote.

Consultants/Ad hoc Reviewers will be required to review the information listed in IRB Member and IRB Consultant Conflicting Interests below to determine if they may have a conflict that would prevent them from acting as a consultant. Consultants/Ad hoc Reviewers are held to the same standards as IRB members when dealing with conflicts of interest of any kind.

Member Attendance and Activities
In August and December of each year, the list of committee meetings to be held in the coming semester and submission deadlines should be published on the IRB website. Additional committee meetings for proposal review, training, policy development and discussion of current issues identified in regular IRB meetings may be scheduled if necessary.

Committee members are expected to attend each scheduled meeting. Copies of all applicable regulations should be available for reference at every convened meeting. Agendas and meeting materials should be sent to all members prior to meetings.

IRB Members should be provided with materials for full review with sufficient time to examine prior to the meeting. The chairperson, or a reviewer designated by the chairperson, should contact the investigator, other IRB members, or experts/consultants to obtain information or clarify issues prior to the meeting. The chairperson or designated reviewer should work with the investigator to resolve issues and concerns prior to the meeting. Clarification of wording or changes in responses to IRB application

questions should be made in advance so that meetings can be devoted to issues or concerns that could not be resolved with the investigator. The chairperson and reviewers should decide in advance whether the investigator's presence at the meeting will facilitate the review process.

Expedited and exempt reviews may be carried out by the IRB chairperson or by one or more reviewers designated by the chairperson from among members of the IRB. In reviewing expedited and exempt research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove presearch. A research activity may be disapproved only after review in accordance with the nonexpedited procedure.

IRB Chair and Member Training and Continuing Education

Once an IRB member has been appointed, the IRB member will meet with the IRB chair to learn about IRB forms, review guidelines, and to receive an IRB member guide and policies and procedures manual. New IRB members must fulfill required training within 6 months of appointment. Members must participate in continued education as arranged by a board quorum, unless the board approves an exception. Members are encouraged to attend other IRB educational workshops or meetings during the course of their tenure on the board.

IRB members should be provided educational reading material and opportunities for discussion at the majority of IRB meetings. Materials should be circulated with the meeting agenda to be discussed at the beginning of the meeting.