

# **BRIDGEWATER STATE UNIVERSITY**

## **Institutional Review Board Guidelines for Investigators**

All research investigations involving human subjects, conducted by faculty, staff or students at or under the auspices or financial support of Bridgewater State University, must be reviewed and approved, or be declared exempt, by the Institutional Review Board before work may begin. The IRB operates under the policies and procedures of the university to ensure compliance with the National Research Act. The purpose of IRB review is to protect the rights and personal privacy of individuals and assure a favorable climate for conduct of scientific inquiry at Bridgewater State University.

### **RESEARCH REQUIRING REVIEW:**

All research conducted by members of the university faculty, staff, and students that involves the use of human subjects must be reviewed by the IRB. Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research conducted as an evaluation of the university or one of its unit's performance for the purpose of improving that performance may be exempt. Research conducted by students as a part of a classroom assignment where the purpose of the data collection is to teach students how to conduct research may also be exempt. The instructor of the class should contact the IRB staff for further information/advice.

### **NATURE OF THE REVIEW**

The IRB applies three basic principles in its review of research using human subjects:

- respect for the personal dignity and autonomy of subjects and special protection for those persons with diminished autonomy
- the obligation to protect subjects from harm by maximizing benefits and minimizing possible risks of harm
- fair distribution of the benefits and burdens of research

These principles underlie the information requested in the application: the need to obtain informed consent; the need to engage in a risk/benefit analysis and to minimize risk; and the need to select subjects fairly.

### **APPLICATION PROCESS**

The project director should respond to the sections outlined on the application and as described in the IRB Application Guidelines. All requests to the IRB for approval of a research project must include, where applicable:

- Completed and signed IRB Application
- Consent form or consent text
- A copy of all recruitment tools (advertisements, posters, etc.)
- A copy of all instruments (surveys, standardized tests, questionnaires, interview topics, etc.)
- Debriefing forms or text
- Copies of other approvals (other IRB, school district, etc.) if applicable
- Copies of any additional materials that will assist the Board in its review
- Copies of any grant proposals if applicable
- Copies of human subjects training certificates if applicable

One copy of the form and all information and documentation must be submitted to the IRB and must bear the original signature of the project director. If the project director is an undergraduate or graduate student, the project proposal form must be signed by the student's faculty advisor and department chairperson. Faxed or scanned signatures are accepted. No handwritten forms are accepted. All materials shall be submitted to: Office of Grants and Sponsored Projects, Maxwell Library, Room 200.

## Review Level

Based on level of risk and the federally defined categories, one of the following review levels will apply:

- ❑ Exempt Review – If the project director believes that the research is exempt from the need for the IRB review and approval, a completed IRB application must be submitted. A decision on the request will be confirmed in writing and will be made as soon as possible after receipt of the request. It is the responsibility of the project director to obtain approval or a determination of exempt status **before** the research activity is initiated.
- ❑ Expedited Review - The chair of the Board or one or more IRB members may conduct expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- ❑ Full Committee Review – Any research involving human subjects that does not meet criteria for exempt or expedited review must be reviewed in a convened meeting of the IRB. The committee currently meets approximately once a month. For full committee reviews, the researcher (and his/her advisor, if appropriate) may be asked to attend the meeting to discuss the research protocol. The researcher may also request attendance at a meeting in which their proposal will be reviewed. To coordinate attendance, send an email to IRB@bridgew.edu.

## AGREEMENTS

Approval: You may not begin your research until it is approved by the IRB. Approvals will be granted for no more than one year.

Renewal: To renew a previously approved protocol, you must submit a **Periodic Review Form** prior to the expiration date of your approval. Be sure to submit a few weeks ahead of expiration to ensure re-approval prior to expiration. If approval expires, all work must stop on the project until a new approval is issued.

Changes: You must submit any proposed changes to the research to the IRB and receive approval of changes prior to implementation. An **amendment form** is available on the website for this process.

Notification of Adverse Effects: You must submit notification of any adverse events to the IRB for review. An **adverse events form** is available on the website for this process.

Suspension of Approval: The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.