BRIDGEWATER STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD APPLICATION GUIDELINES

COMPLETING THE FORM

Respond to the sections outlined on the application as described below. Feel free to contact members of the IRB for further information or to ask clarifying questions. Copies of all materials and instruments, including consent documents, advertisements, debriefing materials, etc. must be included with the application.

1. Investigator(s) Information

Provide contact information for all investigators. Correspondence and final approval will be sent to the primary investigator, unless another party is indicated as the corresponding investigator. Please complete the email address only if it is an acceptable means of communication to you, i.e. you check it daily. Email will be used for correspondence and final approval.

If you are applying for funding from an external agency (NIH, CDC, FDA, etc.), federal regulations now require IRBs to review these grant proposals as part of the IRB review. You must submit a full copy of all such grant proposals related to this research.

2. Study Timeline

The anticipated starting date is the realistic date you hope to begin the contact with subjects (including recruitment) or records, specimens, etc. This date should never precede the date of submission. No work (including advertising or recruitment) can begin prior to IRB approval.

The duration is the total time it will take to complete the project, including data analysis. Approval will not be granted for a period exceeding one year. An amendment will be required for projects that continue beyond that time.

3. Funding Status

Indicate whether the applicant has applied for internal or external funding, any relationship the investigator(s) may have with the funding organization (financial or otherwise), and how the funding will be used.

4. Recruitment/Selection of Subjects

Indicate who will participate and how they will be enlisted. If participants will be recruited from a larger sample, describe the screening and selection process. All materials to which participants or prospective participants will be exposed must be included in the application. If you are accessing private records, the IRB application must include signed letter(s) of on the record-holder's letterhead granting access and indicating support for your research.

The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed. Some points you may be asked to address:

a. Subjects should not feel 'pressured' to participate (e.g. researcher recruiting own students as subjects, offering excessive monetary incentives). Please describe any potential for coercion and describe what steps will be taken to minimize the possibility. For example, instructors recruiting from their own classes would raise issues of pressure and should consider an alternative method of recruiting

students from other departments.

b. Study design should allow for adequate representation of women and minorities where possible, if participants are limited by gender, age, or other criteria, a rationale must be provided.

c. Burdens on those who are already overburdened (e.g. by physical or mental disabilities, institutionalization, or economic or educational disadvantage)

d. Regulations set forth provision for classes of subjects deemed particularly vulnerable:
   - fetuses, pregnant women, and human in vitro fertilization
   - prisoners
   - children/minors
   - mentally disabled persons
   - economically or educationally disadvantaged persons

Provide an estimate of the maximum number of participants. If you intend to contact 500 individuals in order to get the 300 responses needed for statistical validity, list 500 as the number of human subjects. Once approved, this number must not be exceeded without approval of an amendment.

Provide a brief description of the methods that will be used to select and/or recruit subjects. Include copies of notices or advertisements that will be posted to solicit participants and a description of where the notices will be posted or advertised. If recruitment will be oral (by phone or in person), provide a copy of the script.

6. Project Abstract

Provide a brief (less than 500 word) summary of the project in **6a** that can be understood by IRB committee members and reviewers from varied backgrounds. Avoid acronyms and technical terms specific to your field. Please limit this description to simple summary, and provide details as requested in other sections of the application.

In **6b**, describe research goals and purpose, including how previous research has influenced your study design, materials, hypotheses, etc.

In method (**6c**) describe your data collection procedures and an account of what will happen in the study, including all communication with potential participants. Describe your survey, materials, and any other physical objects used in your study. For example, if your study includes a computer/ computer program, exercise equipment, a waiting room, a camera, photographs, etc., you should provide an explanation in this section. Include the order in which activities took place, the ways in which participants and experimenters interact, how participants interact with an apparatus, etc. If deception is used, include details and justification.

All personnel who will interact with participants or otherwise conduct research should be briefly described in **6d**. Include the relevant qualifications, training and preparation of the investigators, student researchers, translators or other research assistants who will be interacting with participants or handling data. Briefly describe relevant formal or informal training, experiences or other qualifications.

In **6e** consider possible risks or discomforts of participation and the steps that will be taken to minimize them. Refer to debriefing or instructions participants receive upon completion of or separation from the study, how withdrawal or incidents will be handled, and how participant concerns will be addressed. If deception is used, include a description of

relevant remedy or debriefing to resolve participant concerns, confusion or distress. If there are questions about suicidal tendencies or thoughts, you must provide a list of counseling resources to all participants. Any time you are asking subjects about personal information (depression, sexual abuse, eating disorders, etc.) and can minimize the risk from research participation by providing resources (pamphlets, list of agencies, list of coping skills, etc.), you should do so.

Describe the anticipated benefits to the individual participants in **6f**. Monetary compensation should not be listed as a benefit, but should be described in **8a-d**. Direct participant benefit is not required for IRB approval, so if there are no identifiable benefits, state that.

Benefits to society and/or the scientific community are a requirement and must be explicitly described in **6g**. The IRB is charged not only with protecting human subjects from harm, but also to ensure that participants are treated with respect and beneficence, which includes respect for their time and individual investment in research.

8. Confidentiality

Indicate whether data will be collected anonymously or will be de-identified, in which case no further explanation is required. If the data will be recorded with a code linked to identifiers, recorded with identifiers, or the nature of the data makes it identifiable, more details regarding the treatment and safeguarding of data and/or participant control over the extent, timing and circumstances of sharing physical, behavioral or intellectual information should be provided in **8b** or **8c**. Indicate whether participants will be audio or video recorded and describe how those materials will be handled. Any other pertinent details related to participant privacy and their control over access to potentially damaging or embarrassing information should be provided in section **8f**.

8. Compensation

If participants will be compensated, describe the type of award, its value, whether it will be a reimbursement or incentive, why it is appropriate, and how the compensation will be disbursed. Consult university and state guidelines for details on using university funds and OGSP and/or grant guidelines for using grant funds for participant compensation.

9. Consent Process

Describe the consent process and consent document. Include a description of how any difficulties will be overcome, including how any semblance of coercion or undue influence will be avoided, how determination of voluntariness and comprehension will be determined, and/or how questions or concerns will be handled. If an instrument contains questions about abuse, include a statement in the consent document regarding instances that might require mandatory reporting to outside officials. If questionnaires include questions about illegal activity, describe in the proposal and consent form the extent to which confidentiality or anonymity will be protected (if records are identifiable, can be subpoenaed, etc., subjects must be informed). Refer to "Basic Elements of Informed Consent" and "Informed consent templates" to ensure that the any consent documents contain the appropriate elements and language.

Not all research requires a formal consent document. However, whenever possible researchers should include a consent process that reminds subjects that participation is voluntary and ensures an understanding of the risks and benefits of participation. In lieu of a signed document, the investigator may still be responsible for obtaining full and voluntary

consent from every subject and providing participants with a written statement regarding the research may be advised.

A waiver of formal consent may be granted when the research involves minimal risk, when the rights and welfare of subject will not be adversely affects, when the research could not be carried out without an alteration of the informed consent process, and/or when debriefing after participation will suffice.

If participants are not competent to give informed consent, describe how these vulnerable individuals will be protected and how their autonomy will be preserved. Also describe who will be charged with giving permission for the subject and their authority to grant that permission. Refer to "Basic Elements of Informed Consent" and "informed consent templates" to ensure that parent/guardian permission and child assent materials contain the appropriate elements and language.

Signatures

Review the investigator assurance before signing.