BRIDGEWATER STATE UNIVERSITY
BASIC ELEMENTS OF INFORMED CONSENT

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language," (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process. Such a revision to the consent form would require IRB review and approval as an amendment prior to use.

An investigator shall seek the consent of the prospective subject, or the subject's legally authorized representative under circumstances that:

- Provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate.
- Minimize the possibility of coercion or undue influence.
- Present the information to the subject or the representative in language understandable to the subject or representative.
- Do not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The informed consent process shall be documented for review by the committee. Unless a waiver is approved, consent should be obtained via a written document that embodies the elements of informed consent enumerated below. The form must be approved by the IRB and signed and dated by the subject or the subject's representative. A copy (not necessarily a signed copy) shall be given to the person signing the form. For readability, all consent forms should be composed in at least 12-point font.

In some research, the requirement for a signed consent form for some or all subjects may be waived by the IRB if it finds either:

a) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality

b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where a signed consent form is not required, the IRB will require the submission of a copy of the oral ‘text’ that will be presented to subjects, and you may be required to provide subjects with a written statement regarding the research.

In seeking informed consent the following information must be provided to each subject:

a) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

b) A description of any reasonably foreseeable risks or discomforts to the subject.

c) A description of any benefits to the subject or to others which may reasonably be expected from the research.

d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that absolute confidentiality cannot be guaranteed, but will be upheld to the extent permitted by law.

f) An explanation of whom to contact for answers to pertinent questions about:
    1. The research - Researcher and Advisor (if applicable)
    2. Research subjects' rights – Institutional Review Board, (508) 531-1242
    3. Whom to contact in the event of a research-related injury to the subject.

g) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The following additional elements may be required, as appropriate:

a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

b) For research involving more than minimal risk, an explanation as to whether any compensation, remedies and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Unless additional arrangements have been made, the following waiver should be used.

    I agree that all known risk to me have been explained to my satisfaction. Bridgewater State University has no policy or plan to pay you for any injuries you might receive as a result of participating in this research protocol.

c) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

d) Any additional costs to the subject that may result from participation in the research.

e) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

f) A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

g) The approximate number of subjects involved in the study.

Waiver of Formal Consent Document
The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above if the research could not practicably be carried out without the waiver or alteration; and provided the IRB finds and documents that:

a) The research involves no more than minimal risk to the subjects;

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c) When appropriate subjects will be provided with additional pertinent information after participation.

Deception or Incomplete Disclosure
In some research, particularly behavioral research, investigators may plan to withhold information about the real purpose of the research or even give subjects false information about some aspect of the research. This means that the subject's consent may not be fully informed. If deception or incomplete disclosure is necessary for your research, please describe why it is necessary on the IRB application.

Consent documents must never be used as part of a deception and should not include anything untruthful. Consent documents should provide as much information as possible, but need not contain details that would jeopardize the integrity of a study that is justified by scientific, educational or applied value that outweighs the risks associated with deception or incomplete information. Participants must not be deceived about physical or emotional risks that might affect their willingness to participate. You must provide subjects with additional information after their participation is complete. This process is referred to as debriefing. A copy of your debriefing information must be included with your application.

Consent in Research Involving Children or Other Vulnerable Populations
Participants who are not competent to give informed consent are considered vulnerable and the principle of respect for persons requires that they be protected so that their autonomy is reasonably preserved. Conducting research based on permission from someone other than the participant requires substituted judgment or an assumption that the parent or guardian knows what the subject would want. Refer to the Parental Consent and Child Assent template to ensure that that the documents contain the appropriate elements and language.

The IRB may approve research without the permission of a parent or guardian if requesting might put participants at risk, provided that an appropriate mechanism for protecting the children is in place and a waiver is consistent with the law.

Assent, or affirmative agreement to participate in research, may be required when a child is capable of assenting. See the Parental Consent and Child Assent templates to ensure that the documents contain the appropriate elements and language.