Bridgewater State University
Policy of Use of Human Subjects in Research

1.0 INSTITUTIONAL RESPONSIBILITIES

1.1 Campus policies and federal requirements regarding research with human subjects are implemented by the Institutional Review Board for the Protection of Human Subjects in Research (IRB). The members of the IRB are appointed by the University President or designee and the Office of Grants and Sponsored Projects serves as the administrative staff of the IRB. Composition and appointment of the IRB is described in Section 17.0.

1.2 The protection of human subjects from undue risks and deprivation of personal rights and dignity can best be achieved through consideration of three issues: 1) that subject participation is voluntary, indicated by free and informed consent (the subject is free to withdraw at any time without jeopardy and may request that his/her data be destroyed); 2) that the degree, nature and management of risk to the subject and the researcher have been delineated explicitly by the researcher; and 3) that appropriate balance exists between potential benefits of the research to the subject and/or to society and the risks assumed by the subjects.

1.3 The IRB has the ultimate responsibility to determine risk with regard to human subject research and to approve or not approve such research performed under the sponsorship of the University or its auxiliaries.

2.0 SCOPE OF THE REVIEW

2.1 The institution must review biomedical and behavioral research involving human subjects conducted at or sponsored by the University in order to protect the rights of human subjects of such research. Activities which are not research but which nevertheless involve people are not covered by this policy, but rather by other appropriate codes of conduct. Research is defined by the *Uniform Federal Policy for the Protection of Human Subjects* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research activities involving people are divided into three categories:

A. Exempt Research. The IRB will review all protocols involving human subjects and determine whether the proposed research is exempt. Researchers should fill out the application and designation of exempt status will be determined by the Chair of the IRB if warranted.

B. Expedited Review: Research Involving No More Than Minimal Risk to Human Subjects. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research in this category may receive expedited review (see Section 5.0). Researchers should submit proposals in the same manner as for proposals involving more than minimal risk (described in Sections 3.0 and 4.0), but should specifically state in the cover memo that research involves "no more than minimal risk" and that expedited review is requested.

C. Full Review: Research Involving More Than Minimal Risk to Human Subjects. Research in this category shall be reviewed by the IRB according to the procedures set out in Sections 5.0 through 8.0. Researchers should submit complete documentation of their research proposals as described in Sections 3.0 and 4.0.

2.2 Human subject research conducted and/or sponsored by the University includes that conducted and/or sponsored by University employees, emeriti faculty, auxiliary employees, and/or students including student/faculty collaborative research under the auspices of the University.

A. For purposes of clarifying the researcher's legal rights and responsibilities, research or related activities conducted under the auspices of the University are defined to be any research or related activity involving human subjects that utilize Bridgewater State University' time, facilities, resources, and/or students.

B. Bridgewater State University affiliated investigators are afforded the normal legal protection by the University, provided that their activities have IRB approval and provided that they are working within the scope of their employment or University association. It is important to recognize that unless these conditions have been met, the University will not be in a position to protect Bridgewater State University-affiliated investigators performing research with human subjects.

2.3 Extramural Support

Researchers requesting extramural support and planning to perform activities involving human subjects under the auspices of the University are required to submit an application for funds through the Bridgewater State University Office of Grants and Sponsored Projects. All extramural support requests should be submitted to the IRB a reasonable time in advance of deadline,

receipt or submission dates specified by the operating agencies. Completed IRB review can, under no circumstances, be expected in less than 15 working days from receipt of a correctly completed application.

2.4 Faculty Collaborative Research

Collaborative research for which faculty, staff member an administrator is considered the principal investigator must be submitted through the channels described below under Section 3.0, "Application Procedures." Co-investigators and their affiliations should be listed in the space provided.

2.5 Student Research Activities

Sponsoring faculty, staff, or administrators are responsible for the application process and for educating student investigators about human subject procedures. Sponsoring faculty, staff, or administrators must be the principal investigator on student research projects that involve human subjects. Students may be listed as co-investigators in the space provided. The sponsoring faculty, staff or administrator should forward the protocol to the IRB as described under Section 3.0.

2.6 Researchers are entitled to timely review of research proposals. The IRB will normally complete its review within 15 working days of the submission of a complete, properly formatted proposal. In the event that the agenda of the IRB is full, and the IRB is unable to complete review of proposals within 15 working days, the researchers shall be informed promptly. Upon request from researchers, the agenda of the IRB shall be reviewed to prioritize proposals by urgency for starting the research. In the case of expedited review, working days will normally be calculated based on days the campus is open. In cases of full review, only faculty work days in regular sessions are counted.

3.0 APPLICATION PROCEDURES

3.1 Researchers are required to submit a protocol describing the research or activity to the IRB. The chair and (depending on the nature of the research) the Board then reviews the protocol and takes action regarding approval.

3.2 All procedures related to the preparation of appropriate protocols as well as processes leading to their submission to the IRB are the responsibility of the University departments and researchers.

3.3 The IRB requires an application form and any other relevant documents such as surveys, questionnaires and consent forms. IRB review should be completed no later than 30, but not less than 15, working days from the submission of a complete, properly formatted application.

A. The Application Form should include the duration of research. If the research extends beyond one year, it is subject to annual review by the IRB. A sample of the form is available from the Office of Grants and Sponsored Projects/IRB website.

B. The application is a description of the research and an explanation of how the research complies with institutional policies regarding human subjects, and contains the information described below.

1. Abstract. This section should state the relation of the proposed research to previous scientific investigations in the field including relevant laboratory and animal studies. Clear justification for the participation of human subjects at this stage of the investigation must be given. Researchers should keep in mind that most members of the IRB are not experts in the research being reviewed. Adequate lay language explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the research implications, as well as the conditions and risks to which human subjects will be exposed.

The specific aims and hypotheses of the investigation should be discussed, including a definition of the area of the problem, the contribution the research is expected to make, and the relevance of the hypothesis to be tested. If specific hypotheses are not being tested, then the questions to be answered or the information hoped to be gained should be discussed. Also, if the investigation is a pilot or exploratory, then a discussion of the way in which the information obtained will be used in future studies should be included.

2. Methodology. A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with subjects and the means of observation to be used. WHEN QUESTIONNAIRES ARE TO BE ADMINISTERED, A COPY SHOULD BE INCLUDED. Standard psychological tests should be identified. Special attention will be given to issues of confidentiality in behavioral studies. In cases where information provided to subjects regarding procedures and purposes of the study would invalidate the objectives, the investigator should report to the IRB specific reasons for not informing subjects of the procedures.

Devices or activities that are not customarily encountered by the subjects in their daily living or unusual applications of such devices or activities must be described in detail.

Any special procedures involving unusual electrical devices, radioisotopes, or investigational new drugs (IND's) must also be described. Approval from appropriate campus or federal agencies must be obtained before IRB approval can be granted. Unusual electrical devices must have Occupational Health and Safety approval. Radioisotopes or research involving any source of radiation must be first approved by the Environmental Health and Occupational Safety Committee, and "new" drug use must be first approved by the Federal Drug Administration. This department on campus may be accessed here: http://www.bridgew.edu/Depts/fmp/Enviro/enviro.htm

A tentative time schedule for the various procedures--or flow-chart where appropriate--should be provided showing how long each aspect of the study will take, the frequency and timing of ancillary procedures, the nature and duration of human discomfort, and the precise location in which the study is to be conducted. Frequency, duration, and location of interviews or observations should be indicated in behavioral or social science studies.

Identify all personnel who will participate in or assist in the conduct of this research. Identify each individual by name, title and responsibility in this research project. Briefly outline each individual's qualifications. For procedures requiring special skills on the part of the investigators, licenses, accreditation, and/or background of the investigators that qualify them for performance of these procedures should be indicated.

3. Participants. Effects of sample size on the magnitude of risk and problems of risk management will be considered by the IRB.

Justification must be provided for the use of subject groups that are members of a population whose capability of providing informed consent is or may be absent or limited. These include children, persons with diminished mental capacity, the senile who are confined to institutions (whether by voluntary or involuntary commitment), and the unborn child or fetus. A pregnant woman's ability to provide consent is limited insofar as she and the unborn child can participate only in activities

where: (1) the purpose is to meet the health needs of the mother, and the fetus will be placed at risk only to minimum extent necessary to meet such needs; or (2) the risk to the fetus is minimal.

A detailed and specific discussion of potential problems involving the subject groups must be given.

4. Potential Risks. A discussion of the risks (see Section 18.0 for definitions), if any, to the subject is required. Such deleterious effects may be physical, psychological or social. Some research involves neither risks nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

A discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described (including confidentiality safeguards). An assessment of their likely effectiveness should be discussed. Management of risk procedures ranges from those applicable to a group (such as the exclusion of pregnant or potentially pregnant women from a study involving a new drug) to those applicable to an individual subject. (The Office of Grants and Sponsored Projects/IRB provide researchers with procedures for management of potential risk.)

5. Potential Benefits. This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the benefits to individuals and/or society with respect to the risks involved in the study.

6. Confidentiality and Anonymity. The researcher will describe how the identity of participants and their confidential information will be protected, including but not limited to:

a. The separation of informed consent documents and research results such as completed surveys or data gathered;

b. The assignment of identifiers designed to protect participant anonymity; this does not suggest, however, that anonymity is

required. If participants' anonymity is not maintained then the researcher must describe why, specifically, participants will not remain anonymous.

c. The protection of confidentiality in publications;

d. The disposition of research materials and informed consent documents.

7. Other. The IRB relies on the expertise of the researchers to provide insight about any peripheral benefits or potentially harmful effects of the conduct of the research. Based on your past experience and knowledge, please identify any extraordinary moral, legal or ethical concerns, either beneficial or harmful, which may have been linked to this type of research.

4.0 DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in item C. of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A COPY SHALL BE GIVEN TO THE PERSON SIGNING THE FORM.

B. Except as provided in item C. of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent (see Section 4.1). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent (see Section 4.1) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. The witness shall sign both the short

form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That 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.

D. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

E. If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never constitute an undue inducement or coercion.

4.1 The Consent Form

The researcher conducting a project that might place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. (The IRB website provides a sample consent form.)

4.2 Requirements for Informed Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or

the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representation 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.

A. Basic elements of informed consent. Except as provided in item C. or item D. of this section when seeking informed consent, the following information shall be provided to each subject:

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

2. A description of any reasonably foreseeable risks or discomforts to the subject;

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

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and,

8. 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.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

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

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

3. Any additional costs to the subject that may result from participation in the research;

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

5. 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; and

6. The approximate number of subjects involved in the study.

C. 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, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

a. Public benefit of service programs;

b. Procedures for obtaining benefits or services under those programs;

c. Possible changes in or alternatives to those programs or procedures; or

d. Possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alternation.

D. The IRB may approve a consent procedure which does not include, or which alters, some or all the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finals and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

F. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable federal, state, or local law.

5.0 REVIEW OF THE APPLICATION BY THE IRB

5.1 Human subjects research that qualifies under the classification "involving no more than minimal risk" may be reviewed according to the procedures of expedited review. Expedited review procedures apply to certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

A. The IRB may use the expedited review procedure to review either or both of the following:

1. Some or all of the research appearing on the list of eligible categories established by the Secretary of the U. S. Department of Health and Human Services and found by the reviewer(s) to involve no more than minimal risk.

2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

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

C. The IRB shall adopt a method for keeping all members advised of research proposals that have been approved under the expedited review procedure.

D. The appropriate federal department or agency head may restrict, suspend, terminate, or choose not to authorize the use of the expedited review procedure by this institution or the IRB.

5.2 All other research proposals are submitted to the Office of Grants and Sponsored Projects for incorporation into the agenda of the next IRB meeting for discussion by the entire membership or quorum of the IRB. A quorum, which is defined as the majority of the total membership (one half the members plus one), must be present before the IRB can be convened.

5.3 The review performed by the IRB will determine whether subjects will be placed at risk.

A. The policy criterion for determining risk is defined as: "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods which are necessary to meet his/her needs or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

B. If risk is involved, the answers to the following three questions will be weighted:

1. Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks?

2. Are the rights and welfare of any such subjects adequately protected?

3. Is legally effective informed consent obtained by adequate and appropriate methods in accordance with the provisions of the *Uniform Federal Policy for the Protection of Human Subjects*?

5.4 Researchers are encouraged to submit proposals for IRB review during the fall and spring semesters or the winter term; also, research proposals are accepted in the summer. Proposals submitted in the summer will be evaluated in the same way and under the same timeline as during the academic year.

6.0 ACTIONS BY THE IRB

6.1 IRB Review of Research

A. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

B. The IRB shall require that certain information be given to subjects as part of informed consent.

C. The IRB shall require documentation of informed consent or may waive the need for such documentation.

D. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

E. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

6.2 IRB Actions

The IRB, after review and discussion of the protocol and application, may take one of four actions.

A. Approve the research.
B. Require modification.
C. Disapprove the research.
D. Suspend or terminate research.

6.3 IRB Approval of Research

A. In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:

a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and

b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subject would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purpose of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

C. The research may involve some risk to the subjects. In such cases the IRB may find that this risk is not unreasonable, that the potential benefits outweigh the risks, and that risk management procedures have been taken to minimize risks.

6.4 IRB Requirement for Modification of Research

This action involves modifications, major or minor, to some part of the proposed study.

A. The IRB may require major modifications. This occurs when the IRB feels that it has insufficient information to take action, or when it feels that the research design contains significant risks and should be revised to minimize those risks to human subjects. The IRB may request that the investigator discuss problems with the full IRB directly or through a selected member.

B. Minor modifications or conditions set by the IRB include such items as revising the consent form to explain the procedures more clearly, adding a version of a consent form in a language other than English, restrictions on the use of certain procedures or subject groups or requiring use of specified safeguards, etc. that are necessary for the protection of human subjects. The IRB may request the investigator to discuss problems with the full IRB directly or through a selected member.

C. Modified research protocols must be resubmitted for approval. The IRB may choose to expedite review (see Section 5.0) for resubmissions involving minor modifications.

6.5 IRB Disapproval of the Research

In case of disapproval of the research, the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject.

6.6 IRB Suspension or Termination of Approval of Research

The IRB has 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. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the University President or designee, and the appropriate federal department or agency head.

7.0 DISPOSITION OF THE RECOMMENDATIONS

7.1 Approvals, recommendations, restrictions, conditions, or disapprovals are communicated to the researcher through the Office of Grants and Sponsored Projects. At the time of transmittal of approval, the IRB will also inform the researcher of the expiration date of approval.

7.2 If an application is not approved as conforming to Federal and College policies, the IRB shall forward to the researcher a statement setting forth in detail the reasons for the nonconformity and the recommendations of the IRB for modification of the research proposal.

A. Compliance with recommendations is expected within 5 working days of request if noncompliance is attributable to an incomplete application, e.g., one of the following reasons: lack of consent, assent, or similar form; missing or incomplete questionnaire(s), surveys, scripts, or similar such forms; an incomplete application for one of the aforementioned reasons or for any other reason(s), for example, failure to adequately address any component of the application.
    1. The researcher will be notified of noncompliance by three methods: 1) phone call; 2) email; and 3) formal, written letter. If the researcher wants to pursue the noncompliant research after 5 working days of noncompliance, then a new IRB application will have to be submitted.
    2. During the period of noncompliance no additional IRB applications will be accepted from the researcher.

B. If noncompliance is for reasons other than an incomplete application, for example potential risk has not been adequately minimized, deception has not been adequately addressed, or some other sampling or methodological concern, the researcher is expected to address the concerns in writing to the IRB within 10 working days.

1. The researcher will be notified of noncompliance by three methods: 1) phone call; 2) email; and 3) formal, written letter. If the researcher wants to pursue the noncompliant research after the 10 working days of noncompliance, then a new application will have to be submitted.
2. Considering the nature of this noncompliance no additional IRB applications may be submitted during the noncompliance period.

8.0 RIGHTS OF APPEAL

8.1 If the applicant believes that a proposal has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, he/she may notify the University President or designee, who shall direct a reconsideration of the proposal by the IRB. Reconsideration of adverse final decisions on specific projects can be requested by the affected researcher(s) and/or department(s). The researcher may provide expanded information and explanation to the IRB. The reconsideration shall take place and a decision shall be reached within 15 working days of the IRB after the initial negative decision. The researcher and the University President or designee shall be notified of the results of the reconsideration immediately by the Office of Grants and Sponsored Projects.

A. At any point in the entire appeals process, the researcher may modify objectionable items to conform to IRB policy.

8.2 If satisfactory resolution has not been reached as a result of the reconsideration, the following appeals procedure will be used:

A. Within 15 working days of the IRB thereafter, the affected researcher(s) must show cause, to the University President or designee, in writing, as to why the IRB should reverse the decision.

1. An appeals committee of three (or more) tenured faculty (from at least two of the schools or colleges) will be appointed by the University President or designee to conduct a special appeals review. A member of the IRB may be added to the special appeals review committee to provide technical knowledge or other appropriate information. At the request of the researcher, an outside reviewer may be added to the appeals committee. The outside reviewer will usually be a member of the IRB of another institution.

2. The appeals committee shall:

a. Review the initial proposal and reconsideration materials, submitted by researchers;

b. Review relevant minutes of the IRB;

c. Review IRB members' confidential evaluation forms; and,

d. Request any expertise necessary for their deliberations.

3. The researcher may request an appearance before the IRB and/or the special appeals committee through the Office of Grants and Sponsored Projects or the IRB chair

4. The special appeals committee may render one of the following recommendations:

a. Return the proposal to the IRB for further reconsideration.

b. Affirm the original decision of the IRB denying approval to the appealing researcher and/or department.

5. The University President, having received the information from the IRB and the special appeals committee, shall make the final decision.

9.0 RECORDS AND DOCUMENTATION

9.1 Researcher

A. The investigator(s) is required to make and keep written records of the IRB reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent of the subjects or their legally authorized representative. Such forms must be retained on file by the responsible individual for a minimum of five years after termination of the project.

B. Researchers will maintain records of research data.

C. Researchers will monitor the duration of their research to assure that a renewal application is submitted if research will continue beyond its initial anticipated duration and/or if it will continue beyond one year.

D. The researchers must periodically review research results to assure that: 1) unanticipated harm has not occurred; and 2) the research protocol is producing adequate results such that benefits of the research continue to balance risks to human subjects. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefit, the researcher must report immediately to the IRB.

9.2 IRB

A. The IRB through its administrative staff, the Office of Grants and Sponsored Projects, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any that accompany the proposals approved, sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in disapproved research proposals; and a written summary of the discussion of controversial issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the investigators.

5. A list of IRB members.

6. Written procedures for the IRB.

7. Statements of significant new findings provided to subjects.

B. The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher, except for purposes of audit or inspection by federal agencies to assure compliance.

9.3 Institution - Bridgewater State University

It is the responsibility of Bridgewater State University through the IRB and the Office of Grants and Sponsored Projects to assure compliance with and provide documentation of compliance with the *Uniform Federal Policy for the Protection of Human Subjects*.

A. Each institution engaged in research which is covered by this policy and which is conducted or support by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.

1. Whenever research is engaged which is covered by this policy and supported by a federal department or agency, written assurance of compliance shall be submitted to the department or agency head or kept on file within the Office for Human Research Protection, U.S. Department of Health and Human Services, 200 Independence Ave. S.W., Washington, D.C., 20201. Any report to federal department or agency heads required by this policy shall also be submitted to the Office for Human Research Protection if an assurance has been filed there.

2. In lieu of requiring separate submission of an assurance, individual federal department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protection, HHS and approved for federal wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protection, HHS.

B. Federal departments and agencies will support research covered by this policy only if Bridgewater State University has an assurance approved as provided in this section, and only if Bridgewater State University has certified to the department or agency head that the research has been reviewed and approved by the IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

1. The Bridgewater State University statement of principles governing the discharge of its responsibilities for protecting the rights and welfare of human subjects in research conducted at or sponsored by Bridgewater State University, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department or agency-supported or regulated research. The requirement need not be applicable to research classified as exempt or specific research activities or classes of research for which, unless otherwise required by law, federal department or agency heads have waived the applicability of some or all provisions of this policy.

2. Designation of the IRB established in accordance with the requirements of this policy and with provisions made for meeting space and for sufficient staff to support the IRB's review and record-keeping duties.

3. A list of IRB members identified by name, earned degrees, representative capacity, indications of experience (such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB membership) shall be reported to the department or agency head, unless the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

4. Written procedures which the IRB will follow, as embodied in this policy:

a. For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

b. For determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

c. For ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may

not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5. Written procedures for ensuring prompt reporting to the IRB, the University President or designee, and the federal department or agency head of:

a. Any unanticipated problems involving risks to subjects or other or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

b. Any suspension or termination of IRB approval.

c. The assurance shall be executed by the University President or designee who is authorized to act for the institution and to assume, on behalf of Bridgewater State University, the obligations imposed by this policy and shall be filed in such form and manner as the federal department or agency head prescribes.

9.4 Federal Departments and Agencies

A. The federal department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

B. On the basis of this evaluation, the federal department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

C. Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived. An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance has been

reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by this policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

10.0 DURATION OF APPROVAL

10.1 The IRB shall conduct at least an annual review of approved research activities. Researchers should indicate the expected overall duration of the research when submitting an initial application. Renewal applications should be made before the date of expiration of IRB approval, bearing in mind the time needed for review and that research activity must cease at expiration date if renewal has not been obtained.

10.2 The IRB will determine the term of approval and will notify the researcher of the date of expiration of approval at the date of approval.

10.3 Approval of a protocol is granted to the principal investigator. If the principal investigator ceases to be responsible for the study, approval automatically ceases. Should a new principal investigator desire to continue the study, reapplication (see 11.0 below) to the IRB is required.

11.0 RENEWAL APPLICATIONS AND MODIFICATIONS OF PROTOCOLS

11.1 Renewal of approved protocols is required annually and is also required if the principal investigator changes. If during the course of any research, training, or demonstration a change in plans is made so that human subjects are now to be used, or that the research methods or techniques are significantly different, or new hazards are evident, a statement of such change in plans must be submitted to the IRB through the Office of Grants and Sponsored Projects, and an approval of modification of the existing protocol must be obtained. In general, any change which alters the risk/benefit balance or which modifies the informed consent in some way requires approval.

11.2 Renewal Applications

Renewal applications require:

A. A copy of the current or new consent form.

B. A copy of the previously approved protocol.

C. A status report which provides a brief discussion of the work accomplished to date, including particularly:

1. The number of subjects studied (and the number approached who refused permission).

2. A discussion of the experience of the subjects undergoing study, with particular reference to any adverse events occurring to them during the conduct of the study. Note that if no adverse events have occurred, it should be stated, rather than omitting this item altogether.

3. A brief description of the scientific or research results, if any, to date.

11.3 Modification Applications

A. Modification applications require:

1. A copy of the current or new consent form.

2. A copy of the previously approved protocol.

3. A description of any modifications to the current or previous protocol which are desired. For these, the description and justification should proceed much as outlined for a new application; that is, the background or reason for modification, benefits, risks, etc. When responsible positions are assumed by new personnel in the execution of the protocol (such as change of the principal investigator), a description of the background of the individuals with regard to the work described in the protocol (as in the original application) should be given.

B. Progress reports should not be photocopies of papers (either published or submitted for publication). The papers primarily inform their readership of scientific advances. It is necessary to inform the IRB, in as concise a manner as possible, of the results as they influence the balance of benefit to risk to human subject. Published papers may be appended as evidence of benefits of the research.

12.0 UNANTICIPATED PROBLEMS

Any unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices must be reported immediately to the IRB and to any federal agency sponsoring the project by the researcher. Reports should include:

A. Identification of individual(s) involved.

B. Identification of principal investigator, title of project and project number.

C. A description of adverse reactions and any possible association with the experimental procedures, drugs, medical devices, etc.

D. Any relevant information on the subject (previous exposure to drugs, therapy, case history, background information, etc.).

13.0 VIOLATIONS OF THESE POLICIES AND PROCEDURES

13.1 Noncompliance with these policies and procedures is subject to disciplinary action and possible litigation**.** Violations of these policies and procedures should be reported to the IRB immediately.

13.2 The IRB will review allegations of violations of these policies and procedures, and will follow the policies and procedures as set forth in the Bridgewater State University Policy on Maintenance of Integrity in Research, and other regulations governing faculty, staff, and student ethical conduct as appropriate.

13.3 If any research which is federally funded is found to be in violation of any of the federally-mandated portions of this policy, or of appropriate federal regulations regarding the protection of human subjects, the IRB shall report such to the University President or designee, who in turn shall report same to the appropriate agency on behalf of the researcher, if the researcher fails to report.

13.4 Violations will follow the disciplinary procedures outlined in the most current collective bargaining contract and/or Title V regulations, as appropriate.

14.0 ADVICE AND CONSULTATION TO RESEARCHERS AND DEPARTMENTS

14.1 Researchers and departments may call the IRB for informational consultation. This panel will consist of current and previous member of the IRB in addition to other individuals approved by the IRB.

14.2 Any consultation extended is informational in nature; it is neither interpretative nor decisional as these are the prerogatives of the IRB in its review function.

15.0 OMISSIONS

In the event that issues related to the use of human subjects in research at Bridgewater State University are not covered by this policy, the IRB will rely on the *Uniform Federal Policy for the Protection of Human Subjects*.

16.0 AMENDMENTS

16.1 This policy shall be amended when necessary by two-thirds vote of the membership of the IRB.

16.2 Should major revision of this policy become necessary, the Academic Deans and the All College Committee will be consulted to provide advice to the Provost/Vice President for Academic Affairs, who will then advise the University President.

16.3 The final authority for amendment of these policies and procedures and for the adoption of a new revision rests with the University President.

17.0 MEMBERSHIP AND APPOINTMENT OF IRB

A. The IRB shall be comprised of no fewer than seven members.

B. The membership of the IRB shall include:

1. Director of Grants and Sponsored Projects who serves as Executive Secretary.

2. At least one faculty member from each college or school of the University, chosen to assure representation by both scientific and nonscientific personnel.

3. At least one person qualified to assess each of the following risks: physical (medical), psychological, social.

4. At least one person qualified to assess the validity of experimental design so the benefits of the research may be adequately addressed.

5. At least one member from the community at large not otherwise affiliated with Bridgewater State University.

6. Additional members as necessary to provide special expertise for adequate attention to the risks of certain research subject populations.

C. Membership shall include a balanced representation of ethnicity and gender.

D. 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.

E. The All College Committee will be informed of any changes in IRB membership.

18.0 DEFINITIONS

18.1 Certification (Uniform Federal Policy definition)

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

18.2 Cooperative Research (Uniform Federal Policy definition)

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort,

18.3 Human Subject (Uniform Federal Policy definition)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

A. Data through intervention or interaction with the individual; or

B. Identifiable private personal information.

18.4 IRB (Uniform Federal Policy definition)

IRB means an institutional review board established in accordance with and for the purposes expressed in this policy.

18.5 IRB Approval (Uniform Federal Policy definition)

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

18.6 Minimal Risk (Uniform Federal Policy definition)

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

18.7 Physical Risk

Physical risks include any potential for physical injury or deleterious effects to subject's health, either short term or long term.

18.8 Psychological Risk

Psychological risk refers to the impact of research that interrupts the normal activity of human subjects resulting in immediate and/or long-term stress that would not otherwise be experienced by the individual.

A. Stress involves any situation that poses a threat to desired goals or homeostatic organismic conditions and thus places strong adaptive demands on the individual.

B. Stress can be experienced during the actual experimental situation (immediate) and/or as a result of participation in the experiment (long term).

C. Some examples of situations that may result in stress are:

1. Undue coercion.

2. Exposure to noxious events.

3. Request or demand for behaviors that are discrepant with individuals, values, morals, and/or ethics.

4. The requirement of excess physical effort.

18.9 Research (Uniform Federal Policy definition)

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

18.10 Social Risk to Groups

Social risk to groups is the extent to which a subject formal or informal group, as a collective, is exposed to loss with respect to factors affecting the viability and vitality of the group. Such loss includes (but is not limited to) derogatory labeling, overt hostile reactions from the social environment, reduced access to resources, diminished ability to recruit and retain members, negative effects on morale and other aspects of internal cohesion and organization, violation of legally required procedures or risk of damage claims through civil action where there is corporate liability, reduced opportunities for communication, distortion of group activities relative to established group purposes and functions.

18.11 Social Risk to Individuals

Social risk to individuals is the extent to which an individual subject is exposed to deprivation with respect to desired relationships with and within both formal and informal social groups, or normal opportunities for such relationships. Such deprivations include (but are not limited to) derogatory labeling, overt hostile reactions by others, diminished access to otherwise available roles, negative effects on social standing or mobility, reduced opportunity for communication, lost or endangered membership in such groups.