

**Fitchburg State College Institutional Review Board
Policies and Procedures Involving the Use of Human Subjects in Research¹**

INSTITUTIONAL REVIEW BOARD POLICIES 3/03

¹ Much of the language in this document is adapted from the IRB policies and procedures of College Misericordia.

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SECTION I

POLICIES AND PROCEDURES

The primary goal of the Institutional Review Board (IRB) is to protect the rights and welfare of those individuals who agree to participate in research. Review and approval by the IRB is meant to aid both the subjects and the researchers by bringing scrutiny to projects by a group of peers who can objectively assess the potential risk and accommodations made to minimize it.

All research involving the use of human subjects conducted by Fitchburg State College (FSC) faculty, staff, or students, or sponsored, in part or in whole, by FSC must be reviewed and approved prior to the start of the project and then conducted in full compliance with IRB policies and procedures. The ultimate goal of this process is to protect research participants. **Research** is defined by federal regulations as a systematic investigation including research development, testing and evaluation designed to develop or contribute to general knowledge. It encompasses work that is conducted on or off campus and includes questionnaires, interviews, surveys, tests, observations, and experiments, even if the work is preliminary to a more extensive study (e.g., pilot study). It also includes any systematic collections of data from human subjects that occurs in conjunction with classroom projects.

It is the responsibility of researchers to refer their projects to the appropriate review committee (see *Type of Review*) whenever humans are used as subjects in research, even if the researchers do not consider the subjects to be at risk. Current law places the burden of liability for negligence and harm directly on the researcher and the institution. In addition to protecting research participants, the IRB policies and procedures are formulated to protect the College, the researcher, and, in the case of the students, the faculty research advisor or instructor, from liability through imposition of minimal standards for the use of human subjects and through procedures for careful review of projects.

Human subject reviews at FSC are conducted by two bodies. Within departments, Departmental Review Boards are established to review specific types of class projects. At the level of the College, the IRB reviews all other research projects either by designating two members to review the proposal or by a special meeting of all IRB members (see *Type of Review*).

If you have questions about the policies and procedures, contact the IRB chairperson or another IRB member.

A. Background

The Public Health Service Act (Title IV, Part G, Section 491a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46), issued on June 18, 1991. These regulations apply to all research involving human participants that is conducted or supported in foreign or domestic settings.

The establishment of FSC IRB and its policies and procedures are primarily derived from 45 CFR 46. The policies and procedures are intended to provide a resource for the preparation and submission of research applications for IRB reviews. A copy of 45 CFR 46 is with each IRB member. Links to the CFR can be found on the IRB web site and another copy of the CFR and other federal documents and guidelines can be found in the library in a three-ring binder entitled *Fitchburg State College Institutional Review Board Policies and Procedures Involving the Use of Human Subjects in Research*. Another binder is in the office of the IRB chairperson.

B. Ethical Principles and Issues for the Use of Human Subjects in Research

The regulations in 45 CFR 46 are based on *The Belmont Report* that was developed in the 1970's by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report presented three basic ethical principles. These principles of respect for persons, beneficence, and justice remain as essential requirements for the ethical conduct of research involving human subjects. Respect for persons recognizes personal dignity and autonomy of individuals and protection of those that have diminished autonomy. Beneficence includes an obligation to protect individuals from harm by minimizing risks of harm and maximizing benefits. Justice requires that the burdens and benefits be distributed fairly.

In addition to *The Belmont Report*, FSC is also guided by the ethical principles regarding research involving human subjects as presented in *The Nuremberg Code* and the *World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*.

In addition to the aforementioned principles, the IRB will be considering the following ethical issues in determining the nature of the risks and extent to which the benefits of the study justify exposing the subjects to risk:

- *Voluntary participation*

Participation of human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise, and understandable way. The researcher must take care to avoid coercing their participation.

- *Inducement to participate*

Subjects are frequently offered some form of incentive or reward for their participation, such as extra credit from their professor, small gifts or prizes, or a chance to win money in a lottery. In general, inducements are allowable as long as they are minimal and are not more attractive to some subjects than to others. The primary ethical issue involves the extent to which an inducement might be sufficiently large enough to cloud a person's judgment about whether or not participation in the study is in his or her best interest.

In cases where students may earn extra credit from their professors, other options to earn extra credit besides research participation must be available. Researchers who are professors (instructors) must not do the recruiting in their classes. (Although they may have one of their colleagues or research students recruit for the study.) Their names should not be associated with the recruitment procedures if recruitment will take place in their classes. These precautions guard against the students' perception that they may be expected to participate in a study that their professor is conducting in order to stay in good terms with that professor.

A second issue involves the extent to which individuals can reasonably choose not to participate, especially in a case where they are approached in a large group (e.g., class). This is particularly a problem if participation involves a sensitive issue. For example, if the study focuses on AIDS and a person chooses not to participate, it might be interpreted that the person has AIDS. In such cases, the researcher/recruiter would need to demonstrate that this concern has been recognized and addressed (e.g., by providing a means for all potential subjects to appear as if they are participating even if they are not).

- *Informed consent*

All subjects must be properly informed about what the participation will entail. This should be initiated in the recruitment process by having the subjects read and sign an informed consent form before participating in the study. It is also crucial that researchers ensure to the best of their ability that the potential subjects understand what is being communicated to them. Consent must be given freely with the subject understanding the nature and consequences of what is proposed. Consent also is an ongoing process, not just a single occurrence. Researchers must inform subjects and/or guardians of any important new information that might affect their willingness to continue in the study.

Federal law stipulates that a person must be 18 years or older to give legal consent for his/her own behalf. Subjects under the age of 18 years may participate in research only with the signature of their parent or legal guardian in addition to their own signature. This also applies to the completion of anonymous questionnaires, since persons under 18 are not permitted legally to make the informed choice to participate. Children should have the information about participation in the research explained to them in language that they can understand (by their parent or guardian), and, if possible, they should sign their consent.

- *Identification and minimizing of risks*

Virtually all research involves some risk, even though it may be slight (e.g., embarrassment over a performance on a task). A risk may be of a physical, social, economic, and/or psychological nature. The IRB will consider the extent to which the researchers have attempted to identify the potential risks to the subject and the extent to which those risks have been minimized as much as possible without interfering with the validity of the research. In cases where there is the possibility of more than minimal risk to the subject, approval will depend on the following: the benefits of the research, the

expertise and prior experience of the researcher(s) in conducting this type of research, the level of inducement to participate, the extent to which the subject is fully informed of the possible risks, and the availability of compensatory treatment or follow-up designed to alleviate any negative consequences from participation. A research procedure may not be used if it is likely to cause serious and lasting harm to subjects (e.g., health problems).

- *Fairness*

The research should be designed to treat all individuals fairly. The selection of subjects must be based upon fair procedures and not overburden, overuse, or unfairly favor or discriminate against any subject pool.

- *Research involving intended deception*

In some types of research it may be necessary to withhold some pertinent information from subjects when disclosure of such information would likely impair the validity of the study. In all such cases, subjects should be told that they are being invited to participate in research in which some features will not be revealed until the research is concluded. Complete nondisclosure of information about the study or its purpose is only justified when the research solely involves observation of a person's behavior in locations where the person might reasonably expect that his/her behavior could be observed by another. In research that involves incomplete disclosure, the following conditions must be met: “(a) researchers do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible; (b) researchers never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences; and (c) any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research” (adapted from the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct, 1992). Truthful answers should always be given to direct questions about the research; this may include telling the subject that revealing certain information may impair the success of the study.

- *Confidentiality and anonymity*

In all research involving human subjects, it is important to assure the subjects of the confidentiality of their responses. This is especially important in cases where the study involves asking the subjects personal questions about themselves or obtaining other information that might put the subject psychologically at risk, if the information was made public. Total anonymity (e.g., where the subject's name or face is never associated with his/her responses, even to the researcher) is preferable, especially in the case of extremely sensitive or personal information. This generally means that the subject must be able to provide information in complete privacy and to submit the information in such

a way that it is mixed in with other subjects' data before it is retrieved by the researcher. Where it is necessary to have the subjects' names or identification numbers associated with their responses (e.g., in order to collate several sets of responses by the same subject), the subjects need to be told who will see their data and specifically how this information will be kept confidential.

- *Debriefing*

In most cases, it is desirable for subjects to be debriefed after their participation in the study (e.g., given further information about the study and given a chance to ask questions). There are three cases in which debriefing is required: first, when the research involves incomplete disclosure; second, when subjects may be left with a misleading or potentially harmful perception or inaccurate information; and third, when compensatory treatment or follow-up is needed. Such debriefing should not be treated as a substitute for informed consent prior to and during the subject's participation in the research.

In some cases, debriefing may not be possible immediately after the study due to a concern about other potential subjects finding out about a deceptive aspect of the study that would preclude further data collection. In these cases, debriefing statements or descriptions could be offered to the subjects at a later date through the mail or other means. In rare instances, debriefing may itself pose a social or psychological risk to a subject. In such a case it may be in the best interest of the subject to forego the debriefing procedure. In most cases, however, this can be avoided by disclosing to the subjects prior to their participation that some harmful information may be uncovered in the course of the study. This would fall under the obligation to disclose any risks that are more than minimal (see *Research involving intended deception*).

- *Compensatory follow-up*

In cases where some physical or psychological harm might result from the subjects' participation, plans for compensatory treatment or follow-up counseling should be provided.

C. Type of Review

The type of review required depends upon the nature of the research, the subjects, and the risk imposed upon the subjects. A decision tree to aid in the researcher's determination of the proper type of review is included at the end of Section I. In all cases the researchers must complete the application and Researcher Assurance Statement (*Section II*).

- **Type 1: class research projects that qualify for review by the Departmental Review Board (DRB)**

Class or student research projects involving use of human subjects who are not students in the class should be reviewed by the IRB or DRB. Class or student projects qualify for Type I Review provided they:

- **do not involve human subjects who are members of a special population, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons**
- **do not involve sensitive topics**
- **do not involve deception**
- **do not involve more than minimal risk to subjects**

Research involving human subjects that qualifies for a Type 1 review must maintain an adequate standard of informed consent and confidentiality of data. Information on subjects should be recorded so that subjects cannot be identified directly or through identifiers linked to the subjects. If a project is likely to be presented outside the college (i.e., conference, journal), it should be sent to the IRB for Type 2 or Type 3 review. Projects involving special populations, sensitive behavioral research, research involving deception, or research that is harmful to subjects automatically require a Type 3 review.

Examples of class projects that might not require DRB review could be journalism interviews, informational interviews, or “shadowing” of case managers for an internship. These projects may not fit the federal definition of research because they may not involve the “systematic collection of data.” If an instructor has any concerns regarding classroom activities that do not involve the use of outside participants or do not fit the definition of research, these activities may also be reviewed by the DRB.

Review of proposals requires a quorum of the DRB members and a proposal must be granted by a majority of the attending members. Proposals that do not receive approval may be resubmitted with changes or resubmitted to the IRB for review.

Each department will send their approved applications to a designated member of the IRB. This IRB member will review the approvals and return a letter of approval to the instructor.

- **Type 2: research that qualifies for review by two members of the IRB**

Research in this category includes minor changes in previously approved research (within one year), or research activities involving no more than minimal risk and which only include involvement of human subjects in one or more of the following categories (carried out according to standard methods):

- a. When educational research meets the following conditions and does not require consent from parents. The assent of a child should be obtained whenever possible.
 - (1). The research is conducted in established or commonly accepted educational settings involving normal educational practices. Examples are research on regular and special education instructional strategies or research on the effectiveness of or the comparison among institutional techniques, curricula, or classroom management methods.
 - (2). If the research involves educational tests (cognitive, diagnostic, aptitude, achievement), this information must be recorded so that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - (3). The research procedures do not represent a significant deviation in time or effort from those educational practices already existing at the research site.
 - (4). The research procedures do not involve an increase in the level of risk or discomfort compared to normal, routine educational practices. Examples of areas of increase in risk are studies in which parenting practices are criticized or teachers' jobs may be jeopardized.
 - (5). Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
 - (6). The research does not involve sensitive topics (e.g., sex education).
 - (7). The cooperating institution grants written approval for the research to be conducted.
- b. When research involving the use of surveys, interview procedures, or observation of public behavior is not part of educational research as defined in "a," but meets the following conditions:
 - (1). Information on these subjects is recorded so that subjects cannot be identified directly or through identifiers linked to the subjects.
 - (2). Disclosure of subjects' responses outside the research setting would not place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

- (3). There is no risk associated with a breach of confidentiality.
 - (4). The research does not deal with sensitive or highly personal aspects of the subjects' behavior, experiences, or attitudes (e.g., substance abuse, detailed health history, sensitive demographic data).
 - (5). The research does not involve subjects under 18 years old.
 - (6). The research does not involve survey or interview procedures when the respondents are elected or appointed public officials or candidates for public office.
- c. When research involves taste and food quality evaluation and consumer acceptance studies where only wholesome foods without additives are consumed or involves only a limited amount of consumption of a food additive at or below a level approved by the Food and Drug Administration, Environmental Protection Agency, and/or the United States Department of Agriculture.
 - d. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth, if patient care indicated a need for extraction.
 - e. Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
 - f. Recording of data from subjects who are 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, encephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).
 - g. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and nor more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
 - h. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is no more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
 - i. Voice recordings made for research purposes such as investigations of speech deficits.

- j. Moderate exercise by healthy volunteers (as defined by the American College of Sports Medicine).
- k. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- l. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the researcher does not manipulate subject's behavior and the research will not involve stress to subjects.
- m. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Applications pertaining to research activities that qualify for a Type 2 review are read by a minimum of two members of the IRB. A formal meeting is not required unless the two members disagree.

Projects involving special populations, sensitive behavioral research, research involving deception, or research that is harmful to subjects automatically require a Type 3 review.

- **Type 3: research that requires a special meeting of IRB members**

Federal regulations require that institutional review boards give special consideration to protecting the welfare of special populations, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons.

Research involving special populations, sensitive behavioral research, research involving deception, or research that is harmful to subjects automatically require a Type 3 review. Type 3 review requires a special meeting involving a quorum of the IRB members and approval by a majority of the attending members.

D. Student Research

These same policies and procedures apply to student research. Instructors are responsible for screening student research projects and determining if they require approval by the IRB or by the DRB. If a project is assigned for the purpose of producing generalizable results that may be presented outside of the class, or published, or may involve risk to the subjects, the researcher(s) must comply with these policies and procedures. Submission of an application and appropriate approval must occur prior to initiating the research.

For class assignments that are intended to provide research experiences and do not require approval by the IRB or DRB, the researcher(s) should adhere to ethical standards and use informed consent and child assent procedures when appropriate. Refer to the definition of research on page 1.

The advisors of Fitchburg State College students serving as research assistants for practica should receive copies of researchers' Human Subject approval before students are allowed to work on the projects. Advisors must assess students' skills in relation to the research project and determine whether students are qualified to serve in the proposed roles. Students should also read the Fitchburg State College Human Subject policy and sign a Researcher's Assurance Statement. If students are proposing new research projects to be conducted during practica, they must be reviewed by the committee at either a Type I or Type II level.

E. Cooperative Research with Another Institution

When cooperative research occurs with another institution, one institution may agree to delegate responsibility for initial and continuing review of all or a portion of the research activity to another IRB. This can occur if the other institution and IRB agree to assume responsibility for the review and if the delegating institution agrees to abide by the reviewing IRB decisions. For any portion of a research activity that FSC researchers do not delegate to another IRB, the researchers remain responsible in complying with FSC's policies and procedures. **Any research conducted on this campus must be reviewed by FSC's IRB.**

Researchers and FSC IRB need to bear in mind the following when contemplating the use of another institution's IRB to review its protocols: local laws, institutional policies and constraints, professional and community standards, and population differences. It may be beneficial to seek IRB counsel prior to engaging in cooperative research involving the use of human subjects.

The agreement for IRB review of cooperative research must be documented in writing with copies furnished to all involved with the agreement and those ensuring compliance with IRB policies and procedures. If FSC researchers obtain IRB approval from another institution, they must submit a copy of the approval letter to the IRB chairperson. **No matter what the agreement, each institution is responsible for safeguarding the rights and welfare of human subjects.**

F. International Research

Procedures for reviewing research in foreign countries may differ from those set forth in this document and in federal regulations. Such international standards as the *Nuremberg Code* and *Declaration of Helsinki* present broad policies, but are not considered sufficient for an institution having an assurance with a federal agency such as DHHS. Because of the varied policies and procedures involved with conducting research in foreign countries, it is best that researchers discuss research projects with the IRB during the planning phase of the project.

G. Research Not Subject to Ethical Review

The following kinds of research are specifically exempted from the need for ethical review:

- a. Research or other study of the published writing or other public utterances of human subjects.
- b. Questionnaires concerning teaching performance or course content distributed to a class by instructors, deans or others.

H. Departmental and Institutional Review Boards

1. Membership

DRBs will consist of a minimum of three members of a department. An instructor may not grant approval for his or her own application.

Faculty members of the College's IRB are appointed by the MSCA to represent the interests of the College and the community. There are at least six faculty members with varying backgrounds and expertise. The IRB must include at least one faculty member whose primary concerns are in scientific areas and at least one faculty member whose primary concerns are in nonscientific areas. Additionally, the President shall appoint at least one administrator from Human Resources and/or Disabilities Services. A respected Fitchburg community member also shall be appointed by the President. All members are appointed annually and may be re-appointed from year to year. The IRB chairperson may request that any board member who frequently does not submit reviews in a timely manner and/or misses meetings be replaced.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, and handicapped and mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about these types of subjects and are experienced in working with them. The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise in addition to that available on the IRB. These individuals will not vote.

2. Meetings and Review Process

Upon receiving and application for a Type 1 review, the DRB chairperson checks the application for completeness. If the application does not need to be returned to the researcher(s), it is distributed to DRB members to be reviewed at the next meeting. Review of proposals requires a quorum of the DRB members. A proposal must be granted by a majority of the attending members, and the DRB must complete and sign the Action Sheet (*see form at the conclusion of this section*). The DRB sends a copy of the application, Researcher Assurance Statement, and Action Sheet to the IRB chairperson. After receiving a copy of this application, the IRB chairperson checks the application to ensure that the appropriate forms are included. If these forms are included, the application is filed and a

letter is sent to the researcher. Proposals that do not receive approval may be resubmitted with changes or resubmitted to the IRB for review. On a random basis or upon request of the DRB, the IRB chairperson reviews Type I applications. DRBs are responsible for establishing their own meeting dates and deadlines as necessary.

Upon receiving an application for a Type 2 review, the IRB chairperson checks the application for completeness. If the application does not need to be returned to the researcher(s), at least two members of the IRB review the application. As soon as the IRB members receive the copies of an application they are allotted up to 10 working days to review the application and provide comments and a decision to the chairperson. These members may communicate with each other in whatever manner is efficient and effective for them: mail, fax, e-mail, telephone, etc. A formal meeting is not required unless the two members disagree. They submit their Action Sheet (*see form at the conclusion of this section*) to the IRB chairperson who then sends a letter to the researcher.

Upon receiving an application for a Type 3 review, the IRB chairperson checks the application for completeness. If the application does not need to be returned to the researcher(s), it is distributed to IRB members to be reviewed at the next meeting. Review of proposals requires a quorum of the IRB members, and a proposal must be granted by a majority of the attending members. IRB members may not vote on their own proposals. IRB meeting dates and deadlines for receipt of application materials will be set at the beginning of every semester. Submissions will be due to the committee approximately 10 working days before a scheduled meeting. The IRB chairperson will send a letter to the researcher within one week following the scheduled meeting.

Since most of the IRB members are only on campus during the fall and spring semesters, it is highly recommended that researchers and faculty research advisors plan accordingly. Applications may be sent to the IRB chairperson or designee at other times, but more time may be needed for the review. Under exceptional circumstances, special meetings can be arranged.

3. Record Keeping

The IRB prepares and maintains documentation of IRB activities. The documents include the following: FSC IRB Policies and Procedures, membership list, copies of research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and researchers, and statements of significant new findings provided to subjects (as presented in federal policies).

The IRB records will be retained for at least three years. The records pertaining to research that is conducted will be retained for three years after completion of the research.

I. Appeal Process

If the application is disapproved, the researcher has the right to appeal to the IRB. The researcher should submit a letter to the IRB chairperson requesting another review and providing rationale. Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether or not an application is approved.

INSERT PROPOSAL SUBMISSION DECISION TREE

FITCHBURG STATE COLLEGE
REVIEW BOARD ACTION SHEET

Type 1 Review Type 2 Review Type 3 Review

Name of contact person: _____ Phone: _____

Faculty research advisor: _____ Advisor's phone: _____
(for student research)

Project title: _____

Proposed Project Dates: from ___/___/___ to ___/___/___

=====

The above project meets the following criteria (please check the appropriate criteria)¹:

- does not involve human subjects who are members of a special population, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons
- does not involve sensitive topics
- does not involve deception
- does not involve more than minimal risk to subjects

=====

Research requiring Type 1 review

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information
- received _____(date)
- requires Type 2 review
- requires Type 3 review
- disapproved

DRB Chair (or designee's) Signature

Date

Research requiring Type 2 review

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information
- received _____(date)
- requires Type 3 review
- disapproved

IRB member's signature

Date

IRB member's signature

Date

Research requiring Type 3 review

Action taken:

- approved as submitted
- approved pending submission of revision and/or additional information
- received _____(date)
- disapproved

IRB chairperson's (or designee's) signature

Date

¹ Projects that fail to meet any of these criteria must be sent to the IRB for Type 3 Review.

SECTION II

INSTRUCTIONS FOR APPLICATION FOR REVIEW OF RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Prior to submitting an application, ensure that you understand the IRB Policies and Procedures involving the use of human subjects. A description of how to prepare an application and required and sample forms are contained in the following pages.

A. Submission of Application Materials

1. If the research qualifies for a Type 1 review, submit **three** copies of the application and researcher assurance statement to your DRB chairperson. If the DRB chairperson is the applicant, he or she should submit three copies of the application to an IRB member. You will receive one of the following decisions:
 - a. Application approved as submitted.
 - b. Approval withheld pending submission of revisions and/or additional information.
 - c. Application requires either a Type 2 or Type 3 review.
 - d. Application disapproved.
2. If the research qualifies for a Type 2 review, submit **three** copies of the application to the IRB chairperson. If the research was initially reviewed by the DRB and determined to require a Type 2 review, the DRB chairperson should forward the materials and action sheet to the IRB chairperson. You will receive one of the following decisions:
 - a. Application approved as submitted.
 - b. Approval withheld pending submission of revisions and/or additional information.
 - c. Application requires a Type 3 review.
 - d. Application disapproved.
3. If the research requires a Type 3 review, submit **nine** copies of the application to the IRB. If the research was initially reviewed by the DRB or by two IRB members for a Type 2 review, the DRB chairperson or IRB members should forward the materials and action sheet to the IRB chairperson. After the formal meeting, you will receive one of the following decisions:
 - a. Application approved as submitted.
 - b. Approval withheld pending submission of revisions and/or additional information.
 - c. Application disapproved.

B. Application Instructions

Keeping in mind that the IRB is composed of both non-academic and academic individuals from different disciplines, the application should be written so that it is understandable to persons outside of the specific field in which the research is conducted. If specific terminology is used (e.g., tests, procedures, equipment), the terms should be explained or a

glossary should be attached. It is difficult for the IRB to make competent judgments about risk if the exact nature of the procedure is not clear. Technical terminology often confuses the issue and may delay the review process.

The following instructions are to be adhered to in the preparation of an application. Make copies of the forms from this document. Complete the Application for the Conduct of Research Involving Human Subjects and the Researcher's Assurance Statement. To facilitate the review of your application, respond to each statement and do not refer the reviewers to information in a previous or later response. You may indicate N/A (not applicable) when appropriate. If, however, you think that it may not be obvious to IRB/DRB reviewers why you used N/A, provide an explanation.

1. Application for the Conduct of Research Involving Human Subjects
 - a. Complete each section of the application either on the application itself or in an attachment that is numbered to match the format of the application.
 - b. Attach all relevant materials (e.g., copies of all questionnaires or survey instruments, informed consent documents, minor assent documents, letters of approval from cooperating institutions).
2. Researcher Assurance Statement
 - a. Attach the signed Researcher Assurance Statement. If the researcher is a student, both the student and the faculty research advisor must sign.

C. Continuing Review and Submission of the Annual Update

Applications are approved for a maximal period of one year. For research projects that continue beyond one year, it is the responsibility of the researcher(s) to submit a Request for Annual Update to the IRB/DRB. The first update is due 12 months following the date the application was approved. If the IRB/DRB determines that a project requires review more often than annually, the researcher (contact person) or advisor will be notified. Projects can be updated annually for a maximum of five years. Continuation of projects beyond five years requires resubmission of an application.

D. Reporting Changes in a Research Protocol

Any change in a protocol that affects the human subjects must be approved by the IRB/DRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the subjects. Researchers should submit a Request for Change in Protocol to the IRB/DRB. If the change in the protocol requires changes in the consent form, attach the new consent form to the Request for Change.

E. Reporting End of Project

When the project is completed, the researcher must submit an End of Project Report to the IRB/DRB chairperson.

F. Submission of a Report of Injury

If a subject sustains an injury during the study, the researcher must take immediate action to assist the subject and notify the IRB of the injury within 48 hours.

G. Reporting Non-Compliance with IRB Policies and Procedures

Any incident of non-compliance with IRB policies and procedures should be reported immediately to the IRB.

H. Record Keeping

The principal researcher must retain the approved application and signed consent forms for a minimum of three years following the completion of the research project, or longer if judged necessary. For student research, the faculty research advisor must retain these. The IRB may request copies of these. Government organizations that provide grants often require that all documents associated with the research be retained for three years following the completion of the project.

I. Researcher Forms

Hard copies of the forms, any other parts of this document, or the document as a whole will not be distributed. Make copies of these materials as needed.

APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS¹

The Fitchburg State College IRB and/or DRBs review all requests to conduct research involving human subjects. In completing the IRB application, be advised that persons reviewing it may be entirely unfamiliar with the field of study involved. Present the information in non-technical terms. It is the investigator's responsibility to provide information in typewritten form regarding the procedures, the informed consent process, and supply the required documentation listed at the bottom of this page.

1. Based on Institutional Review Board Policies, indicate which level of review is appropriate for this project:

- Type 1 Review:** class research projects involving the use of human subjects who are not students in the class and who are not considered to be members of a special population, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons. Projects involving special populations, sensitive behavioral research, research involving deception, and research that is harmful to the subjects automatically require a Type 3 review.
- Type 2 Review:** minor changes in previously approved research (within one year), or research activities involving no more than minimal risk and which only include involvement of human subjects in one or more of the categories detailed in the Institutional Review Board Policies.
- Type 3 Review:** any research involving special populations (i.e., children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons) and/or sensitive behavioral research, research involving deception, or research that is harmful to subjects.

PROJECT TITLE: _____

2. Principle Investigator's Name _____

Department _____ Phone _____ Mailing Address _____

Faculty Sponsor _____ Phone _____
(required if principle investigator is a student)

3. Project Start Date: _____ Project End Date: _____

4. Is a proposal for external support being submitted? Yes ___ No ___

Agency or Sponsor: _____ Deadline: _____

If yes, you must submit one complete copy of the proposal with this application.

¹ Adapted from materials created by the IRB of Bridgewater State College.

5. In order for the IRB/DRB to evaluate your application, the following required information must be provided:

- A copy of all questionnaires or survey instruments
- Informed consent document(s) or minor assent document(s)
- Letters of approval from cooperating institutions (if appropriate)
- All required signatures

Failure to provide all required information will result in return of your application for correction prior to IRB/DRB approval.

In the space provided below, provide complete answers to the following questions:

6. **Project Description and Purpose of Research:** Provide a brief summary of the proposed research and its goals. The IRB/DRB must have sufficient information about what will happen to the subjects and why the research is being undertaken in order to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of transactions between the investigator and subject.

7. Subject Selection:

Will subjects be less than 18 years of age? Yes___ No___

Age range of subjects From_____ To_____

Will subjects be students at Fitchburg State College? Yes___ No___

How many subjects will participate? _____

How will subjects be selected, enlisted or recruited?

8. **Informed Consent Process:** Describe the informed consent process and attach a copy of all consent and/or assent documents.

9. **Procedures:** Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.

10. **Confidentiality and Anonymity:** How will subjects' privacy be maintained and confidentiality be guaranteed?

11. **Risks:** Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.

12. **Benefits:** Describe the anticipated benefits.

13. **Responsibilities of the Principal Investigator:** Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being put into practice. Any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the IRB Chair. The principal investigator and his or her designee are responsible for retaining Informed Consent Documents for a period of three years after completion of the project.

14. **Signatures:** In preparing this IRB application, I certify that I have read and understand the Procedures and Guidelines of the IRB, and that I intend to comply with the letter and the spirit of the Fitchburg State College policy. I certify to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

A. Signature of Principal Investigator

Principal Investigator

Date

B. Approval by Faculty Sponsor (required for all students)

I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.

Faculty Sponsor

Date

NOTE: Do not begin collection of data (including pilot studies) until you receive notification that your application has been approved by the IRB/DRB.

FITCHBURG STATE COLLEGE
RESEARCHER ASSURANCE STATEMENT

I have read and understand Fitchburg State College's Policies and Procedures concerning research involving the use of human subjects and agree:

1. to accept responsibility for the ethical conduct of this research project.
2. to obtain approval from the College's IRB prior to instituting any change in the research project.
3. to report to the College's IRB serious adverse reactions or unexpected effects on subjects.
4. to submit to the IRB an End of Project Report at the completion of the research project.

a. _____ Department/Program
 Researcher's printed name

_____ Date
 Researcher's signature

b. _____ Department/Program
 Researcher's printed name

_____ Date
 Researcher's signature

c. _____ Department/Program
 Researcher's printed name

_____ Date
 Researcher's signature

d. _____ Department/Program
 Researcher's printed name

_____ Date
 Researcher's signature

e. _____ Department/Program
 Researcher's printed name

_____ Date
 Researcher's signature

For student research:

I have approved the procedures of the research project described in the attached application. I agree to assist the student with the policies for conducting research involving human subjects.

_____ Department/Program
 Faculty research advisor's printed name

_____ Date
 Faculty research advisor's signature

FITCHBURG STATE COLLEGE
REQUEST FOR ANNUAL UPDATE FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Name of contact person: _____ Dept./Program: _____

Address: _____ Phone: _____

Faculty research advisor: _____ Advisor's phone: _____
(for student research)

Project title: _____

Project dates: from ____/____/____/ to ____/____/____/

Number of subjects who completed the study _____

Number of subjects who are currently involved in the study _____

Number of subjects to be enrolled in the study in the next 12 months _____

Number of subjects who voluntarily withdrew from the study _____

Number of subjects experiencing adverse reactions, complications, or injuries resulting from participation in the study _____

Attach a one page description of the known reasons for voluntary withdrawal of subjects from the study and the adverse reactions, complications, or injuries resulting from the study. Include a brief summary of progress on the project and preliminary results.

Primary researcher's printed name

Department/Program

Primary researcher's signature

Date

For Student Research:

Faculty research advisor's printed name

Department/Program

Faculty research advisor's signature

Date

=====
Committee use only: Date of first IRB approval: _____ IRB project number: _____

Date received by IRB: _____ Date approved by IRB: _____

FITCHBURG STATE COLLEGE
REQUEST FOR CHANGE IN PROTOCOL FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Name of contact person: _____ Dept./Program: _____

Address: _____ Phone: _____

Project title: _____

Project dates: from ____/____/____/ to ____/____/____/

Description of proposed changes (Attach additional pages and revised consent forms if needed.):

Justification for proposed changes (Attach additional pages if needed.):

Primary researcher's printed name Department/Program

Primary researcher's signature Date

For Student Research:

Faculty research advisor's printed name Department/Program

Faculty research advisor's signature Date

=====
Committee use only: IRB project number: _____
Date received by IRB: _____ Date approved by IRB: _____

FITCHBURG STATE COLLEGE
END OF PROJECT REPORT FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Complete the following information and submit one copy to the IRB chairperson.

Project title: _____

Name of contact person: _____ Dept./Program: _____

Address: _____ Phone: _____

Project dates: from ____/____/____/ to ____/____/____/

This is to verify that the above named research involving the use of human subjects was performed according to the procedures approved by the IRB. The research project is now complete.

A total of _____ subjects participated in this research project. _____ subjects voluntarily withdrew from the research project. _____ subjects experienced complications, adverse reactions, or injuries resulting from participation in the research project. All records for this project will be maintained for 3 years by the researcher or faculty research advisor and will be accessible if review of the data is necessary. If the faculty member is no longer at FSC, the Department/Program will maintain the records.

Primary researcher's printed name Department/Program

Primary researcher's signature Date

For Student Research:

Faculty research advisor's printed name Department/Program

Faculty research advisor's signature Date

=====
Committee use only:

Date received by IRB: _____ IRB project number: _____

SECTION III

RESEARCH INVOLVING THE USE OF SPECIAL POPULATIONS

Federal regulations require that IRBs give special consideration to protecting the welfare of vulnerable populations. For example, the Department of Health and Human Services (DHHS) requires additional safeguards for research involving fetuses, pregnant women, and human in-vitro fertilization (45 CFR 46, Subpart B), prisoners (45 CFR 46, Subpart C), and children (45 CFR 46, Subpart D). If faculty, staff, or students are associated with research involving fetuses and in-vitro fertilization, they should consult with the IRB chairperson and the Vice President of Academic Affairs. Some of the federal regulations, state, and local laws need to be strictly adhered to concerning these areas. For example, in some instances the DHHS requires approval by their Ethical Advisory Board prior to conducting a study.

Research involving any of the other special populations must follow all requirements as indicated in 45 CFR 46. The remainder of this section concentrates on some aspects of research involving children, incapacity, and AIDS/HIV- related research studies.

A. Research Involving Children

The special vulnerability of children makes consideration involving them as research subjects important. Special procedures are required for research involving children except for research that is conducted in educational settings as previously described in this document.

What constitutes minimal risk is central to the IRB's consideration of research involving children. The IRB also must determine that adequate provisions have been made for getting the permission (assent) of children and the permission (informed consent) of their parents or guardians. The IRB's policy regarding obtaining consent and assent is as follows:

1. In most situations, parental consent is required if the research involves minors (under the age of 18 years old). Unless the requirement is waived by the IRB, a parent or guardian must complete an informed consent form.
2. Unless the requirement is waived by the IRB, assent is required from all children. In most situations, a written form should be used to document assent. The form should include a simplified version of the contents of the informed consent. This explanation should be written so as to be understandable to the child. If the child's developmental ability does not enable him or her to understand the written explanation, documented oral assent is appropriate.

B. Research Involving Subjects with Incapacities

Incapacity refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to

make a choice. Persons with incapacities who either have been adjudicated to lack the capacity to give informed consent or have been judged by the researcher(s) to lack the capacity cannot participate as research subjects unless proxy consent is obtained by their legally authorized representative. The assent of the potential subject must be obtained whenever possible. Depending on their situation and the research being planned, durable power of attorney may be requested from the IRB.

C. AIDS/HIV - Related Research

A paramount concern in HIV research is confidentiality. Breaches of confidentiality could have severe adverse consequences such as loss of employment or insurance coverage or criminal charges. For example, if identifiers are not needed, they should not be recorded. If they are recorded, they should be separated, if possible, from the data, and combined with the data only when necessary. It also has been suggested that no lists should be retained identifying those who elected not to participate.

The procedures for obtaining informed consent need to be accurate and complete. Subjects should be informed of exactly what information will be recorded and whether any state laws require disclosure of information.

SECTION IV

SAMPLE FORMS FOR RESEARCH INVOLVING HUMAN SUBJECTS

SAMPLE INFORMED CONSENT FORM

The following is a sample consent form containing the elements common to many informed consent forms. You should feel free to substitute language pertinent to your research project. The italicized language is offered for example only.

Title of Project:

Researcher(s): _____

Invitation to Participate: *e.g., You are invited to participate in this research study. The following information is provided to help you make an informed decision whether or not to participate. If you have any questions, please do not hesitate to ask.*

Purpose: *e.g., We hope to learn (in lay language, state as clearly and accurately as possible what the study is designed to do. This statement of purpose should help the subject assess the importance of the study relative to individual values.). This research is supported by (a grant from) (name of entity).*

Subjects: *State why this subject is eligible to participate, e.g., because you are a student, male, over 50 years old, because you live in Northeast Pennsylvania, because you have diabetes, etc. When appropriate, state criteria for subject exclusion, e.g., pregnancy, health restrictions, etc.*

Procedures: *e.g., If you decide to participate, we will (in language understandable to your population, describe the procedures to be followed, including their purposes, duration, frequency, and recovery time, if applicable. Any drug or device should be described. If a placebo is to be administered to a portion of the subjects, this information must be included, though individual subjects need not be informed as to whether they will actually receive the placebo. Quantities, such as blood to be drawn should be stated in terms familiar to the subjects. If audio/videotaping or motion pictures are a procedure of the study, insert a statement permitting the subject to review and/or edit the tapes. Define usages and describe the disposition of such material at the end of the study.).*

Alternatives: *Describe alternative procedures or treatments that might be advantageous to the subject. Any standard treatment that is being withheld must be disclosed, with its relative risks and benefits. When treatment is hazardous or very unpleasant, or the quality of prolonged life is seriously at risk, the option of no treatment must be candidly presented. If no alternative drug or treatment is available, this should also be stated. If your study only involves interviewing without any interventions, this section may not be applicable.*

Timetable: Clearly identify the amount of time that will be required of the subject and the length of time that will be needed for the completion of the study.

Risks: Present a fair, reasonably detailed and understandable description of any physical, psychological, social, legal, and/or economic risk(s) resulting from the research. If there are no known risks, including discomfort, burden, or inconvenience, this should be stated.

Benefits: Present a fair, reasonably detailed and understandable description of any benefit that might result from the research. If the individual will receive no direct benefit, this should be explicitly stated. Describe potential societal benefits in this section.

Compensation for Participation: *Any compensation for participation should be clearly stated. Cash payments should be stated in dollar amount. Any conditions such as partial payment or no payment if early termination and bonuses for completion should be stated. If compensation will be in the form of academic credit that will be awarded for research participation, the amount and type of credit should be clearly stated as well as any conditions that must be fulfilled in order for credit to be awarded. The nature, amount, and method of payment of compensation must not constitute undue inducement of the subject. When establishing the amount/type of compensation, the researcher should consider the background and socioeconomic status of the subject population. Compensation for children involved in research is generally discouraged.*

In Case of Emergency Contact Procedure / Emergency Care and Compensation in Case of Injury: *These sections are required for research involving greater than minimal risk. They deal with research-related injuries and adverse reactions. If your research involves such risk to the subjects, seek counsel in writing these sections as they legally obligate the College.*

Confidentiality: *e.g., Any information obtained during this study which could identify you will be kept strictly confidential. This information may be published in professional (or scientific) journals or presented at professional meetings. (State the way in which the subject's confidentiality will be maintained. State the persons or agencies to whom the information from the study will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.)*

Right to Refuse or Withdraw: *e.g., You may refuse to participate and still receive the care you would receive if you were not in the study. You may change your mind about being in the study and quit after the study has started. If the study design or use of the data is changed, you will be informed and your consent obtained for the revised research study.*

Questions: *e.g., If you have any questions at this time, please ask them. If you have questions later, (give the name of the principal researcher or assistant) we will be happy to answer them at (give an address and phone number; in some instances, a 24-hour number should be included. For student research, use or add the name and number of the faculty research advisor).*

You will be given a signed and dated copy of this form to keep upon request.

Your signature below indicates that you voluntarily decided to participate in this research project as a subject and that you read and understand the information provided above.

Subject's signature

Date

Subject's printed name

My signature as witness certifies that the subject voluntarily signed this consent form in my presence. (required only for research with greater than minimal risk)

Witness's signature

Date

Witness's printed name

In my judgment, the subject is voluntarily and knowingly giving informed consent to participate in this research study.

Researcher's signature

Date

Researcher's printed name

SAMPLE CHILD ASSENT FORM

The following is a sample child assent form. Write this form in language that is appropriate for your subject(s). The italicized language is offered for example only. An informed consent form for the parent or guardian must accompany this form; modify the aforementioned informed consent form so that the parent or guardian is appropriately informed.

Title of project: _____

Researcher(s): _____

Invitation to Participate: *e.g., You are invited to participate in this research study. You are eligible to participate in this study because ... Please talk this over with your parents (or guardian) before you decide whether or not to participate. Your parents (or guardian) will also be asked to give their permission for you to take part in this study. If you have any questions at any time, please ask.*

Purpose: *e.g., In this study, we hope to learn (in a simple sentence or two, state as clearly and accurately as possible what the study is designed to do).*

Procedures: *e.g., If you decide to participate, we will (in understandable language describe the procedures to be followed).*

Risks: *Present a fair and understandable description of any discomfort, burden, or inconvenience.*

Benefits: *Present an understandable description of any benefit that might result from the research.*

You and your parents (or guardian) will be given a signed and dated copy of this form to keep upon request.

Your signature below indicates that you voluntarily decided to participate in this research project as a subject and that you read and understand the information provided above.

_____	_____
Subject's signature	Date

Subject's printed name	
_____	_____
Researcher's signature	Date

Researcher's printed name	

GLOSSARY

ASSENT: Agreement by an individual not competent to give legally valid informed consent (e.g., child or cognitively impaired individual). Failure to object cannot be construed as assent.

ASSURANCE: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

DEBRIEFING: Giving subjects previously undisclosed information about the research project following completion of their participation in research. This usage departs from standard English, in which debriefing is getting rather than imparting information.

DECLARATION OF HELSINKI: A code of ethics approved by the World Medical Association and adopted by medical associations in many countries as guidelines for their clinical research.

GUARDIAN: See legally authorized representative.

HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventive procedure.

LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body who is authorized under applicable state or local law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research.

MINIMAL RISK: 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.

MINOR: Any person under the age of 18 years.

NUREMBERG CODE: A code of ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting humans subjects during research.

PARENT: A child's biological or adoptive parent.

PREGNANCY: The period of time from confirmation of implantation of a fertilized egg, through any of the presumptive signs of pregnancy, such as missed menses or by medically acceptable pregnancy tests, until expulsion or extraction of the fetus.

PRINCIPAL INVESTIGATOR OR PRINCIPAL RESEARCHER: The scientist or scholar with primary responsibility for the design and conduct of a research project.

PRISONER: An individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial, or sentencing.

PRIVACY: Control over the extent, timing, and circumstances of sharing oneself (intellectually, physically, behaviorally) with others.

PRIVATE INFORMATION: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical records).

RESEARCH PROTOCOL: The formal design or plan of an experiment or research activity; specifically, the plan submitted to the IRB or designated representative for review and to an agency for research support.

VOLUNTARY: A subject's decision to participate (or to continue to participate) in a research activity that is made free of coercion, duress, or undue inducement.