

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

INSTITUTIONAL REVIEW BOARD POLICIES
Updated May 2018

¹ This document is from or adapted from the Department of Health and Human Services, Code of Federal Regulations Title 45, Part 46.

Fitchburg State University Institutional Review
Board Policies and Procedures Involving the Use of
Human Participants in Research

A. Background.....	4
B. Ethical Principles and Issues for the Use of Human Participants in Research....	5
Voluntary participation	5
Inducement to participate	5
Informed consent	5
Documentation of informed consent	7
Identification and minimizing risk	9
Fairness	9
Research involving intended deception	9
Research involving the use of special population	10
Confidentiality and anonymity.....	10
Debriefing	10
Compensatory follow-up	11
Periodic reviews of research	11
Records and Documentation	11
C. Policies and Procedures....	11
Categories of research	13
Review process	15
Approval process	16
D. Cooperative Research with Another Institution.....	16
E. International Research	16
F. Projects Not be Subject to Initial Review by the IRB	16
G. Application Instructions to Conduct Research Involving the Use of Human Participants.....	17
Training Requirements.....	17

Preparation of application material	17
Submission of application material	18
Determination of review	18
H. Continuing Review and Submission of the Annual Update	19
I. Reporting Change in a Research Protocol.....	19
J. Reporting End of Project	20
K. Submission of a Report or Injury	20
L. Reporting a Non-Compliance with IRB Policies and Procedures.....	20
N. Researcher Forms.....	20
O. Glossary.....	19
P. Frequently Asked Questions.....	21

Preamble: Activities Subject to the Scrutiny of the Institutional Review Board (IRB)

In compliance with Federal laws and regulations, Fitchburg State University has established an Institutional Review Board (IRB) for reviewing research with humans. Any research involving human participants conducted by any University faculty, staff, or students, or sponsored, in part or in whole, by the University must be reviewed and approved prior to the start of the project by the IRB and then conducted in full compliance with IRB policies and procedures. These policies govern research that involves human participants.

Only activities that fit the Federal definition of research are participant to review under these policies. The definition is set forth in the Code of Federal Regulations (CFR), at 45 CFR 46.102 (d). According to the CFR,

Research means a systemic 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 which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

If a project does not fall within this definition, these policies do not apply to it. However, it is still expected that University community members conduct their activities in accordance with the highest ethical and moral standards and accepted practices within their discipline.

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 participants 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 (CFR 45.46), issued on June 18, 1991 and updated on July 14, 2009. These regulations apply to all research involving human participants that is conducted or supported in foreign or domestic settings.

The regulations in CFR 45.46 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 participants. 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.

The establishment of Fitchburg State University Institutional Review Board (IRB) and its policies and procedures are primarily derived from CFR 45.46 and are 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 (1964)*.

The policies and procedures are intended to provide a resource for the preparation and

submission of research applications for IRB approval.

Links to the CFR 45.46 can be found on the IRB web site and well as in the library where other relevant federal documents on research using human subjects can be found.

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

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 participants to risk:

Voluntary participation

Participation of human participants 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

Participants 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 participants 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 participants to appear as if they are participating even if they are not).

Informed consent

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

circumstances that provide the prospective participant 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 participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(1) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each participant:

- (a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (b) A description of any reasonably foreseeable risks or discomforts to the participant;
- (c) A description of any benefits to the participant or to others which may reasonably be expected from the research;
- (d) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- (e) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- (f) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- (g) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- (h) *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;

(2) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each participant:

- (a) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
- (b) Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
- (c) Any additional costs to the participant that may result from participation in the research;

- (d) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
 - (e) A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and
 - (f) The approximate number of participants involved in the study.
- (3) An 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:
- (a) The research or demonstration project is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
 - (b) The research could not practicably be carried out without the waiver or alteration.
- (4) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
- (a) The *research involves no more than minimal risk to the participants*;
 - (b) The waiver or alteration will not adversely affect the rights and welfare of the participants;
 - (c) The research could not practicably be carried out without the waiver or alteration; and
 - (d) Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- (5) 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.
- (6) 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.

Documentation of Informed Consent

- (1) Except as provided in paragraph '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 participant or the participant's legally authorized representative. A copy shall be given to the person signing the form.
- (2), The consent form may be either of the following:

- (a) A written consent document that embodies the elements of informed consent required in this policy. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or
 - (b) A short form written consent document stating that the elements of informed consent required by this policy have been presented orally to the participant or the participant'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 participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, 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 participant or the representative, in addition to a copy of the short form.
- (3) *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:*
- (a) That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
 - (b) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

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

All participants must be properly informed about what the participation will entail. This should be initiated in the recruitment process by having the participants 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 participants understand what is being communicated to them. Consent must be given freely with the participant understanding the nature and consequences of what is proposed. Consent also is an ongoing process, not just a single occurrence. Researchers must inform participants 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. Participants 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.

REMINDER: Researchers who engage participants who are college students should recognize that a significant percentage of these students in their first year may not be 18 years of age.

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 participant 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 participant, 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 participant 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 participants (e.g., health problems).

Fairness

The research should be designed to treat all individuals fairly. The selection of participants 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 participants when disclosure of such information would likely impair the validity of the study. In all such cases, participants 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 participant that revealing certain information may impair the success of the study.

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 (CFR 45.46, Subpart B), prisoners (CFR 45.46, Subpart C), and children (CFR 45.46, Subpart D). If faculty, staff, or students are associated with research involving fetuses and in-vitro fertilization, they should consult with the IRB chairperson, their Academic Dean and the Institutional Official (President or designee). 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

Confidentiality and anonymity

In all research involving human participants, it is important to assure the participants of the confidentiality of their responses. This is especially important in cases where the study involves asking the participants personal questions about themselves or obtaining other information that might put the participant psychologically at risk, if the information was made public. Total anonymity (e.g., where the participant'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 participant 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 participants' data before it is retrieved by the researcher. Where it is necessary to have the participants' names or identification numbers associated with their responses (e.g., in order to collate several sets of responses by the same participant), the participants need to be told who will see their data and specifically how this information will be kept confidential.

Debriefing

In many cases, it is desirable for participants 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 are required: first, when the research involves incomplete disclosure; second, when participants 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 participant's participation in the research.

In some cases, debriefing may not be possible immediately after the study due to a concern about other potential participants 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 participants at a later date through the mail or other means. In rare instances, debriefing may itself pose a

social or psychological risk to a participant. In such a case it may be in the best interest of the participant to forego the debriefing procedure. In most cases, however, this can be avoided by disclosing to the participants 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 participants' participation, plans for compensatory treatment or follow-up counseling should be provided.

Periodic reviews of research

Researchers must periodically review research data during the research results and other observations to assure that unanticipated harm has not occurred and that the research protocol is producing adequate results such that benefits of the research continue to outweigh the risk to participants. If unanticipated harm does occur or if results are inadequate to assure a balance of benefit to risk, the researcher(s) must report immediately to the IRB.

Researchers are responsible to apply for an extension if it appears that their research will extend beyond the approval period (a maximum of 1 calendar year). An extension will require an annual update progress report

Records and Documentation

The principal researcher must retain all relevant forms and documents for a minimum of three (3) years following the completion of the research project, or longer if judged necessary. For student research, the faculty research advisor must retain these documents. The IRB may request copies of these. Government organizations that provide grants often require that all documents associated with the research be retained according to their own records retention policies. Records that you may be required to retain include:

- (1) Records of IRB reviews and decisions.
- (2) Documentary evidence of informed consent of participants
- (3) Records of research data

All records and other documents must be kept in a locked and safe place. Digital records must be protected by secure passwords or other appropriate methods.

C. 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 participants 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 participants conducted by Fitchburg State University faculty, staff, or students, or sponsored, in part or in whole, by the University must be reviewed by the IRB 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. The IRB is charged with protection of the rights and welfare of those participating in research conducted by those affiliated with the university.

Research required for review by the IRB may also fall into the following three categories.

- (1) Research that is conducted or supported by a federal department or agency.
- (2) Research that is neither conducted nor supported by a federal department or agency but fits under the definition of research stated in this policy
- (3) Research that is voluntarily submitted by an applicant(s) for a federal-level institutional review.

If a research project does not fall into one of these three categories, this policy may still apply to it. Clarification should be sought from the IRB chair. Regardless, it is still expected that university community members conducting research do so in accordance with the highest ethical and moral standards and accepted practices within their discipline.

It is the responsibility of researchers to refer their projects to the appropriate review committee (see *Categories of Review below*) whenever humans are used as participants in research, even if the researchers do not consider the participants 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 University, 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 participants and through procedures for careful review of projects.

The IRB prepares and maintains documentation of IRB activities. The documents include the following: 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 participants (as presented in federal policies).

Only the IRB can review and approve research projects that involve human participants. Other organizations, committees or boards may make pre-submission recommendations to researchers on projects that require IRB approval, but they may not authorize the conduct of research involving human participants.

The composition of the IRB is as follows:

Faculty and staff members of the University's IRB are appointed the University administration, via the Institutional Official, to represent the interests of the University 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 Institutional

Official shall appoint at least one administrator or staff member. A Fitchburg community member also shall be appointed by the Institutional Official. The IRB chairperson will be a faculty member appointed by the Institutional Official. Members will be assigned to the committee on rotating terms. All of the members listed in this paragraph shall be voting members.

Other, ex-officio, non-voting members of the IRB will be appointed by the Institutional Official to a 1-year term.

Effective 1-January-2018, all IRB members must complete CITI program training as specified in the Training Requirements section of this document

A voting member may not vote on research that they have a present or potential conflict of interest. This member may be present to disseminate information, but will not be present during the final discussion and voting phase.

The IRB Chair may request that any board member who frequently does not submit reviews in a timely manner and/or miss's meetings be replaced.

If the IRB regularly reviews research that involves a vulnerable category of participants, 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 participants 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 be voting members.

Categories of Research

Research applications to the IRB can fall into one of three defined categories: Exempt, Expedited, and Full.

- (1) Exempt Review applies to research activities in which the involvement of human participants is limited to one or more of the following definitions below (1-6), and is not otherwise required to be reviewed by the IRB by a federal funding or other sponsoring agency, are classified as Exempt.
 - (a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - (I) research on regular and special education instructional strategies, or
 - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - (b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
 - (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be

damaging to the participants' financial standing, employability, or reputation.

(iii) does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

(c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 2.b above, if:

(i) the human participants are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

(e) Research and demonstration projects which are conducted by or participant to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(f) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(2) Expedited Review applies to research that involves either of both of the following:

(a) No more than minimal risk to participants. A risk is minimal “where the probability and magnitude of harm or discomfort anticipated in the proposed 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.” (CFR 45.46)

(b) Minor Changes in previously approved research during the period (of one year or less) for which approval is authorized are proposed.

(3) Full Review applies to research that involves more than minimal risk to participants and will receive a full review by the IRB. A participant at risk means any individual who may be exposed to the possibility of injury, including physical, psychological, or social, as a consequence of participating as a participant 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 risk of daily life, including the recognized risks inherent in a chosen occupation or field of service.

Review Process

The IRB has final authority to approve the research, disapprove the research, require modifications for approval, or suspend or terminate research.

Approval of research allows researcher(s) to begin collecting data and running pilot studies. Application approvals are for one year (12 months) and there is a process to extend the application deadline

Major Modifications of research require applicants to resubmit their application. These occur when the committee does not have sufficient information to take action, or when it believes the research design contains significant risks and should be revised to minimize risks to participants.

Minor Modifications of research require applicants to resubmit their application. These may include revisions to the consent or other forms, revision of language in the application, restrictions on the use of certain procedures or participant groups, or requiring other specific safeguards that are necessary for the protection of participants.

Suggestions for modifications made by the committee may be revised and the application can be resubmitted for approval or researchers may provide expanded information and explanation to the IRB and may, at any time in the appeals process, modify objectionable items to conform to IRB policy.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Suspensions or terminations of approval will include a written statement of the reasons for the IRB's action and will be reported promptly to the researcher, appropriate Fitchburg State University officials, and any supporting department or agency head.

If an applicant believes a proposal has been disapproved, suspended or terminated because of incorrect, unfair, or improper evaluation by the IRB, they may notify the University President or designee (the Institutional Official) by written document within 15 working days of the FSU IRB decision, who may direct a reconsideration of the proposal by the FSU IRB. If the reconsideration is not adequate to the researcher a special committee of three or more tenured faculty members will be appointed by the University President or designee (the Institutional Official). A member of the FSU IRB may also be appointed to the committee. The appeals committee shall, (i) review the initial proposal and reconsider materials submitted by the researcher, (ii) request any expertise necessary for their deliberations. The researcher may request an appearance before the special committee. The special committee may take one of two actions, they may (1) affirm the original decision by the IRB (2) return the proposal to the researcher with specific recommendations for further reconsiderations.

Exempt status may be assigned to projects submitted to the IRB by the IRB Chair or their designee.

Expedited reviews are carried out by the IRB Chair and at least two reviewers from the committee. When the two reviewers do not agree on the nature of the expedited review, the IRB Chair will bring the proposal to the full IRB for consideration. If one or both of

the reviewers is unable to complete their review in a timely manner, the IRB chair may assign the proposal to a second reviewer or team.

Full reviews submitted require incorporation into the agenda of the next scheduled FSU IRB meeting for discussion by the entire membership or quorum of the FSU IRB. The vote must be a majority vote taken from a quorum of voting members.

D. 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 FSU researchers do not delegate to another IRB, the researchers remain responsible in complying with FSU's policies and procedures. *Any research conducted on this campus must be reviewed by the IRB.*

Researchers and 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 participants.

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 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 participants.*

E. 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.

F. Projects Not be Subject to Initial Review by the IRB

The following kinds of research may be exempted from the need for IRB review: Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that participants may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving participants remain to be selected; and projects in which human participants' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications may not need to be reviewed by an IRB

before an award may be made. However, except for research exempted or waived under CFR Title 45-Part 46.101, no human participants may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

G. Application Instructions to Conduct Research Involving the Use of Human Participants

Prior to submitting an application, ensure that you understand the IRB Policies and Procedures involving the use of human participants and that your procedure and documents are prepared appropriately. A description of how to prepare an application follows:

When completing the application keep 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. If it is difficult for the IRB to make competent judgments about risk if the exact nature of the procedure is not clear, the review process will be hindered.

Training Requirements

Previously approved NIH based training will be accepted for projects approved by the IRB during calendar year 2017. This also applies to projects that receive an *annual update authorization in 2017*. Effective 1-January-2018, only the CITI training collaborative modules will be accepted as meeting IRB requirements for the training of researchers and IRB members.

CITI modules meeting IRB requirements can be accessed at the following website:

- [CITI Program Registration Responsible Conduct in Research Required for ALL Researchers at Fitchburg State](#)
- [CITI Program Registration and Training Requirements for Fitchburg State University IRB Applicants and Researchers](#)
- [CITI Collaborative Institutional Training Initiative](#)

Each completed CITI training module has an authorization of three years. Researchers have the option of completing the entire module or the associated refresher training before the expiration of their three-year certificate. Modules are required based on the nature of the project and the role of the researcher or IRB member. IRB members are also subject to similar training requirements. Training certification must not expire within the period of the proposed project.

Note: All researchers MUST complete the *Responsible Conduct in Research Training*

Role	CITI Training Module(s)
Institutional Official (President or Designee)	Institutional/Signatory Official: Human Subject Research
IRB Chairperson	IRB Chair
IRB Member	IRB Members - Basic/Refresher
Faculty Member or Graduate Student	Training is dependent on the disciplinary area for the research project, for example ¹ : Biomedical Data or Specimens Only Research - Basic/Refresher Biomedical Research - Basic/Refresher Social & Behavioral Research - Basic/Refresher
Undergraduate Student	Students - Class Projects

¹Researchers who are unsure of which training they should take, or who are affiliated with the university but with roles not clearly defined above should contact the IRB Chair for guidance on which modules will be required.

Preparation of Application Materials

- (1) Complete all sections of the application. Ensure that the sections under the ‘description of project’ are complete, thorough and concise.
 NOTE: You can facilitate the review of your application through responding to each statement and not referring 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 reviewers why you used N/A, provide an explanation.
- (2) All researchers should be included as co-investigators on the application and all should sign the signature page.
- (3) Prepare all relevant materials for submission (e.g., copies of all questionnaires or survey instruments, informed consent documents, minor assent documents, letters of approval from cooperating institutions).
- (4) Copies of certificates for all required training must accompany each application. Training must not expire within the period covered by the application or subsequent annual extensions.
- (5) All student research requires a faculty advisor. The student may act as the primary investigator, however the faculty advisor is responsible to review and approve the research proposal prior to submission of the application. The faculty advisor is also responsible to guide the student throughout the project, including but not limited to ensuring the student follows the policies and procedures within this document.

Submission of Application Materials

- (1) Submit one hard copy of the application including signatures and all other relevant documents to the IRB chair. If the chair is the applicant, he or she should submit their application to an IRB member for processing.
- (2) Submit through email to the IRB chair an electronic copy of the application and all relevant documents.
- (3) The IRB committee meets on average of every 4-weeks, but meeting frequency may be adjusted based on demand (specific meetings days for semester are listed on the Human Subjects Committee webpage). Review of applications will typically be completed within 4-weeks or less. Application reviews may take longer if the IRB has many applications to review or during times of high workload for committee members (e.g. the end of the semester) Please prepare accordingly when determining the submission of your application.
- (4) The IRB committee is active on a 12-month cycle. However, during the months between the spring and fall semesters, the committee will only review applications that are working under a grant approval or those considered under unconceivable or uncontrollable deadlines.
- (5) The IRB Chair may return an application prior to review if material is not considered complete or further information is required for sufficient review.

Determination of Review

Following review of the application, the research project will be either:

- (1) Approved as submitted
- (2) Require modification(s) for approval
- (3) Returned as incomplete
- (4) Disapproved as submitted

Refer to the ‘Review process’ and ‘Approval process’ for an explanation of the determination of the application review.

H. Continuing Review and Submission of the Annual Update

Applications are approved for a maximum period of one year (12 months). For research projects that continue beyond one year, it is the responsibility of the researcher(s) to submit a “*Request for Annual Update*” application to the IRB chair 11-months following the date the application was approved.

If the IRB 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.

I. Reporting Changes in a Research Protocol

Any change in a protocol that affects the human participants must be approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the participants.

Researchers should submit a *“Request for Change in Protocol”* to the IRB. If the change in the protocol requires changes in the consent form, attach updated consent form with your request.

J. Reporting End of Project

When the project is completed, the researcher must submit an *“End of Project Report”* to the IRB chair within 3 months of project completion. Researchers who do not submit reports to the IRB in a timely manner will not have access to IRB review of new applications until reports are complete.

K. Submission of a Report of Injury

If a participant sustains an injury or is harmed during the study, the researcher must take immediate action to assist the participant and notify the IRB chair of the injury within 24 hours.

L. 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.

N. 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.

O. Glossary

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 participants 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 participants 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.

Guardian: See legally authorized representative.

Human participant: 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 participant to the participant'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.

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.

Principle investigator: Also the principle 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).

Quorum: The number (as a majority) of voting officers or members of a body that when duly assembled is legally competent to transact business

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 participant's decision to participate (or to continue to participate) in a research activity that is made free of coercion, duress, or undue inducement

P. Frequently Asked Questions

- 1) When do I need to submit an IRB application?
 - An application should be submitted anytime you plan on conducting research with human participants. The definition of *research* set forth in the Code of Federal Regulations (CFR), at 45 CFR 46.102 (d) is “a systemic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If you are uncertain if the activities you are planning fall under the scope of this definition, please feel free to contact the chairperson of the IRB (Humansubjects@fitchburgstate.edu) for consultation.
- 2) How long will it take for the IRB to review my application?
 - This depends on the type of proposal an applicant submits. Proposals that fall under the *Exempt* and *Expedited* categories can typically be approved quickly, often times in no more than 2 weeks. Proposals requiring a *Full Review* are reviewed at the IRB’s monthly meeting. Depending on when an application is submitted, and the extent to which further information is required by the IRB, it may take 4 weeks or more for the IRB to review an application