Framingham State University

Institutional Review Board

This document describes the charge, scope, and policies of the Framingham State University Institutional Review Board (FSU IRB).

The FSU IRB reviews human subjects research in the following three categories*:

1) research that is federally funded,

2) research for which the sponsoring agency requires federal-level institutional review, and

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 does not apply to it. However, it is still expected that the FSU community member conducting the research does so in accordance with the highest ethical and moral standards and accepted practices within his/her discipline.

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I. Introduction: History of the Human Subjects Protection System[1]

The *Nuremberg Code*, developed for the Nuremberg Military Tribunal as standards by which to judge human experimentation by the Nazis, is the foundation for the principles that guide ethical behavior in the conduct of research involving human subjects. The first provision of the code, that "voluntary consent of the human subject is absolutely essential," is the cornerstone. Implied in this phrase are capacity to consent, freedom from coercion, and comprehension of risks and benefits involved. Further provisions of the code require minimization of risk and harm, a favorable risk/benefit ratio, qualified researchers using appropriate research designs, and freedom for the subject to withdraw from the research at any time.

These principles were reiterated by the World Medical Association in 1964 in its *Declaration of Helsinki*. This document further distinguished therapeutic from non-therapeutic research. In 1966, the National Institutes of Health in the U.S. raised concerns about protection of human subjects, and in 1974 the Department of Health, Education and Welfare instituted regulations protecting human subjects.

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted *The Belmont Report*. The report sets forth the basic principles underlying acceptable conduct for research involving human subjects. The three essential requirements for ethical conduct are: respect for persons (the need to obtain informed consent), beneficence (the need to engage in a risk/benefit analysis and to minimize risks), and justice (the need to select subjects fairly for inclusion in research studies).

The Federal Policy for the Protection of Human Subjects (or "Common Rule"), affecting the federal agencies[2] that conduct, support, or regulate human subjects research, was finalized in 1981. The Federal Drug Administration also adopted many of the provisions of that policy.

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[1] Source for this information: *Institutional Review Board Guidebook*, "Introduction"

[2] The agencies include: Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of Health and Human Services, National Science Foundation, Department of Transportation, and Central Intelligence Agency. The Food and Drug Administration operates under a somewhat different set of regulations, in part because it does not support or conduct research.

II. The Framingham State University Institutional Review Board [FSU IRB]

A. The FSU IRB is a Special Committee[3] charged with protecting the rights and welfare of human subjects participating in research conducted at FSU. The FSU IRB reviews research in the following three categories*:

1) research that is federally funded,

2) research for which the sponsoring agency requires federal-level institutional review, and

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 does not apply to it. However, it is still expected that the FSU community member conducting the research does so in accordance with the highest ethical and moral standards and accepted practices within his/her discipline.

The FSU IRB has the authority to approve, require modification of, or disapprove all research activities that fall within its jurisdiction as stipulated by federal regulations and this FSU IRB policy.

B. The FSU IRB has the ultimate responsibility to determine risk. Research covered by this policy that has been approved by the FSU IRB may be subject to further review by officials of Framingham State University. However, officials may not approve research that has been disapproved by the FSU IRB. The FSU IRB's decisions regarding risks to human subjects are final. See section VIII-D for the appeals process.

C. The FSU IRB shall review research involving human subjects as defined in Section II–A conducted at or sponsored by Framingham State University. This includes research conducted by University employees, emeriti faculty, auxiliary employees, students, and faculty/student collaborative research. "Research" is defined by the *Uniform Federal Policy for the Protection of Human Subjects*[4] as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." "Human subjects" as defined by the above mentioned policy document are "living individual(s) about whom an investigator (whether professional or student)

[3] Pursuant to the *Agreement between the Board of Higher Education and the Massachusetts Teachers Association/NEA Massachusetts State University Association*.
[4] U.S. Department of Health and Human Services, Office for Human Research Protections, *The Uniform Federal Policy for the Protection of Human Subjects*, § 46.102 (d).

conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

D. Composition of the FSU IRB is as follows:

1. Voting Members: Voting members are volunteers who are solicited and chosen by both the Vice President for Academic Affairs and the Framingham State University Professional Association President.

    a. The IRB will be composed of an odd number of members, but no fewer than 5, appointed from the categories below:
        i.) The University community who are tenured or tenure-track faculty or librarians.
            1. Of these members, at least one person must be qualified to assess the appropriateness of the scientific methodology with respect to projected risks and benefits of the research.
            2. Of these members, at least one member must have primary concerns that are not in the scientific arena.
            3. No more than one member of any department may serve on the FSU IRB at one time.

        ii.) A member of the community who is otherwise not affiliated with the University and who is not part of the immediate family of a person who is affiliated with the institution.

2. Non-voting Members: Non-voting members of the FSU IRB will consist of:

    a. An Administrator designated by the University, with responsibilities as defined in the Department of Health and Human Services' Institutional Review Board Guidebook, Chapter One.

    b. Temporary consulting experts as deemed necessary by the FSU IRB. The FSU IRB may call upon consultants to address questions such as risk to federally designated vulnerable research subject populations (e.g., fetuses, pregnant women, prisoners, and children).

3. Diversity: Composition of the FSU IRB will be sensitive to diversity of member backgrounds, including academic discipline, racial and cultural heritage, and understanding of issues such as community attitudes.

4. Term of Service: Voting members of the FSU IRB will serve for two years (24 months) with the option of two consecutive reappointments. The term of service shall commence on September 1 and shall expire

August 31 two (2) years thereafter. After a 1-year hiatus from the FSU IRB, previously appointed members may apply for another term.

As a Special Committee[1] that must be re-established with each new collective bargaining agreement (CBA), it is expected that, when a CBA expires, members in the midst of a 2-year term of service will be re-appointed to the committee for the duration of their term once the new CBA becomes effective.

5. Chair: The chair of the FSU IRB will be elected for a one year term commencing on September 1 and expiring on August 31. The chair will be elected by the voting members of the FSU IRB, and the FSU IRB will elect a Chair each year by May 31 for the upcoming academic year. The newly elected Chair will assume responsibility on September 1 of the new academic year.

6. Vacancies: If a member of the FSU IRB resigns or is unable to serve (due to sabbatical, leave of absence, etc.), the member will be replaced by the Provost/Vice-President for Academic Affairs and the Framingham State University Professional Association President. The replacement will be appointed for a new 2-year term.

   If a Chair of the FSU IRB is unable to fulfill his or her term, a replacement Chair will be elected by the voting members of the FSU IRB for a new term pursuant to II-D-5.

   Members of the FSU IRB who resign or are unable to serve can request a new 2-year appointment provided, pursuant to II-D-4, at least one year has passed since their last appointment.

7. A researcher may be a member of the FSU IRB. However, the researcher-as-member cannot participate in the review and approval process for any research project in which s/he has a present or potential conflict of interest. Under these circumstances, s/he may be present only to provide information requested by the FSU IRB. S/he shall be absent during the discussion and voting phases of the process. FSU IRB minutes shall reflect whether or not these requirements have been met.

8. Quorum. At any meeting of the FSU IRB, a majority of voting IRB members in office shall constitute a quorum, provided at least one member is present whose primary concern is in a non-scientific area.

9. Action by Vote. Each voting member of the FSU IRB shall have one vote. A majority of votes cast shall decide any question.

10. Action by Writing. Any action required to be taken at any meeting of the FSU IRB may be taken without a meeting if all the IRB members entitled to vote consent to the action in writing and the written consent is filed with the records of the meetings of the IRB.

11. Presence through electronic means. While FSU IRB members are expected to attend meetings in person, there may be an occasional circumstance which prevents attendance in person. In these cases, FSU IRB members may participate in a meeting of the IRB by means of conference telephone or similar communication equipment in which all persons participating in the meeting can hear one another at the same time. Participation by such means shall constitute presence in person at the meeting.

E. Members of the FSU IRB will receive training in the regulations, guidelines, and policies applicable to research using human subjects.

F. A list of names of FSU IRB members; their earned degrees; their representative capacity on the committee; their experience such as board certifications and licenses, etc.; and their employment or other relationship to the University shall be kept on file with FSU IRB records.

G. The FSU IRB will maintain a rotating panel of consultants for the purpose of providing information to researchers and/or departments. The panel will be composed of current and previous members of the FSU IRB, in addition to individuals approved by the FSU IRB. Any consultation will be purely informational in nature; it is not decisional.

III. Records, Documentation, and Adherence to Policy

A. *Responsibilities of Researchers*

1. Researchers are required to:
    a. make and keep written records of FSU IRB reviews and decisions on the use of human subjects;
    b. obtain and keep documentary evidence of informed consent of subjects or their legally authorized representative; and
    c. retain informed consent forms on file for a minimum of five (5) years after termination of the research project.

2. Researchers must maintain records of research data during the research process and retain research data for a minimum of five (5) years.

3. Researchers must periodically review research results to assure that
    a. unanticipated harm has not occurred and

b. the research protocol is producing adequate results such that benefits of the research continue to balance risks to subjects.
c. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefits, the researcher(s) must report immediately to the FSU IRB.

4. Researchers are responsible for submitting progress reports for ongoing projects. See Section X for further details.

5. Researchers are responsible for applying for an extension if it appears that their research will extend beyond the approval period. See section XI for modification of approved applications.

B. *Responsibilities of the Institutional Review Board*

1. The FSU IRB, through its administrative staff, shall prepare and maintain adequate documentation of FSU IRB activities, including:
    a. written procedures, policies and documents utilized by the FSU IRB;
    b. a list of FSU IRB members;
    c. copies of all research proposals reviewed; sample consent documents; progress reports submitted by researchers; reports of injuries to subjects;
    d. minutes of FSU IRB meetings which shall be in sufficient detail to show attendance at meetings; actions taken by the FSU IRB; votes on actions, including the number of members voting for, against, and abstaining; bases for requiring changes in disapproved research proposals; written summaries of discussions of controversial issues and their resolutions;
    e. records of continuing review activities;
    f. copies of all correspondence between the FSU IRB and the researchers;
    g. statements of significant new findings provided to subjects by researcher(s).

2. Records relating to research that is conducted, and records required by this policy, shall be kept for at least five (5) years after completion of the research.

3. Records of the FSU IRB pertaining to individual research activities shall be accessible only to the FSU IRB and the individual researcher, except for purposes of audit or inspection by the University or federal agencies to assure compliance.

4. By May 15 of each year, the FSU IRB will submit a report of its activities to the University President, Provost/Vice-President of

Academic Affairs, and the All University Committee. The annual year-end report will contain information on IRB policy, processes, summary of applications received and approved, and related activities.

C. *Responsibilities of Framingham State University*

1. It is the responsibility of Framingham State University, through the FSU IRB, to assure compliance with and provide documentation of compliance with the *Uniform Federal Policy for the Protection of Human Subjects*.
    a. Framingham State University must provide written Assurances that it will comply with requirements of the Policy and must certify that research has been reviewed and approved by the FSU IRB. [The FDA does not require such Assurances.]
    b. Approval procedures must be devised such that the University supports only well-designed and properly executed research as defined in Section II-A.

2. The *Assurance*
    a. The University shall have a set of principles and guidelines that govern the institution, its faculty, and its staff in the discharge of its responsibilities for protecting the rights and welfare of subjects taking part in research conducted at, or sponsored by, the institution, regardless of source of funding.
    b. *The Belmont Report*[5] shall serve as the source for ethical principles, codes, and declarations.
    c. Framingham State University will make this set of principles available to all faculty and staff.

3. The University shall have written procedures and guidelines to be followed by the FSU IRB
    a. when conducting its initial and continuing review of research and
    b. for reporting its findings and actions to the researcher and the University administration.

4. The University shall promptly report to the FSU IRB, appropriate administrative officials, and any supporting agency head of:
    a. any unanticipated problems involving risks to subjects;
    b. any serious or continuing noncompliance with the Federal Policy or requirements or determinations of the FSU IRB; and/or
    c. any suspension or termination of FSU IRB approval.

[5] Department of Health, Education, and Welfare, 1979, *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*

5. Framingham State University shall provide a specified official of the University with sufficient legal authority for the oversight of research and FSU IRB functions.

6. Framingham State University shall provide meeting space and staff to support the FSU IRB's review and record keeping responsibilities.

7. Framingham State University shall ensure FSU IRB members have open and ready access to the highest levels of authority within the University.

8. Framingham State University shall institute internal audit procedures to ensure that the FSU IRB is properly following the policies and procedures set forth in this document.

9. Framingham State University shall establish mechanisms through which any issues or instances of noncompliance with Policy are handled so that the credibility of researchers, the FSU IRB, and the institution are maintained.

IV. FSU IRB Regulations and Policies

A. All researchers conducting research as defined in Section II–A are required to submit a protocol describing the research or activity to the FSU IRB. The FSU IRB then reviews the protocol and renders a decision regarding approval. No such research may begin prior to the FSU IRB's decision. Preparation of applications and adherence to FSU IRB Policy are the responsibility of researchers.

B. *The Application*:
All researchers conducting research as defined in Section II–A must complete the FSU IRB *Application for the Conduct of Research Involving Human Subjects*. This application can be found on the FSU IRB website. The application contains details of information required. Researchers must be careful to complete the application in full. Only complete applications will be considered for review. The application calls for:

1. Project and contact information, including name of Principal Investigator and other researchers
2. Review Category Requested (Exempt, Expedited, or Full; see Section IV-H)
3. Project description, including
    a. Purpose and background
    b. Description of informed consent process
    c. Subjects

d. Methodology
e. Methods for ensuring privacy and confidentiality
f. Known and anticipated risks[6] to subjects
g. Anticipated benefits to society and/or subjects
h. Letters of agreement

4. Subject selection information
5. Signatures of researchers (which will indicate agreement to comply with all FSU IRB Policies if submitting a proposal)

C. *Cooperative research:*
Cooperative research projects are those that involve more than one institution. In the conduct of cooperative research, each institution is responsible for safeguarding the rights and welfare of subjects. Framingham State University may enter into a joint review agreement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

D. *Timely Submissions:*
Applications must be submitted to the FSU IRB in a timely manner such that the FSU IRB can render a decision in advance of deadline, receipt or submission date of a funding or granting agency. Initial FSU IRB responses cannot, under any circumstances, be expected in less than seven (7) business days from FSU IRB receipt of a completed application.

E. *Timely Reviews:*
Researchers are entitled to a timely review of applications. The FSU IRB will normally complete its initial review within seven (7) business days of the submission of a complete and properly formatted application. Should the FSU IRB determine that modifications need to be made to the application, the FSU IRB will respond within seven (7) business days of the revised application.

In the event that the workload of the FSU IRB precludes review of applications within seven (7) business days, Principal Investigators will be notified immediately. Upon request, the FSU IRB will prioritize proposals by urgency of start date of proposed research or submission deadlines of sponsoring agencies.

[6] Risks to individuals include: physical injury; deleterious effects on health; experience of undue stress; deprivation of desired relationships or opportunities for such relationships; derogatory labeling; hostile reactions by others; diminished access to roles; negative effects on social standing or mobility; reduced opportunities for communication; and lost or endangered membership in social groups. Risks to social groups include: derogatory labeling; hostile reactions; reduced access to resources; diminished ability to recruit and retain members; and negative effects on morale.

F. *Incentives for participation:*
In some cases, researchers may deem it appropriate and/or necessary to offer subjects a reward for participation in a research project. This may be a monetary payment or a reward in lieu of money. It is the responsibility of the FSU IRB to determine that subjects are recruited fairly, informed adequately, and rewarded appropriately. If the researcher intends to offer extra credit to a student subject, or such an offer is to be considered by the researcher, the researcher must include information on an equitable alternative to the student's participation in the research study in his/her submitted protocol, and this alternative must be approved by the FSU IRB as part of the proposed research protocol.

G. The FSU IRB is charged with the protection of human subjects from undue risk and/or deprivation of personal rights and dignity. This is achieved through consideration of three issues:

1. Voluntary subject participation. This is indicated by free and informed consent of the subject and the subject's right to withdraw from participation at any time without jeopardy.
2. Delineation by the researcher of the degree, nature and management of risk to the subject.
3. An appropriate balance between potential benefits of the research to society and/or the subject and the risks assumed by the subject.

H. Research Review Categories: Research applications to the FSU IRB can fall into one of three federally-defined review categories: Exempt, Expedited, and Full[7]. **Each review category requires a complete application;** however, each one differs in the extent of the review process (see Section VI-B).

1. *Exempt Review*: If the application conforms to criteria outlined below, the FSU IRB may confirm the review category as Exempt.

   Specifically, research activities in which the involvement of human subjects is limited to one or more of the following categories (and which are not otherwise required to be reviewed by the FSU 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

[7] See the *Uniform Federal Policy for the Protection of Human Subjects, Subpart A.*

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 subjects can be identified, directly or through identifiers linked to the subjects, and
   ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

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 item 2 of this section, if:
   i. the human subjects are elected or appointed public officials or candidates for public office, or
   ii. federal statue(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 subjects cannot be identified, directly or through identifiers linked to the subjects;

e. Research and demonstration projects which are conducted by or subject 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."[8]

2. *Expedited Review:* This applies to research that involves no more than minimal risk to subjects. 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."[9]

3. *Full Review:* Research in this category involves more than minimal risk to subjects and will receive a full review by the entire FSU IRB.

V. Documentation of Informed Consent

A. For a research project that might place an individual at risk, the researcher must obtain and document legally effective informed consent. Informed consent "assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate".[10] Subjects must be able to exercise choice without undue inducement and without element of force, fraud, deceit, duress, or other form of constraint or coercion.

B. Informed consent shall be documented by the use of a written consent form approved by the FSU IRB and signed by the subject or the subject's legally authorized representative. No researcher may involve a human subject in research covered by this policy unless s/he has obtained the legally effective informed consent of the subject or the subject's representative, or unless the requirement for a written informed consent document has been waived by the FSU IRB. (Please see Section V–G and H for exceptions.)

C. Types of Consent Forms: The consent form may be one of the following:

1. *A written consent document*.

[8] *Uniform Federal Policy for the Protection of Human Subjects,* § 46.101 (b).
[9] *Ibid,* § 46.102 (i).
[10] *IRB Guidebook, Chapter III*

This should include the elements of informed consent (see Sections V - D and E below) and may be read to the subject or the subject's legally authorized representative. The researcher must also give the subject or his/her representative adequate opportunity to read the document before it is signed. A copy of the signed form shall be given to the individual signing the form.

2. *Documentation of oral informed consent.*
This document must state that the elements of informed consent have been presented orally to the subject and his/her representative. The FSU IRB must approve a written summary of what is to be said. There must be a witness to the oral presentation. The witness must sign the document, and both the witness and the person obtaining consent must sign a copy of the summary. An electronic recording may be substituted for the written document. A copy of the oral informed consent document and a copy of the summary shall be given to the subject or his/her representative.

D. Basic *elements of the informed consent* include:

1. A statement that the study involves research; an explanation of the purposes of the research; the expected duration of the subject's participation; a description of procedures to be followed; and identification of any experimental procedures.
2. A description of foreseeable risks or discomforts to the subject.
3. A description of benefits to the subject and/or society that may reasonably be expected from the research.
4. A statement of the extent, if any, to which confidentiality of records will be maintained.
5. A statement that participation is voluntary and that refusal to participate or decision to withdraw from the study at any time will incur no penalty or loss of benefits to which the subject would otherwise be entitled.
6. Information about whom to contact for answers to questions about the research; whom to contact for answers to questions about subjects' rights; and whom to contact in the event of a research-related injury to the subject.

E. *Additional elements* of the informed consent may include (where relevant and appropriate):

1. An explanation as to whether compensation or medical treatments are available if injury occurs for research involving more than minimal risk.
2. Disclosure of appropriate alternative procedures or courses of treatment that may be advantageous to the subject.
3. A statement that there may be currently unforeseeable risks.

4. Identification of circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.
5. Identification of additional costs to the subject that may result from his/her participation.
6. A statement of the consequences of the subject's decision to withdraw and procedures for orderly termination of his/her participation.
7. A statement that new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
8. Identification of the approximate number of subjects involved in the research.

F. *Requirements of the Consent Form*:
The language used in the consent form must be understandable to the subject or the subject's representative. No informed consent, oral or written, may include any exculpatory language through which the subject or subject's representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the researcher, the sponsor, the University, or its agents from liability for negligence.

G. The FSU IRB may waive the requirement for the researcher to obtain a signed consent form in any of the following circumstances:

1. The only record linking the subject and the research would be the consent document, and the primary risk would be potential harm resulting from a breach of confidentiality.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
3. The research is conducted using oral history as collected per the American Historical Association and the Oral History Association policy statement developed with the Office for Human Research Protection.[11]

Where consent form documentation is waived, the FSU IRB may require the researcher to provide subjects with a written statement regarding the research.

H. The FSU IRB may approve a consent procedure which does not include, or which alters, some or all of the above elements, or waive the

[11] http://alpha.dickinson.edu/oha/org_irb.html *Oral History Excluded from IRB Review* & *An Update on the Exclusion of Oral History from IRB Review.* Donald A. Ritchie, Oral History Association. Linda Shopes, American Historical Association. (2004)

requirement to obtain informed consent provided that one of the following situations exists:

Situation One:

1. The FSU IRB finds and documents that the research is to be conducted by or subject to the approval of state or local government officials and is designed to study:
    a. public benefit of service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternatives to those programs or procedures; or
    d. possible changes in methods or levels of payment for benefit or services under those programs,

    AND
2. The research could not practically be carried out without waiver or alteration.

Situation Two:

The FSU IRB finds and documents that

a. the research involves no more than minimal risk to subjects;
b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. the research could not practically be carried out without waiver or alteration;
d. whenever appropriate, subjects will be provided with additional pertinent information after participation.
    i. 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.
    ii. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable federal, state, or local law.

VI. Review of Applications Submitted to the FSU IRB

A. The review performed by the FSU IRB will determine whether subjects will be placed at risk in the proposed research. "*Subject at risk* means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods which are

necessary to meet his/her needs or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."[12]

B. As stated in Section IV-H, research applications may be one of three types: Exempt Review, Expedited Review, or Full Review.

1. *Exempt Review* is that which meets specific federal guidelines as defined in Section IV-H.1. For the proposal to be adjudged exempt, the Chair and one other voting member of the FSU IRB must both agree that the proposal satisfies the criteria for exempt status. Failing this judgment, the application will undergo expedited or full review as outlined below.

2. *Expedited Review* applies to research that involves no more than minimal risk to subjects. (See Section IV-H.2 for a definition of minimal risk.)

    a. The expedited review process may be used by the FSU IRB to review an application when either or both of the following conditions exist:

        i. Some or all of the research on the list of eligible categories established by the Secretary of the U.S. Department of Health and Human Services and determined by the FSU IRB reviewer(s) involves no more than minimal risk;

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

    b. An expedited review may be carried out by the FSU IRB Chair and at least two reviewers designated by the FSU IRB Chair from among voting members of the FSU IRB. The proposal will be approved on an expedited basis if all three reviewers agree that criteria for expedited review and approval have been met.

    c. All members of the FSU IRB will be advised, in writing, by the Chair of the FSU IRB, of research proposals that have been approved under the exempt or expedited review procedure.

[12] Department of Health, Education and Welfare, *Protection of Human Subjects, Proposed Policy*, 1973, § 46.3.

d. The appropriate federal department or agency head may restrict, suspend, terminate, or choose not to authorize the use of expedited review procedures by Framingham State University or the FSU IRB.

3. *Full Review* applies to research that involves more than minimal risk to subjects. All research proposals not covered by the requirements for exempt review or expedited review will be submitted to the FSU IRB for incorporation into the agenda of the next scheduled FSU IRB meeting for discussion by the entire membership or quorum of the FSU IRB. A quorum of the voting membership (defined as one half of the members plus one) must be present for the FSU IRB to be convened. A quorum requires at least one member whose primary concern is in a nonscientific area.

VII. Criteria for FSU IRB Approval of Research

In order to approve research, the FSU IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized by a) using procedures consistent with sound research design and which do not unnecessarily place subjects at risk or b) using procedures already being performed on subjects for diagnostic or treatment purposes.

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

3. Selection of subjects is equitable. In making this assessment the FSU IRB should take into account the purposes of the research and the setting in which the research will be conducted.

4. Informed consent will be sought in accordance with the basic elements of informed consent (see Section V-D).

5. Informed consent will be appropriately documented.

6. The proposed protocol makes adequate provision for monitoring data collected to ensure the safety of subjects.

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

8. Additional safeguards are included to protect the rights and welfare of subjects vulnerable to coercion or undue influence (i.e., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons).

VIII. Procedures of the FSU IRB

A. *FSU IRB Review of Research*:

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

2. The FSU IRB shall require that information given to subjects is in accordance with § 46.116 of *The Uniform Federal Policy for the Protection of Human Subjects*. In accordance with § 46.109 of this same policy, the FSU IRB may require additional information that would meaningfully add to the protection of the rights and welfare of subjects.

3. The FSU IRB shall require documentation of informed consent or may waive the need for such documentation in accordance with § 46.117 of *The Uniform Federal Policy for the Protection of Human Subjects*.

4. The FSU IRB shall notify investigators in writing of its decisions with regard to the proposed research. If a proposed protocol is disapproved, the FSU IRB shall include in its written notification a detailed statement of the reasons for its decision and provide the researcher with an opportunity to respond in person or in writing. See Section VIII-D for the appeals process.

5. The FSU IRB, at the time of initial approval of the protocol, will determine whether an independent Data and Safety Monitoring Board may be required.

6. In accordance with § 46.109 of *The Uniform Federal Policy for the Protection of Human Subjects*, the FSU IRB shall conduct continuing

review of research covered by this policy at intervals appropriate to the degree of risk. Also per the federal guidelines, such reviews shall occur not less than once per year. Ongoing reviews are necessary to determine:

a. whether the risk/benefit ratio has shifted; and/or
b. whether there are unanticipated findings involving risks to subjects; and/or
c. whether any new information regarding the risks and benefits should be provided to subjects.

See Section X for further information.

7. The FSU IRB shall have authority to observe, or have a third party observe, the consent process and the research.

B. *FSU IRB Actions*:

Within the above described process, the FSU IRB, after review and discussion of the protocol and application, may take one of four actions. The actions that may be taken are: approve the research; disapprove the research; require modification of the research; or suspend or terminate the research.

1. *Approval of research*:
   Please see Section VII for information on applicable criteria.

2. *Disapproval of research*:
   The decision to disapprove the research will be rendered when the FSU IRB determines that the potential benefits of the research do not outweigh the risks to the subjects. See Section VIII-D for rights of appeal.

3. *Modification of the research*:
   The FSU IRB may determine that modifications, major or minor, must be made to the research protocol.

   a. *Major modifications*: This requirement occurs when the FSU IRB does not have sufficient information to take action, or when it believes the research design contains significant risks and should be revised to minimize those risks to subjects. The researcher may be asked to revise his/her application in accordance with IRB recommendations.

   b. *Minor modifications*: This requirement may include: revising the consent form to explain procedures more clearly; adding a

version of a consent form in a language other than English; restrictions on the use of certain procedures or subject groups; or requiring the use of specific safeguards, etc. that are necessary for the protection of subjects. The researcher may be asked to revise his/her application in accordance with IRB recommendations.

c. Modified research protocols must be resubmitted for approval. The FSU IRB may choose to expedite review for resubmissions involving minor modifications. Failure to provide modified research applications within 90 days of receipt of FSU IRB response will render the application inactive.

4. *Suspension or Termination of Approval of Research*:

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

C. *Reporting of Recommendations*

Approvals, disapprovals, recommendations, restrictions, or conditions will be communicated, in writing, to the researcher by the FSU IRB. Approvals will be accompanied by the expiration date of the approval.

D. *Rights of Appeal*

1. If an applicant believes a proposal has been disapproved because of incorrect, unfair, or improper evaluation by the FSU IRB, s/he may notify the University President or designee, who may direct a reconsideration of the proposal by the FSU IRB. The researcher may provide expanded information and explanation to the FSU IRB and may, at any time in the appeals process, modify objectionable items to conform to FSU IRB policy.

2. Any reconsideration shall take place and a decision reached within seven (7) business days of the FSU IRB after the appeal has been filed. The researcher and the University President or designee shall be notified of the results of the reconsideration as soon as the decision has been made.

3. If a satisfactory resolution has not been reached as a result of the reconsideration, the following appeals process shall be used:

    a. Within seven (7) business days of the FSU IRB decision, the affected researcher(s) must show cause, to the University President or designee, in writing, as to why the FSU IRB should reverse its decision.

    b. An appeals committee of three (or more) tenured faculty will be appointed by the University President or designee and the FSUPA President, to conduct a special appeals review. A member of the FSU IRB may serve on this committee as a non-voting consultant to provide technical knowledge or other appropriate knowledge. At the request of the researcher, an outside reviewer may be added to the committee. (The outside reviewer will usually be a member of an IRB of another institution.)

    c. The appeals committee shall:
        i. review the initial proposal and reconsider materials submitted by the researcher;
        ii. review the relevant minutes of the FSU IRB;
        iii. review FSU IRB members' confidential evaluation forms; and
        iv. request any expertise necessary for their deliberations.

    d. The researcher may request an appearance before the FSU IRB and the special committee.

    e. The special committee may take one of two actions:
        i. affirm the original decision of the FSU IRB denying approval of the proposed research, or
        ii. return the proposal to the FSU IRB, with specific recommendations, for further reconsideration.

    f. The FSU IRB, having received the information from the special committee, will carefully consider the committee's report. It shall then make a final decision. This decision will be sent, in writing, to the researcher(s), special committee, and President or University designee, with a point-by-point response to the special committee's recommendations.

IX. Duration of Approval

The FSU IRB will determine the term of approval and will notify the researcher of the date of expiration of approval when approval is granted. Notice of expiration of approval will be sent to the Principal Investigator by the designated institutional administrator approximately six weeks before the expiration date of any currently approved protocol.

X. Progress Reports

A. Review of Annual Progress Reports

1. In accordance with § 46.109 of *The Uniform Federal Policy for the Protection of Human Subjects*, the FSU IRB shall conduct continuing review of approved research at least once per year. Therefore, any researcher engaged in an ongoing, approved research project must submit a progress report at least once a year from the approved project start date.

2. Progress reports should be submitted before the date of FSU IRB approval expiration, bearing in mind the time needed for review and that research activity must cease at expiration date if the progress report has not been approved.

B. Progress Report Requirements

1. A copy of the current consent form.
2. A copy of the previously approved protocol.
3. A report which provides a brief discussion of the work accomplished to date, including in particular:
    a. the number of subjects studied (and the number approached who refused to participate);
    b. a discussion of the experience of the subjects undergoing study, with particular reference to any adverse events that occurred to them during the conduct of the study. If no adverse events occurred, this should be specifically stated.
    c. a brief description of the scientific or research results, if any, to date.

C. Progress reports must not be photocopies of papers (either published or submitted for publication). The FSU IRB should be informed, in as concise a manner as possible, of the results as they influence the balance of benefit to risk to human subjects. Published papers (or those submitted for publication) may be appended as evidence of benefits of the research.

XI. Modifications of Approved Applications

A. Any *modification* of an approved application requires submission of a modification application. Modifications include:

1. inclusion of human subjects where none existed in the original application;
2. a significant change in research methods or techniques;
3. evidence of new hazards;
4. any change that alters the risk/benefit balance;
5. any modification in informed consent.
6. a change to the Principal Investigator (PI).
7. extension of project duration.

B. Modification Application Requirements

1. A copy of the current and/or new consent form.
2. A copy of the previously approved protocol.
3. A description of any modifications to the current or previous protocol which are desired.
    a. The description and justification should be outlined for a new application:
        i. Background or reason for modification
        ii. Benefits
        iii. Risks
    b. If positions of responsibility are to be changed (such as change of the Principal Investigator), a description of the background of the individuals with regard to the work described in the protocol should be given.

XII. Unanticipated Problems

Any unanticipated problems, including unexpected serious harm to subjects or others, must be reported immediately to the FSU IRB and any agency sponsoring the research. Reports should include:

1. Identification of individual(s) involved.
2. Identification of Principal Investigator (PI), title of research project, and project number.
3. A description of the unanticipated problem(s).
4. Any additional relevant information.

XIII. Violations of these Policies and Procedures

A. Violations of these policies and procedures should be reported to the FSU IRB immediately upon occurrence.

B. The FSU IRB will review allegations of violations and/or noncompliance and will follow the policies and procedures set forth within designated University procedures, as appropriate. A finding of violation of policies and procedures could result in a suspension of research. (Please see Section VIII–B.4.)

C. Federally-funded research found by the FSU IRB to be in violation of federally-mandated portions of this Policy, or of appropriate federal regulations regarding the protection of human subjects, will be reported to the University President or his/her designee. The President or his/her designee will report said violations to the appropriate agency on behalf of the researcher, should the researcher fail to report.

D. Violations will be handled in accordance with established University disciplinary procedures, as appropriate.

XIV. Amendments

A. When necessary, this Policy will be amended by a two-thirds vote of the membership of the FSU IRB, subject to approval by appropriate governance committees.

B. The final authority for amending these polices and procedures rest with the University President.

XV. Referral to Federal Guidelines

The FSU IRB will refer to the *Uniform Federal Policy for the Protection of Human Subjects* when further clarification is required.

XVI. Definitions[13]

A. *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

[13] Definitions used in this section and throughout this Policy by the FSC IRB will match either the *Uniform Federal Policy for the Protection of Human Subjects,* the *Institutional Review Board Guidebook* of the Department of Health and Human Services, or the *Protection of Human Subjects, Proposed Policy* of the Department of Health, Education and Welfare.

be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

B. *Data and Safety Monitoring Board*

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

C. (The) *Federal Policy*

The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. This is also known as the "Common Rule".

D. *Full Board Review*

Review of proposed research at a convened meeting at which a majority of the membership of the FSU IRB are present, including at least one member whose primary concerns are in nonscientific areas. For research to be approved, it must receive the approval of a majority of the members present at the meeting.

E. *Human Subjects*

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

F. *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. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

G. *Institutional Review Board*

A specifically constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

H. *Legally Authorized Representative*

A person authorized either by statute or by court appointment to make decisions on behalf of another person.

I. *Minimal Risk*

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 examination or tests. The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults.

J. *Office for the Protection from Research Risks (OPRR)*

The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations.

K. *Physical Risk*

Any potential for physical injury or deleterious effects to a human subject's health, either short term or long term.

L. *Principal Investigator*

The scientist or scholar with primary responsibility for the design and conduct of a research project.

M. *Protocol*

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an FSU IRB for review and to an agency for research support.

N. *Psychological Risk*

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

O. *Research*

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

P. *Social Risk to Groups*

The extent to which a formal or informal subject group, as a collective, is exposed to loss with respect to factors affecting the viability and vitality of the group as a function of participation in research.

Q. *Social Risk to Individuals*

The extent to which an individual subject is exposed to social and interpersonal deprivations as a function of participation in research.