

Framingham State University Institutional Review Board (IRB)

Applications Instructions (including information and deadlines for application submissions)

Information:

1. Research meeting the criteria as identified in the FSU-IRB document (<http://framingham.edu/academic-affairs/institutional-review-board/index.html>) involving human subjects conducted at Framingham State University by students, faculty, or staff must be approved by the FSU IRB. Applications must be submitted, and approval obtained, before research is undertaken. (IRB approval will not be granted retroactively.)
2. An electronic copy of the application and a hard copy of the application should be submitted to Mr. Jonathan Lee, Office of Academic Affairs. Applications will be considered complete only when the following are submitted:
 - a. Application form;
 - b. Complete supporting documentation, including an advertising flyer, if applicable, and an informed consent form;
 - c. Signature of Principal Investigator (PI) and, in the case of student or other-sponsored research, signature of the supervisor as well.
3. Applicants will be notified of the IRB's decision within 15-30 working days of a submission of application deadline. In the case of student research associated with course work, decisions will be rendered within 15 working days of a submission of application deadline. (See page 4 for deadline information.)
4. **Levels of review:**
 - a. *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:

- 1) "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - a) research on regular and special education instructional strategies, or
 - b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;
- 2) Research involving the use of educational tests (cognitive,

- diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
- a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
 - b) 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;
- 3) 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:
- a) the human subjects are elected or appointed public officials or candidates for public office, or
 - b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;
- 4) 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;
- 5) 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:
- a) Public benefit or service programs,
 - b) Procedures for obtaining benefits or services under those programs,
 - c) Possible changes in or alternatives to those programs or procedures, or
 - d) Possible changes in methods or levels of payment for benefits or services under those programs;
- 6) Taste and food quality evaluation and consumer acceptance studies,
- a) If wholesome foods without additives are consumed or
 - b) 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.”¹

b. *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.”²

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

5. **Informed consent** must be obtained from all human subject participants.

Each subject must:

- a. sign a consent form (see sample below) explicitly indicating that s/he has been informed about the nature of the research and agreeing to participate in the research or
- b. be read a disclosure statement. A disclosure statement may be used only when subjects will remain totally anonymous and there are no risks to the subjects. This statement is not sufficient if subjects’ responses are to be tape recorded. The disclosure statement should contain the same information as that found in an informed consent form. The statement may be read or given to the subject, but does not require the subject’s signature.

When a consent form is used, a copy of the signed form must be offered to the subject to keep for his/her records. The PI must maintain the original copy of the signed form in locked storage for three years after completion of the research project.

Consent for a subject under 18 years of age, or a subject not competent to give informed consent, must be obtained from parent(s) or legal guardian(s).

6. **Extensions or renewal of approval:**

- a. According to Federal guidelines, approval for a research project can be or a maximum of one year. If a research project extends beyond one year, the researcher must apply for an extension of the approval.
- b. If the research will not be completed by the project end date specified in the original application to the FSU IRB, the researcher must apply for an extension of approval.

7. **Modifications of previously approved protocol:**

- a. Any modifications to previously approved protocol need to be reviewed by the FSU IRB to ensure that modifications continue to meet the requirements of the originally approved proposal. The researcher must apply for approval of said modifications.

¹ *Uniform Federal Policy for the Protection of Human Subjects*, § 46.101 (b).

² *Ibid*, § 46.102 (i).

- b. Students conducting research that involves a two-stage approval process must submit an original application in Stage One that describes the proposed research, and a second application, using the Modification form, in Stage Two that includes any additional information not available at the time of the Stage One application.
8. Questions about the IRB process should be directed to the Chair of the FSU IRB. Contact information can be found at the IRB website at (<http://framingham.edu/academic-affairs/institutional-review-board/index.html>).

Application Instructions:

Please read the following instructions before completing the FSU IRB *Application for the Conduct of Research Involving Human Subjects* or the FSU IRB *Request for Extension of Approval Or Modification of Previously Approved Protocol* forms. (These can be found at <http://framingham.edu/academic-affairs/institutional-review-board/index.html>.)

1. Applications forms can be found online at <http://framingham.edu/academic-affairs/institutional-review-board/index.html>.
2. Complete the application appropriate for your request. Submit an electronic copy and a hard copy of the application to Mr. Jonathan Lee, Office of Academic Affairs.
3. Be sure to include all required information and supporting documentation. Only complete applications will be reviewed.
4. Applications will be reviewed by the FSU IRB Administrator and Chair of the IRB. A decision of approval, disapproval, or request for additional information will be made by the FSU IRB within 15-30 working days (or within 15 working days for class-related student research) after the submission deadline date. The Principal Investigator (and faculty sponsor, where relevant) will be notified via email of the IRB's decision.
5. All applications must be received by the third Friday of the month.
6. *No research may begin prior to IRB approval.*

Sample Consent Form

Title of Study

I, _____, agree to participate in the *(title of study)* conducted by *(name of researchers or Principal Investigator and institutional affiliation)*. I understand that the purpose of this research is to study *(purpose of study)*,

As part of my participation in this research, I understand that *(what the subject will be asked to do during the research. Include information on any procedures which are experimental). (If the research involves access to information about subjects other than through direct questioning or observation, include a sentence about the additional access.)* My time commitment is approximately *(amount of time)*. *(If relevant, include: I will need to keep researchers informed of any changes in name, address, or telephone number.)* I understand that I am at risk for *(list of risks, if any. If there are no foreseeable risks, eliminate the sentence.)* I understand that this research may provide *(identify possible benefits to the subject and/or others. Indicate if the subject is not likely to receive any direct benefit from his/her participation.) (If relevant, include a sentence about compensation.)*

I understand that my participation in this research is completely voluntary and that I may withdraw at any time without penalty. *(If relevant, include a sentence describing circumstances under which the subject's participation may be terminated.)* I understand that I may decline to participate in any activity or decline to answer any questions that cause me discomfort.

I understand that my name or identity will not be used in reports or presentations of findings of this research. Information I provide to researchers will be kept confidential, with the exception of the following, which must be reported under Massachusetts law: suspected cases of child or elder abuse and information that individuals intend to harm themselves or others. *(The last part of this sentence, beginning with "with the exception...", may not be relevant to the particular research and may be excluded.)*

I have read and understand this information and agree to participate in this study. I will be offered a copy of this document to keep.

Participant's signature

Date

Investigator's signature

Date

If you have questions or concerns about this research, please contact *(Name of Principal Investigator and telephone number)*. If you have concerns about your treatment as a research participant, please contact the Institutional Review Board at Framingham State University, c/o Mr. Jonathan Lee, Office of Academic Affairs, 508-626-4697.