



### **Instructions for Submitting an IRB Application:**

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.

#### **Submission of a New Application**

*To submit a new application, follow the steps below. Please note that Part Three of the application should be prepared in a separate document. **It is advisable that applicants review and complete Part Three prior to filling out the online application.***

1. *Navigate your browser to the FSU IRB webpage: <https://www.framingham.edu/about-fsu/grants-and-sponsored-programs/institutional-review-board/index>*
2. *Click on the button for “IRB Application Form”.*
3. *Complete Part One by providing the required project information.*
4. *Complete Part Two by indicating whether any of the study subjects will be members of vulnerable populations and by providing the anticipated number of subjects.*
  - a. *A “Yes” response indicates that such individuals are expected to be study subjects. Please note that special care must be afforded in the project methodology to protect the well-being of these subjects.*
  - b. *A “No” response indicates that such individuals will not be study subjects.*
  - c. *A response of, “Not a target population” indicates that it is possible that such subjects may be included in the study but that the study will not collect information about their group membership.*
5. *Complete Part Three by preparing a project description in a separate document. Please use the same headings and alphanumeric outline structure as provided in the Part Three instructions. Submit an electronic copy or a hard copy of Part Three to Patricia Bossange, Office of Grants & Sponsored Programs. **For ease and speed of review, electronic copies are preferred.***
  - a. *Be sure to include all required information and supporting documentation, such as informed consent or assent form(s), any research instruments (e.g. surveys, interview scripts, tasks/assignments to be completed by subjects, etc.) and/or any recruitment materials (e.g. flyers, email notices, etc.). Incomplete applications will delay approval.*
6. *Complete Part Four by typing the name of the Principal Investigator (PI), which will serve as the PI’s electronic signature. For student research involving a faculty sponsor, the sponsor’s name should also be entered.*

7. Click “Submit” to send Parts One, Two, and Four to the IRB. Be sure to submit Part Three by email or hard copy to Patricia Bossange, Office of Grants & Sponsored Programs. **For ease and speed of review, electronic copies are preferred.**

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. Please note that 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. 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 receipt 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. **Please note that research seeking IRB approval may not begin until approval is granted.**

#### Request for Extension of Previously Approved Research

To request an extension for research previously approved by the FSU IRB, follow the steps below.

1. Navigate your browser to the FSU IRB webpage: <https://www.framingham.edu/about-fsu/grants-and-sponsored-programs/institutional-review-board/index>
2. Click on the button for “Request for Extension/Modification”.
3. Check the button to indicate you are requesting an “Extension of approval”.
4. Provide the IRB number assigned to the project (e.g. “FSU-###”), the approval date (i.e. the data appearing on the IRB approval letter), and the study title, as it appeared on the original application.
5. Provide the name and contact information for the Principal Investigator (PI).
6. Click “Submit”.
7. In an email addressed to [pbossange@framingham.edu](mailto:pbossange@framingham.edu), please describe the reason(s) for extension of the research project and provide a revised anticipated end date for the research. Be sure to include:
  - a. a copy of the current or new consent form,
  - b. a copy of the previously approved protocol,
  - c. [a status report on the approved research.](#)

## Request for Modification of Previously Approved Research

*To request a modification to research previously approved by the FSU IRB, follow the steps below.*

1. *Navigate your browser to the FSU IRB webpage: <https://www.framingham.edu/about-fsu/grants-and-sponsored-programs/institutional-review-board/index>*
2. *Click on the button for “Request for Extension/Modification”.*
3. *Check the button to indicate you are requesting a “Modification”.*
4. *Provide the IRB number assigned to the project (e.g. “FSU-###”), the approval date (i.e. the data appearing on the IRB approval letter), and the study title, as it appeared on the original application.*
5. *Provide the name and contact information for the Principal Investigator (PI).*
6. *Click “Submit”*
7. *In an email addressed to [pbossange@framingham.edu](mailto:pbossange@framingham.edu), please describe each of the planned changes to the original protocol, and provide a justification for each. [The FSU IRB must review modifications to the previously approved protocol to ensure that the modified protocol continues to meet IRB requirements.] Be sure to include:*
  - a. *a copy of the current or new consent form,*
  - b. *a copy of the previously approved protocol.*