

**Framingham State University Institutional Review Board  
Forms Checklist**

The following forms are provided on the FSU IRB Web site.

The main document, "Policy Regarding Use of Subjects in Research," on the Web site offers information on the charge, scope and policies of the FSU IRB.

**1. Application for the Conduct of Research Involving Human Subjects**

- a. Project information \_\_\_\_\_
- b. Subject selection \_\_\_\_\_
- c. Project description \_\_\_\_\_
  - i. Summary of the project \_\_\_\_\_
  - ii. The protocol \_\_\_\_\_
    - 1. Purpose and background \_\_\_\_\_
    - 2. Description of the informed consent process \_\_\_\_\_
    - 3. Subjects \_\_\_\_\_
    - 4. Methodology \_\_\_\_\_
    - 5. Description of methods for insuring privacy and confidentiality \_\_\_\_\_
    - 6. Description of all known and anticipated risks to subjects \_\_\_\_\_
    - 7. Description of anticipated benefits to subjects and/or society \_\_\_\_\_
    - 8. Letters of agreement \_\_\_\_\_
- d. Signatures \_\_\_\_\_

**If needed:**

**2. Request for Extension of Approval**

- a. Reason(s) for extension of the research project \_\_\_\_\_
- b. Revised anticipated end date for the research \_\_\_\_\_
- c. Copy of the current or new consent form \_\_\_\_\_
- d. Copy of the previously approved protocol \_\_\_\_\_
- e. Status report of the approved research \_\_\_\_\_

### **3. Modification of Previously Approved Protocol**

- a. Description of each of the planned changes to the original protocol and justification for each \_\_\_\_\_
- b. Copy of the current or new consent form \_\_\_\_\_
- c. Copy of the previously approved protocol \_\_\_\_\_
- d. Description of desired modifications \_\_\_\_\_

### **4. Stage Two Request**

- a. Description of any elements of the original application that were not able to be specified at the time of the original IRB approval request \_\_\_\_\_
- b. Any documents missing at the time of the Stage One request for approval \_\_\_\_\_
- c. Copy of the current or new consent form \_\_\_\_\_
- d. Copy of the previously approved protocol \_\_\_\_\_
- e. Description of the elements of the research design for which Stage Two approval is being requested \_\_\_\_\_