# Florida State University Policy 7-IRB-7

Title of Policy: Procedures for reviewing expedited, exempt, and full committee applications

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

## I. INTRODUCTION

This policy requires all research proposals involving human subjects be reviewed by the IRB prior to the start of the research project. This policy applies to all research conducted, regardless of funding. The policy outlines the procedure regarding how the applications are processed, reviewed and maintained.

## II. POLICY

1. Florida State University requires that all research proposals involving human subjects be reviewed by the University's Human Subjects Committee (IRB), prior to any interaction with the research subjects. This requirement applies to all research conducted by faculty, staff or students, regardless of funding. Researchers are advised of this requirement through the University's webpage, by grants administrators in the Office of Research, training in the CREATE program, and the Office of Graduate Studies.

2. The University IRB operates within the ethical principles set forth in the Belmont Report and the U.S. Code of Federal Regulations, Title 45 Part 46 "Protection of Human Subjects".

3. Investigators are required to complete an Application for Review, to answer a series of questions about their research and to submit copies of all forms or other documentation to be used in the proposed research. These materials are initially submitted to the Secretary of the Human Subjects Committee (IRB) for a review of facial compliance.

4. Applications are received by the Office staff of the IRB via the online system (HSRS). The Secretary of the IRB completes a facial compliance review and a determination as to eligible categories of review (full, exempt, or expedited). After review by the Secretary, the applications are provided to the student assistant for creation of an actual project file.

5. The project files are uniformly maintained for inspection, retention as required by federal regulation, and eventual archiving pursuant to University process. Projects requiring full Committee review are added by the Secretary to the agenda for the next monthly IRB meeting. Projects that fall into the exempt or expedited categories, as described by 45 CFR 46 are handled as follows:

    a) For proposals eligible for exempt or expedited review, the applications are provided by the student to the Program Associate (PA) serving the IRB, and who facilitates the review process. The PA promptly selects one committee member based on background and experience and assigns a project for review and comment. The application proposal is sent to the reviewer via the HSRS system. The review notes, modification requests, or recommended approval from the reviewer are maintained in the project file. Upon receipt of such communication from the reviewer, the PA sends the file to the Chair for final review and approval.

    b) The Chair reviews the application, and any changes or modifications requested by the reviewer to ensure the changes have been made. If the Chair determines the project is ready for approval, the Chair completes the chair review form. The PA generates the approval letter. Such correspondence shall be maintained in the project file. The IRB approval as indicated in the generated form letter is effective for exactly one year (365 days) minus one day from the approval date. (The approval letter is provided to the student assistant to be place in the file and transmitted to the researcher, the department chair, and if the researcher is a student, a copy of such will be sent to the faculty advisor.) The approved consent form is attached to the approval letter. The following information is added as a footer or stamped at the bottom of the consent forms: the date of approval; the application number; and the expiration (void) date, which is calculated to be one year minus one day from the approval date of the consent form and approval letter. Example: Project approved and approval letter dated June 1, 2003. Project and consent form approval begin on June 1, 2003 and remain in effect until May 31, 2004, the expiration date.

6. For projects reviewed by the full Committee, researchers may be required to attend the Committee meeting and answer any questions posed by the Committee members. A record of the discussion and revisions requested, if any, are noted in the minutes of the meeting, and may be excerpted and sent to the researcher as needed. If no revisions are needed the Secretary issues an approval notice letter to the researcher within a reasonable time

thereafter. If revisions are required, the researcher is expected to provide same in a timely manner to the Secretary, who then forwards the revisions to the Chair for final review and approval. Date of approval for full committee projects is the date approved at the meeting. Consent form approval date is the same as the date of project approval, and the expiration date is one year (365 days) minus one day from the approval date. Example: Project approved at June 1, 2003 full committee meeting. Approval date on notice is June 1, 2003, and consent approval is June 1, 2003, and both will expire on May 31, 2004.

7. Note that approval notices contain information regarding the researcher's obligation to obtain Committee approval prior to implementing any changes to the project's previously approved procedures, to keep the Committee advised of any problems or injuries to subjects and of the need for renewal of the project if the research is not completed within one year.

The IRB office notifies the researchers of the need to renew their project approval prior to the approval's expiration date. Renewal requests receive an "R" after the human subject's application number on the project file. Projects are reviewed for renewal in the same manner as their original review, i.e. expedited projects are reviewed by the Chair and one Committee members, projects approved by full Committee are renewed by the full Committee. This process is called "Continuing Review" under the federal regulations. Researchers who do not respond to the renewal reminder are sent a notification that approval has been terminated and that no further research is authorized by the Committee. The Office of Research provides administrative support for the IRB (Human Subjects Committee). All applications are filed with the Secretary of the Committee and files are maintained within the Office of Research. The Chair conducts an annual review and this information is reported to the Vice President for Research.

## III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103