

Florida State University Policy 7-IRB-13

Title of Policy: IRB Continuing Review (Renewals)

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

I. INTRODUCTION

This policy outlines the renewal process for continuing research. Continuing review of research activities is necessary to determine whether the risk/benefit ratio has changed and should be reviewed at least annually. The policy also describes what information must be submitted for the IRB to review renewals.

II. POLICY

1. Continuing review of research activities is required to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. All research protocols, including those which have been determined to be exempt in status, must be periodically reviewed at least annually, unless the following has occurred:
 - a) A research protocol for which no new subjects will be enrolled (closed) shall be subject to continuing review until such time that the initial analysis of the data has concluded that no new information needs to be provided to enrolled subjects, and there is no further need to re-contact enrolled subjects to obtain additional research information.
2. Based on the continuing review, the IRB may require that the research be restricted, modified, or terminated.
3. Review by the full IRB Committee at a regularly scheduled meeting, is required unless the research is otherwise appropriate for expedited or exempt review.

- a) The full IRB Committee must conduct a continuing review of a protocol using full committee review procedures if the protocol was initially reviewed by the full committee, unless the protocol has been modified such that it can be reclassified as eligible for expedited review. Note that research activities that have previously been determined to be exempt or expedited, may change so that a full review may now be required for continuing review.
 - b) When conducting continuing review by full IRB Committee, the IRB may use a primary reviewer system for continuing review. However, the full IRB Committee must be informed of the reviewers' findings at the convened meeting. Primary reviewers shall receive a copy of the complete protocol including any modifications previously approved by the IRB Committee, any reported adverse events, and any monitoring or audit reports conducted since the last review. The full IRB Committee must discuss the protocol and make a determination with recorded vote.
 - c) A protocol that originally received an expedited or exempt review, may receive its continuing review on an expedited basis as well. Thus, the IRB Chairperson and designated IRB Committee members conduct the continuing review on behalf of the full IRB Committee.
- 4. Continuing review of protocols is required to be substantive and meaningful. The criteria for continuing review is the same as those for initial review. The IRB Committee (or the reviewers for protocols under an expedited procedure) must determine:
 - a) that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
 - b) that the selection of subjects continues to be equitable;
 - c) that the informed consent continues to be appropriately obtained and documented;
 - d) that there are adequate provisions for monitoring the data collected to ensure the safety of the subjects, adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and appropriate safeguards for vulnerable populations.
- 5. The full IRB Committee should receive and review:
 - a) the continuing review application (Request for Renewal);
 - b) a protocol summary and status report on the progress of the research which should include:
 - the number of subjects accrued, and the total number of subjects withdrawn from the study since the previous

- review,
 - a summary of any unanticipated problems involving risks to subjects or adverse events that were serious or unanticipated, and resulted in a change to the risk/benefit ratio since the previous review, even if the event occurred at a location for which the FSU IRB is not the IRB of record
 - an explanation of any subject's withdrawal from the research or any complaints about the research since the previous review,
 - a summary of any recent literature, findings obtained thus far, amendments or modifications to the research, reports on multi-center trials and any other relevant information, especially information about risks associated with the research since the previous review
- c) a copy of the current approved informed consent document as well as an unstamped copy of the informed consent document eligible to be stamped with continuing approval.
6. In addition, primary reviewers should receive a copy of the current, approved IRB application that should include any prior modifications previously approved by the IRB Committee and supporting documentation such as an investigator's brochure, sponsor's protocol, or grant application. Reviewers should also receive copies of any monitoring or audit reports conducted since the last review.
 7. The currently approved consent document should be reviewed to ensure that the information is still accurate and complete. Any significant findings that may relate to a subject's willingness to continue participation should be provided to the subject in an updated consent document.
 8. Amendments and addenda to a research protocol may be submitted at the time of continuing review. The amendment may not be implemented by the investigator until review and approval by the IRB Committee.
 9. Continuing IRB review is required as long as individually identifiable follow-up data are collected on subjects enrolled in HHS-supported Cooperative Protocol Research Program (CPRP) protocols.
 10. The IRB Committee must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. The interval is set for each protocol. The phrase "not less than once per year" means that the research must be reviewed within one year of the date of the IRB meeting at which the research was approved (with or without revisions) even though the research activities may not begin until after the IRB Committee has given approval.

- a) Factors to be considered by the IRB in determining the appropriate interval for review include the following:
 - involvement of vulnerable populations,
 - research conducted internationally,
 - the involvement of recombinant DNA or other types of gene transfer protocols,
 - the use of waiver of informed consent procedures,
 - research for which subjects would be exposed to additional risks, such as breach of confidentiality, number or severity of Serious Adverse Events (SAE),
 - previous suspension of the research due to compliance, record-keeping, or other concerns,
 - recommendations from other institutional committees.
 - b) The intervals for review shall be assigned a surveillance level described as:
 - Yearly - require review at annual intervals,
 - Six Months – requires every six months intervals
 - Other – requires more frequent review interval whenever risks are greater than minimal.
11. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Any requests for extensions beyond the expiration date will not be granted.
12. If the continuing review does not occur within the required period the project will be administratively terminated. No further subjects may be enrolled until continuing review has occurred and the administrative termination is lifted.

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

BOG 1.001(3)(m), 45 CFR 46.103,109