

Florida State University Policy 7-IRB-6

Title of Policy: Full Committee Review

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

I. INTRODUCTION

This policy states the authority the IRB has to make decisions regarding the research activities that fall within its jurisdiction. The policy also outlines the requirements for when a full committee review is necessary. The policy describes how full committee reviews should be decided and when conditional approvals are allowable during a full committee review.

II. POLICY

1. The IRB has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction.
2. The full committee review category is used for research that does not qualify for expedited or exempt review, and at FSU is reserved generally for protocols involving vulnerable subjects, such as children, prisoners, decisionally impaired persons, and pregnant women, fetuses, and neonates. The full committee review of protocols may occur only at convened meetings of the IRB Committee at which a quorum is present.
3. The full committee review category is used for research that does not qualify for expedited or exempt review. The full committee review of protocols may occur only at convened meetings of the IRB Committee at which a quorum is present.
4. Substantive review of protocols must take place at the convened meetings.
 - a) Applications undergoing review must be individually presented and

- discussed at a convened meeting of the IRB Committee.
- b) The Secretary to the IRB shall assign a Primary Reviewer from among the Committee members for each full review protocol. The Primary Reviewer shall conduct an in-depth review of all pertinent documentation and present the protocol to the full Committee.
 - c) In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting.
5. The IRB Committee may only approve an application when its decision is based on consideration of the following:
- a) Risks to subjects are minimized, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c) The selection of subjects must be equitable. In making this assessment, the IRB Committee should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - d) Informed consent shall be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulation.
 - e) Informed consent will be properly documented, in accordance with, and to the extent required by federal regulation.
 - f) When appropriate, the research plan shall make adequate provision for monitoring the data collected to ensure the safety of the subjects.
 - g) There must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
6. Determination of Review Interval. The IRB Committee shall determine an appropriate review interval at which to conduct continuing review of all full committee protocols. The review interval must be appropriate to the degree of risk, but not less than once per year. The records of the IRB Committee meeting should clearly reflect these

determinations regarding risk and approval period (review interval).

7. Consideration of Vulnerable Populations. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, the IRB Committee must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.
8. Full Committee Determination of Conditional (Contingent) Approval. When the IRB Committee requests clarifications, protocol modifications, or informed consent revisions, IRB Committee approval must be deferred until the investigator timely submits satisfactory revisions. Such revisions must be finally approved by the IRB Chair, the Full Committee, or as otherwise specified by the Committee. The minutes of the IRB Committee meeting shall clearly reflect conditional approval with final review requirements.

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

BOG 1.001(3)(m), 45 CFR 46.103,108, 111