

Florida State University Policy 7-IRB-10

Title of Policy: Final Action by the IRB Committee

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised _____

I. INTRODUCTION

This policy describes the types of action that may be taken by the IRB Committee.

II. POLICY

1. Pursuant to 45 CFR 46.109, an IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by federal regulations and as described in FSU's federal wide assurance.
2. Such authority shall be implemented by final action by the IRB as described by this policy herein. Any final action of the IRB will be decided upon only after appropriate discussion and voting by a majority of the quorum members present. The investigator will receive a written notice which will include the type of action taken, the type of review accepted, and any other relevant instruction from the IRB.
3. The various types of action possible by the IRB Committee are as follows:
 - a) Approved. This action means that the investigator has met all conditions and the project may be implemented.
 - b) Conditional Approval. This action means that the IRB has required modifications in the project in order to secure the approval of the IRB. There are two levels of conditional approval:
 - Review by Committee Required. Responses to this level must be brought before the Committee for action at a regularly scheduled meeting for full review.

- Review by Chairperson Required. Responses to this level may be reviewed by the Committee Chairperson and, if considered satisfactory, the conditions may be removed by the Chair.
- c) Tabled. This action is taken by the Committee whenever it has not completed its review or does not have sufficient information for definitive action. If the project is tabled due to insufficient information, the deficiencies noted will be transmitted to the investigator in the Committee minutes and no further action will be taken by the Committee until revisions of the project is submitted by the investigator.
- d) Disapproved. This action means that the Committee has identified major conflicts or deficiencies in the project which cannot be remedied without major revision. Thus, the Committee will disapprove such a project.
- e) Administrative Termination. This action is taken by the secretary to the IRB Committee, and occurs whenever there has been a failure to comply with any of the requirements of the IRB Committee
- f) Reviewed, No Action Taken. This action means that the IRB has reviewed the project and has found that the activity proposed is not “research”, does not involve human subjects, or otherwise does not fall within the purview of the IRB responsibility. The Chairperson or Office Staff shall respond in writing to the Investigator for this action.

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

BOG 1.001(3)(m), 45 CFR 46.103,108,109