

Florida State University Policy 7-IRB-16

Title of Policy: Suspension or Termination of IRB Approval for Cause

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 explains the authority of the IRB to suspend or terminate approval of research that is not in accordance to IRB policies, federal regulations, or has been associated with unexpected serious harm to subjects.

II. POLICY

1. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. Serious or continuing noncompliance with the determinations of the IRB may result in the IRB withdrawing approval for a study. Failure to provide a response in a timely manner to a request of information for continuing review is considered cause for suspension or termination of IRB approval. Any letter of suspension or termination of approval to an Investigator shall include a statement of the reasons for the IRB's action. The Investigator shall have an opportunity to respond in writing or in person to the letter of suspension or termination.
2. All suspensions or terminations of approval for cause must be promptly reported to the Associate Vice President for Research at Florida State University. The Vice President for Research shall notify the relevant Department Head, the Dean of the Investigator's School, and the Chairperson of the IRB Committee.
3. Regulatory authorities such as OHRP, the FDA, NIH or other federal sponsoring departments or agencies shall be promptly notified by the Vice President of Research of any terminations or suspensions for cause.

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

BOG 1.001(3)(m), 45 CFR 46.113