

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 016
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.113

SUBJECT: Suspension or Termination of IRB Approval for Cause

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.