

Florida State University Policy 7-IRB-20

Title of Policy: Prompt Reporting of Serious or Continuing Noncompliance

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 states that all reports of serious or continuing noncompliance in human subjects research must be investigated by the IRB Office and Associate Vice President of Research. The policy outlines the authority of the IRB concerning issues of noncompliance.

II. POLICY

1. All credible reports of inappropriate involvement of human subjects in research must be investigated by the IRB Office and Associate Vice President of Research. Such reports of noncompliance may come from any source including IRB Committee members, investigators, subjects, institutional personnel, the media, anonymous sources or the public. The results of the investigation will be reported to the Vice President of Research. Thereupon, the Vice President shall notify the Department head, Dean of the Investigator's School, and the Chair of the IRB. When applicable, notification will also be forwarded to the Faculty Advisor. Regulatory authorities such as OHRP, FDA, NIH, or other federal sponsoring departments or agencies will also be promptly notified by the Associate Vice President of Research of any serious or continuous noncompliance.
2. Between IRB continuing reviews of a protocol and at the time of continuing review of a protocol, it is the Investigator's responsibility to keep the IRB Office informed of any unanticipated problems involving risks to subjects or adverse events that were serious, unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record. An investigator is responsible for the accurate documentation, investigation and follow-up of all possible study related adverse events. Investigators are also responsible for informing government and other sponsors of any unanticipated events, as appropriate.

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

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

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