

# Florida State University Policy 7-IRB-22

Title of Policy: General Responsibilities of Investigator

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 responsibilities of the Investigator in relation to human subject research and the FSU IRB.

## II. POLICY

1. Human Subject Protection. The individual Investigator is the ultimate protector of the subject's rights and safety. Each Investigator is obligated to be personally certain that each subject is adequately informed and freely consents to participate in the Investigator's research.
2. Use of Investigational Devices and/or Investigational Drugs. Prior to the initiation of any research involving an investigational device or drug, the Investigator is responsible for obtaining the IND or IDE from the FDA in accordance with federal regulations.
3. Additional University Committee or Institution Approval. Prior to the initiation of any research that requires additional review and approval from other University committees or institutions, it is the responsibility of the Investigator to obtain the necessary approval from that committee and /or institution. Examples of prior approvals include the FSU Biosafety Office, and Superintendent's Office for school systems where research will be conducted.
4. Supervision and Auditing of Research. It is the responsibility of each Investigator to assure that all procedures in a study are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them

under the laws of Florida and the policies of FSU. It is the responsibility of the Investigator to regularly review the research process and address any deficiencies identified in the process.

5. Investigator Training. Each Investigator is encouraged to complete periodic training to remain up-to-date with federal regulations, FSU policies and procedures, and compliance expectations. Each Investigator must ensure that key personnel who are responsible for the design and conduct of the study are adequately trained with regard to the use of human subjects in research. Such training may be through NIH or CREATE program at FSU.
6. Congruence with Funding Proposals. Each investigator shall ensure that the IRB protocol is consistent with the proposal for funding for extramural or intramural support. Further, the Investigator should act as a liaison between the IRB and the sponsor.
7. Amendments/Requests for Change to IRB Application. It is the responsibility of the Investigator to not deviate in any way from the IRB approved protocol until the Investigator has received written approval from the IRB.
8. Researcher Records. Investigators must maintain research records for at least three (3) years from the date of completion of the research. All records must be accessible for inspection and copying by authorized representatives of the IRB and the department or agency supporting the research. Beyond three years, requirements for record retention vary with the type of research conducted and the provisions of the Investigator's funding source. It is the Investigator's responsibility to clearly understand the retention requirements of the sponsor.
9. Adverse Events. The Investigator must report to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research in accordance with FSU policy.
10. Confidentiality and Privacy. The conditions for maintaining confidentiality and privacy of the subjects and the research records are required for the life of the data. These rules apply equally to any and all research conducted or assisted by students, staff, and faculty. Note: Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations.
11. Prisoner Research. If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the IRB promptly.

12. Additional Requirements for Activities Involving Fetuses, Pregnant Women, or Neonates. For activities involving fetuses, pregnant women, or neonates, the Investigator must ensure that adequate provision has been made for monitoring the actual informed consent process.
13. Continuing Review. All approved research proposals, including those which qualify for exemption in accordance with 46 CFR 46.101(b), must receive continuing review at intervals appropriate to the degree of risk as determined by the IRB. Continuing review must be conducted not less than once per year. It is the responsibility of the Investigator to provide the IRB with all of the information requested for Continuing Review in a timely manner.

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

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