Florida State University Policy 7-IRB-1

Title of Policy: Institutional Oversight of Ethical Principles Regarding Research Involving Humans as Subjects

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New AUGUST 13, 2003

I. INTRODUCTION

This document establishes a policy of ethical principles by which human subjects research should be conducted.

II. POLICY

1. Florida State University, which includes faculty, staff, employees, and students, are guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (referred to as “The Belmont Report”) regardless of whether the research is subject to Federal Regulation or with whom conducted or the source of support or sponsorship.

2. The three quintessential requirements relevant to the protection of human subjects in biomedical and behavioral research as set forth in the Belmont report are:
   a) Respect for Persons: Involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy;
   b) Beneficence: Entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
   c) Justice: Requires that the benefits and burdens of research be distributed fairly.

The principle of Respect for Persons underlies the need to obtain informed consent; the principle of Beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of Justice requires that subjects be fairly selected.
3. Florida State University holds a Federalwide Assurance of Protection for Human Subjects (Department of Health and Human Services), Number 00000168, approved on March 26, 2001, in which it agrees to uphold the ethical principles of The Belmont Report and to apply the Code of Federal Regulations (45 CFR Part 46) to all research involving human subjects regardless of sponsorship or support.

4. The Vice President for Research and the Associate Vice President for Research are responsible for exercising appropriate administrative oversight to ensure that Florida State University’s policies and procedures designed for protecting the rights and welfare of human subjects are effectively applied in compliance with its Federalwide Assurance with the Office for Human Research Protections (“OHRP”), Department of Health and Human Services.

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

BOG 1.001(3)(m), 45 CFR 46.101,103