Florida State University Policy 7-IRB-3

Title of Policy: Policy and Procedures Development

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 describes how policies and procedures are developed.

II. POLICY

1.  Pursuant to 45 CFR 46.103, an Institution must assure that it has adequate written procedures in place to support compliance with the federal regulations governing research involving human subjects.

2.  Any written procedures shall be approved by the IRB, and be presented to the Vice President for Research for his/her review and final adoption.

3.  The Vice President of Research, Associate Vice President of Research, Chair or designated members of the IRB, or legal counsel to the IRB (Human Subjects Committee) shall perform periodic review of the written procedures and recommend to the IRB any revisions or additions to the procedures, consistent with federal regulations, guidelines, or rules and procedures governing Florida State University. Any such revisions approved by the IRB shall be presented to the Vice President of Research for his/her final adoption.

Minor revisions to any IRB blank forms, checklists, guides or webpages may be performed by IRB Office Staff as needed subject to the approval of Legal Counsel to the IRB. Any major revisions shall be presented to the IRB for review and approval.

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

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