FLORIDA STATE UNIVERSITY

7A-31 POLICY ON CLINICAL TRIALS REGISTRATION, REPORTING, AND TRAINING

Responsible Executive:	Gary K. Ostrander, Vice President for Research
Approving Official:	Gary K. Ostrander, Vice President for Research
Effective Date:	April 16, 2018
Revision History:	None

I. INTRODUCTION

This policy outlines the requirements for NIH funded awards that are classified as a clinical trial based upon (1) the FDA definition of an "applicable clinical trial" and/or (2) the NIH definition of a clinical trial. These requirements include the requirement to register, report and complete specific training. The FDA and NIH have established strict timelines for these activities and have incorporated heavy penalties for failing to meet these timelines. Failure to comply with this policy may result in the following: inability to publish; civil monetary penalties levied against the University; suspension of protocol approval from the IRB; and/or loss of additional or continued funding from federal agencies and other entities.

II. POLICY

Any award that is classified as a clinical trial based upon(1) the FDA definition of an "applicable clinical trial" and/or (2) the NIH definition of a clinical trial and is funded by the NIH is required to comply with the following:

- For PI-initiated clinical trials, the PI is required to register the project in ClinicalTrials.gov within 21 days of enrollment of the first subject, complete periodic updates as required, and report summary results information within one year of the primary completion date.
- The NIH requires that language on the dissemination of clinical trial information be included in new or competing applications submitted.
- All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials are required to be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). FSU provides free online GCP training at https://www.research.fsu.edu/research-compliance/training/citi-login-instructions/good-clinical-practice/.

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

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm

FDAAA, Section 801, and the Final Rule (42 CFR Part 11)
https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82

Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

State of Florida Statutes, Chapter 1004 Part II.A.
http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=1000-1099/1004/1004PARTIIAContentsIndex.html

This policy will be reviewed periodically and updated when necessary.

/s/ Gary K. Ostrander

[Proof of approval retained in file]