NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
TITLE: REQUIRED TRAINING FOR CLINICAL TRIAL KEY PERSONNEL	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT	
FUNCTION: Clinical Trial Management	**POLICY CODE NO: OCR-2**
EFFECTIVE DATE: April 1 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE: n/a	

I. DEFINITIONS

Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Good Clinical Practice (GCP): defined by the FDA as a set of international ethical and scientific quality standards expected in the design, conduct, and reporting of clinical research. FDA provides guidance as to these standards (https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials) and FDA regulated studies are required to follow GCP standards.

Key Personnel: an individual with specific duties associated with the conduct of a research study (may be referred to as study personnel).

Schedule of Events (SOE): A timeline of specific activities required by a research participant enrolled in a Clinical Trial. The SOE may include virtual or in person interactions and may include research and/or standard of care activities if they are required as part of the study protocol.

II. POLICY

A. Purpose

To provide guidance on required training for NSU faculty, staff, and students performing Clinical Trials.

B. Policy Statement

All NSU faculty, staff, and students performing research utilizing human participants will maintain training in Human Research Training with the Collaborative Institutional Training Initiative (CITI). Required training must be complete prior to submission of IRB protocol for IRB review and re-certified every three years as long as the individual remains Key Personnel on any human research study, as governed by IRB Policy 1.3 (https://www.nova.edu/irb/policies-procedures/1-3-investigator-responsibilities-v2023-08-10.pdf).

Key Personnel, including the Principal Investigator, of all externally funded Clinical Trials and internal grant or College funded Clinical Trials that test interventions (such as drugs, devices, or diagnostics) regulated by FDA, who engage in research activities that include informed consent; obtaining, documenting, or otherwise handling study data; or drug/device handling or accountability will also maintain Good Clinical Practice training. Good Clinical Practice (GCP) training must be complete prior to submission of IRB protocol for IRB review and re-certified every three years if the individual is Key Personnel on any externally funded Clinical Trial.

If the funding agency of a Clinical Trial requires GCP training for additional individuals other than those described above, the funding agency's requirements must also be followed.

Protocol submissions will not be approved by the IRB until all Key Personnel have completed the requisite training.

III. Procedures

1. NSU offers Human Research Training and Good Clinical Practice training free of charge to all investigators via CITI at https://about.citiprogram.org/.

2. Key personnel must affiliate with Nova Southeastern University on the CITI website to access these trainings free of charge.

3. Instructions on how to access these trainings can be found on the CITI Training page of the NSU IRB website at (https://www.nova.edu/irb/training.html).

4. All key personnel must have a current GCP training uploaded into IRBManager via the *Good Clinical Practice xForm*.

    a. Principal Investigators are responsible for verifying that the GCP is properly uploaded via this form and that all training is current.

5. IRB reviewers will verify the following:
    a. All study team members requiring GCP are listed among the key personnel.
    b. All key personnel have current GCP properly loaded into IRBManager.

c. All key personnel maintain current GCP training at time of subsequent submissions to the IRB.

IV. REFERENCES

NSU IRB Policy on Study Personnel Training (https://www.nova.edu/irb/policies-procedures/1-3-investigator-responsibilities-v2023-08-10.pdf)

NIH 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)

V. COMPLIANCE CONTACT

If you would like further information on this NSU Policy, or have additional questions, please contact us via email to the Office of Clinical Research point-of-contact at ocr@nova.edu.

VI. ENFORCEMENT

All employees having roles or responsibilities covered under this policy are expected to be thoroughly familiar with the policy and its procedures and obligations as they pertain to the employee's role. Failure to comply with this policy may result in disciplinary action pursuant to all applicable university policies and procedures.