CT-102 Qualified Investigators and Research Staff

EFFECTIVE DATE: May 2023

Purpose

The purpose of this Policy and Procedure is to describe the training required for new research personnel as well as continuous education and training for all research personnel. This policy and procedure ensures all physicians and staff members involved in clinical research are properly trained concerning FDA regulations, ICH GCP guidelines, study protocol/Sponsor requirements, and USA policies & procedures.

Scope

This Policy and Procedure applies to Principal Investigators, Sub-Investigators, Clinical Research Coordinators, and any other USA personnel that perform significant, trial related tasks in research studies performed through the Clinical Trials Office at the University of South Alabama. This Policy and Procedure will also apply to non-USA personnel who perform significant trial related tasks on USA property or facilities.

Definitions

Good Clinical Practice: Good Clinical Practice (GCP) is an international ethical and scientific quality standard that helps ensure that the results of a clinical trial are credible and that the rights, welfare and confidentiality of the human subject are protected. Good Clinical Practice provides guidance on the best practices for the way a clinical trial is designed, conducted, performed, monitored, audited, recorded, analyzed, and reported.

Principal Investigator: The individual of record who assumes the authority and responsibility ffidp thy and resre ap

health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered to be health information.

Qualified Investigator: A qualified Investigator is a Principal Investigator or Sub-Investigator that is qualified by education, training, and experience in the area in which the research is being conducted.

Policy

A qualified Principal Investigator must meet the eligibility criteria set forth in the Sponsored Projects Administration's Principal Investigator Policy.

Qualified Investigators must be familiar with all applicable regulations and guidelines, Good Clinical Practice, state laws, and institutional policies and procedures. Qualifications should be documented through licensure and/or Curriculum Vitae. Only a physician is qualified to be Principal Investigator on a biomedical interventional study.

Research personnel who will perform significant research functions should have experience in research fundamentals including, but not limited to, all applicable regulations and guidelines, Good Clinical Practice, state laws, and institutional policies and procedures. Comprehensive training should be completed if new research personnel lack the previous stated experience.

All Investigators and research personnel should complete the required training set forth by the Office of Research Compliance and Assurance. Additionally, Investigators and research personnel should seek at least 4 continuing education credit hours in a calendar year. These credit hours should be specific to clinical research. Training modalities include webinars, seminars, conferences, or classroom/lecture.

Procedures

1. Only individuals qualified by training and experience shall be involved in the -104 0idd.333 0aduted ie s, Good

of all GCP certificates should be sent to the Clinical Trials Office for retention in study records. Instructions on required training can be found on the Office of Research Compliance web page.

5. Depending on study activities, job specific training may be required. Common training required by clinical research staff include:

   5.1. [illegible]

Sponsored Projects Administration- Principal Investigator Policy

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