UNIVERSITY OF SOUTH ALABAMA

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 for the conduct of a clinical study.

Protected Health Information (PHI): Individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium. This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a

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 conduct of clinical research.

2. Prior to new staff starting, establish the research orientation and training plan based on the new hire's position and job functions.

3. Training in HIPAA Research and privacy protection specific to research is required prior to accessing Protected Health Information (PHI); training is provided through the Office of Research Compliance and Assurance. Training completed as part of USA healthcare operations is not acceptable. The HIPAA Research training is located on the Office of Research Compliance web page.

4. Training in human subjects' protection and good clinical practice (GCP) is required. This training must be completed before the investigator or research staff is permitted to participate in the conduct of any research activity. GCP certification is valid for three years, and must be maintained by each research staff member without lapse throughout their employment. A copy

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. All employees who have potential occupational exposure to bloodborne pathogens will need to complete the biosafety training through the Collaborative Institutional Training Initiative (CITI). Employees must understand the modes of germ or pathogen transmission, types of protective equipment available, how to handle spills and emergencies, as well as the different categories of pathogens (germs) and review of biohazardous tasks. Training must be renewed annually. Instructions on this training can be found on the Office of Research Compliance web page.

   5.2. Those employees engaged in shipping specimens must complete and maintain approved shipping training for the shipment of infectious agents and biological substances. This training must be renewed every two years. Instructions on this training can be found on the Office of Research Compliance web page.

6. The Research and Education Learning website, should be reviewed for specific training requirements according to the type of research activity and roles. The website also provides instructions on how to access training.

7. Before conducting protocol activities, research staff shall receive protocol specific training provided by the Sponsor representative, monitor and/or the clinical investigator. Ancillary staff such as a pharmacist, floor nurses, etc. should be trained on all applicable protocol tasks prior to performing the task. SOP CT- 205 should be followed.

8. Research staff and investigators should be trained on protocol amendments if the changes affect their delegated role. Ancillary staff such as pharmacist, floor nurses, etc. should be trained on any changes that affect their delegated role. SOP CT- 205 should be followed.

9. It is recommended that all investigators and research staff obtain 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.

10. All study specific and IRB required training must be documented. Documented training should be kept in the employee's individual file and in the study specific regulatory file.

Additional Resources

FDA Guidance for Industry: Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects

RELATED SOPS:
CT-205 Protocol Training Records

RELATED FORMS:

- **EXAMPLE-DOCUMENT OF SITE PERSONNEL TRAINING**
- **EXAMPLE-TRAINING LOG**

History

N/A

Next Review Date

January 2026

Responsible Party

Director, Clinical Trials Office