UNIVERSITY OF SOUTH ALABAMA

CT-205 PROTOCOL TRAINING RECORDS

EFFECTIVE DATE: June 2023

Purpose

Research personnel shall be appropriately qualified by education, training and experience to carry out their respective tasks in accordance with the CT-102. This SOP explains when training on the protocol is required and best practices for documentation of training.

Scope

This SOP applies to all Investigators and staff participating in research projects through the Clinical Trials Office at the University of South Alabama. It may apply to non-research staff who are involved in the care of the subject, but are not performing specific research-related tasks.

Policy

Prior to participating in a clinical research study, the Principal Investigator (PI), Sub-Investigators, and staff listed on the study delegation log must receive initial specific study/protocol training. Training on amendments to the study protocol and study-specific documents should be performed and documented per the below procedures. Non-delegated clinic staff who contribute to the patient's standard of care should be made aware of the investigational product's safety profile and administration guidelines.

All studies requiring a training log will use our site-specific document. Sponsor specific training logs will no longer be completed for studies in which the USA CTO was selected as a site after July 1, 2023.

Procedures

Initial Protocol Training

1. Prior to any study-related procedures being performed, initial protocol-specific training is typically conducted by the sponsor, a sponsor representative, or a delegated trainer during a site initiation visit (SIV) or initial training meeting.

2. Study personnel unable to attend the SIV or initial training meeting, or who are added to the research team after study initiation, initial protocol training must be completed and documented prior to performing any study-related research procedures.

    2.1. Training must be conducted by the PI, sub-investigator, regulatory staff, clinical research coordinator, or other appropriate study personnel who has been previously trained.

    2.2. While procedures outlined above are encouraged, self-training is permitted provided the staff is provided with all appropriate study materials.

3. All personnel listed on the delegation log should be initially trained on the protocol regardless of their delegated task. However, training should be specific to the study related task. For example, the pharmacist should receive basic protocol training AND investigational product training.

Ongoing and Continuing Training

1. Training should be documented for all protocol amendments. The personnel that are trained will depend on the changes to the protocol. For example, the pharmacist may not need to be trained if the changes are only to the inclusion and exclusion.

2. For administrative changes made in a protocol amendment, such as typographical corrections or other minor edits and changes to non-operational sections, re-training is not required.

Maintenance of Training Records

1. All training records should be kept in the study specific regulatory binder as a hard copy and/or electronic file.

2. All training should be documented. Each documentation must contain the following:

    2.1. Study name and/or protocol number

    2.2. PI name

    2.3. Document trained on, including version number

    2.4. Date of training

    2.5. Name of the person trained

    2.6. Signature of the person trained

    2.7. Name and Signature of the trainer, if applicable

3. A training record can be in the form of an ongoing log or an individual document for each topic trained.

Additional Resources

RELATED SOPS:
CT-102 Qualified Investigators & Staff
CT-206 Delegation Log

RELATED FORMS:
TRAINING LOG

History

N/A

Next Review Date

January 2026

Responsible Party

Director, Clinical Trials Office