# 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.

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.

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