



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.

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