UNIVERSITY OF SOUTH ALABAMA

CT-201 REGULATORY DOCUMENTS

EFFECTIVE DATE: May 2023

Purpose

The documentation required for clinical trials is dictated by regulatory agencies and by the ICH Good Clinical Practice Guidelines. The purpose of this Standard Operating Procedure is to define the preferred method for the set-up and use of the study files, including the regulatory documents binder ("Reg. Binder"), to assure regulatory compliance for completeness and retrievability of records.

Scope

This SOP applies to all research operated through the Clinical Trials Office at the University of South Alabama. The below policy and procedure define the essential documents that may need to be on file for each clinical study. Documents on file will depend on the type of clinical trial. Essential documents are those that individually and collectively permit evaluation of the conduct of a study and the quality of data produced.

Definitions

Essential Documents: Documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

Policy

Study sites are not required to adopt the structure outlined in this procedure, but are urged to consider a standardized approach such as this when developing their filing approach to study data management. It is strongly recommended that sites adhere to the order of documentation of the regulatory checklist appended to this SOP (Regulatory Binder Checklist) in order to facilitate routine inspection by study monitors, internal auditors or regulatory agencies.

The files/binders suggested here may be subdivided, consolidated, and/or re-organized to conform to specific study needs.

The formalized compilation of study records dealing with the conduct of the study as a whole will be referred to as the "Reg. Binder". Study participant records, including visit notes and patient information, should be kept separate from the Reg. Binder.

Procedures

The following procedures apply to all of the study files.

1. Good Clinical Practice (GCP) requires that all study related activities be documented.

    1.1. The regulatory binder checklist provided for this SOP includes the documents expected to fully capture regulatory activities.

    1.2. Specific studies may require additional documents.

2. Essential documents shall be stored in files (electronic or paper) and maintained for the required duration specified by regulations and the clinical trial agreement.

    2.1. Study files must be stored in a secure location.

    2.2. Files or file room shall be locked to prevent unauthorized access.

3. The filing system shall be segmented so that individual trials remain separate, in particular when sponsored by different entities.

4. A complete record must be maintained of all approved documents. When required documents are modified or updated, the original and all modified or updated versions must be maintained. Some workable ways to control use of the correct version include:

    4.1. Documents that have been superseded may be moved from the active binder to an "historical" binder or can be kept electronically. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. The historical binder should maintain the same contents format as the active binder.

    4.2. All version copies may be kept together, with the most recent version to the front of the binder. If kept electronically, most recent versions should be separate from previous versions and easily identifiable.

5. A Study File should be prepared as soon as is practical after the first contact with a potential Sponsor (or Contract Research Organization).

    5.1. All correspondence regarding a potential study should be kept.

    5.2. If the Principal Investigator (PI) decides not to participate in the study then confidential materials should be returned or destroyed, as agreed between the two parties. Verification of destruction (include method, date, responsible party) should be sent to the Sponsor, with the PI retaining a copy of the notification.

    5.3. Keeping the information as to why a study was declined may help with future decisions.

6. When the regulatory binder is supplied by the Sponsor, the initial departmental Study File should be merged with the Sponsor binder. Format of the regulatory binder is at the discretion of the study team so long as there is a clear organizational outline (i.e. table of contents).

7. To preserve blinding, certain documents related to the investigational study products may be stored separately, e.g. in site pharmacies, until after the final "data-lock" following study close-out.

8. Label each binder with relevant information such as the Sponsor name, PI name, and the protocol number and the binder number. Disclosure issues should be considered regarding labeling information in order to protect Sponsor confidentiality.

Additional Resources

RELATED SOPS:
None

RELATED FORMS:
- **REGULATORY BINDER CHECKLIST**

History

N/A

Next Review Date

January 2026

Responsible Party
Director, Clinical Trials Office