UNIVERSITY OF SOUTH ALABAMA

CT 303 **DOCUMENTATION PRACTICES**

EFFECTIVE DATE: February 2024

Purpose

To encourage authenticity and the production of quality data. Good documentation efforts support the completion of all regulation requirements, such as ALCOA-C, accurate communication and action planning, human subjects protections, and effective corrective and preventive actions for any clinical trial.

Scope

This standard operating procedure (SOP) covers all source data and source documents supporting human subject studies, especially manual records (paper records / hard copies) such as entries to the source. It affects all personnel involved in recording, correcting or keeping information, either hard copy documents or electronic files, that supports a study using human subjects.

Definitions

Clinical Trial Agreement (CTA): A clinical trial agreement (CTA) or clinical study agreement (CSA) is a legally binding agreement that governs the conduct of a particular study and sets forth the obligations of each party to the agreement.

Principal Investigator (PI): The individual of record who assumes the authority and responsibility for the conduct of a clinical study

Source Documents: all information in original records and certified copies of original records of clinical findings, observations, or other activities (in a clinical investigation) used for the reconstruction and evaluation of the trial

Sub-Investigator (Sub-I) - The Sub-Investigator is a medical professional who is under the supervision of the Principal Investigator and is responsible for performing some study–related procedures and /or making important study-related decisions, but they do not accept primary responsibility for the research study.

Policy

All documentation practices are held to standards as defined in ICH-GCP. GCP training is required for all staff documenting clinical trial data, as outlined in SOP 101.

Principal Investigators (PIs) are required to provide adequate oversight of all clinical research activities at the site, whether the activity is conducted by the PI, by study team members, or by applicable third parties. Adequate oversight encompasses many activities and obligations, such as ensuring regulatory compliance, staff training, and subject medical care. Oversight must be clearly documented in the subject's chart.

Procedure

1. PI oversight of site documentation practices include:
   1.1. Signing of inclusion/exclusion source to indicate review and verification of the subject's qualification. Review should be performed prior to subject's enrollment on study.
   1.2. Research specific progress notes at protocol required visits.
   1.3. Review and signature of safety reports and important sponsor communication.
   1.4. Review, assess, and sign diagnostic reports.
   1.5. Assessment of adverse events.

2. Source documents are original documents, data, and records. This is the first place information is recorded.
   2.1. Information must be recorded by study personnel authorized on the study delegation log, unless recorded for standard of care. Entry should be signed.
   2.2. All blanks of a form should be filled in. This can be accomplished by filling in the applicable data or writing 'N/A' with explanation of why the data is missing.
   2.3. If original records are damaged or obliterated, those records shall be retained when possible with the reconstruction of the record, including an explanation and supervisory sign-off.

3. Data must meet quality attributes as defined by ALCOA+to be acceptable, including:
   - Attributable: Entries shall be signed or initialed by the entrant.
   - Legible: All information/entries must be clear and readable.
   - Contemporaneous: Promptly record activities and results, date the signature or initials at the time the entry is recorded.
   - Original: The first record of an event or data collection is source data.
   - Accurate: Records must be true values given with reasonable precision.
   - Complete: Records should be complete with no missing data
   - Consistent: All elements are dated or time stamped in expected sequences.
   - Enduring: Data is recorded in official laboratory notebooks and/or electronic media.

- Available: Data record is available for review, audit, or inspection, over its lifetime.
- Traceable: Data should be traceable throughout the data life cycle. Original data entry and all changes must be signed or initialed at the time of entry.
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4. All data should be recorded in uneditable black or blue ink. Do not use pencil.

5. All activities must be recorded. Examples include:
   - Telephone logs, including communications with subject, monitor or Sponsor.
   - Records of research team meetings.
   - All study visits as outlined in the protocol
   - Return and dispensation of investigational product or devices.

6. Corrections shall not alter or obscure an earlier entry. Original entry must remain legible.
   - Do not make erasures.
   - Do not use correction fluids ("white-out").
   - Do not over-write an entry

6.1. To make a correction to a hard copy:
   - Cross out the wrong entry with a single line that keeps the first entry legible.
   - Write the correct entry near the wrong entry, or indicate location of correction if space is limited.
   - Initial the correction. This should be the initials of the person making the correction.
   - Date the correction. This should be the date the correction was made.
   - Explain the correction (if necessary).
   - Any later corrections (those not made the date of the original entry) to a record must be explained.

6.2. Electronic source records are subject to the Food and Drug Administration (FDA) rules, and must maintain a valid audit trail including any changes or edits.

7. Electronic signatures through a system that is 21 CFR Part 11 compliant may be used on source documents.

8. Test results should be assessed for clinical significance by the PI or Sub-Investigator (Sub-I). Such assessments should be initialed or signed, and dated.

9. All source documents must be kept confidential as outlined in CT 104.

9.1. All protected health information must be redacted when being transmitted to a sponsor or a sponsor designee.

9.2. Data that is collected for the sole purpose of the sponsored research is property of the sponsor unless otherwise stated in the Clinical Trial Agreement (CTA).

Additional Resources

RELATED SOPS:
CT 101 Good Clinical Practice
CT 104 Protecting Confidential Information

RELATED FORMS:

RELATED POLICIES

History

N/A

Next Review Date

February 2027

Responsible Party

Director, Clinical Trials Office