UNIVERSITY OF SOUTH ALABAMA

CT-310 CLINICAL RESEARCH DATA MANAGEMENT

EFFECTIVE DATE: April 2024

Purpose

The overall purpose of this Standard Operating Procedure (SOP) is to provide guidance for managing clinical trial data and ensuring all data is collected, verified, validated and reconciled in the appropriate manner to preserve the scientific integrity of the research. Additionally, this SOP works to ensure the integrity of electronic data collected in the course of a clinical trial.

Scope

This SOP applies to all personnel involved in the management of data for clinical research conducted through the Clinical Trials Office. This SOP oversees set up, access, management and security of electronic data capture systems. This SOP does not apply to computerized medical devices, diagnostic laboratory devices or analytical laboratory devices used during a clinical trial, nor does it apply to paper records that are transmitted electronically.

Definitions

Case Report Forms (CRF): A paper or electronic form used in clinical trial research to collect data from each participating patient. All data on each patient participating in a clinical trial are held and/or documented in the CRF.

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.

Procedure

Data Collection and Transcription

1. Only study staff delegated by the PI on the delegation of authority log may enter data into the CRF/eCRF. Designated individuals must have documented training on file for entry into the e-CRF systems (as applicable).

2. All CRFs/eCRFs must be complete and/or updated per protocol requirements. Timelines for entry into eCRFs must be confirmed with the sponsor and designated staff should include data entry time into their schedules.

3. All information documented on the CRF/eCRF must have corresponding source documents present in the research chart or in the electronic medical records (as applicable) to substantiate the information entered into the sponsor-provided CRF/eCRF.

4. Use the sponsor supplied CRF Completion Guidelines if provided.

5. The site staff should record the data generated from the visit into the CRF/eCRF or data entry system no more than five business days from the visit. When entering data:

    a. Fill in all of the spaces provided. If data is not available for an entry, do not leave blank; instead, indicate reason there is no data, for example:
        i. Use "UNK" for unknown
        ii. Use "ND" for not done
        iii. Use "NA" for not applicable.
    b. Record measurable values in the unit of measure specified by the protocol, CRF Completion Guidelines, or source documents.
    c. Avoid using abbreviations in written comments.
    d. Ensure all data has been obtained, confirmed and documented in the source record by the designated staff member.

6. If a correction is necessary (either the paper CRF or source document):

    a. Cross out the entry with a single line (in a manner that allows the original entry to be seen).
    b. Record the correct information.
    c. If needed, briefly state why the change was made (for example, write 'error' next to the correction).
    d. If applicable, ensure the source document is updated to match CRF.

7. Review all entries against the source document for accuracy.

8. If there are outstanding documents (test results, read-outs, etc.), indicate the section missing. Follow up until all documentation is received.

<u>Electronic Data Capture (EDC) Systems</u>

1. The designated research personnel will work with the sponsor to facilitate set-up, implementation and maintenance of the electronic data capture (EDC) system.

2. Ensure that computerized systems are secure and protected when not in use.

3. Ensure that user names and passwords are secure and protected throughout the duration of the study.

4. Log off the program when data entry/management activities are completed.

5. The sponsor providing the system or software is responsible for training site staff on its use. Document all training and maintain certificates in the site regulatory binder.

6. Check and correct (or annotate) all data before transmitting the e-CRF or entering into electronic data capture systems to the sponsor.

7. Queries should be resolved no greater than five business days of issuance.

Additional Resources

RELATED SOPS:
CT 104 Confidential Information
CT 303 Documentation Practices

RELATED FORMS:

Responsible Party
Director, Clinical Trials Office