Investigator Standard Operating Procedures

SOP No.: 702

Clinical Research Data Management

Author: Office of Human Research

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This SOP pertains to: All personnel involved in the collection and management of data for human subject research within the Memorial Healthcare System

Responsibility for executing this SOP: Investigator and Designated Research Personnel

Approved By (Sign & Date):

Senior Vice President & Chief Medical Officer, NHS

Approved By (Sign & Date):

Chief Medical Research Officer, CHIR

1 PURPOSE

This procedure describes the process for the collection and transcription of clinical research data onto case report forms (CRFs) or other related forms, and the management of the data, including procedures for quality control, data query resolution, record retention, and archiving.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITES

a) The Investigator is responsible for all aspects of data management and for properly instructing key study personnel on how to collect, transcribe, correct, and transmit the data onto CRF or other data collection forms or logs.

b) The Investigator is responsible for having procedures in place for ensuring that data management activities occur as required by applicable regulations.

c) The Sponsor is responsible for ensuring that all participating clinical sites have the appropriate tools for, and are properly trained in collecting, evaluating, correcting and transmitting subject data.

d) The Monitor is responsible for reviewing the clinical study data collected and held at the site during monitoring visits for accuracy, integrity, reliability and quality.

3 SPECIFIC PROCEDURES
3.1 Collection of Clinical Data

a) The Sponsor will ensure that the clinical protocol describes in detail, appropriate methods for collecting, evaluating, changing, and transmitting subject data.

b) The Sponsor will develop protocol-specific CRF and other appropriate data forms to facilitate the capture of all required study information.

c) The Monitor will identify site requirements for data collection, storage, transmission, and retention during an Investigator’s qualification visit.
d) During the Site Initiation Visit, the Monitor will train study personnel on proper completion of all CRF and other data forms.

e) The Monitor will also train study personnel on proper correction of incorrect data entries (query resolution).

f) The Monitor will specify methods for study personnel to review and/or audit data prior to transmission to the Sponsor.

3.2 Data Transcription to CRF

3.2.1 Site CRF Completion Tasks

Study personnel will be instructed by the Monitor to use the following specific CRF completion procedures:

- Ensure that data for the CRF are transcribed in a timely manner from the source documentation.

- A source document is where data is first collected for a clinical trial i.e. original documents, data or records that are necessary for the reconstruction and evaluation of a trial. Examples include informed consent, progress notes, patient diaries, questionnaires, quality of life surveys, eligibility criteria asked directly to the patient, creatinine clearance calculations, pharmacy dispensing records, laboratory results, etc.

  - The source documentation should be filed in the subject’s study file. If electronic, it should be printed from the electronic medical record and filed in the subject’s study file, or the location adequately referenced for future verification.

  - Source documentation should also abide by the ALCOA acronym:
    Attributable – is the author obvious?
    Legible – is it easy to read?
    Contemporaneous – is the information current and in the correct time frame (dated and timed)?
    Original – is it a copy? Has it been altered? Is it a certified copy?
    Accurate – is there any conflicting data recorded elsewhere?

- Record all subject data and information in black ballpoint pen on paper CRF

- Complete all fields in the CRF according to protocol specification and site initiation training

- Correct errors by striking through the error with a single straight line, making the correction and then dating and initialing the correction

- Ensure the original entry is not obliterated by the correction, and if necessary, note an explanation or clarification in the CRF margin for why the change was required.

- The source documentation should tell the whole story without any assumptions being made. Careful documentation of unique or extenuating circumstances should be captured and dated by the author.
3.3 Data Management, Storage, and Retention

a) The Monitor will assess CRF completion status at each monitoring visit that is conducted during the course of the study, and at the closeout visit when the study is completed or otherwise suspended or terminated.

b) The Monitor will address any discrepancies noted in the monitoring visit report or on the Query Report Form (if provided) to ensure an audit trail of clarifications and corrections. If queries are captured electronically, query reports do not need to be printed as they will be tracked by an audit trail electronically.

c) The Sponsor’s version of the CRF and site’s version should be compared to verify they are identical.

d) The Monitor will advise the site’s personnel to keep copies of each Query Report Form (if provided) attached to the copies of the corresponding CRF and filed with the other study records in the appropriate subject’s file.

e) Errors on the CRF noted at the monitoring visit will be pointed out to the site personnel and corrected using the procedures described above prior to the completion of the monitoring visit (where possible).

f) If the Sponsor’s designee discovers errors on the CRF transmitted between monitoring visits, the designee should contact the site and request the CRF be corrected as required and resubmitted, and retain a record of the request for correction.

g) If data management procedures are not being followed, the Monitor will document this, discuss and/or implement corrective actions (e.g., retraining) with the site Investigator, and report all findings to the Sponsor.

h) If sites do not comply with data management procedures on an ongoing basis, the Monitor will document the pattern of non-compliance.

i) In cases of ongoing non-compliance, the Sponsor may institute site suspensions and/or termination procedures.

j) At the conclusion of the study, the Monitor will reiterate regulatory and Sponsor requirements for data retention, and remind the Investigator to contact the Sponsor and request written approval prior to destroying any study-related data (Reference SOP 503, Documentation and Records Retention and SOP 505, Study Closeout Visit).

4 REFERENCES TO OTHER APPLICABLE SOPS

- 301 Clinical Protocol Development, Implementation and Compliance
- 401 Initiation Visit and Site Training
- 503 Documentation and Records Retention
- 504 Routine Monitoring Visits
- 505 Study Closeout Visit
- 701 Case Report Forms
- 703 Use of Electronic Data Systems
5 ATTACHMENTS
None

6 APPLICABLE REGULATIONS AND GUIDELINES
- Electronic Records, Electronic Signatures (21 CFR 11)
- Investigator Recordkeeping and Record Retention (21 CFR 312.62)
- Records (21 CFR 812.140)
- The Principles of ICH GCP (ICH E6, Section 2.10)
- Records and Reports (ICH E6, Section 4.9)
- Quality Assurance and Quality Control (ICH E6, Section 5.1)
- Trial Management, Data Handling and Record Keeping (ICH E6, Section 5.5)
- Recordkeeping in Clinical Investigations (FDA Information Sheets, October 1998)