1. PURPOSE

To describe the requirements for preparing and managing source documents (SDs) at the clinical research site.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for all aspects of a clinical research study by maintaining accurate study documentation, including SDs and Case Report Forms (CRFs).

4. BACKGROUND

PIs are required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each subject. SDs include all original medical records available to the clinical investigator (e.g., progress notes, laboratory reports, and radiology reports) from which clinical trial CRFs are completed.

5. PROCEDURE

5.1. The PI is responsible for ensuring that source documentation is sufficient to support subject participation in a clinical research study, and that CRF entries are accurate, contemporaneous, legible, and verifiable (attributable). The PI may delegate the task of source documentation to appropriate clinical research personnel.

5.2. Study-specific SD templates will be developed to ensure thorough, prospective data collection. Sponsor-generated data collection tools may be used for source documentation, if acceptable to the SC and research facility medical records policy. Sponsor and IRB approval of developed SDs will be obtained if necessary.

5.3. The Investigator will review study-specific protocol requirements and data collection procedures with applicable clinical research personnel. The Investigator will work closely with clinical research personnel to ensure protocol compliance and appropriate documentation of protocol-required data points.

5.3.1. Each Study Participant (SP) has a research record that includes all observations and other data pertinent to the study.

5.3.2. All SDs are the property of the institution and do not leave the research premises except when written permission to do so has been obtained from the institution.

5.3.3. The SDs include:

5.3.3.1. Demographic information (name, address, date of birth, phone)

5.3.3.2. Name/address of primary care physician

5.3.3.3. Original signed/dated consent/assent form (Refer to SOP CLN-12.0, "Informed Consent")

5.3.3.4. Progress notes

5.3.3.5. Copies of information given to participants

5.3.3.6. Copies of CRFs (typically maintained in a separate binder due to length)

5.3.4. Progress note sheets are included to record all procedures performed in executing the protocol, including medication administration and the dose specified by the protocol, the consent process (refer to SOP CLN-12.0, "Informed Consent"), adverse event identification and outcome, etc.

5.3.5. All entries are dated and signed as they are recorded.

5.3.6. All SDs are archived with the research chart UNLESS documented otherwise on the study Termination Form.

5.3.7. No "stick-on," "Post-It" notes should be used. All notes ('Note to File') belong in the progress notes and must be signed and dated. All contacts (phone, fax, email, etc.) must be recorded similarly

5.4. The PI or designee will document in the subject's case history that informed consent was obtained prior to the SP's participation in any aspect of the research protocol. If an enrolled SP is being admitted to Creighton University Medical Center while participating in a Creighton-sponsored clinical research study, copies of signed consent forms should be filed in the SP's medical record.

5.5. All study-related SDs are labeled with appropriate subject identification. All documentation pertaining to clinical assessments and medical evaluations should be signed and dated by the appropriate healthcare practitioner, as designated by the Delegation of Authority Log (see SOP CLN-10.0, "Delegation of Authority").

5.6. SC(s) and/or other appropriate clinical research personnel are permitted to make late entries or addenda to medical records, if appropriate, for the purpose of research documentation, as allowed and directed by the research facility's institutional policy (see SOP CLN-44.0, "Document Handling").

5.7. The SC and/or other appropriate clinical research personnel will ensure that personal identifying information on copies of SDs that are to be submitted to the sponsor in support of CRF entries will be anonymized through the removal of all subject identifiers and replaced with the subject's initials and study identification number, in order to protect subject confidentiality.

5.8. If required by a study sponsor, the PI will validate the SD record by signing at the end of each visit.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
FDA Food and Drug Administration
IRB Institutional Review Board
PI Principal Investigator
SC Study Coordinator
SD Source Documents
SP Study Participant

7. REFERENCES

7.1. Title 21 CFR 50.26 - Documentation of Informed Consent
7.2. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
7.3. Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
7.4. ICH GCP Consolidated Guideline - Part 4.9 Records and Reports
7.5. Clinical Research Site SOP 10.00 - Documenting Delegation of Authority
7.6. Clinical Research Site SOP 12.00 - Informed Consent

8. ATTACHMENTS

None