**PURPOSE:** This SOP describes the standard procedures to be followed for the collection, transcription, and management of clinical research data to Case Report Forms (CRFs) at Kent State University.

**SCOPE:** This SOP applies to data management for all clinical trials involving human subjects at KSU.

**RESPONSIBILITY:** The delegation of responsibility for CRF completion by the investigator should be documented on the appropriate delegation of authority log. CRF completion should only be carried out by the investigator or qualified research team members listed on this form.

**DEFINITIONS:**

**Case Report Form (CRF):** A paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

**Data clarification form (DCF)**: A document that requests additional information and/or clarification of data entered on a specific case report form and with its completion with dated signature(s) serves as confirmation, clarification and/or correction of the original data entry.

**Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

**Good Documentation practices (GDP):** The practice of ensuring that source documents are reliable, accurate and adequate to help ensure that study results are built on the foundation of credible and valid data. ALCOA criteria are key attributes for good documentation practices.

**Quality Assurance (QA):** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

**Query**: Any question raised during the review of a particular entry on a case report form which is open to different interpretations including various data errors.

**Source Data**: All information contained in original records and certified copies of results, observations or other facets required for the reconstruction and evaluation of the research that is contained in source documents.

**Source Documents:** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the laboratories and departments involved in the clinical trial).

**PROCEDURE:**

1. Research staff members who complete CRFs and eCRFs must receive prior training either by the sponsor or research designee. Proof of individual staff training should be documented in training log.
2. Record all documentation in black ballpoint pen. Do not use pencils.
3. Ensure that all entries are accurate, legible, and verifiable with appropriate source documents. Ensure that entries are:

• Attributable: It should be obvious who wrote or did what.

• Legible: Can it be read? Never use pencils to record source documents, use dark colored ink. Avoid abbreviations.

• Contemporaneous: The information should be current and documented in the correct time frame.

• Original: Original or a certified copy or a printout from an electronic data source.

• Accurate: Consistent and real representation of facts. Are conflicting data recorded elsewhere? Content should precisely reflect the event being recorded.

• Available and accessible: Easily reviewable for review of treating physicians and during audits/inspections

• Complete

• Consistent: Demonstrates the required attributes consistently

• Corroborated: Backed up by evidence

• Credible: Based on real and reliable facts

• Enduring: Long-lasting and durable

1. As required by the protocol, remove patient identifiers from the source document copies and the CRF. Label these documents with the subject identification code as defined by the sponsor.
2. Complete all fields on the case report forms (CRF’s) according to sponsor specifications. If data are unavailable then write ‘unknown’, ‘not applicable’ or ‘missing’ on the CRF. Do not leave blank spaces.
3. Do not create additional fields on the CRF. Provide only requested information.
4. Correct an error by striking through the error without obliterating the original entry, dating and initialing it, and explaining the correction. Never use correction fluid or obliterate entries made on the CRF.
5. Ensure that data for the CRFs are transcribed promptly after the each subject visit and accurately from the source documentation. Institute quality assurance measures, such as “double checking” entries, to maximize efficiency and eliminate unnecessary data clarifications.
6. If the sponsor uses an eCRF system, ensure that data is entered promptly and accurately from the source documentation, according to sponsor specifications.
7. If the sponsor or CRO utilizes a DCF as the primary data clarification tool, the research coordinator or designee is responsible for clarifying discrepancies and documenting on the form accordingly.
8. CRFs should be stored in the Investigator site file during the course of the study and archived when the study has finished. See SOP 504: Archiving Study Records.
9. When all entries and corrections are deemed to be complete, the CRF must be signed by the principal investigator and/ or designee to assert that he/she believes it to be complete and correct.

|  |  |
| --- | --- |
| **REFERENCES:**  | 21 CFR 11 Electronic Records21 CFR 312.60 General responsibilities of investigators21 CFR 312.62 Investigator recordkeeping and record retentionFDA Information Sheets, October 1995 Recordkeeping in ClinicalInvestigationsGuidelines for the Monitoring of Clinical Investigations, January 1988International Conference on Harmonization; Good Clinical Practice:Consolidated Guideline, May 1997Delegation of Authority LogBargaje, C. (2011). Good documentation practice in clinical research. *Perspectives in Clinical Research*, *2*(2), 59–63. http://doi.org/10.4103/2229-3485.80368 |
| **RELATED POLICIES:**  | SOP 102: Training Clinical Research StaffSOP 103: Responsibilities of the Research TeamSOP 502: Source DocumentationSOP 504: Archiving Study Records  |
| **APPENDICES:**  |  |
| **REVISION HISTORY:** Keep a running history of all revision dates. |

|  |  |  |
| --- | --- | --- |
| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |
|  |  |  |
|  |  |  |