**PURPOSE:** The purpose of this SOP is to describe a standardized procedure for research personnel to record source data and manage source documents for clinical research studies conducted by Kent State University.

**SCOPE:** This SOP applies to the Investigator and designated research personnel who are responsible for maintaining source documentation.

**RESPONSIBILITIES:** Principal Investigators are responsible for ensuring that research personnel are appropriately delegated and trained on recording and categorizing data collected during the duration of the study on an approved source documents and in accordance with the sponsor, protocol, applicable regulations, laws and ICH guidelines.

**DEFINITIONS:**

**ALCOA Criteria:** Source data that should be attributable, legible, contemporaneous, original and accurate.

**Certified Copy:** A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.

**Case Report Form (CRF):** A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

**Good Documentation practices:** 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.

**Source Data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are 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 and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories involved in the clinical trial).

**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 Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

**PROCEDURE:**

1. Designated research personnel will prepare source documentation of every visit, conversation, and procedure associated with the clinical trial.

1. Research staff will capture data from the source document for every data point on the case report form (CRF), an important GCP rule.
2. Research staff will ensure that all data is verifiable and all documentation has an audit trail.
3. Qualified research personnel will apply the **ALCOA** standard to achieve data quality.
* **A**ttributable: It should be obvious who wrote or did what.
* **L**egible: Can it be read? Never use pencils to record source documents, use dark colored ink. Avoid abbreviations.
* **C**ontemporaneous: The information should be current and documented in the correct time frame.
* **O**riginal: Original or a certified copy or a printout from an electronic data source.
* **A**ccurate: Consistent and real representation of facts. Are conflicting data recorded elsewhere? Content should precisely reflect the event being recorded.

Other attributes of quality data include:

* 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. Research personnel will ensure that documentation such as study participant diaries are initialed or signed and dated by the person completing the form in order to be considered source documentation.
2. If the information recorded on the CRF is incorrect, incomplete, or otherwise deficient, research personnel may correct and/or complete by making an additional entry or addendum to the CRF. The corrected entry must be signed/initialed and dated in present time by person making the entry.
3. Research personnel must NOT modify past-dated source documentation in research records in an attempt to resolve deficiencies. Altering past-dated records is potentially fraudulent.
4. If it is noted in the research record that data are missing and those data are then obtained/found at a later date, study personnel will ensure that its incorporation in the research record is noted in the research record. The notation must be signed/initialed and dated.
5. Study staff will follow any source documentation procedures outlined in the protocol in addition to above procedures.
6. The Investigator and his/ her research team are strongly encouraged to perform intermittent internal QAs to identify incomplete/deficient source documentation.
7. Documents must be stored securely and with adequate protection of participant confidentiality for a period of at least 2 years after the last approval of a marketing application, until there are no pending or contemplated marketing applications… or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. (ICH E6, Section 4.9)

|  |  |
| --- | --- |
| **REFERENCES:**  | FDA Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance ICH E6WHO Handbook for Good Clinical Research Practice (GCP)Bargaje, C. (2011). Good documentation practice in clinical research. *Perspectives in Clinical Research*, *2*(2), 59–63. <http://doi.org/10.4103/2229-3485.80368> Source Documentation Checklist |
| **RELATED POLICIES:**  | SOP 402: Informed Consent ProcessSOP 405: Study VisitsSOP 204: Adverse event ReportingSOP 501: Case Report Form CompletionSOP 504: Archiving Study RecordsSOP 505: Printing and Certifying Medical Records  |