**GUIDANCE: Source Documents**

**Policy:**  Researchers must create and maintain source documents in compliance with Good Clinical Practice guidelines.

**Key Terms**

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

***Certified Copies*:** A copy that is certified to be an accurate and complete representation of the original document.

***Shadow Charts***: A chart made of certified copies of relevant sections of the original paper or electronic medical records.

***Source Data:*** All the information in original records and certified copies of clinical findings, observations or other activities in a clinical research that is necessary for the construction and evaluation of the research.

***Source Documents*:** Documents that contain original data/observations that accurately describe all of the conditions and events that occurred during the conduct of the study or as a result of study procedures are called source documents.

**Purpose of Source Documents:** The purpose of source documents is to document the existence of the research subject and substantiate the integrity of the research data collected. Source documents should include original documents related to the research, to medical treatment and to the history of the subject. Source data includes medical history information, medical examination results, lab results, demographic data, subject ID, drug or device dispensing information, informed consent, IRB approval, visit dates, concomitant medication, and intercurrent illnesses. Inadequate and inaccurate records represent the second most common finding in FDA’s GCP inspections of clinical investigators. (CDER Inspections in FY2008). Some examples of source documents are:

* hospital records,
* clinical and office charts,
* laboratory notes,
* subjects' diaries or evaluation checklists,
* pharmacy dispensing records,
* recorded data from automated instruments,
* copies or transcriptions certified after verification as being accurate copies,
* photographic negatives,
* microfilm or magnetic media,
* x-rays,
* subject files,
* records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the research.

**Recording Source Data:** Before initiation of the research, the research team should clearly identify the data and documents that will be maintained as source data and documents for the research. An important GCP rule is to have source data for every data point on the case report form.

***Flowsheets as Source Documents***: Research teams may develop flowsheets that correspond to data points on CRFs to ensure that source documentation is complete. When using flowsheets, there should be a provision to allow for free form entries. Flowsheet must be initialed (signed) and dated by the individuals responsible for entries. In this case, the flowsheets would be considered to be the source document. Some research teams upload these flowsheets into the patient’s electronic medical records or place a copy of the Flowsheet in the paper medical records. If the research team plans to upload flowsheets into the patient’s medical records, it is important to use ‘approved’ forms (e.g. progress notes) for creating these flowsheets, as medical records office may cull pages that are not in approved forms.

***Research Specific Medical Records***: Researchers teams may choose to maintain research specific information in a separate file from the medical records that contain information pertaining to the patient’s care. When two separate sets of records are maintained, the research team should ensure that the medical records have adequate information about the patient’s participation in the research study. This would differ based on the type of research. If the research involves an intervention, the medical records should have enough information for the other healthcare professionals caring for the patient to know about the affect of the patient’s participation on his/her health and treatment. Care should also be taken to ensure consistency when the information is present in both the research records as well as the patient’s medical records.

***Shadow Charts***: A research team may create a shadow charts for each research subject that contains certified copies of the relevant sections of medical records. When medical records are electronic, the research team may print relevant sections, sign and date them and maintain them in shadow charts. These shadow charts are kept along with other research files, rather than with the patients’ medical records. Even if the sponsor monitor or FDA inspector agrees to use shadow charts for monitoring, audits and inspections, they must be given access to the original medical records, if requested. The research team should ensure that shadow charts contain all the relevant pages from the medical records. The team should have a procedure that outlines which pages will be copied and how often. This is especially important if the research team plans to rely on the shadow charts for detecting adverse events.

***Multiple Source Data:*** Sometimes the same information may be recorded twice by two different individuals and this might result in a situation where the source data in the two source documents is not consistent. The research team should make an effort to ensure that this does not happen. For example, when part of a research study is being conducted in the CRU, the CRU may maintain certain data to be compliant with their own policies and procedures. Before the research begins, the research team and the CRU staff should determine which records will be considered source documents for the research study. This should be documented for future reference.

***CRF as Source Document:*** Research teams may choose to record information directly in the CRF, in this case, there should be clear documentation identifying the data directly recorded in the CRF as source data. Photocopies of completed CRF pages are not considered valid source documents. Some research teams may file original completed CRF with the medical records. In this case, the CRF is a valid source document.

**Data Quality:** Source documents should be labeled with at least one identifier such as hospital identification number, medical record number, patient identification number or full name. The ALCOA criteria provide guidance on creating good quality source documents. The ALCOA criteria are:

* *Attributable*: Sign/initial and date each time a new entry is made.
* *Legible*: Never use pencils to record source documents, use dark colored ink. Avoid abbreviations.
* Contemporaneous: Data should be current and entered in the right time frame.
* Original: The place where the source data was first recorded.
* Accurate: Data should be correct.

The research team should ensure that source documents and CRFs are complete. Data should be reported to the sponsor in the CRFs and in all required reports in a timely manner. Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained in a Note to File.

**Certified Copies:** Theresearch team should have a procedure for certifying copies of original source documents. The person who certifies the copy as accurate and complete representation of the original should be the same person who made the copy from the original. This person should either initial and date each page of the document copied or initial and date one page that certifies that all the pages of the copied document are an accurate and complete representation of the original document.

**Source Data Corrections**: Any change or correction to source data should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained). This applies to both written and electronic changes and corrections. The amended record should include:

* the old value,
* the new value,
* the date of the change and
* the initials of person making the change.

If source documentation is incomplete, or otherwise deficient, it may be completed by making an additional entry or addendum to the source documentation. The later entry must be signed/initialed and dated. All addenda must be signed and dated in present time by the person making the entry. Research teams should not modify past-dated source documentation in research records in an attempt to resolve deficiencies.

**Summary:** In summary, it is best for the research team to follow their standard practice for recording source data and maintain source documents. FDA has advised research sites to use standard office medical records over a form that is research specific and likely to be unfamiliar to the research team. Once a record keeping practice that the research team is most comfortable with has been chosen, the same practices for recording source data should be used consistently by the entire research team. Sometimes industry monitors may insist on their way of recording information in source documents, research teams should negotiate with them to adhere to their own method for source documentation.

**Retention of Source Documents:** Source documents must be retained according to the institutional policy. (*Guidance Records Retention*). The research team should ensure that medical records retained by the institution’s medical records office are maintained for the required period of time and are accessible when needed for audits and inspections.

**Applicable Regulations and Guidelines**

* Requirements for Source Documents in DAIDS Funded and/or Sponsored Clinical Trials (Feb 2007).
* ICH Good Clinical Practice Guideline
* Stan W. Woollen, Deputy Director, Division of Scientific Investigations, FDA, DIA Annual Meeting, Jun 1999.
* Good Clinical Practice: A Question and Answer Reference Guide, Ed. Mark P.Mathieu, May 2009.

**Applicable Institutional Policies and Procedures**

* Records Retention

**Attachments**

* Template for Flowsheet
* Template for Note to File

**If you find errors in this document, contact** [**clinicaltrials@uth.tmc.edu**](mailto:clinicaltrials@uth.tmc.edu)

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