Source Documents

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What is a Source Document?

Put simply, source documents are the evidence that verifies that study data are accurate.

Examples of Source Documents include:

- **Original forms:** a follow-up survey or a drug diary that the study participant fills out
- **Certified records:** a printout from an Electronic Medical Record
- **Original data:** a laboratory results report
- **Signed written notes:** items signed by an approved study personnel

Sponsors can vary as to what they consider a source document. Check with your protocol, study monitor, or sponsor representative to see what you should be collecting.

Source Document Collection

Source Documents are collected as part of the research subject record. In most cases, the documents are filed into a subject binder. Some find it helpful to use dividers to separate source documents by subject encounter.

The subject binders are then used by Clinical Research Associates (also called Study Monitors) as they verify the accuracy of the study data. In addition to the subject binder, your study monitor may also request access to the Electronic Medical Record as part of the source document verification process.

The study monitor may request a copy of select source documents (e.g., a progress note related to an Adverse Event). For any Source Documents removed from the research site, ensure that any Personal Health Information (PHI) is redacted and replaced with the research subject number (or other identifier).

Subject binders should remain with the study team throughout the duration of the research study. Check with the IRB regarding appropriate storage and archival of these documents after the close of the study.

Why collect Source Documents when data is reported in the Electronic Data Capture software?

One major reason is that mistakes occur when transcribing or translating data, so it is important to have original records to verify the accuracy of the study data.

Source Documents are also an important component of Good Clinical Practice (GCP) requirements. GCP outlines two important reasons for the collection of source documents:

1. Document the existence of study participants in order to prevent research misconduct
2. Substantiate the integrity of the study data collected

IGH Glossary Definitions

View the entire glossary.

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 (original records or certified copies). [ICH 1.51]

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 pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). [ICH 1.52]