

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Source Documentation Requirements	
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Applicable Regulations & Guidelines: ICH GCP Guidelines
21 CFR Parts 11, 50, 56, and 312

Other References: CTEO Tip Sheet on Good Study Documentation Practices

Responsible Personnel: Investigators, study staff (study coordinators, regulatory affairs coordinators, and research nurses), pharmacists

Policy Statement: All study data must be verifiable from the written source documentation that meets DF/HCC standards.

Definitions:

Source Document: Original documents, data, and records.

Source Data: All information in original records or 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 the source documents.

Certified Copy: A certified copy is a copy of original information that has been verified as being an exact copy, i.e., having all of the same attributes and information as the original.

Procedure:

- 1) Prepare source documentation of every visit, conversation, and procedure associated with the clinical trial.
- 2) Apply the **ALCOA*** standard to achieve data quality.
 - a. **Attributable:** It should be obvious who wrote or did what.
 - b. **Legible**
 - c. **Contemporaneous:** The information should be current and documented in a timely manner.
 - d. **Original:** Original or a certified copy (as defined above) or a printout from an electronic data source.
 - e. **Accurate:** Content should precisely reflect the event being recorded

* Source: "The Facts About Source Documents" by Stan W. Woollen, Presented at the 1999 DIA Annual Meeting

- 3) Documentation such as study participant diaries must be initialed or signed and dated by the person completing the form in order to be considered source documentation.
- 4) In addition to the above requirements for source documentation, refer to any source documentation procedures outlined in the protocol and follow them.
- 5) Local, state, institutional review board/independent ethics committee policies and procedures must be followed if they are more stringent than the DF/HCC Clinical Research Policy.

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