

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4008.00
	Requirements for Source Documentation in DAIT Funded and/or Sponsored Clinical Research	Page 1 of 4
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1.0 PURPOSE

The purpose of this policy is to provide guidance to research personnel about the Division of Allergy, Immunology, and Transplantation (DAIT) requirements for documentation of the source of data collected during the conduct of clinical research. Documentation of source data is necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities during a clinical research study.

2.0 SCOPE

This policy applies to anyone who has been delegated responsibilities for acquisition and documentation of data collected for all DAIT funded and/or sponsored clinical research.

3.0 BACKGROUND

Source documentation serves to substantiate the integrity of research data and to confirm observations that are reported. This policy also serves to ensure data quality by creating audit trails and enabling verification that data are present, complete, and accurate.

This policy is based upon 1) the Code of Federal Regulations (CFR); 2) U.S. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), and National Institutes of Health (NIH) guidance applicable to the involvement and protection of human subjects in clinical research; and 3) International Conference on Harmonisation (ICH E6) standards for good clinical practice (GCP).

4.0 DEFINITIONS

Audit Trail: Documentation that allows reconstruction of the course of events. (ICH E6)

Case Report Form (CRF): A printed, optical, or electronic document designed to record information to be reported to the sponsor on each trial subject. (ICH E6)

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms)

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that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken. (ICH E6)

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in clinical research necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies). (ICH E6)

Source Documents: Original documents, data, and records (e.g., case report forms, 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, and at medico-technical departments involved in the clinical research). (ICH E6)

5.0 RESPONSIBILITIES

DAIT is responsible for maintaining detailed documentation standards for all of its funded and/or sponsored clinical research. It is the responsibility of DAIT to assist and provide guidance to clinical research site staff regarding recordkeeping and retention, as needed.

The Principal Investigator is responsible for ensuring that all clinical research site personnel who have been delegated responsibilities for acquisition and documentation of data collected for DAIT funded and/or sponsored clinical research are trained in and comply with this GCP standard.

It is the responsibility of the Principal Investigator or designee and site research personnel to maintain records consistent with this policy, and federal, state, and local regulations, as applicable.

6.0 POLICY

6.1 All data elements collected for a given research study must be verifiable from a source document. As an example, documentation of the informed consent process for research subjects is necessary.

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- 6.2 There should be no loss of quality when an electronic system is used in place of a paper system.
- 6.3 Source documentation requirements for DAIT funded and/or sponsored clinical research are updated as necessary.
- 6.4 Local, state, institution, and institutional review board (IRB)/independent ethics committee (IEC) policies and procedures must be followed.
- 6.5 Source documentation will be original, attributable, legible, contemporaneous and accurate.
- 6.6 Source documents shall be retained and stored in accordance with applicable regulations.

7.0 REFERENCES

International Conference on Harmonisation E6: Good Clinical Practice: Consolidated Guidelines
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm>

U.S. Code of Federal Regulations Title 45 Part 46, and Subpart D
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>

U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 56, and 312
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the DAIT Clinical Research Operations Program (CROP) Policy Group at:
NIAIDCROPPolicyGroup@niaid.nih.gov

9.0 AVAILABILITY

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This policy is available electronically at
<http://www.niaid.nih.gov/LabsAndResources/resources/DAITClinRsrch/Pages/default.aspx>

10.0 CHANGE SUMMARY

This policy is the first version: it does not supersede any other version.

11.0 APPENDICES

None.

12.0 APPROVAL

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