

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 1 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

1.0 PURPOSE

The purpose of this policy is to identify the Division of Allergy, Immunology and Transplantation (DAIT) requirements for recordkeeping at sites conducting clinical research funded and/or sponsored by DAIT.

2.0 SCOPE

This policy applies to all sites conducting DAIT funded and/or sponsored clinical research, both domestic and internationally.

3.0 BACKGROUND

Essential documents serve to demonstrate compliance with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. These document files may be audited by the sponsor and regulatory authorities to confirm the validity of the clinical research conduct and integrity of the data. This policy is based on: 1) the U.S. Code of Federal Regulations (CFR), 2) regulatory guidance that applies to the involvement of human subjects in clinical research, and 3) other standards for GCP, including the International Conference on Harmonisation (ICH E6).

4.0 DEFINITIONS

Clinical research: Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include *in vitro* studies using human tissues not linked to a living individual. Studies falling under [45 CFR 46.101\(b\) \(4\)](#) are not considered clinical research for purposes of this definition. The [NIH](#) definition of clinical research is research conducted on human subjects or on material of human origin identifiable with the source person. (NIH)

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 2 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

Clinical Research Site(s): Discrete locations (e.g., hospitals, outpatient clinics, health maintenance organizations, community health centers, private practices, clinics, etc.) where qualified professionals conduct clinical research in accordance with Good Clinical Practices. (DAIT)

Essential Documents: Documents (records, reports) that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. (ICH E6)

5.0 RESPONSIBILITIES

5.1 DAIT, Principal Investigators and their respective delegates (e.g., clinical research staff, contractors, and grantees) are required to comply with GCP, ICH E6, the CFR, and all DAIT policies.

5.1.1 It is the responsibility of DAIT program staff to assist and provide guidance to grantees and site staff regarding recordkeeping and retention as appropriate.

5.1.2 It is the responsibility of the Principal Investigator to ensure the site staff is trained in GCP to include record retention, and that clinical research sites conducting clinical trials sponsored and/or funded by DAIT adhere to this policy.

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

6.0 POLICY

6.1. All DAIT funded and/or sponsored clinical research sites will collect and store records (e.g., documents) in compliance with GCP, ICH E6, and the CFR.

6.2 ICH E6 GCP guidance details essential documents that must be on file at each site 1) before any clinical research can open, 2) during the conduct of the research, and 3) after completion and termination of the clinical research study.

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 3 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

6.3 Additional required essential documents include:

6.3.1 Federalwide Assurance (FWA) Number ([45 CFR 46.103](#)).

6.3.2 DAIT Protocol Approvals (e.g., DAIT Medical Officer and Regulatory Officer sign-off/approval of clinical research protocol, consent/assent documents, and other relevant documents).

6.3.3 DAIT Financial Disclosure form or 1) consortium-specific 2) network-specific Conflict of Interest (COI) form.

6.3.4 DAIT Investigator of Record Agreement form (for non-Investigational New Drug (IND) studies) or U.S. Food and Drug Administration (FDA) Form 1572 (for IND studies).

6.3.5 Institutional review board (IRB)/independent ethics committee (IEC) initial and continuing review/approval of the protocol and informed consent documents.

6.3.5.1 The continuing review and approval of the research must be substantive and meaningful, and at least annual (and more frequent, if required) 45 CFR 46.103(b) (4); 45 CFR 46.108(b); 45 CFR 46.109(e); 45 CFR 46.111; 46.115(a) (2); for FDA regulated clinical investigations, 21 CFR 50 and 21 CFR 56).

6.3.6 Site Clinical Research Staff Training documents: GCP Training, Ethics Training, and Site Initiation Protocol-specific Training.

6.3.7 Additional DAIT documents are protocol dependent. Contact DAIT for additional information on unique research requirements.

6.4 The essential documents should be set up in a secure central location at the beginning of the clinical research and maintained throughout the study. It is acceptable to combine some of the documents, as long as the individual elements are readily identifiable. Documents may be saved in an electronic format when appropriate.

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 4 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

- 6.5 All electronic and hard copy (e.g., paper) documents identified in this policy must be available for audit/inspection by the sponsor and regulatory authorities.
- 6.6 In addition to DAIT requirements, clinical research sites are expected to comply with local, state, institution, and/or IRB)/IEC policies and regulations and follow any procedures that are more stringent than those of DAIT.
- 6.7 Timelines for record retention established in U.S. Federal regulations such as 45 CFR 46.115, 21 CFR 312.57 and 312.62 are considered minimum durations and are frequently superseded by other policies. Retention or destruction of essential documents must be in accordance with local institution/IRB/IEC policies and procedures. No clinical research files should be destroyed without consulting DAIT and current DAIT policy.
- 6.8 Contact DAIT for additional information and guidance on essential documents recordkeeping at clinical research sites.
- 6.9 For IND studies, the DAIT Regulatory Officer will provide detailed instructions on essential documents recordkeeping.
- 6.10 Refer to Section 7.0, References, for URLs where more comprehensive guidance on compliance with GCP, ICH E6, and the CFR is available.

7.0 REFERENCES

Glossary & Acronym List, Office of Extramural Research, National Institutes of Health, U.S. Department of Health & Human Services

<http://grants.nih.gov/grants/glossary.htm>

International Conference on Harmonisation E6: Good Clinical Practice: Consolidated Guidelines

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm>

Office for Human Research Protections (OHRP)

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 5 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

Code of Federal Regulations, Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Federalwide Assurances, IRB/IEC Registration and Assurances

<http://www.hhs.gov/ohrp/assurances/assurances/index.html>

Guidance on Continuing Review, OHRP, Department of Health and Human Services

<http://www.hhs.gov/ohrp/policy/index.html>

U.S. Code of Federal Regulations (CFR), Title 21, Parts 11, 50, 54, 56, and 312 and search URL for CFR Title 21 Database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

U.S. Code of Federal Regulations, Title 45, Part 46 and Subpart B

Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>

Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

U.S. Code of Federal Regulations, Title 45, Part 46 and Subpart C

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>

Additional Protections for Children Involved as Subjects in Research

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. Food and Drug Administration (FDA)

<http://www.fda.gov/>

8.0 INQUIRIES

DAIT, NIAID, NIH Bethesda, MD USA	POLICY	DAIT CRS POL No.: 4007.00
	Requirements for Essential Documents at Clinical Research Sites Conducting DAIT Funded and/or Sponsored Clinical Research	Page 6 of 6
	Approval Date: 1 Oct 2015 Effective Date: 1 Oct 2015	

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

9.0 AVAILABILITY

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

Jennifer S. Read, MD, MS, MPH, DTM&H
Director, Clinical Research Operations Program, DAIT, NIAID, NIH