

|                              |  |                       |
|------------------------------|--|-----------------------|
| DAIDS<br>Bethesda, MD<br>USA | <b>POLICY</b>  | No.: DWD-POL-CL-04.00 |
|                              | Requirements for Source Documentation<br>in DAIDS Funded and/or Sponsored<br>Clinical Trials | Page 1 of 4           |
|                              | Approval Date: 20 DEC 06<br>Effective Date: 05 FEB 07  | Replaces: V 1.0       |

## 1.0 PURPOSE

The purpose of this policy is to provide guidance to research personnel about The Division of Acquired Immunodeficiency Syndrome (DAIDS) requirements for documentation of the source of data collected during the conduct of clinical trials. Documentation of source data is necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities during a clinical trial.

## 2.0 SCOPE

This policy applies to any staff member who has been delegated responsibilities for acquisition and documentation of data collected for all DAIDS funded and/or sponsored therapeutic, vaccine, or prevention clinical trials both domestic and international.

## 3.0 BACKGROUND

Source documentation serves to substantiate the integrity of trial data, confirm observations that are recorded, and confirm the existence of subjects. This policy also serves to ensure data quality by creating audit trails and enabling verification that data are present, complete, and accurate. In multi-site clinical trials it is important for documentation of source data to be standardized across all clinical research sites to ensure consistency of the trial data. 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

**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).

**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 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 trial).

|                              |  |                       |
|------------------------------|--|-----------------------|
| DAIDS<br>Bethesda, MD<br>USA | <b>POLICY</b>  | No.: DWD-POL-CL-04.00 |
|                              | Requirements for Source Documentation<br>in DAIDS Funded and/or Sponsored<br>Clinical Trials | Page 2 of 4           |
|                              | Approval Date: 20 DEC 06<br>Effective Date: 05 FEB 07  | Replaces: V 1.0       |

For additional definitions see DAIDS glossary.

## 5.0 RESPONSIBILITIES

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

The Principal Investigator is responsible for ensuring that all clinical research site personnel involved in the conduct of the trial are trained in GCP. All clinical research sites under the Principal Investigator's direction must adhere to this policy for studies funded and/or sponsored by DAIDS.

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

## 6.0 POLICY

- 6.1. All data must be verifiable from the written source documentation that meets DAIDS standards.
- 6.2. Source Documentation Requirements for DAIDS funded and/or sponsored clinical trials are updated as necessary and available in Appendix 1 and on the NIAID website "DAIDS Clinical Research Policies and Standard Procedures."
- 6.3. Local, state, institution, institutional review board (IRB)/independent ethics committee (IEC) policies and procedures must be followed if they are more stringent than the DAIDS Policy.
- 6.4. The "**ALCOA**"\* method should be applied to help achieve and maintain data quality:
  - 6.4.1. **Attributable**: is it obvious who wrote it?
  - 6.4.2. **Legible**: can it be read?
  - 6.4.3. **Contemporaneous**: is the information current and in the correct time frame?
  - 6.4.4. **Original**: is it a copy; has it been altered?

|                              |  |                       |
|------------------------------|--|-----------------------|
| DAIDS<br>Bethesda, MD<br>USA | <b>POLICY</b>  | No.: DWD-POL-CL-04.00 |
|                              | Requirements for Source Documentation<br>in DAIDS Funded and/or Sponsored<br>Clinical Trials | Page 3 of 4           |
|                              | Approval Date: 20 DEC 06<br>Effective Date: 05 FEB 07  | Replaces: V 1.0       |

6.4.5. **Accurate:** are conflicting data recorded elsewhere?

\*Source: The facts About Source Documents” by Stan W. Woollen, Presented at the 1999 DIA Annual Meeting

**7.0 REFERENCES**

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

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>

International Conference on Harmonisation Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidelines  
<http://www.fda.gov/oc/gcp/guidance.html>

**8.0 INQUIRIES**

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: [NIAIDOPCROPOLICYGROUP@mail.nih.gov](mailto:NIAIDOPCROPOLICYGROUP@mail.nih.gov)

**9.0 AVAILABILITY**

This policy is available electronically at the following URL:  
<http://www3.niaid.nih.gov/research/resources/DAIDSCLinRsrch/Default.htm>

The signed original is maintained in the OPCRO policy office.

**10.0 CHANGE SUMMARY**

| Version # | Date      | Replaces | Date of Revision | Rationale for Revision/Retirement |
|-----------|-----------|----------|------------------|-----------------------------------|
| 2.0       | 20 DEC 06 | V 1.0    | 20 DEC 06        | DAIDS Final Review                |
| 1.0       | 14 JUL 06 | N/A      | N/A              | N/A                               |

|                              |  |                       |
|------------------------------|--|-----------------------|
| DAIDS<br>Bethesda, MD<br>USA | <b>POLICY</b>  | No.: DWD-POL-CL-04.00 |
|                              | Requirements for Source Documentation<br>in DAIDS Funded and/or Sponsored<br>Clinical Trials | Page 4 of 4           |
|                              | Approval Date: 20 DEC 06<br>Effective Date: 05 FEB 07  | Replaces: V 1.0       |

## 11.0 APPENDICES

Appendix 1 - DAIDS Source Documentation Requirements

## 12.0 APPROVAL

| Signature   | Program/Branch  | Date                     |
|---|---|--------------------------|
| Authorized By: <u><i>Richard Hafner</i></u><br>Richard Hafner, MD<br>Director | Office for Policy in<br>Clinical Research<br>Operations (OPCRO) | <u>December 20, 2006</u> |

Archived