

Policy
Requirements for Essential Documents for DAIDS Sponsored Network Clinical Trials

Effective Date: 06/15/21

Document No.: **POL-A15-OPC-019.00**

1.0 PURPOSE

1.1 The purpose of this policy is to provide guidance to DAIDS' collaborators about the requirements for essential documents collected during the conduct of Division of Acquired Immunodeficiency Syndrome (DAIDS)-Sponsored clinical trials conducted by the DAIDS Clinical Trial Networks (Network Trials).

2.0 SCOPE

2.1 This policy applies to all DAIDS' collaborators who have responsibility for creation, collection, documentation, maintenance, and storage of all data and documents collected for DAIDS-Sponsored Network trials. Specific requirements for DAIDS' Network clinical research sites are defined in the DAIDS SCORE Manual.

3.0 DEFINITIONS

For additional definitions, see [DAIDS glossary](#).

3.1 **Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. (see section 8. "Essential Documents for the Conduct of a Clinical Trial"). (ICH E6 R2 section 1.23). Essential documents are necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities during a clinical trial. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

4.0 RESPONSIBILITIES

4.1 Contractor and Grant Recipients:

The recipient of the contract or grant award (awardee) and the recipients of their sub-awards are responsible for ensuring that,

4.1.1 there are documented procedures in place on requirements for essential documents.

4.1.2 all staff involved in the conduct of DAIDS-Sponsored clinical research are trained in GCP and Good Documentation Practice as well as on the institutional SOP for essential documents.

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4.1.3 Essential documents are created, collected, documented, maintained, and stored consistent with this policy, and all applicable federal, state and local regulations, as well as applicable guidelines.

5.0 POLICY

- 5.1 All Essential documents must be collected, documented, maintained, and stored in compliance with all applicable laws, regulations, guidelines and NIH, NIAID and DAIDS policies.
- 5.2 When multiple sets of requirements apply, the most stringent of the applicable laws, regulations, policies and guidelines must be followed.
- 5.3 As applicable, documentation must be verifiable from the source documentation.
- 5.4 The "ALCOA+" method, (attributable, legible, contemporaneous, original, and complete, consistent, enduring, and available), should be applied to help achieve and maintain the quality of essential documents.

6.0 REFERENCES

- 6.1 [U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 56, and 312](#)
- 6.2 [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6\(R2\)](#)

7.0 APPENDICES

Not Applicable

8.0 REVISION HISTORY

- 8.1 POL-A15-OPC-019.00 is the initial version of the Essential Documents Policy in the DAIDS QMS as version 00. There was one previous version of the Essential Documents Policy, version 1.0 dated December 2006, published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.