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1.0 PURPOSE

1.1 This policy describes guidance to contractors and grant recipients 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.

2.0 SCOPE

2.1 This policy applies to all contractors and grant recipients 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**: Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. (ICH E6)

4.0 RESPONSIBILITIES

4.1 Contractors 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 standard operating procedures (SOPs) 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.

4.1.3 all essential documents are created, collected, documented, maintained, and stored consistent with this policy, and all applicable federal, state, and local regulations, as well as other 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, accurate, complete, consistent, enduring, and available) should be applied to help achieve and maintain the quality of essential documents.

6.0 REFERENCES

6.1 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11U.S. Code of Federal Regulations, Title 21, Part 11

6.2 U.S. Code of Federal Regulations, Title 21, Part 50

6.3 U.S. Code of Federal Regulations, Title 21, Part 56

6.4 U.S. Code of Federal Regulations, Title 21, Part 312

6.5 Integrated Addendum to the ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

7.0 APPENDICES

Not Applicable

8.0 REVISION SUMMARY

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 2008, published othe DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.

8.2 DAIDS-OPC-A15-POL-00019 rev 01 is the first revision of this policy in MasterControl. The document format and document numbering were updated to reflect current requirements. The policy was also modified to: 1) replace the term "DAIDS Collaborator" with "contractors and grant recipients", 2) revise definition for "Essential Documents" to be consistent with the updated DAIDS Policy Glossary, 3) revise links to references.