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1.0 PURPOSE

1.1 This policy describes the requirements for Investigators to acknowledge, review, verify, and sign-off on the clinical trial data from NIAID/DAIDS Network studies, that are entered into electronic Case Report Forms (eCRFs) in accordance with regulatory requirements and Good Clinical Practice (GCP) guidelines. Delays in eCRF sign-off may impact data quality, analysis timelines, and regulatory compliance.

2.0 SCOPE

2.1 This policy applies to clinical trial data generated at the clinical research site (CRS) and eCRFs for NIAID-supported, including DAIDS-sponsored, clinical trials within the NIAID/DAIDS Network studies.

3.0 DEFINITIONS

For additional definitions, see DAIDS glossary

4.0 RESPONSIBILITIES

4.1 **Sponsor**: The sponsor requires investigator endorsement of their clinical trial data at predetermined milestones.

4.2 **Data Management Center (DMC):** The Data Management Center establishes the procedures for Investigator sign-off on eCRFs.

4.3 **Investigator:** The Investigator is responsible for timely review and sign-off of the eCRFs to ensure accuracy, and completeness, in compliance with the protocol and regulations.

5.0 PROCEDURE

5.1 The Investigator must review and sign-off on protocol eCRF data on a quarterly basis, prior to interim analyses, and the final analysis. Important data related to, for example, reporting of serious adverse events (SAEs), adjudication of important events and endpoint data, must be signed-off in a timely manner throughout the study

6.0 REFERENCES

6.1 DAIDS SCORE Manual

6.2 ICH E6 (R2) Good Clinical Practice: Integrated Addendum to International Conference of Harmonization

6.3 https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf

6.4 https://www.gmp-compliance.org/gmp-news/ema-clarifies-investigators-responsibilities-regarding-the-ecrf

6.5 Form FDA 1572:

6.6 DAIDS-OPC-A15-POL-00019, Requirements for Essential Documents for DAIDS Sponsored Network Clinical Trials

7.0 APPENDICES

Not applicable

8.0 REVISION SUMMARY

8.1 DAIDS-OD-A-POL-00014 rev 01 is the original version of this policy.