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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-funded/sponsored, clinical trials within the NIAID/DAIDS Networks. The policy does not apply to observational, cohort, or biobanking studies, as determined by DAIDS.

3.0 DEFINITIONS

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

4.0 RESPONSIBILITIES

- 4.1 **Sponsor:** DAIDS as the funder and/or regulatory sponsor of applicable Network trials is responsible for overall oversight of the policy implementation. Roles and responsibilities of specific DAIDS staff will be the following:
- 4.1.1 DAIDS Network Leadership Program Officers (NLGPOs): The NLGPOs will be responsible for providing guidance to the Network Leadership and Operations Center (LOCs) and the Data Management Centers (DMCs) on the implementation of the policy.
 - 4.1.2 DAIDS Office of Clinical Site Oversight Program Officers (OCSO POs): The OCSO POs will serve as an escalation pathway for the Data Management Centers (DMC) regarding non-compliant sites, and follow-up with sites upon notification of escalation by the DMC.
 - 4.1.3 DAIDS RSC: The RSC will disseminate the policy to their sites and the Data Management Centers.
- 4.2 **Data Management Center (DMC):** The DMCs will establish the procedures for Investigator sign-off on eCRFs, communicate site-facing procedures to the clinical research sites, and will actively monitor site compliance with eCRF sign-off. The DMC will escalate site non-compliance with the eCRF policy to the OCSO PO in accordance with DMC procedures.
- 4.3 **Investigator of Record (IoRs) or Designee:** The IoRs or their designees will be responsible for timely review and sign-off of the eCRFs to ensure accuracy, and completeness, in compliance with the protocol and regulations.

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5.0 POLICY

- 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 \(R3\) Harmonized Guidelines for Good Clinical Practice](#)
- 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-ecrfregarding-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.
- 8.2 DAIDS-OD-A-POL-00014 rev 02 – 21 March 2025 to update the Responsibilities, Scope, and References sections of the document.