

Site Clinical Operations and Research Essentials (SCORE) Manual Policy

Effective Date: 01/26/21

Document No.: POL-A28-OCS-003.00

1.0 PURPOSE

1.1 This policy describes the requirement for clinical research sites (CRSs) participating in DAIDS sponsored clinical research conducted by DAIDS Clinical Trials Networks to comply with the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual. The SCORE Manual defines sponsor procedural requirements and facilitates consistency in clinical site implementation and operations in conjunction with DAIDS clinical research policies and procedures, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines, and applicable regulatory requirements.

2.0 SCOPE

2.1 The policy applies to all DAIDS CRSs participating in DAIDS sponsored clinical research conducted by DAIDS Clinical Trials Networks.

3.0 DEFINITIONS

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

4.0 RESPONSIBILITIES

4.1 Investigator of Record (IoR)/Principal Investigator (PI):

For a given protocol, the IoR/PI is responsible for ensuring that all applicable personnel at the CRS review and comply with the SCORE Manual.

4.2 CRS Leader:

The CRS Leader is responsible for overall oversight of site compliance, day to day operations, and performance of the CRS.

4.3 CRS Staff:

CRS Staff must review and comply with the requirements outlined in the SCORE manual.

5.0 POLICY

5.1 All CRS Staff must comply with the requirements outlined in the SCORE manual.

5.2 In addition to adhering to the SCORE Manual and Network requirements, CRS staff must comply with all DAIDS policies and procedures as well as the regulations and requirements noted below. When multiple requirements apply, the most stringent of any of the requirements, processes, and/or procedures must be adhered to.

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- 5.2.1 All DAIDS-supported clinical research, including DAIDS-Sponsored clinical research is subject to the U.S. Department of Health and Human Services (HHS) regulations delineated in 45 CFR 46.
- 5.2.2 All clinical research that meets the NIH definition of a clinical trial should follow ICH E6 and all applicable NIH, NIAID and DAIDS policies and procedures.
- 5.2.3 Clinical research subject to U.S. Food and Drug Administration (FDA) regulations must adhere to the applicable FDA regulatory requirements.
- 5.2.4 Clinical research subject to a non-US regulatory authority (e.g., EMA, SAHPRA, etc.), must adhere to the applicable national regulatory authority requirements.

6.0 REFERENCES

- 6.1 [DAIDS Site Clinical Operations and Research Essentials \(SCORE\) Manual](#)
- 6.2 [DAIDS Clinical Research Policies and Standard Operating Procedures](#)
- 6.3 ICH/GCP Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)
- 6.4 [21 CFR part 11 \(Electronic Records; Electronic Signatures\)](#)
- 6.5 [45 CFR part 46 \(Protection of Human Subjects\)](#)
- 6.6 [21 CFR part 50 \(Protection Of Human Subjects\)](#)
- 6.7 [21 CFR part 54 \(Financial Disclosure By Clinical Investigators\)](#)
- 6.8 [21 CFR Part 56 \(Institutional Review Boards\)](#)
- 6.9 [21 CFR 312 \(Investigational New Drug Application\)](#)

7.0 APPENDICES

Not applicable

8.0 REVISION HISTORY

- 8.1 POL-A28-OCS-003.00 is the original version of this policy.