Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

List of Standard Operating Procedures Required at DAIDS Clinical Research Sites

Area	Standard Operating Procedures (SOP)	Office of Clinical Site Oversight (OCSO) Approval Required [1]
Regulatory	Personnel Qualifications	
	Personnel Training and Certification Documentation	
	Communication with Institutional Review Board (IRB)/Ethics Committee (EC) and Regulatory Authorities	
	Informed Consent/Assent Development	
	Essential Documents	
	Equipment Maintenance and Calibration	
	Retention of study records including electronic records - long term storage	
Participant Management or Clinical	Informed Consent/Assent Process and Documentation	Yes
	Process for Enrolling Children and Adolescents into DAIDS Clinical Research (if applicable)	Yes
	Clinical Research Site (CRS) Process to Verify Participant Age and Identity[2]	
	CRS Process to Identify and Prevent Co-Enrollment [2]	
	Source Documentation	
	Confidential Human Immunodeficiency Virus (HIV) Counseling and Testing Procedures (if applicable)	
	Unblinding for Safety (blinded trials)	
	Basic Infection Control Practices	
	Emergency Management	
Safety and Assessment	Reporting Adverse Events	
	Reporting Expedited Adverse Events (EAEs) or Serious Adverse Events (SAEs) to DAIDS	

Area	Standard Operating Procedures (SOP)	Office of Clinical Site Oversight (OCSO) Approval Required [1]
Laboratory Management	Biohazard Safety and Containment and Occupational Safety	
	Laboratory Data Management and Storage	
	Laboratory Quality Management Plan (Non-United States sites)	
	Specimen Acquisition, Processing, Tracking, and Storage Lost, Broken, and Leaking Samples Receipt and Processing all Samples	
	Specimens Chain of Custody (if applicable)	
	Specimen Transport Shipping Specimens Locally Shipping Specimens Internationally	
Clinical Site Data Collection and Reporting	Access and Authentication	
	Data Collection and Handling	
Pharmacy	Pharmacy Quality Management Plan	
Site Monitoring	Review and Follow-up of Monitoring Report Findings	
Quality Management	SOP Development and Version Control	
	Clinical Quality Management Plan (CQMP)	Yes
	CRS Regulatory Inspection Preparation	Yes
	Vendor Management (if applicable)	

NOTE: In some cases, institutional policies and procedures may satisfy some of the DAIDS Required SOPs. Sites should consult their OCSO PO on a case-by-case basis.

1. DAIDS OCSO review and approval is required for initial version of these SOPs and also for any substantial revisions, including any change in site procedure or policy, but would not include minor typographical, grammatical, or administrative changes.

2. SOP must be submitted to and approved by **local** IRB/EC before implementation. Documentation of approval should be kept on file at the site. If IRB/EC will not review, site should keep documentation of the IRB/EC review decision with the SOPs. Please see SCORE manual section Screening, Enrollment/Randomization, and Unblinding of Participants and the appendices for more information about these SOPs, the requirement to submit to the IRB, and template letters to the IRB.

Version History

V1.0	1/19/2021	Original Version
V2.0	6/30/2021	Removed 8 SOPs as required from the Clinical Site Data Collection and Reporting section, leaving two required SOPs in that section. Removed Electronic Systems section.
V3.0	8/27/2021	Added Co-Enrollment Prevention SOP.
V4.0	11/04/2024	Noted the new requirement for 4 SOPs submitted to DAIDS to also be submitted in the future for any substantial changes. Added note about submitting two SOPs to local IRBs for approval.