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
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	
	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
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	System Set-up and Installation	
	Security	
	Access and Authentication	
	Information Security	
	Data Collection and Handling	
	Change Control	
	Data Collection Training	
	Data Integrity	
	System Maintenance	
	Data Back-up, Recovering and Contingency Plans	
	Randomization Procedures	
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)	
Electronic Systems	Use of Electronic Systems	