REQUIRED SITE SOPS

The following Standard Operating Procedures (SOPs) are required prior to the initiation of a clinical trial. Appendix 2 is a Sample Table of Contents that includes these as well as other policy, procedure, and study information that may be included in a MOP.

ADMINISTRATIVE

- SOP Development and Version Control
- Personnel Qualifications
- Personnel Training and Certification Documentation
- Site Quality Management Plan (QMP)

REGULATORY

- Essential Documents
- Source Documents

SAFETY ASSESSMENT AND REPORTING

- Reporting Adverse Events
- Reporting Expedited Adverse Events (EAEs) or Serious Advers Events (SAEs) to DAIDS

PROTOCOL IMPLEMENTATION

- Confidential HIV Counseling and Testing Procedures (if applicable)
- Unblinding for Safety (blinded trials)

LABORATORY MANAGEMENT

- Biohazard Safety and Containment and Occupational Safety
- Laboratory Data Management and Storage
- Lab Quality Management Plan (international sites)
- Specimen Acquisition, Processing, Tracking, and Storage
    - Lost, Broken, and Leaking Samples
    - Receipt and Processing all Samples
- Specimen Transport
    - Shipping Specimens Locally
    - Shipping Specimens Internationally

CLINICAL SITE DATA COLLECTION AND REPORTING

- Computer Room, Hardware, and Data Security (including system user account maintenance)
- Data Acquisition, Entry, and Processing
- Data Queries and Data Error Correction
- Data Collection Training
- Data Quality Management
- Data Storage

PHARMACY

- Pharmacy Operations SOPs
  (Refer to the Site Pharmacy Department SOPs and the DAIDS Pharmacy Policies: Requirements for Pharmacy Facilities, Activities, and Personnel.)

- Protocol Specific Pharmacy SOPs
  - Specific Requirments for a Particular Study Agent
  - Regimens and Administration
  - Protocol Specific Prescriptions

SITE MONITORING

- Review and Follow-up of Monitoring Report Findings