The following list includes policy, procedure, and study information sample SOPs that may be contained within in a MOP. The MOP may list the SOPs in any order. The bolded items below indicate SOPs that are required prior to the initiation of a clinical trial. These required SOPs are specifically listed in Appendix 1 of this policy and their nomenclature here matches that one given there.

INTRODUCTION

- Purpose of the Manual
- Brief Overview of Project/Study

1. ADMINISTRATIVE
   1.1. SOP Development and Version Control
   1.2. Clinical Research Site (CRS) Staff Training
       1.2.1. Protocol Specific Training
       1.2.2. DAIDS’ Policies Training
       1.2.3. CRS Specific Training
       1.2.4. Other Certification/Training Documentation
   1.3. Site Clinical Quality Management Plan (CQMP)
   1.4. Delegation of Responsibilities Log
   1.5. Steering Committee(s)
       1.5.1. Committee Membership
   1.6. Conflict of Interest and Financial Disclosure
   1.7. Publication and Presentation Policy

2. REGULATORY
   2.1. Essential Documents
   2.2. Source Documents
   2.3. Protocol Signature Page (PSP)
   2.4. Protection of Human Subjects
       2.4.1. The Informed Consent Process
       2.4.2. Informed Consent Documentation Requirements
       2.4.3. Translation of Informed Consent Forms
   2.5. Background of Regulations and Regulatory Bodies
   2.6. U.S. Federal Wide Assurance (FWA) Documentation
   2.7. DAIDS Protocol Registration
   2.8. E-Source Data
       2.8.1. Training Documentation
       2.8.2. Management
APPENDIX II
SAMPLE STANDARD OPERATING PROCEDURES (SOPs) LIST

Approval Date:                         No.:  DWD-POL-CL-05.00A2
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2.8.3. Distribution and Access

3. SAFETY ASSESSMENT AND REPORTING
   3.1. Reporting Adverse Events
   3.2. Reporting Expedited Adverse Events (EAEs) or Serious Adverse Events (SAEs) to DAIDS
   3.3. Medical Emergency Preparations
   3.4. Reporting Adverse Events
   3.5. Social Impact Reporting

4. PROTOCOL IMPLEMENTATION
   4.1. Confidential HIV Counseling and Testing Procedures (if applicable)
   4.2. Unblinding for Safety (blinded trials)
   4.3. Basic Infection Control Practices
   4.4. Study Objectives
      4.4.1. Design
      4.4.2. Study Population
      4.4.3. Duration
      4.4.4. Primary Objectives
   4.5. Participant Education, Counseling and Voluntary HIV Testing Program
      4.5.1. Overview
         4.5.1.1. Community Education
         4.5.1.2. Individual Counseling Sessions
         4.5.1.3. Determining Eligibility for Enrollment
         4.5.1.4. Obtaining Informed Consent
      4.5.2. Counseling Team Responsibilities and Tasks
      4.5.3. Equipment and Supplies
   4.6. Individual Post Test Counseling for Volunteers
   4.7. Participant Identification (PID) Numbers
      4.7.1. PID Numbers for Project/Study
      4.7.2. Assigning PID Numbers
      4.7.3. Case Report Form Completion
   4.8. Protocol Modifications/Amendments
   4.9. Managing Follow-Up Visits
      4.9.1. Pregnancy Prevention Counseling

5. LABORATORY MANAGEMENT
   (Refer to Division of AIDS (DAIDS) Clinical Research Laboratory and Specimens Management for complete policies and standard procedures related to requirements for DAIDS-supported laboratories and specimens derived from DAIDS supported-
and/or -sponsored clinical trials.)

5.1. Biohazard Safety and Containment and Occupational Safety
5.2. Laboratory Data Management and Storage
5.3. Personnel Training and Competency
5.4. Equipment Maintenance, Calibration, and Use
5.5. Lab Quality Management Plan
5.6. Specimen Acquisition, Processing, Tracking, and Storage
  5.6.1. Lost, Broken, and Leaking Samples
  5.6.2. Receipt and Processing all Samples
5.7. Specimen Transport
  5.7.1. Shipping Specimens Locally
  5.7.2. Shipping Specimens Internationally
5.8. Laboratory Module
  5.8.1. Overview
  5.8.2. Laboratory Technician: Responsibilities and Tasks
  5.8.3. Laboratory certification and QA
  5.8.4. GCLP Training
  5.8.5. IATA Training and Certification
5.9. Specimen Collection
  5.9.1. Overview
  5.9.2. Equipment and Supplies
  5.9.3. Procedure for Adult Specimen Collection
  5.9.4. Procedure for Pediatric Specimen Collection
  5.9.5. Label the Tubes or Other Specimen Container
5.10. Transport Protocol
  5.10.1. Overview
  5.10.2. The Specimen Tracking Log
  5.10.3. Completing the Specimen Tracking Log
  5.10.4. Supplies for Packaging the Specimens
  5.10.5. Transport of Specimens from the Clinical Site(s) to the Laboratory(ies)
    5.10.5.1. Shipping Containers
    5.10.5.2. Packaging Instructions
    5.10.5.3. Courier Transport
  5.10.6. Specimen Transport Responsibilities
5.11. Transfer of Laboratory Results to Clinical Site(s)
5.12. Contact Information for the Laboratory(ies)
5.13. Overview of Tests to be Performed in each Lab
6. CLINICAL SITE DATA COLLECTION AND REPORTING

6.1. Computer Room, Hardware, and Data Security (including system user account maintenance)
6.2. Data Acquisition, Entry, and Processing
6.3. Data Queries and Data Error Correction
6.4. Data Collection Training
6.5. Data Quality Management
6.6. Data Storage
6.7. Facility Computer and Data Security
6.8. Randomization Procedures (If appropriate)
6.9. Data Archiving

7. PHARMACY

7.1. Pharmacy Operations SOPs
(Refer to Division of AIDS (DAIDS) Clinical Research Pharmacy and Study Products Management for Site Pharmacy Department SOPS and the DAIDS Pharmacy Policies: Requirements for Pharmacy Facilities, Activities, and Personnel.)

7.1.1. Communication between Study Staff and Study Pharmacist
7.1.2. Procedure for Study Prescriptions
7.1.3. Participant Returns
7.1.4. Disposition of Study Agents

7.2. Protocol Specific Pharmacy SOPs

7.2.1. Adherence Assessment
7.2.2. Participant Counseling

8. SITE MONITORING SOPS

8.1. Review of Site Monitoring Report
8.2. Corrective Action and Preventive Action (CAPA) for findings in the Site Monitoring Report
8.3. Purpose of Site Monitoring
8.4. Preparing for the Site Monitoring Visit
8.4.1. Scheduling the Site Monitoring Visit
8.4.2. Frequency of Site Monitoring Visits
8.4.3. Confirming the Site Visit
8.5. Components of Site Monitoring
8.5.1. Informed Consent Verification
8.5.2. Record Review
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8.5.3. Accessibility of Electronic Systems for Monitoring Purposes
8.5.4. Regulatory Review
8.5.5. Site Monitoring Visit Log
8.5.6. Pharmacy Assessment
8.5.7. Laboratory Specimen Verification
8.5.8. Site Operations Assessments
8.6. Site Monitoring Findings
8.6.1. Informed Consent Findings
8.6.2. Enrollment Findings
8.7. The Site Monitoring Visit Debriefing
8.7.1. Scheduling the Debriefing
8.7.2. Issues to Discuss at the Debriefing
8.7.3. Regulatory Compliance
8.7.4. Recruitment/Enrollment (only if applicable)
8.7.5. Requests for Corrective and Preventive Actions
8.8. The Site Monitoring Report

9. SITE ACTIVATION
9.1. Setting Up the Site
9.2. Project Staff Organization
9.2.1. Clinical Trials Unit (CTU) Project Staff/and Roles and Responsibilities
9.2.2. Clinical Research Site (CRS) Project Staff and Roles and Responsibilities
9.2.3. Staff Education and Training
9.2.3.1. Good Clinical Practice (GCP)
9.2.3.2. SOP Training
9.2.3.3. Protocol Training
9.2.3.4. HSP Training (specific)
9.2.4. Maintenance of Participant Confidentiality
9.3. General Supplies Needed For Implementing Project
9.3.1. Participant Screening Supplies
9.3.2. PID Logbook
9.3.3. Case Report Forms
9.3.4. Ordering Supplies

10. COMMUNITY PARTICIPATION
10.1. Community Advisory Board (CAB)
10.1.1. Membership
10.1.2. CAB Mission Statement
10.1.3. CAB By-laws
195  10.1.4. Roles and Responsibilities
196   10.2  Community Education Plan