

DAIDS	Appendix 2	No.: DWD-POL-CL-05.00A2
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MANUAL OF OPERATIONS (MOP) SAMPLE TABLE OF CONTENTS

The following is a Sample Table of Contents that includes policy, procedure, and study information that may be included in a MOP. The MOP may be developed in any order. The bolded items below indicate Standard Operating Procedures (SOPs) that are required prior to the initiation of a clinical trial.

- 1 INTRODUCTION
 - 1.1 Purpose of the Manual
 - 1.2 Brief Overview of Project/Study

- 2 ADMINISTRATIVE
 - 2.1 Steering Committee(s)
 - 2.1.1 Committee Membership
 - 2.2 Conflict of Interest and Financial Disclosure
 - 2.3 Publication and Presentation Policy
 - 2.4 **SOP Development and Version Control**
 - 2.5 **Personnel Qualifications**
 - 2.6 **Personnel Training and Certification Documentation**
 - 2.7 **Site Quality Management Plan (QMP)**

- 3 REGULATORY
 - 2.1 Background of Regulations and Regulatory Bodies
 - 2.2 U.S. Federal Wide Assurance (FWA) Documentation
 - 2.3 Protection of Human Subjects
 - 2.3.1 The Informed Consent Process
 - 2.3.2 Informed Consent Documentation Requirements
 - 2.3.3 Translation of Informed Consent Forms
 - 2.4 DAIDS Protocol Registration
 - 2.5 **Essential Documents**
 - 2.6 **Source Documents**

- 3 SITE IMPLEMENTATION
 - 3.1 Setting Up the Site
 - 3.2 Project Staff Organization
 - 3.2.1 Clinical Trials Unit (CTU) Project Staff/and Roles and Responsibilities
 - 3.2.2 Clinical Research Site (CRS) Project Staff and Roles and Responsibilities
 - 3.2.3 Staff Education and Training
 - 3.3.3.1 Good Clinical Practice (GCP)
 - 3.3.3.2 SOP Training
 - 3.3.3.3 Protocol Training
 - 3.2.4 Maintenance of Participant Confidentiality
 - 3.4 General Supplies Needed For Implementing Project
 - 3.4.1 Participant Screening Supplies
 - 3.4.2 PID Logbook
 - 3.4.3 Case Report Forms
 - 3.4.4 Ordering Supplies

- 4 SAFETY ASSESSMENT AND REPORTING
 - 4.1 Adverse Experiences (AEs) Assessment
 - 4.2 Social Impact Reporting

DAIDS	Appendix 2	No.: DWD-POL-CL-05.00A2
-------	------------	-------------------------

- 4.4 **Reporting Adverse Events**
- 4.5 **Reporting Expedited Adverse Events (EAEs) or Serious Adverse Events (SAEs) to DAIDS**

5 PROTOCOL IMPLEMENTATION

- 5.1 Study Objectives
 - 5.1.1 Design
 - 5.1.2 Study Population
 - 5.1.3 Duration
 - 5.1.4 Primary Objectives
- 5.2 Participant Education, Counseling and Voluntary HIV Testing Program
 - 5.2.1 Overview
 - 5.2.1.1 Community Education
 - 5.2.1.2 Individual Counseling Sessions
 - 5.2.1.3 Determining Eligibility for Enrollment
 - 5.2.1.4 Obtaining Informed Consent
 - 5.2.2 Counseling Team Responsibilities and Tasks
 - 5.2.3 Equipment and Supplies
 - 5.2.4 **Confidential HIV Counseling and Testing Procedures (if applicable)**
- 5.3 Individual Post Test Counseling for Volunteers
- 5.4 Participant Identification (PID) Numbers
 - 5.4.1 PID Numbers for Project/Study
 - 5.4.2 Assigning PID Numbers
 - 5.4.3 Case Report Form Completion
- 5.5 Protocol Modifications/Amendments
- 5.6 Managing Follow-Up Visits
 - 5.6.1 Pregnancy Prevention Counseling
- 5.7 **Unblinding for Safety (blinded trials)**

6 LABORATORY MANAGEMENT

- 6.1 Laboratory Module
 - 6.1.1 Overview
 - 6.1.2 Laboratory Technician: Responsibilities and Tasks
 - 6.1.3 Laboratory certification and QA
 - 6.1.4 GCLP Training
 - 6.1.5 IATA Training and Certification
- 6.2 Specimen Collection
 - 6.2.1.1 Overview
 - 6.2.1.2 Equipment and Supplies
 - 6.2.1.3 Procedure for Adult Specimen Collection
 - 6.2.1.4 Procedure for Pediatric Specimen Collection
 - 6.2.1.5 Label the Tubes or Other Specimen Container
- 6.3 Transport Protocol
 - 6.3.1 Overview
 - 6.3.2 The Specimen Tracking Log
 - 5.3.2.1 Completing the Specimen Tracking Log
 - 6.3.3 Supplies for Packaging the Specimens
 - 6.3.4 Transport of Specimens from the Clinical Site(s) to the Laboratory(ies)
 - 6.3.4.1 Shipping Containers
 - 6.3.4.2 Packaging Instructions
 - 6.3.4.3 Courier Transport
 - 6.3.5 Specimen Transport Responsibilities

DAIDS	Appendix 2	No.: DWD-POL-CL-05.00A2
-------	------------	-------------------------

- 6.4 Transfer of Laboratory Results to Clinical Site(s)
- 6.5 Contact Information for the Laboratory(ies)
 - 6.5.1 Overview of Tests to be Performed in each Lab
- 6.6 **LABORATORY SOPS**
 - 6.6.1 **Biohazard Safety and Containment and Occupational Safety**
 - 6.6.2 **Laboratory Data Management and Storage**
 - 6.6.3 **Lab Quality Management Plan (international sites)**
 - 6.6.4 **Specimen Acquisition, Processing, Tracking, and Storage**
 - 6.6.4.1 **Lost, Broken, and Leaking Samples**
 - 6.6.4.2 **Receipt and Processing all Samples**
 - 6.6.5 **Specimen Transport**
 - 6.6.5.1 **Shipping Specimens Locally**
 - 6.6.5.2 **Shipping Specimens Internationally**
- 7 CLINICAL SITE DATA COLLECTION AND REPORTING
 - 7.1 **Computer Room, Hardware, and Data Security (including system user account maintenance)**
 - 7.2 **Data Acquisition, Entry, and Processing**
 - 7.3 **Data Queries and Data Error Correction**
 - 7.4 **Data Collection Training**
 - 7.5 **Data Quality Management**
 - 7.6 **Data Storage**
- 8 PHARMACY
 - 8.1 **PHARMACY OPERATIONS SOPS**
(Refer to the Site Pharmacy Department SOPS and the DAIDS Pharmacy Policies: Requirements for Pharmacy Facilities, Activities, and Personnel.)
 - 8.1.1 Communication between Study Staff and Study Pharmacist
 - 8.1.2 Procedure for Study Prescriptions
 - 8.1.3 Participant Returns
 - 8.1.4 Disposition of Study Agents
 - 8.2 **PROTOCOL SPECIFIC PHARMACY SOPS**
 - 8.2.1 **Specific Requirements for a Particular Study Agent**
 - 8.2.2 **Regimens and Administration**
 - 8.2.3 **Protocol Specific Prescriptions**
 - 8.3 Adherence Assessment
 - 8.4 Participant Counseling
- 9 SITE MONITORING
 - 9.1 Purpose of Site Monitoring
 - 9.2 Preparing for the Site Monitoring Visit
 - 9.2.1 Scheduling the Site Monitoring Visit
 - 9.2.2 Frequency of Site Monitoring Visits
 - 9.2.3 Confirming the Site Visit
 - 9.3 Components of Site Monitoring
 - 9.3.1 Informed Consent Verification
 - 9.3.2 Record Review
 - 9.3.3 Regulatory Review
 - 9.3.4 Site Monitoring Visit Log
 - 9.4 Site Monitoring Findings
 - 9.4.1 Informed Consent Findings

DAIDS	Appendix 2	No.: DWD-POL-CL-05.00A2
-------	------------	-------------------------

- 9.4.2 Enrollment Findings
- 9.5 The Site Visit Summary Meeting
 - 9.5.1 Scheduling the Summary Meeting
 - 9.5.2 Issues to Discuss at the Summary Meeting
 - 9.5.3 Regulatory Compliance
 - 9.5.4 Recruitment/Enrollment
 - 9.5.5 Requests for Corrective Action
- 9.6 The Site Monitoring Report
- 9.7 **Monitoring SOPS**
 - 9.7.1 **Review and Follow-up of Monitoring Report Findings**

- 10 COMMUNITY PARTICIPATION
 - 10.1 Community Advisory Board (CAB)
 - 10.1.1 Membership
 - 10.1.2 CAB By-laws
 - 10.1.3 Roles and Responsibilities
 - 10.2 Community Education Plan