Site Assessment

1. Staffing and Training

        Study Staff Involved in Project

        Delegation/signature log on file – Principal Investigator (PI) signed delegations

        Curriculum Vitae (CV) on file - sign and dated by each person

                Qualifications

                Experience

        Job descriptions – on file, signed by staff

        Protocol specific training – who, what, when, where on file

        Good Clinical Practice (GCP) training – certificate on file

        Human Subject Protection (HSP) training – certificate on file for staff having direct patient contact

        International Air Transport Association (IATA) training – valid certification on file for laboratory technicians or other staff responsible for packaging and shipping samples

2. Facilities

        Location of PI office and other research staff

        Communication services and equipment, i.e, Internet access, printer, photocopier, etc. – availability and location

        Clinical Facilities

                Where, how, and who consent patients for this study

                        Adequate privacy

                Where, how, and who see patients on this study

                        Adequate privacy

                        Biohazard waste containers (if applicable)

                What emergency systems are in place

Crash Carts

Paging/contact systems

24/7 research unit

On call staff

Where and how are study supplies received and stored

Where and how are research specimens obtained

Standard Operating Procedure (SOP) for research staff

exposure

Post Exposure Prophylaxis (PEP) plan

Biohazard waste containers

Disposal process

Where and how are research specimens processed

SOP for research staff exposure

PEP plan

Biohazard waste containers

Disposal process

Where and how are research specimens stored?

Monitoring of temperature

Ambient

Refrigerator

Freezer

Alarm system

Locked/security/access

Back up generator with adequate supply

Where and how is study medication received, dispensed and

returned

Alarm system

Locked/security/access

Back up generator with adequate supply

Where and how are study records (source and research file) stored

Locked/security/access

Where is data processing area

Locked/security/access

3. SOPs or Policy and Procedures – Site specific, signed by PI or other appropriate director, i.e., Laboratory Director, Pharmacy Director

Source documentation

Essential documents

Communications

Recruitment and retention of study participants

Informed Consent Process

Maintaining confidentiality of records

Study visit policy and procedure

Verification of Eligibility

HIV Voluntary Counseling and Testing (VCT)

Laboratory procedures, including specimen plan

Exposure control plan, including PEP procedures

Pharmacy procedures

Data management procedures

Quality management plan

Essential documents

Data

Specimens

Medications

Assessing, managing and reporting adverse events and serious adverse events

Data and safety monitoring and reporting

Managing medical emergencies

4. Day to day management and medical oversight of the study

Regulatory Obligations

Institutional Review Board and/or Institutional Ethics Committee [IRB(s)/IEC(s)] with oversight responsibility – local and other(s)

Current Office of Human Research Protection (OHRP) assurance

Membership rooster

Evidence that PI or other study staff absent from voting on protocol if on IRB/IEC

Other applicable regulatory authorities

Host country regulations and approval process

United States and/or Tanzania (US/TZ) Food and Drug Administration (FDA) Investigational New Drug (IND) application (if applicable)

Federalwide Assurance (FWA)

National Institute of Allergies and Infectious Diseases (NIAID)

Clinical Terms of Award (if applicable)

Essential documents file

Locked/security/access

Timely submissions and notifications

All versions on file

Correspondence to and from regulatory officials on file

Documented approval for original submission and any revisions

approval letter

stamp date legible

version # and date on submission letter and ICF

Serious adverse event (SAE) and unexpected events related to research

Data Safety Monitoring Board (DSMB) reports

Safety reports

Investigator Brochure(s)

Annual reports

External audit reports (if applicable)

Coordinated version date and amendment and/or addendum # captured on ICF and submissions

Recruitment/study referral material submitted prior to use

Communication/coordination with all research staff

    Procedure for coordinating IRB/IEC submissions

    Current working version

    SAE and unexpected events

    Independent safety monitoring or DSMB

    Internal quality assurance and quality management (QA/QM) findings (if applicable)

    Regular staff meetings and documentation

    Documentation of correspondence with regulatory authorities

Laboratory Certification or training

    Normal value range

Monitoring log

Sample case report forms

Clinical obligations

    Subject Recruitment

    Screening record

    Subject enrollment log

    Informed Consent Form (ICF) verification

        Original signed and dated on file

        Documentation of process in source documentation

        Illiterate patients have ICF witnessed and signed by impartial third person

        Signatures in proper signature line

        Each page initialed by potential subject

        Subject dates on line (if literate, document who dates and writes patient name, in addition to "mark" by subject)

Backward translation consistent with English approved and documentation exists to confirm

Source to research file verification

AEs/SAEs reporting and management

Quality Assurance and Quality Control Activities (QA & QC)

Responsible person identified

Established QC processes

Eligibility checklist

Visit calendars

Visit reminders

Data entry and transmission reports

Data queries

Delinquency lists

Established QA processes

Verification of ICF

Eligibility criteria

Protocol required evaluations

Concomitant medications

AE & SAE identification and reporting

Written procedures for assessing, managing, and reporting

Who assesses seriousness and causality

How is seriousness and causality assessed

Comply with regulatory requirements

Immediate reporting

Annual report to regulatory authorities

Tracked to resolution

Written procedures for management of medical emergencies

Clinical endpoint identification

Identifying trends in missed visits and follow up

5. Other

        Adequate patient population for study

        Competing trials at site

        Availability of study staff

        Adequate space for auditing

        Other observations