

# HPTN 074 SSP

## Table of Contents

### **Section 1. .... Introduction**

- 1.1. Overview of Section 1
- 1.2. Source of Procedural Information
- 1.3. Investigator Responsibilities
- 1.4. Study Activation Process
  - 1.4.1. Protocol Distribution
  - 1.4.2. Development and LOC Review of Site-Specific Informed Consent Forms (ICFs): English Language Version
  - 1.4.3. Development and LOC Review of Site-Specific ICFs
  - 1.4.4. IRB/EC Review
  - 1.4.5. Protocol Registration
  - 1.4.6. Study Activation
  - 1.4.7. Abbreviated Study Activation for Protocol Amendments
- 1.5. Continuing Review

### **Section 2. .... Protocol**

- 2.1. Overview of Section 2

### **Section 3. .... Documentation Requirements**

- 3.1. Overview of Section 3
- 3.2. Essential Documents
- 3.3. Participant Research Record
  - 3.3.1. Concept of Source Documentation
  - 3.3.2. Source Documentation
  - 3.3.3. Examples of Source Documentation
    - 3.3.3.1. Chart Notes
    - 3.3.3.2. Case Report Forms
    - 3.3.3.3. Eligibility Criteria
  - 3.3.4. Document Organization
- 3.4. Reportable Protocol Deviations
- 3.5. Record Retention Requirements
- 3.6. Ancillary Studies
- 3.7. Study Publications

## **Section 4. .... Index and Partner Accrual**

- 4.1. Overview of Section 4
- 4.2. Target Enrollment
  - 4.2.1. Index participants
  - 4.2.2. Network injection partners
- 4.3. Screening and Enrollment Logs
- 4.4. Site Specific Recruitment Plan
- 4.5. Recruitment Plans and Targets
- 4.6. Screening
  - 4.6.1. Index
  - 4.6.2. Injection drug partners
- 4.7. Age Verification Procedures
- 4.8. HIV Disclosure of Index Participants
- 4.9. Compensation
- 4.10. Eligibility Determination
- 4.11. Informed Consent
  - 4.11.1. Deliver All Required Information in a Manner that is Understandable to Potential Participants
  - 4.11.2. Assure That Informed Consent Is Obtained In A Setting Free Of Coercion And Undue Influence
  - 4.11.3. Confirm That the Participant Comprehends the Information
  - 4.11.4. Document the Process
  - 4.11.5. Continue the Informed Consent Process throughout the Study
  - 4.11.6. ICF Requirements for Protocol Amendments
  - 4.11.7. Informed Consent SOP
- 4.12. Screening procedures
- 4.13. Enrollment/Randomization Visit

## **Section 5. .... Follow-up and Retention**

- 5.1. Overview of Section 5
- 5.2. Length of Study participation
- 5.3. Follow-up visits
  - 5.3.1. Protocol required visits
  - 5.3.2. Intervention-Related Visits (Psychosocial or Systems navigator encounters)
  - 5.3.3. Interim Visits
  - 5.3.4. Follow-up visit scheduling

- 5.3.5. Site visit windows
- 5.3.6. Visits conducted over multiple days (split visits)
- 5.3.7. Missed Visits
- 5.3.8. Follow up visit procedures - Index
  - 5.3.8.1. Week 4 Visit
  - 5.3.8.2. Quarterly visits
  - 5.3.8.3. Exit Visit
  - 5.3.8.4 Study Extension Visits (for Indexes only)
- 5.3.9. Follow up visit procedures – Network Partners
  - 5.3.9.1. Enrollment Visit
  - 5.3.9.2. Week 4
  - 5.3.9.3. Quarterly visits
  - 5.3.9.4. Exit Visit
- 5.3.10. Modified Follow-up Visit Procedures for participants with a positive or reactive HIV result
- 5.4. Participant Withdrawal and termination
- 5.5. Qualitative component
- 5.6. Retention Definition
- 5.7. Retention Plan
- 5.8. Retention Target
- 5.9. Retention Strategies
- 5.10. Obtaining and Updating Locator Information

**Section 6. .... Visit Checklists**

- 6.1. Overview of Section 6
- 6.2. Visit Checklists as Source Documentation
- 6.3. Use of the Checklists
- 6.4. Checklists for the Study Extension
- 6.5. Template Eligibility Checklists
- 6.6. Template Visit Checklists

**Section 7. .... Safety/AE/Social Impact**

- 7.1. Overview of Section 7
- 7.2. Definitions and General Reporting Guidance
  - 7.2.1. Adverse Event
  - 7.2.2. Serious Adverse Events (SAEs)
  - 7.2.3. Reporting Adverse Events to SDMC (SCHARP)

- 7.2.4. Reporting Adverse Events in an Expedited Manner
- 7.3. Adverse Event: Terminology
- 7.4. Adverse Event: Relationship
- 7.5. Adverse Event: Severity
- 7.6. Reporting Serious Adverse Event Follow-Up and Outcome
- 7.7. Reporting Adverse Events at a Final Study Visit
- 7.8. Reporting Recurrent Adverse Events
- 7.9. Social Harms
- 7.10. Suicide Ideation
  - 7.10.1. Assessment for Suicide Risk
  - 7.10.2. Source Documentation: Suicide Risk Assessment Form
- 7.11. Safety Monitoring, Review, and Oversight
- 7.12. Clinical Management of Pregnancy
- 7.13. Deaths
  - 7.13.1. Verbal Autopsy Form

## **Section 8. ....Lab and Specimen Management Procedures**

- 8.1. Overview of Section 8
- 8.2. Specimen Labeling
  - 8.2.1. Local Specimen Testing
  - 8.2.2. Remote Specimen Testing
- 8.3. Use of the LDMS
- 8.4. LDMS Export Back up
- 8.5. LDMS Reconciliation
- 8.6. Protocol related testing and sample collection
- 8.7. HIV Testing
  - 8.7.1. HIV Testing for Index Participants
    - 8.7.1.1 HIV Testing for Index Participants Who Initially Screened as Network Injection Partners But Had a Reactive or Positive HIV Test Result
- 8.8. Blood Collection and Processing
  - 8.8.1. Plasma Processing and Storage
  - 8.8.2. QA for HIV Testing
- 8.9. Urine Collection for Substances of Abuse Testing
  - 8.9.1. On Site Urine Testing for Substances of Abuse
  - 8.9.2. Urine Testing for Substances of Abuse at the LC
  - 8.9.3. Frozen Urine

- 8.9.4. Dried Urine
  - 8.9.4.1. Preparation of Dried Urine Filter Paper
  - 8.9.4.2. Preparation of Dried Urine Cartridge (VIETNAM SITE ONLY, INDEX ENROLLMENT)
- 8.10. Shipping of Samples to the HPTN Laboratory Center
- 8.11. Laboratory Monitoring

## **Section 9. .... Data Management**

- 9.1. SDMC Contact Information
- 9.2. DataFax Overview
  - 9.2.1. Receiving CRFs
  - 9.2.2. Data Entry/Quality Control
  - 9.2.3. DataFax Quality Control Reports
  - 9.2.4. Resolving QCs
- 9.3. Data Management Quality Reports
- 9.4. Case Report Forms
  - 9.4.1. CRF Distribution
  - 9.4.2. Updates to Case Report Forms
  - 9.4.3. Standard CRF Elements
    - 9.4.3.1. Participant IDs
    - 9.4.3.2. Visit Codes
    - 9.4.3.3. Page Numbers
    - 9.4.3.4. Staff Initials and Date
  - 9.4.4. CRF Completion Guidelines
    - 9.4.4.1. Marking Response Boxes
    - 9.4.4.2. Recording Numbers
    - 9.4.4.3. Recording Dates
    - 9.4.4.4. Recording Time
  - 9.4.5. Data Corrections and Additions to CRFs
    - 9.4.5.1. Correcting a Participant Identification Number (PTID) Error
    - 9.4.5.2. Missing and Unknown Data
  - 9.4.6. Site Review of CRFs
- 9.5. Faxing CRFs
- 9.6. Visit Scheduling
  - 9.6.1. Target Days

- 9.6.2. Visit Windows
- 9.6.3. Missed Visits
- 9.6.4. Split Visits
- 9.6.5. Interim Visits
  - 9.6.5.1. Interim Visit Codes
- 9.7. Termination and Reactivation
- 9.8. Schedule of Forms
  - 9.8.1. Schedule of Forms- Index Participant
  - 9.8.2. Schedule of Forms – Network Partner Participants
  - 9.8.3. Schedule of Forms – Additional Forms Requirements

**Section 10. ....Randomization**

- 10.1. Participant Randomization Overview
- 10.2. Requesting FSTRF User Accounts
- 10.3. Requesting Participant Randomization Using the FSTRF System
- 10.4. Log Out of FSTRF
- 10.5. Randomization Technical and Operational Support

**Section 11. ....Reporting Plan**

- 11.1. Purpose of Reporting Plan
- 11.2. Reports

**Section 12.....Data Communiqués**

**Appendix A.....Intervention Manual**

**Appendix B.....Qualitative Manual**

**Appendix C.....DAIDS Table for Grading the  
Severity of Adult and Pediatric Adverse Events**