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. ..................................................

Overview of Section 4

Target Enrollment

4.2.1. Index participants

4.2.2. Network injection partners

Screening and Enrollment Logs

Site Specific Recruitment Plan

Recruitment Plans and Targets

Screening

4.6.1. Index

4.6.2. Injection drug partners

Age Verification Procedures

HIV Disclosure of Index Participants

Compensation

Eligibility Determination

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

Screening procedures

Enrollment/Randomization Visit

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

Overview of Section 5

Length of Study participation

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