

**HPTN 033**  
**HIV Prevention Preparedness Study**

**Study-Specific Procedures Manual**

**Sponsored by:**

**Division of AIDS (DAIDS)**  
**US National Institute of Allergy and Infectious Diseases (NIAID)**  
**US National Institutes of Health (NIH)**  
**US National Institute of Child Health and Human Development (NICHD)**  
**US National Institute on Drug Abuse (NIDA)**  
**US National Institute of Mental Health (NIMH)**

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# Table of Contents

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LIST OF APPENDICIES.....	3
LIST OF ABBREVIATIONS AND ACRONYMS.....	4
SECTION 1. INTRODUCTION.....	5
1.1 SOURCES OF PROCEDURAL INFORMATION.....	5
1.2 INVESTIGATOR RESPONSIBILITIES.....	5
1.3 STUDY ACTIVATION PROCESS.....	7
SECTION 2. PROTOCOL.....	10
SECTION 3. DOCUMENTATION REQUIREMENTS.....	11
3.1 ADMINISTRATIVE AND REGULATORY DOCUMENTATION.....	11
3.2 CASE HISTORY DOCUMENTATION.....	12
3.3 RECORD RETENTION REQUIREMENTS.....	18
SECTION 4. PARTICIPANT ACCRUAL.....	19
4.1 RECRUITMENT AND TARGET ENROLLMENT.....	19
4.2 SCREENING AND ENROLLMENT.....	19
4.3 INFORMED CONSENT.....	19
4.4 ELIGIBILITY DETERMINATION.....	22
SECTION 5. STUDY VISITS FOR SITES PERFORMING RAPID HIV TESTING (CHENNAI ONLY.....	23
5.1 SCREENING AND ENROLLMENT VISIT (DAY 0).....	23
5.2 LOCATOR CONTACTS (MONTH 3 AND MONTH 9).....	25
5.3 FOLLOW-UP VISITS (MONTH 6 AND MONTH 12).....	25
5.4 INTERIM CONTACTS AND VISITS.....	27
SECTION 6. VISIT CHECKLISTS FOR CHENNAI.....	28
SECTION 7. STUDY VISITS FOR SITES NOT PERFORMING RAPID HIV TESTING (RUSSIA AND CHINA ONLY).....	38
7.1 SCREENING VISIT (DAY -14).....	38
7.2 BETWEEN SCREENING AND ENROLLMENT.....	39
7.3 ENROLLMENT VISIT (DAY 0).....	39
7.4 LOCATOR CONTACTS (MONTH 3 AND MONTH 9).....	40
7.5 FOLLOW-UP VISITS (MONTH 6 AND MONTH 12).....	41
7.6 INTERIM CONTACTS AND VISITS.....	43
SECTION 8. VISIT CHECKLISTS FOR RUSSIA AND CHINA.....	44
SECTION 9. PARTICIPANT RETENTION.....	57
9.1 OBTAINING AND UPDATING LOCATOR INFORMATION.....	57
9.2 RETENTION PLAN.....	58
SECTION 10. DATA COLLECTION.....	61

10.1	DATAFAX INTRODUCTION .....	61
10.2	DATAFAX QUESTIONS AND ANSWERS .....	61
10.3	FORM COMPLETION TIPS .....	62
10.4	QUESTION COMPLETION, ORDER, AND SKIP PATTERNS .....	64
10.5	STUDY SITE REVIEW OF DATA COLLETCION FORMS .....	65
10.6	WHEN TO FAX THE FORMS .....	66
10.7	PAGES TO BE FAXED.....	66
10.8	SCHEDULE OF FORMS .....	66
10.9	FORMS AND PAGES EXPECTED AT SCREENING AND ENROLLMENT VISITS .....	69
10.10	VISIT CODES .....	72
10.11	INTERIM VISIT CODES .....	73
10.12	HPTN 033 PARTICIPANT ID's (PTIDs) .....	73
10.13	RECORDING OF DATES .....	74
10.14	COMMON ELEMENTS OF HPTN 033 FORMS.....	74
10.15	HPTN 033 FORMS DESCRIPTIONS AND INSTRUCTIONS .....	76
SECTION 11. STUDY REPORTING REQUIREMENTS .....		123
11.1	REPORTS .....	123
SECTION 12. LABORATORY PROCEDURES .....		127
12.1	BIOHAZARD CONTAINMENT .....	127
12.2	SPECIMEN COLLECTION AND INITIAL PROCESSING.....	127
12.3	HPTN CLINIC AND LOCAL LDMS LABORATORY SPECIMEN COLLECTION, LABELING, STORAGE AND SHIPPING FOR THE HPTN 033 PROTOCOL.....	127
12.4	HIV ANTIBODY TESTING AT THE LOCAL LAB .....	134
12.5	PLASMA STORAGE AT THE LOCAL LAB .....	134
12.6	LONG TERM SPECIMEN ARCHIVE .....	134
12.7	SHIPPING OF SPECIMENS TO A THIRD COUNTRY OR THE US .....	134
12.8	JHU SHIPPING INSTRUCTIONS.....	134
SECTION 13. SAMPLE TABLES.....		136

## **LIST OF APPENDICES**

Appendix A	45 CFR 46, ICH consolidated Guideline for GCP
Appendix B	DAIDS SOP for Essential Documents
Appendix C	DAIDS SOP for Source Documentation
Appendix D	Biohazard Containment Guidelines
Appendix E	Interviewing Techniques
Appendix F	Study Counseling
Appendix G	Local Lab Procedures – to be inserted here and in translated version of the SSP
Appendix H	IATA Shipping regulations Packaging, Labeling, Shipping - Infectious Substances

## LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
CFR	Code of Federal Regulations
CL	Central Lab
CORE	HPTN Coordinating and Operations Center
CV	Curriculum Vitae
DAIDS	Division of AIDS
DHHS	US Department of Health and Human Services
EIA	Enzyme Immunoassay
FDA	Food and Drug Administration
FHI	Family Health International
FSR	Financial Status Report
GCP	Good Clinical Practices
HIV	Human Immunodeficiency Virus
HPTN	HIV Prevention Trials Network
HPTU	HIV Prevention Trials Unit
ICH	International Conference for Harmonization
IFA	Immunofluorescence Assay
IRB	Institutional Review Board
LL	Local Lab
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institute of Health
PRO	Protocol Registration Office
PTID	Participant Identifier Number
QA	Quality Assurance
QC	Quality Control
ROC	Regulatory Operations Center
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SOP	Standard Operating Procedure
SSP	Study-Specific Procedures
WB	Western Blot

# Section 1. Introduction

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This section specifies the sources of HPTN 033 procedural information available to HIV Prevention Trials Unit (HPTU) staff, the responsibilities of the HPTU Investigator, and the process by which each HPTU will be approved to begin HPTN 033 study implementation.

## 1.1 Sources of Procedural Information

All study procedures must be conducted in accordance with the study protocol and this manual. In the event that this manual is inconsistent with the protocol, the specifications of the protocol take precedence. The current protocol is included as Section 2 of this manual and all applicable clarifications.

HPTU staff are encouraged to contact the HPTN Coordinating and Operations Center (CORE) Protocol Specialist with all questions related to interpretation and proper implementation of the protocol. HPTU staff should contact the Statistical Center for HIV/AIDS Research and Prevention (SCHARP) Protocol Operations Coordinator with questions related to data collection. HPTN staff should contact the HPTN Central Lab (CL) Manager with questions related to the collection, processing, and storage of local and central lab specimens.

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## 1.2 Investigator Responsibilities

As with all DAIDS-sponsored studies, HPTN 033 must be conducted according to the US Code of Federal Regulations (CFR) and guidelines for Good Clinical Practice (GCP).

Copies of the US Department of Health and Human Services (DHHS) regulations for the conduct of research (45 CFR 46) and the International Conference on Harmonization (ICH) Consolidated Guideline for Good Clinical Practices are included in Appendix A.

The *DAIDS Standard Operating Procedures for Essential Documents and Source Documentation*, which are useful for interpreting and operationalizing the regulations and GCP guidelines, are included in Appendices B and C.

HPTN 033 also must be conducted in accordance with all other US and local regulations, policies, or guidelines applicable to human subjects research in general and/or the conduct of study procedures in particular.

The Investigator of Record at each HPTU participating in HPTN 033 is required to sign an HPTN Investigator's Agreement to formally indicate his/her agreement to conduct the study in accordance with the protocol; this SSP manual; all applicable US and in-country regulations, policies, and guidelines; and HPTN policies. By signing this form, the Investigator obligates himself/herself and, by delegation, all study staff, to:

- Conduct the study in accordance with the relevant, current protocol and not make changes in the protocol without prior permission of the study sponsor and the HPTN CORE, except when necessary to protect the safety, rights, or welfare of study participants. [NOTE: If no prior permission for a deviation from the protocol has been obtained, the investigator will inform the study sponsor and the HPTN CORE as soon as possible afterwards.]
- Personally conduct or supervise the study.
- Ensure that the requirements relating to ethical review and approval and obtaining informed consent in 45 CFR 56 are met.
- Maintain adequate and accurate study records (as described in Section 3 of this manual) and to make those records available for inspection in accordance with HPTN specifications.
- Ensure that an Institutional Review Board (IRB) that complies with the requirements of 45 CFR 46 will complete initial and continuing review and approval of the study. Also to promptly report to the IRB all changes in the study and all unanticipated problems involving risks to study participants or others. Additionally, to not make any changes in the study without prior sponsor, HPTN CORE, and IRB approval, except where necessary to eliminate apparent immediate hazards to study participants. [NOTE: If no prior permission for a deviation from the protocol has been obtained, the investigator will inform the HPTN CORE and the IRB as soon as possible afterwards.]
- Comply with all other requirements in 45 CFR 46 and any applicable local regulations, policies, and guidelines.
- Comply with all study data collection and documentation requirements specified in this manual and/or required by HPTN policies.
- Ensure that all staff members involved in the conduct of the study are informed of their obligations in meeting the above commitments.

Investigators may delegate work involved in conducting the study to other study staff members, however delegation does not relieve the Investigator of his/her ultimate responsibility for all study procedures performed and all study data collected.

### **1.3 Study Activation Process**

Prior to undertaking any study procedures, the HPTU must obtain approval to conduct the study from all responsible US and local IRBs. Thereafter, the HPTU must complete Protocol Registration procedures with the DAIDS Regulatory Operations Center (ROC) and Study Activation procedures with the HPTN CORE. This section outlines the steps required to complete these procedures. HPTN 033 study procedures may not be conducted prior to completing each of these steps.

#### **1.3.1 Protocol Distribution**

The CORE Protocol Specialist will distribute the final implementation version of the protocol to the HPTU.

#### **1.3.2 Development and CORE Review of Site-Specific Informed Consent Form: English Language Version**

Upon receipt of the protocol, HPTU staff will adapt the sample informed consent forms (contained in the final implementation version of the protocol) as required to reflect local procedures and IRB requirements and forward the form for review by the CORE Protocol Specialist prior to IRB submission.

It is recommended that HPTU staff submit the English language version of the forms to the CORE Protocol Specialist prior to translation into local languages, so that any review comments received from the Protocol Specialist may be incorporated into the forms before translation. The Protocol Specialist will provide review comments to HPTU staff as quickly as possible.

#### **1.3.3 Development and CORE Review of Site-Specific Informed Consent Form: Local Language Version(s)**

After incorporating review comments from the CORE Protocol Specialist, HPTU staff will translate the informed consent forms into all applicable local languages, obtain an independent back-translation of the forms, and then submit the translated forms and back-translations for review by the CORE Protocol Specialist. The Protocol Specialist will provide review comments to HPTU staff as quickly as possible.

#### **1.3.4 IRB Review**

After incorporating review comments received from the CORE Protocol Specialist, HPTU staff will submit the study protocol and site-specific informed consent forms for review by the responsible US and local IRBs. Also submitted will be any participant information sheets, promotional materials, advertisements, flyers, etc, and any other study-related materials required by the IRBs.

It is likely that both the US and local IRBs will provide comments on the study documents, and it is the responsibility of the Investigator to incorporate all such comments into a single final version of the study informed consent forms, and

to obtain approval of this final version from all responsible IRBs. It is acknowledged that this may require multiple submissions to the responsible IRBs.

### **1.3.5 Protocol Registration**

*Note: Additional details on the protocol registration process can be found in the DAIDS Protocol Registration Policy and Procedure Manual (dated April 12, 2001).*

Upon obtaining approval from all responsible IRBs, HPTU staff will submit the following documents to the CORE Protocol Specialist:

- Current (no older than 2 years) Curriculum Vitae (CV) of the Investigator of Record. The Curriculum Vitae (CV) must be in English and have a date on the CV that shows that the information is current.
- Documentation of approval from all responsible IRBs of the study protocol, informed consent forms, and other required materials.

*Note: Documentation of IRB approval must reference the exact protocol number, title, and version number, as listed on the cover page of the protocol.*

*Note: If the approval documentation is provided by the IRB in a language other than English, the document must be translated into English, and both the local language version and the English language version must be submitted.*

- A copy of the approved site-specific informed consent forms: English language version, local language version, and back-translation.

*Note: The approved informed consent forms must include the exact protocol number, title, and version number, as listed on the cover page of the protocol.*

*Note: The name and title of the translators must be documented on the local language version of the informed consent forms and on the back translations.*

*Note: When an IRB approves a single informed consent form that will be used at multiple sites, and the approved form contains blank spaces for site contact information, a memo specifying the relevant information for each site must be submitted together with the approved form.*

Once all documents meet the CORE review criteria, the Protocol Specialist will forward them for review by the DAIDS Regulatory Operations Center (ROC) Protocol Registration Office (PRO). PRO staff will communicate their review findings to the CORE Protocol Specialist, who will forward the findings to HPTU staff and coordinate any required re-submissions.

### **1.3.6 Study Activation**

In addition to the above, HPTU staff will submit the following documents to the CORE Protocol Specialist to complete the study activation process as soon as available:

- A completed HPTN Investigator's Agreement.
- Study staff roster and signature sheet.
- Standard operating procedure (SOP) for participant eligibility determination and confirmation.
- Site-specific HIV pre-test, risk reduction, and post-test counseling policies and procedures.
- Study-specific participant recruitment plan.
- Study-specific participant retention plan.
- SOP for obtaining informed consent.
- SOP for HIV counseling and referrals.
- SOP for specimen collection, transport, testing, and results reporting (may be part of the local lab SOP).
- Study-specific source documentation table (see Table 2 in Section 3.2.2).
- Documentation from the HPTN Central Laboratory of adequate proficiency and quality control/quality assurance procedures at the local laboratory.
- Other requirements, as individually specified.

Upon receipt, the Protocol Specialist will review these documents and notify the HPTU of any deficiencies and required re-submissions. After study-specific training has taken place, the Protocol Registration process described in Section 1.3.5 has been completed, and all required study activation documents are found to be satisfactory, the Protocol Specialist will provide written approval to the HPTU to begin study implementation.

## **Section 2. Protocol**

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This section contains a complete reference copy of the current version of the HPTN 033 protocol. Upon receipt of any protocol modification, study staff must replace this copy with the revised version, so that this manual always reflects current study requirements. Any clarification memos will be added on top of the current version of the protocol in chronological order until a new version of the protocol which includes all clarifications takes its place.

## Section 3. Documentation Requirements

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This section contains a listing of required administrative and regulatory documentation that each HIV Prevention Trials Unit (HPTU) must maintain and keep current throughout the study, as well as procedures for establishing adequate and accurate study participant case histories.

### 3.1 Administrative and Regulatory Documentation

The *DAIDS SOP for Essential Documents* (see Appendix B) specifies the administrative and regulatory documents that each HPTU must maintain for DAIDS-sponsored studies. Based on this SOP, the documentation listed below must be maintained for HPTN 033. When required documents are modified or updated, the original and modified/updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location at each HPTU site.

- Protocol with completed signature page (version 1.0 and any subsequent amendments, clarifications, etc).
- Protocol Registration documents (see Section 1.3.5) and documentation of approved registration from the ROC SRO.
- Documentation of study activation from the CORE Protocol Specialist.
- HPTU project assurance number and expiration date.
- IRB membership roster (or documentation from the IRB stating the roster is not available).
- All correspondence to and from all responsible IRBs.
- SSP manual.
- Participant information/education materials (if not filed with IRB correspondence).
- Study staff roster and signature sheet; job description and CV for each study staff member. All CVs must be dated.
- Documentation of delegation of investigator's responsibilities. (Note: This can be part of the study staff roster/signature sheet)
- Documentation of staff members' humans subjects training.
- Documentation of staff members' study-specific training.
- Documentation of study staff meetings.
- Local laboratory certifications and any applicable reference ranges for protocol-specified laboratory tests.

- Documentation from the HPTN CL of adequate proficiency and quality control/ quality assurance procedures at the local laboratory.
- Applicable US and local public health reporting requirements pertinent to study procedures; documentation of any exemptions from these requirements.
- Any other US or local regulations, policies, or guidelines applicable to the conduct of study procedures (e.g. Appendix A).
- Site-specific HIV pre-test, risk reduction, and post-test counseling policies and procedures.
- Other local study-specific SOPs.
- Monitoring visit log and reports.
- Source documentation table (see Section 3.2.2 and Table 2).
- Documentation of study-related conference calls and meetings.
- Other study-related communications.

### **3.2 Case History Documentation**

Each HPTU Investigator must establish and maintain adequate and accurate participant case history records containing all information pertinent to the study for each study participant.

#### **3.2.1 Case History Contents**

Participant case histories should contain all of the following elements:

- Basic participant identifiers.
- Documentation that the participant provided written informed consent to participate in the study prior to the conduct of any study procedures.

*Note: The DAIDS SOP for Source Documentation provides detailed requirements and suggestions for documenting the informed consent process.*

- Documentation that the participant met the study's selection criteria.
- A record of all contacts with the participant.

*Note: For purposes of participant retention, a record of all attempts to contact the participant also should be maintained. In addition, the DAIDS SOP for Source Documentation requires that all attempts to locate a participant to complete a missed visit must be documented.*

- A record of all procedures performed by study staff during the study.
- Study-related information on the participant's condition before, during, and after the study, including data obtained directly from the participant (e.g., questionnaire responses), data ascertained by study staff (e.g., laboratory test results), and data obtained from non-study sources (e.g., medical records).

*Note: In addition to the above, the DAIDS SOP for Source Documentation requires that all protocol departures/deviations/violations be documented in participants' study records, along with reasons for the departures and/or attempts to prevent or correct the departures, if applicable.*

### 3.2.2 Concept of Source Documentation

A source document is defined as the first document on which study-related information is recorded. HPTUs must adhere to the standards of source documentation specified in the *DAIDS SOP for Source Documentation* (see Appendix C).

For this study, participant case histories will consist of narrative chart notes, contact and visit checklists, laboratory reports, and DataFax forms. Other local source documents may also be used. Although it is the responsibility of the HPTU to determine the most appropriate source document for each case history element, Table 1 provides a guide that HPTU staff may follow for this study. Supplemental information on use of chart notes, checklists, and DataFax forms as source documents is provided below.

**Chart Notes:** Study staff must document every study-related contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. Chart notes also must be used to document the informed consent process (see also Section 4.3.4); procedures performed that are not recorded on other source documents; pertinent data about the participant that are not recorded on other source documents; and all protocol departures/deviations/violations that are not otherwise captured other source documents.

**Visit and Contact Checklists:** The checklists provided in Section 6 (for Chennai) and Section 8 (for Russia and China) of this manual provide a convenient tool for study staff to fulfill the requirement of documenting all study procedures performed with each study participant. In order to fulfill the source documentation requirement of identifiability, individual study staff members must initial only those procedures that they complete. In addition, if procedures listed on a single checklist are completed across multiple dates, the date upon which each procedure is completed must be clearly noted.

Note that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those specified on a checklist may have been performed and/or why procedures specified on a checklist were not performed. Chart notes also may be required

to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

**DataFax Forms:** The case report forms for this study are designed for use with the DataFax data management system described in Section 10. The forms also have been designed, to the extent possible, to serve as source documents. HPTU staff must complete Table 2 below to document the DataFax forms that they routinely will use as source documents. Once completed, this table needs to be signed and dated by the Investigator of Record. The completed, signed, and dated Table 2 will be submitted to the CORE Protocol Specialist as part of the study activation process and maintained with the HPTU's administrative and regulatory documentation for this study.

HPTU staff must follow their designations in Table 2 consistently for all study participants throughout the study.

In the event that staff are not able to record data directly onto DataFax forms designated as source documents, the following procedures must be undertaken:

- Record the data onto an alternative source document;
- Enter the alternative source document into the participant's study chart;
- Transcribe the data from the alternative source document onto the appropriate DataFax form; and
- Enter a chart note stating the relevant study visit code and date and the reason why an alternative source document was used.

**Table 1**  
**HPTN 033 Required Case History Elements and Source Document Guide**

<b>Required Case History Element</b>	<b>Source Documents</b>
Basic participant identifiers.	Local Locator Form; Demographics Form.
Documentation that the participant provided written informed consent to participate in the study. <sup>Ψ</sup>	Signed and dated informed consent form; signed and dated chart notes stating that informed consent was obtained prior to initiating study procedures.
Documentation that the participant met the study selection criteria.	Eligibility Form; Eligibility Checklist; Enrollment Form; result reports from the local lab; <sup>§</sup> signed and dated chart notes.
A record of all study related contacts with the participant. <sup>†*</sup>	Signed and dated chart notes.
A record of all study related procedures performed by study staff. <sup>†</sup>	Completed Visit and Contact Checklists; signed and dated chart notes detailing (a) procedures performed in addition to those contained on the checklist and/or (b) the reason why procedures contained on the checklist were not performed.
Information on the participant's condition before, during, and after the study.	Eligibility Form; Eligibility Checklist; Enrollment Form; Participant Encounter Form; Risk Assessment, result reports from the local lab; <sup>§</sup> Termination Form; signed and dated chart notes.

<sup>Ψ</sup> The *DAIDS SOP for Source Documentation* provides detailed requirements and suggestions for documenting the informed consent process.

<sup>§</sup> A designated study staff member must review all study laboratory reports, as well as reports of information pertinent to the study from non-study providers, and sign and date the reports to document his/her review.

<sup>†</sup> The *DAIDS SOP for Source Documentation* requires that all protocol departures/ deviations/violations be recorded in participants' study records, along with reasons for the departures and/or attempts to prevent or correct the departures, if applicable.

\*For purposes of participant retention, a record of all attempts to contact the participant also should be maintained. In addition, the *DAIDS SOP for Source Documentation* requires that all attempts to locate a participant to complete a missed visit must be documented.

## **Instructions for Completing Table 2**

1. Table 2 lists each DataFax form used in this study. The third column of the table (labeled “Source”) designates whether each form may be used as a source document.
  - ☞ If “yes” is entered in the Source column, the form may be used as a source document. SCHARP recommends that all such forms be used as source documents.
  - ☞ If “no” is entered in the Source column, the form may not be used as a source document. Data entered on such forms must be supported by information recorded first on another source document.
  - ☞ If “mixed” is entered in the Source column, the form may be used as a source document for some, but not all, items on the form. SCHARP recommends that such forms be used as source documents for the items designated in the Comments column of the table.
2. Table 2 must be completed, signed, and dated by the HPTU Principal Investigator and forwarded to the CORE Protocol Specialist as part of the study activation process (see Section 1.3.6). A copy of the completed table also must be maintained with the HPTU’s administrative and regulatory documentation for this study.
3. Once completed, Table 2 forms the basis for monitoring study data, and its specifications must be followed consistently for all study participants.
  - ☞ If the HPTU intends to follow all of the designations in the Source column of the table, the Investigator of Record should simply sign and date the table in the space provided.
  - ☞ If the HPTU wishes to follow an alternative approach to source documentation, this should be indicated by marking changes directly on to the table and then signing and dating the table the space provided.

**Table 2**  
**HPTN 033 DataFax Forms as Source Documents**

<b>Form Name</b>	<b>Acronym</b>	<b>Source</b>	<b>Comments</b>
Demographics	DM-1,2,3	Yes	Form is interviewer-administered.
Eligibility	EL-1,2,3	Yes	Form is interviewer-administered.
Eligibility Checklist	EC-1,2F	Mixed	Form may be source for items: <b>11. (only if answer is “no”)</b> <b>12.</b> <b>13.</b>
Enrollment Form	EN-1,2	Mixed	Form may be source for items: <b>2. (only if answer is “no”)</b>
Risk Assessment	RA-1-10	Yes	Form is interviewer-administered.
Local Lab Results	LL-1	No	All items on this form require local lab documentation as source.
Participant Encounter	PE-1	Mixed	Chart note serves as source that the visit took place and for the visit date. Form may be source for all other items.
Missed Visit	MV-1	Yes	
Comments	COM-1	Yes	
Termination Form	TM-1	Yes	

*See next page for instructions for completing this table.*

\_\_\_\_\_  
**Name of Investigator of Record**

\_\_\_\_\_  
**Signature of Investigator of Record**

\_\_\_\_\_  
**Date**

### **3.2.3 Document Organization**

All case history records must be stored securely at the HPTU. All DataFax forms, laboratory specimens, reports, process, and administrative forms must be identified by a coded number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access.

### **3.3 Record Retention Requirements**

All study records must be retained for at least three years after submission of the HPTU's final Financial Status Report (FSR), which is due within 90 days after the end of the HPTU's cooperative agreement with DAIDS, unless otherwise specified by DAIDS or the HPTN CORE. All records must be retained on-site throughout the study's period of performance. The CORE Protocol Specialist will provide each HPTU with instructions for long-term storage of records after the study is completed.

## Section 4. Participant Accrual

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This section provides an overview of requirements and procedures for recruiting, screening, and enrolling participants in the study.

### 4.1 Recruitment and Target Enrollment

Each HPTU will enroll 500 participants in the study over the course of a six-month accrual period. HPTU staff are responsible for establishing a recruitment plan for this study, and for updating the plan and recruitment efforts undertaken, if needed, to meet the study accrual goals. The recruitment plan should be stored with the “local study-specific SOPs” (noted in Section 3.1 of this Study Specific Procedures Manual).

### 4.2 Screening and Enrollment

The study screening and enrollment procedures are described in detail in Sections 5 (Chennai) and 7 (Russia and China), and the checklists in Sections 6 (Chennai) and 8 (Russia and China) of this Study Specific Procedures Manual.

Although it is expected that all screening procedures typically will be completed in one visit at sites performing rapid HIV testing (i.e., at the Screening and Enrollment Visit described in SSP Section 5.1) and at two visits at sites not performing rapid testing (i.e., at the Screening and Enrollment Visits described in SSP Sections 7.1 and 7.2), the required procedures may be completed over the course of multiple additional visits, if needed. For example, additional time may be required to complete the study informed consent process or to provide adequate HIV pre-test and risk-reduction counseling. Regardless of the number of visits required, however, all screening and enrollment procedures must be completed within 28 days of initiating the screening process. If all required procedures are not completed within 28 days, the screening process must be repeated.

In accordance with HPTN policies, HPTU staff will report the number of participants screened for and enrolled in the study to the CORE Protocol Specialist on a weekly basis. The Protocol Specialist will distribute this information to the Protocol Team as needed to monitor the accrual process. In addition, SCHARP will report weekly the number of participants screened and enrolled at each site based on data submitted to the DataFax system.

### 4.3 Informed Consent

Informed consent is a process by which an individual voluntarily expresses his/her willingness to participate in research, after having been informed of all aspects of the research that are relevant to his/her decision. Informed consent is rooted in the ethical principle of respect for persons. It is not merely a form or a signature, but a process, with four key considerations — information exchange, comprehension, voluntariness, and documentation — as described below.

Informed consent must be obtained from participants prior to undertaking any study screening or enrollment procedures. Informed consent also must be construed as an ongoing process that continues throughout the study product use and follow-up period.

45 CFR 46 (attached as Appendix A) specifies the elements of informed consent that must be conveyed to research participants through the informed consent process. It is the responsibility of the Investigator, and his/her assigned staff, to deliver all required information to potential research participants.

Based on the numerous technical and regulatory reviews that are completed as part of the HPTN protocol development and study activation processes, there is adequate assurance that once the HPTN CORE has “activated” an HPTU for study implementation, the site-specific informed consent form specifies all information required by the Federal regulations.

However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It also is the responsibility of the Investigator and designated study staff to:

**4.3.1 Deliver all required information in a manner that is understandable to potential participants.**

As a starting point, at the Screening/ Enrollment Visit, if the participant is literate, give him a copy of the informed consent form to read. Be sure to use the correct (current) version of the form. Also provide the participant with other (IRB-approved) informational materials developed to complement the informed consent form, if any.

If the participant is not literate, read the materials to him verbatim. The informed consent process for illiterate participants has to be verified by signature of an impartial witness on the signature page of the informed consent document.

After the participant has read the written material (or had it read to him), verbally review the information provided. A checklist or a highlighted version of the informed consent form itself may serve as a useful guide for this. For example, you may note the main point described in each paragraph of the informed consent form, and ask if the participant has questions or concerns about that point. Listen carefully to the questions and/or concerns expressed by the participant, and discuss these thoroughly. Take as much time as is needed to address all questions and concerns.

Staff must ensure that they use the correct version of the informed consent and that participants enter the date themselves (if able).

**4.3.2 Assure that informed consent is obtained in a setting free of coercion and undue influence.**

During the informed consent discussion, take care to not overstate the possible benefits of the study, nor to understate the risks. Also emphasize to the participant that his medical care and any other services obtained from the recruitment site and/or research institution will not be

affected by his decision whether or not to take part in the study. Encourage the participant to take as much time as he needs — and to talk about his potential participation with others, if he chooses — before making a decision.

#### **4.3.3 Confirm that the participant comprehends the information.**

The participant must not be asked to agree to take part in the study, or sign the informed consent form, until he fully understands the study. Study staff are responsible for implementing procedures to ensure that each participant understands the study prior to signing the informed consent form and undertaking any study procedures. Included among the “local study-specific SOPs” (noted in Section 3.1 of this Study Specific Procedures Manual) should be a description of how study staff will fulfill this responsibility.

One approach to assessing comprehension is to use a locally developed “quiz” (either oral or written) which participants must complete prior to enrolling in the study. Another approach is to use open-ended questions to ascertain participant understanding during the informed consent discussion. Some sample questions are as follows:

- *If friends asked you about this study, and why you are in it, what would you tell them?*
- *What do you think you will get out of being in this study?*
- *Are there things about being in this study that you would be worried about?*
- *How do you think it would affect your day-to-day life to be in this study?*
- *What would you do if you joined the study and then you didn't feel comfortable about the way the way you were treated in the study?*

If the participant’s responses to either the quiz or open-ended questions — or other methods used to assess comprehension — indicate misunderstanding of certain aspects of the study, review those aspects again until the participant fully understands them. If after all possible efforts are exhausted, the participant is not able to demonstrate adequate understanding of the study, do not ask him to sign the informed consent form or screen for/enroll in the study. Similarly, if the participant has concerns about possible adverse impacts on him if he were to take part in the study, or indicates that he may have difficulty adhering to the study requirements, do not ask him to sign the informed consent form or screen for/enroll in the study.

#### **4.3.4 Document the process.**

*Note: See the DAIDS SOP for Source Documentation for detailed requirements and suggestions for documenting the informed consent process.*

Regulations require that informed consent be documented by "the use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent." To fulfill this requirement, ensure that the participant complete all participant signature and date blocks on the informed consent form per IRB requirements. Then complete all study staff signature and date blocks per IRB

requirements. It is essential that the date documented on the form either precede or coincide with the (first) study screening date. In addition, enter a note in the participant chart documenting that informed consent was obtained prior to the initiation of any study procedures. Finally, regulations require that participants be given a copy of the informed consent form. Offer a copy to each participant. If a participant opts not to receive a copy, document this in a chart note.

The signed informed consent form is considered a permanent part of each screened and or enrolled participant's study record. As described in Section 3.2.3, because the informed consent form bears the participant's name, it must not be stored with study documents bearing the participant's study ID number.

Study staff will have to ensure that when consenting an illiterate participant (cannot read nor write) that a third person sit in during the informed consenting process. Preferably this third party will not be a staff member of HPTN 033 but it is acknowledged that this may be difficult. In any event, a third party must be able to witness to the delivery of the consent, to verify that to the best of their knowledge the participant understood and agrees with the consent form. Study staff cannot sign participant names on to informed consent forms. For an illiterate participant, the study staff member delivering the informed consent may print the participant name on the name line and have the participant imprint their thumb print on the signature line. The third person then write, sign and date as the witness.

The above describes aspects of obtaining informed consent from study participants prior to initiating their involvement in the study. Given the ongoing nature of informed consent, key elements of informed consent also should be reviewed at study follow-up visits. In this study, the Month 6 Follow-up Visit provides an ideal opportunity for this, since at this visit participants' HIV status and eligibility and willingness to continue in the study are confirmed. At these visits, HPTU staff are encouraged to review key elements of informed consent with participants, focusing on the remainder of their study participation. For example, the discussion at Month 6 would focus on the fact that the participant has completed half of his/her expected study participation, and therefore will complete one more locator contact and one more six-month follow-up cycle before completing the study.

#### **4.4 Eligibility Determination**

It is the responsibility of the HPTU Investigator, and other designated staff, to ensure that only participants who meet the study eligibility criteria (see protocol Section 3) are enrolled in the study. Included among the "local study-specific SOPs" (noted in Section 3.1 of this Study Specific Procedures Manual) should be a description of how study staff will fulfill this responsibility. A copy of this SOP must be provided to the CORE Protocol Specialist as part of the study activation process (see Section 1.3.6 of this manual).

## Section 5. Study Visits For Sites Performing Rapid HIV Testing (Chennai Only)

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This section contains the study visit procedures and flow, and checklists for scheduled and unscheduled (interim) study visits. The study visit procedures and checklists are designed to guide the study staff in proper study procedures and sequence. The study checklists are used to ensure that a study participant completes all required procedures before he/she leaves the study site. Sample Study Checklists for Chennai are included in section 6.

The sequence of procedures must be followed in the order described. If local staffing and logistical requirements demand certain modifications, the sequence of some procedures may be changed, and these changes should be described in the local Standard Operating Procedures (SOPs). Modifications to the checklists will be done with input from FHI. However, the sequence for the following procedures must be followed without exception:

- Informed consent must be obtained **prior** to initiation of any screening or study procedures.
- The Risk Assessment must **always** be administered **before** HIV pre-test and risk reduction and by a staff member who has not previously provided HIV counseling to the participant.
- Pre-test counseling must be provided **before** HIV specimen collection for testing.

### 5.1 Screening and Enrollment Visit (Day 0)

Study participants will undergo eligibility screening and potential enrollment in the study during an in-person study visit. Written informed consent will be obtained prior to the conduct of any study procedures. Demographic and behavioral eligibility will be determined based on participant responses to a standard interview instrument. Eligibility related to HIV serostatus will be ascertained via rapid local HIV testing in accordance with the algorithm in Appendix III of the protocol. Participants who test HIV-negative and meet behavioral eligibility criteria will be enrolled in the study. Participants who test HIV-positive will not be enrolled.

- Ascertain participant identity and assign Participant ID number.
- Explain the purpose of the visit and the informed consent and eligibility determination processes.
- Obtain written informed consent for study participation.
- Obtain written informed consent for specimen storage.
- Collect participant contact and locator information.
- Administer Demographics Form.
- Administer Eligibility Form.

- ⇒ If the participant **does not** meet the study eligibility criteria, he/she is ineligible; discontinue participation.
- ⇒ If the participant **does** meet the study eligibility criteria, proceed with the following:
  - Administer Risk Assessment. *Note: The Risk Assessment must be administered prior to the delivery of HIV counseling*
  - Deliver HIV pre-test and risk reduction counseling; obtain written informed consent for HIV counseling if required by local regulations. *Note: Counseling must be delivered after administration of the Risk Assessment.*
  - Collect, process, and deliver blood (one 10 ml purple top tube) for HIV testing at the LL, according to Appendix III of the protocol; process and store plasma.
  - Receive and document the participant's HIV test results; prepare accordingly for the post-test counseling session. Refer participant to local healthcare, social service, and/or other providers if needed.
  - Deliver HIV test result and post-test counseling.
- ⇒ If HIV infection is suspected (i.e., the rapid EIA is reactive), the participant is presumptively ineligible:
  - Discontinue the study screening and enrollment process.
  - Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing at the LL, according to Appendix III of the protocol; process and store plasma. (This step is optional, unless mandated by local law or if two rapid tests have been provided discordant results.)
  - Schedule appointment for participant to receive confirmatory test results. If HIV infection is confirmed by Western blot (WB) or immunofluorescence assay (IFA), refer participant to appropriate medical and psychosocial services and other available research studies.
  - Complete and submit all required data collection forms.
- ⇒ If HIV infection is ruled out (i.e., the rapid EIA is not reactive), the participant is eligible:
  - Refer participant to local healthcare, social service, and/or other providers if needed.
  - Schedule first Locator Contact to occur at study Month 3 and first semiannual Follow-up Visit to occur at study Month 6.

- Provide study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 3 contact.
- Complete and submit all required data collection forms.

## 5.2 Locator Contacts (Month 3 and Month 9)

Locator Contacts are scheduled to take place three and nine months from each participant's study enrollment date. However, the Month 3 contact may take place any time between the three-month timepoint and the participant's Month 6 Follow-up Visit, and the Month 9 contact may take place any time between the nine-month timepoint and the participant's Month 12 Follow-up Visit. The contacts also may take place via any modality that the study site deems appropriate for its local study population.

- Confirm participant identity and ID number.
- Update locator information.
- Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the next scheduled visit.
- Refer participant to local healthcare, social service, and/or other providers if needed.
- Confirm schedule for Month 6 Follow-up Visit.
- Complete and submit all required data collection forms.

## 5.3 Follow-up Visits (Month 6 and Month 12)

Follow-up Visits are scheduled to take place six and twelve months from each participant's study enrollment date, however they may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date. Visits that do not take place during this interval are treated as "interim visits" (see Section 5.4) in which HIV counseling and testing can be provided, however the behavioral risk assessment will not be administered. Participants who test HIV-negative at study Month 6 will be maintained in study follow-up. Participants who test HIV-positive will be discontinued from the study.

- Confirm participant identity and ID number.
- Update locator information.
- Administer Risk Assessment. *Note: The Risk Assessment must be administered prior to the delivery of HIV counseling, by a staff member who has not previously provided HIV counseling to the participant.*
- Deliver HIV pre-test and risk reduction counseling; obtain written informed

consent for HIV counseling if required by local regulations. *Note: Counseling must be delivered after administration of the Risk Assessment.*

- Collect, process, and deliver blood (one 10 ml purple top tube) for HIV testing at the LL according to Appendix III of the protocol; process and store plasma.
- Receive and document the participant's HIV test results; prepare accordingly for the post-test counseling session.
- At Study Month 12, obtain permission to contact the participant regarding future studies.
- Deliver HIV test result and post-test counseling; refer participant to local healthcare, social service, and/or other providers and research studies, if needed::

⇒ If HIV infection is suspected (i.e., the rapid EIA is reactive):

- Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing at the LL according to Appendix III of the protocol; process and store plasma.
- Schedule appointment for participant to receive confirmatory test results after about 14 days. If HIV infection is confirmed by WB or IFA, discontinue the participant from this study and refer him/her to appropriate medical and psychosocial services and other available research studies.
- Complete and submit all required data collection forms.

⇒ If HIV infection is ruled out (i.e., the rapid EIA is not reactive):

- At Study Month 6, schedule next Locator Contact to occur at Study Month 9 and next Follow-up Visit to occur at Study Month 12.
- At Study Month 6, reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 9 contact.
- At study Month 12, obtain permission to contact the participant regarding future studies.
- Complete and submit all required data collection forms.

#### **5.4 Interim Contacts and Visits**

Interim contacts and visits may be conducted at participant request at any time during the study in addition to the regularly scheduled visits and contacts. Interim HIV

counseling and testing will be provided as needed in response to participant reports of potential exposure to HIV. All interim contacts and visits, and the results of all interim HIV tests, will be documented in participants study records and on applicable case report forms.

If the site provides service delivery, an SOP needs to be developed distinguishing between research visits and service delivery visits. Interim Visits for service delivery do not need to be documented with the participants' study records and on case report forms.

## Section 6. Visit Checklists for Chennai

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This section contains visit and contact checklists for each scheduled study visit and contact. As noted in Section 3.2.2, these checklists are a convenient tool for study staff to fulfill the requirement of documenting all procedures performed with study participants. They also guide staff in proper study procedures and sequence and help ensure that all required procedures are completed before participants leave the study site.

Unless prior approval is obtained from the CORE Protocol Specialist, procedures must be performed in the order presented in this section and the corresponding visit checklists in section 8 of this manual. In particular, the following specifications must be followed without exception.

- Informed consent must be obtained **prior** to initiation of any screening or study procedures.
- Risk Assessment must **always** be administered **before** HIV pre-test and risk reduction counseling
- Risk Assessment must be administered by a staff member who has **not** previously provided HIV counseling to the participant.
- Pre-test counseling must be provided **before** HIV specimen collection for testing.

Site-specific tailoring of the checklists may be undertaken in consultation with the CORE Protocol Specialist prior to initiation of study operations. All checklists should bear a version number and date.

Staff need to initial and date each procedure when completing visit checklists.

# Screening and Enrollment Visit for Chennai, page 1

Participant ID:

Visit Date:

Visit Code: **1.0**

Target Study Date: **Day 0**

\_\_\_\_\_ Confirm participant identity and assign Participant ID number.

\_\_\_\_\_ Obtain written informed consent for study participation:

- Introduce the study and explain the informed consent process.
- Give the participant the informed consent form to read; discuss any questions/concerns.
- Verify participant understanding of the study.
- Obtain participant signature on the informed consent form; complete all signature blocks per local IRB requirements.
- Give participant a copy of the informed consent form.
- Document the informed consent process in a chart note and on the **Enrollment Form**.

☞ *If the participant does not provide informed consent, stop. Fax the **Enrollment Form** to SCHARP.*

\_\_\_\_\_ Obtain written informed consent for specimen storage.

- Give the participant the informed consent form to read; discuss any questions/concerns.
- Obtain participant signature on the informed consent form; complete all signature blocks per local IRB requirements.
- Give participant a copy of the informed consent form.
- Document the informed consent process in a chart note.

☞ *If the participant does not provide informed consent, continue*

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.

\_\_\_\_\_ Obtain participant contact and locator information..

\_\_\_\_\_ Administer the **Demographics Form**.

\_\_\_\_\_ Administer the **Eligibility Form**.

☞ *If the participant does not meet the eligibility criteria, stop and fax the **Demographics Form**, **Enrollment Form** and **Eligibility Form** to SCHARP.*

\_\_\_\_\_ Administer the **Risk Assessment**.

☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling.*

\_\_\_\_\_ Provide HIV pre-test and risk reduction counseling.

☞ *Obtain written informed consent for HIV counseling if required by local regulations.*

☞ *Counseling must be delivered **after** administration of the Risk Assessment.*

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for HIV testing and plasma storage at the local lab:  
*The Local Lab will process and store plasma according to Appendix G.*

\_\_\_\_\_ Receive and document the participant's HIV test results. Complete the **Local Lab Results**. Prepare accordingly for the post-test counseling session.

## Screening and Enrollment Visit for Chennai, page 2

Participant ID:	Visit Date:
Visit Code: <b>1.0</b>	Target Study Date: <b>Day 0</b>

\_\_\_\_\_ Deliver HIV test result and post-test counseling:

⇒ ***If HIV infection is suspected*** (i.e., the rapid EIA is reactive), the participant is presumptively ***ineligible***:

\_\_\_\_\_ Discontinue the study screening and enrollment process.

\_\_\_\_\_ Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing and storage at the LL, according to Appendix III of the protocol .

\_\_\_\_\_ Schedule appointment for participant to receive confirmatory test results.

*(If HIV infection is later **confirmed**, participant will **not be eligible** for study enrollment; If HIV infection is later **not confirmed**, participant will be **eligible** for study enrollment.)*

⇒ ***If HIV infection is ruled out*** (i.e., the rapid EIA is not reactive), the participant is ***eligible***:

\_\_\_\_\_ Schedule first Locator Contact to occur at study Month 3

\_\_\_\_\_ Schedule the first Month 6 Follow-up Visit.

\_\_\_\_\_ Provide study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 3 contact.

\_\_\_\_\_ Refer participant to local healthcare, social services, and/or other providers if needed.

\_\_\_\_\_ Complete **Eligibility Checklist** and **Enrollment Form**.

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

- Demographics Form (DM-1-3)
- Eligibility Form (EL-1,2)
- Risk Assessment Form (RA-1-10)
- Eligibility Checklist (EC-1-3)
- Enrollment Form (EN-1,2)
- Local Lab Results form (LL-1)

## Locator Contact (Month 3) for Chennai

Participant ID:

Visit Date:

Visit Code:       **2.0**

Target Study Date:       **Day 91**

- The Month 3 Locator Contact is scheduled to take place three months from each participant's study enrollment date, however, it may take place any time between the three-month timepoint and the participant's Month 6 Follow-up Visit.
- The contact may take place via any modality that the study sites deems appropriate for its local study population.

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 6 Follow-up visit.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Confirm schedule for the Month 6 Follow-up Visit

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

- Participant Encounter Form (PE-1)

## Follow-up Visit (Month 6) for Chennai, Page 1

Participant ID:	Visit Date:
Visit Code: <b>3.0</b>	Target Study Date: <b>Day 182</b>

- This Month 6 Follow-up Visit is scheduled to take place six months from each participant’s study enrollment date, however, the visits may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date.
- Visits that do not take place during this interval are treated as "interim visits" in which HIV counseling and testing should be provided, however, the behavioral risk assessment should not be administered (see Interim Contact Checklist later in this section).

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the visit.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Administer the **Risk Assessment**.

☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling, by a staff member who has **not** previously provided HIV counseling to the participant.*

☞ *If the visit is an “interim visit” as defined above, do not administer the Risk Assessment.*

\_\_\_\_\_ Provide HIV pre-test and risk reduction counseling.

☞ *Obtain written informed consent for HIV counseling if required by local regulations.*

☞ *Counseling must be delivered **after** administration of the Risk Assessment.*

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for HIV testing :

*The Local Lab will process and store plasma according to Appendix G.*

\_\_\_\_\_ Receive and document the participant’s HIV test results. Complete the **Local Lab Results Form**. Prepare accordingly for the post-test counseling session.

\_\_\_\_\_ Deliver HIV test result and post-test counseling:

⇒ ***If HIV infection is suspected*** (i.e., the rapid EIA is reactive):

\_\_\_\_\_ Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing at the LL, according to Appendix III of the protocol ; process and store plasma.

\_\_\_\_\_ Schedule appointment for participant to receive confirmatory test results.

\_\_\_\_\_ If HIV infection is confirmed, disenroll the participant and complete and submit **Termination Form**.

*(If HIV infection is later **not confirmed**, participant will **remain enrolled**)*

\_\_\_\_\_ Complete the **Participant Encounter Form**.

## Follow-up Visit (Study Month 6) for Chennai, Page 2

Participant ID:	Visit Date:
Visit Code: <b>3.0</b>	Target Study Date: <b>Day 182</b>
<p style="margin-left: 40px;">⇒     <b><i>If HIV infection is ruled out</i></b> (i.e., the rapid EIA is not reactive):</p> <p style="margin-left: 80px;">_____     Refer participant to local healthcare, social service, and/or other providers if needed.</p> <p style="margin-left: 80px;">_____     Schedule Month 9 Locator Contact.</p> <p style="margin-left: 80px;">_____     Schedule Month 12 Follow-up Visit.</p> <p style="margin-left: 80px;">_____     Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 9 contact.</p> <p>_____     Document the visit in a signed and dated chart note.</p> <p>_____     Review required data collection forms for accuracy and completeness and fax to SCHARP:</p> <p><b>Forms required at this visit:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Participant Encounter Form (PE-1)</li> <li><input type="checkbox"/> Risk Assessment Form (RA-1-10)</li> <li><input type="checkbox"/> Local Lab Results Form (LLR-1)</li> </ul> <p><b>Optional form (use if applicable):</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Termination Form (TM-1)</li> </ul>	

## Locator Contact (Month 9) for Chennai

Participant ID:

Visit Date:

Visit Code: **4.0**

Target Study Date: **Day 273**

- The Month 9 Locator Contact is scheduled to take place nine months from each participant's study enrollment date, however, it may take place any time between the nine-month timepoint and the participant's Month 12 Follow-up Visit.
- The contact may take place via any modality that the study sites deems appropriate for its local study population.

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 12 Follow-up visit.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Confirm schedule for the Month 12 Follow-up Visit.

\_\_\_\_\_ Document the contact in a signed and dated chart note.

\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Participant Encounter Form (PE-1)

## Follow-up Visit (Month 12) for Chennai, Page 1

Participant ID:	Visit Date:
Visit Code: <b>5.0</b>	Target Study Date: <b>Day 365</b>

- This second Follow-up Visit is scheduled to take place 12 months from each participant's study enrollment date, however, the visits may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date.
- Visits that do not take place during this interval are treated as "interim visits" in which HIV counseling and testing should be provided, however the behavioral risk assessment should not be administered (see Interim Visit Checklist later in this section).

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the visit.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Administer **Risk Assessment**.

☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling, by a staff member who has **not** previously provided HIV counseling to the participant.*

☞ *If the visit is an "interim visit" as defined above, do not administer the Risk Assessment.*

\_\_\_\_\_ Provide HIV pre-test and risk reduction counseling

☞ *Obtain written informed consent for HIV counseling if required by local regulations.*

☞ *Counseling must be delivered **after** administration of the Risk Assessment.*

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for HIV testing:

*The Local Lab will process and store plasma according to Appendix G.*

\_\_\_\_\_ Receive and document the participant's HIV test results. Complete the **Local Lab Form**. Prepare accordingly for the post-test counseling session.

\_\_\_\_\_ Deliver HIV test result and post-test counseling:

⇒ ***If HIV infection is suspected*** (i.e., the rapid EIA is reactive):

\_\_\_\_\_ Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing and plasma storage at the LL; according to Appendix III of the protocol.

\_\_\_\_\_ Schedule appointment for participant to receive confirmatory test results.

## Follow-up Visit (Study Month 12) for Chennai, Page 2

Participant ID:

Visit Date:

Visit Code: **5.0**

Target Study Date: **Day 365**

⇒ ***If HIV infection is ruled out*** (i.e., the rapid EIA is not reactive):

\_\_\_\_\_ Obtain permission to contact the participant regarding future studies.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Complete the **Termination Form**.

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

- Participant Encounter Form (PE-1)
- Risk Assessment Form (RA-1-10)
- Local Lab Results Chennai Form (LLC-1)
- Termination Form (TM-1)

## Interim Contact/Visit for Chennai

Participant ID:	Visit Date:
Visit Code: <b>x. 1, x.2, etc.</b> (variable, depends on previous visit code)	Target Study Date: <b>N/A</b>

- Visit and contacts are treated as “Interim Contact/Visit” when they do not take place during the targeted study visit window for a follow-up visit and do not take the place of a Locator Contact, but occur in addition. They may be conducted at the participant request at any time during the study.
- The contact may take place via any modality that the study sites deems appropriate for the participant.

- \_\_\_\_\_ Confirm participant identity and ID number.
- \_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.
- \_\_\_\_\_ Review/update locator information.
- \_\_\_\_\_ Provide interim HIV counseling and testing as needed in response to participant concerns and/or reports of potential exposure to HIV.  
☞ *Document all test results on a **Local Lab Results Form**.*
- \_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.
- \_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed.
- \_\_\_\_\_ Confirm schedule for the next scheduled contact/ visit.
- \_\_\_\_\_ Document the visit in a signed and dated chart note.
- \_\_\_\_\_ Complete the **Participant Encounter Form**.
- \_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Participant Encounter Form (PE-1)

**Optional form (use if applicable):**

- Local Lab Results (LL-1)

## Section 7. Study Visits For Sites NOT Performing Rapid HIV Testing (Russia and China Only)

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This section describes the study visit and contact schedule and procedure requirements for each visit and contact. It is mainly based on protocol section 5, but also contains further procedural instructions that are not available in the protocol.

The study sites in Xinjiang, Guangxi, and Saint Petersburg will perform standard (non-rapid) HIV testing for this study, and will adhere to the visit and procedures schedule specified in this section.

### 7.1 Screening Visit (approximately Day –7 to Day –14, or earlier if HIV test results are available)

Study participants will undergo eligibility screening during an in-person study visit. Written informed consent will be obtained prior to the conduct of any study procedures. Demographic and behavioral eligibility will be determined based on participant responses to a standard interview instrument. Eligibility related to HIV serostatus will be ascertained via local HIV testing in accordance with the algorithm in Appendix IV of the protocol.

- Ascertain participant identity and assign Participant ID number.
  - Explain the purpose of the visit and the informed consent and eligibility determination processes.
  - Obtain written informed consent for study participation.
  - Obtain written informed consent for specimen storage.
  - Collect participant contact and locator information.
  - Administer Demographics Form.
  - Administer Eligibility Form.
- ⇒ If the participant **does not** meet the study eligibility criteria, he/she is ineligible; discontinue participation.
- ⇒ If the participant **does** meet the study eligibility criteria, proceed with the following:
- Administer Risk Assessment. *Note: The Risk Assessment must be administered prior to the delivery of HIV counseling.*
  - Deliver HIV pre-test and risk reduction counseling; obtain written

informed consent for HIV counseling if required by local regulations.  
*Note: Counseling must be delivered after administration of the Risk Assessment.*

- Refer participant to local healthcare, social service, and/or other providers if needed.
- Collect, process, and deliver blood (one 10 ml purple top tube) to the local lab (LL) for HIV testing (according to Appendix IV of the protocol); Process and store plasma.
- Schedule Enrollment Visit to occur in approximately 7-14 days (or earlier if HIV test results are available before).
- Provide study site contact information and instructions to contact the site for additional information about the study and/or HIV counseling, if needed, prior to the Enrollment Visit.
- Complete and submit the Local Lab form and store it for faxing to SCHARP after the Enrollment Visit.

## **7.2 Between Screening and Enrollment**

- Receive and document the participant's HIV test result; prepare accordingly for the participant's Enrollment Visit.
- Complete and submit all required data collection forms.

## **7.3 Enrollment Visit (Day 0)**

Regardless of HIV test result, participants who undergo HIV testing at a Study Screening Visit also will complete an Enrollment Visit during which — at a minimum — their HIV test results will be disclosed and HIV post-test counseling will be provided. Participants who test HIV-negative and return for test results and enrollment within 28 days after their Screening Visit will be enrolled in the study, provided they are still willing to participate. Participants who test HIV-positive are ineligible and will not be enrolled.

- Confirm participant identity and ID number.
- Update locator information.
- Deliver HIV test result and post-test counseling; refer participant to local healthcare, social service, and/or other providers and research studies.

⇒ If HIV infection is confirmed by WB or IFA, the participant is ineligible:

- Discontinue the study screening and enrollment process.
- Complete and submit required data collection forms.

⇒ If HIV status is indeterminate (i.e., EIA is reactive and WB or IFA is indeterminate):

- Collect, process, and deliver blood (one 10 ml purple top tube) for repeat testing at the LL, according to Appendix IV of the protocol; process and store plasma.
- Schedule post-test visit in 7-14 days (or earlier if HIV test results are available before).
- Complete and submit required data collection forms.
- Repeat counseling, specimen collection, and testing procedures until HIV status is resolved.

⇒ If HIV infection is ruled out (i.e., the EIA is not reactive or the WB/IFA is negative), the participant is eligible:

- Schedule first Locator Contact to occur at study Month 3 and first Follow-up Pre-Test Visit to occur at study Month 6.
- Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 3 contact.
- Complete and submit all required data collection forms.

#### **7.4 Locator Contacts (Month 3 and Month 9)**

Locator Contacts are scheduled to take place three and nine months from each participant's study enrollment date. However, the Month 3 contact may take place any time between the three-month timepoint and the participant's Month 6 Follow-up Visit, and the Month 9 contact may take place any time between the nine-month timepoint and the participant's Month 12 Follow-up Visit. The contacts also may take place via any modality that the study site deems appropriate for its local study population.

- Confirm participant identity and ID number.
- Update locator information.
- Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if

needed, prior to the next scheduled visit.

- Refer participant to local healthcare, social service, and/or other providers if needed.
- Confirm schedule for next Month 6 Follow-up Pre-Test Visit.
- Complete and submit all required data collection forms.

## **7.5 Follow-up Visits (Month 6 and Month 12)**

Follow-up Pre-Test Visits are scheduled to take place six and 12 months from each participant's study enrollment date, however they may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date. Visits that do not take place during this interval are treated as "interim visits" (see Section 7.6) in which HIV counseling and testing will be provided, however the Risk Assessment will not be administered.

Follow-up Post-Test Visits are scheduled to take place 7-14 days (or earlier, if HIV test results are available before) following each Pre-Test visit.

At Study Month 6, reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 9 contact.

### **7.5.1 Follow-up Pre-Test Visits**

- Confirm participant identity and ID number.
- Update locator information.
- Administer Risk Assessment.
- Deliver HIV pre-test and risk reduction counseling; obtain written informed consent for HIV counseling if required by local regulations.
- Refer participant to local healthcare, social service, and/or other providers if needed.
- Collect, process, and deliver blood (one 10 ml purple top tube) to the LL for HIV testing (according to Appendix IV) of the protocol; Process and store plasma.
- Schedule Follow-up Post-Test Visit to occur in 7-14 days (or earlier, if HIV test results are available before).
- Reiterate study site contact information and instructions to contact the site for

additional information about the study and/or HIV counseling, if needed, prior to the Follow-up Post-Test Visit.

- Complete and submit all required data collection forms.

### **7.5.2 Between Pre-Test and Post-Test Visits**

- Receive and document the participant's HIV test result; prepare accordingly for the participant's Follow-up Post-Test Visit.
- Complete and submit all required data collection forms.

### **7.5.3 Follow-up Post-Test Visits**

Regardless of HIV test result, participants who undergo HIV testing at a Follow-up Pre-Test Visit will complete a Follow-up Post-Test Visit during which — at a minimum — their HIV test results will be disclosed and HIV post-test counseling will be delivered. Participants who test HIV-negative at study Month 6 will be maintained in study follow-up. Participants who test HIV-positive will be discontinued from the study.

- Confirm participant identity and ID number.
  - Update locator information for those participants who test HIV-negative.
  - Deliver HIV test result, and post-test counseling; refer participant to local healthcare, social service, and/or other providers and research studies.
- ⇒ If HIV infection is confirmed by WB or IFA:
- Collect, process, and deliver blood (one 10 ml purple top tube) for confirmatory re-testing at the LL according to Appendix IV of the protocol; process and store plasma.
  - Discontinue the participant from the study.
  - Schedule appointment for participant to receive confirmatory test results.
  - Complete and submit required data collection forms.
- ⇒ If HIV status is indeterminate (i.e., the EIA is reactive and the WB or IFA is indeterminate):
- Collect, process, and deliver blood (one 10 ml purple top tube) for

repeat testing at the LL, according to Appendix IV of the protocol ; process and store plasma.

- Schedule post-test visit in 7-14 days (or earlier, if HIV test results are available before).
- Complete and submit required data collection forms.
- Repeat specimen collection, counseling, and testing procedures until HIV status is resolved.

⇒ If HIV infection is ruled out (i.e., the EIA is not reactive or the WB/IFA is negative):

- At study Month 6, schedule next Locator Contact to occur at study Month 9 and next Follow-up Pre-Test Visit to occur at study Month 12.
- At study Month 6, reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 9 contact.
- At study Month 12, obtain permission to contact the participant regarding future studies.
- Complete and submit all required data collection forms.

## **7.6 Interim Contacts and Visits**

Interim contacts and visits may be conducted at participant request at any time during the study in addition to the regularly scheduled visits and contacts. Interim HIV counseling and testing will be provided as needed in response to participant reports of potential exposure to HIV. All interim contacts and visits, and the results of all interim HIV tests, will be documented in participants study records and on applicable case report forms.

If the site provides service delivery, an SOP needs to be developed distinguishing between research visits and service delivery visits. Interim Visits for service delivery do not need to be documented with the participants' study records and on case report forms.

## Section 8. Visit Checklists for Russia and China

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This section contains visit and contact checklists for each scheduled study visit and contact. As noted in Section 3.2.2, these checklists are a convenient tool for study staff to fulfill the requirement of documenting all procedures performed with study participants. They also guide staff in proper study procedures and sequence and help ensure that all required procedures are completed before participants leave the study site.

Unless prior approval is obtained from the CORE Protocol Specialist, procedures must be performed in the order presented in this section and the corresponding visit checklists in section 8 of this manual. In particular, the following specifications must be followed without exception.

- Informed consent must be obtained **prior** to initiation of any screening or study procedures.
- Risk Assessment must **always** be administered **before** HIV pre-test and risk reduction counseling
- Risk Assessment must be administered by a staff member who has **not** previously provided HIV counseling to the participant.
- Pre-test counseling must be provided **before** HIV specimen collection for testing.

Site-specific tailoring of the checklists may be undertaken in consultation with the CORE Protocol Specialist prior to initiation of study operations. All checklists should bear a version number and date.

Staff need to initial and date each procedure when completing visit checklists.

# Screening Visit for Russia & China, page 1

Participant ID:

Visit Date:

Visit Code: N/A

Target Study Date: Day -1 to -14

\_\_\_\_\_ Confirm participant identity and assign Participant ID number.

\_\_\_\_\_ Obtain written informed consent:

- Introduce the study and explain the informed consent process.
- Give the participant the informed consent form to read; discuss any questions/concerns.
- Verify participant understanding of the study.
- Obtain participant signature on the informed consent form; complete all signature blocks per local IRB requirements.
- Give participant a copy of the informed consent form.
- Document the informed consent process in a chart note and on the **Enrollment Form**.

☞ *If the participant does not provide informed consent, stop. Fax the **Enrollment Form** to SCHARP.*

\_\_\_\_\_ Obtain written informed consent for specimen storage.

- Give the participant the informed consent form to read; discuss any questions/concerns.
- Obtain participant signature on the informed consent form; complete all signature blocks per local IRB requirements.
- Give participant a copy of the informed consent form.
- Document the informed consent process in a chart note.

☞ *If the participant does not provide informed consent, continue.*

\_\_\_\_\_ Obtain participant contact and locator information.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.

\_\_\_\_\_ Administer the **Demographics Form**.

\_\_\_\_\_ Complete the **Eligibility Form**.

☞ *If the participant does not meet the eligibility criteria, stop and fax the **Demographics Form**, **Eligibility Form**, and **Eligibility Checklist** to SCHARP.*

\_\_\_\_\_ Complete the **Eligibility Checklist**.

\_\_\_\_\_ Administer the **Risk Assessment**.

☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling.*

\_\_\_\_\_ Provide HIV pre-test and risk reduction counseling.

☞ *Counseling must be delivered **after** administration of the Risk Assessment.*

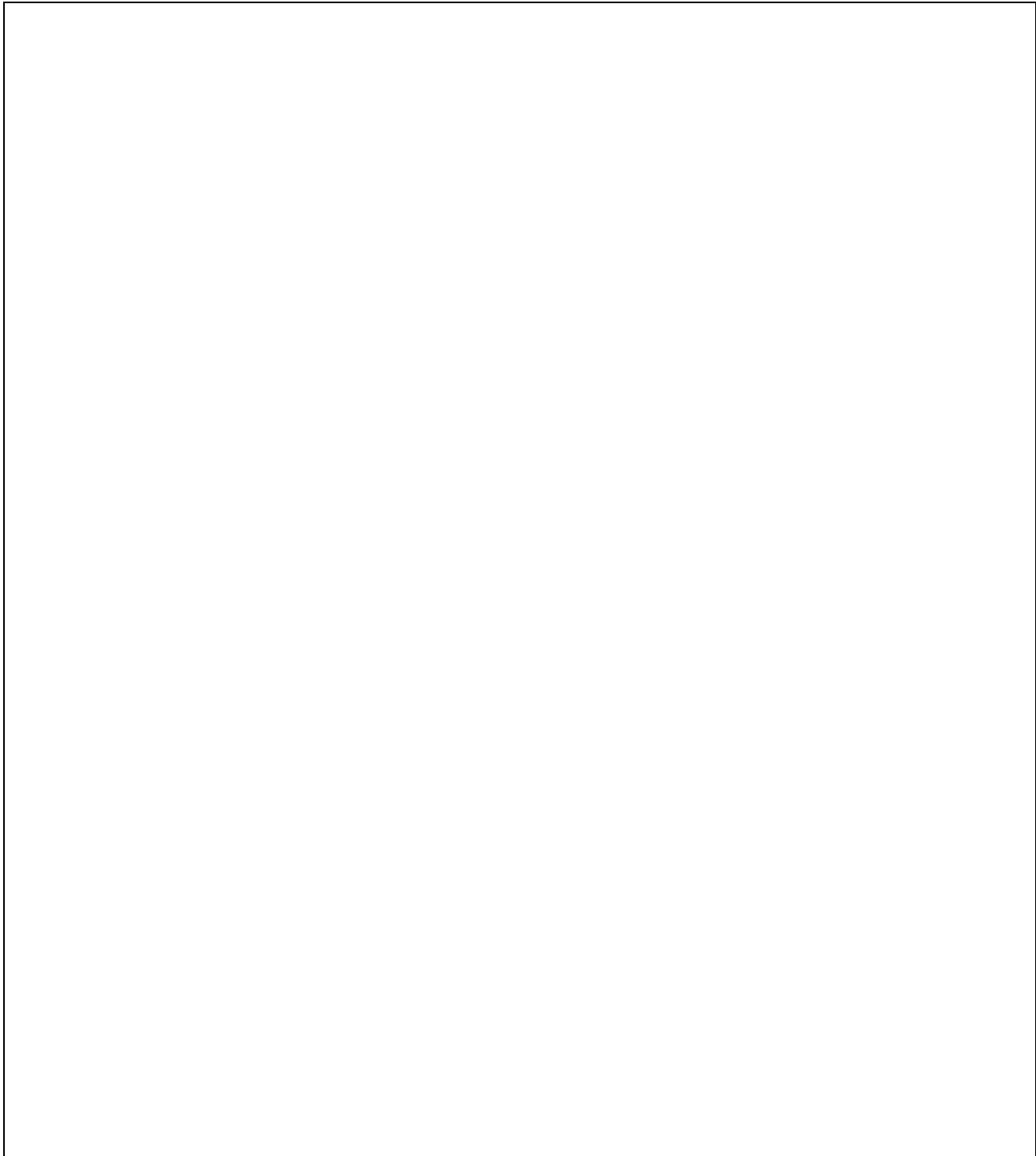
\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) to deliver to Local Lab (LL) for HIV EIA/ WB and storage.

☞ *Log the sample into LDMS.*

\_\_\_\_\_ Schedule Enrollment Visit to occur in 7-14 days (or earlier, if HIV test results are available before).

\_\_\_\_\_ Provide study site contact information and instructions to contact the site for additional information about the study and/or HIV counseling, if needed, prior to the Enrollment Visit.



## Screening Visit for Russia & China, page 2

Participant ID:	Visit Date:
Visit Code:       N/A	Target Study Date: <b>Day -1 to -14</b>

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Demographics Form (DM-1-3)
- Eligibility Form (EL-1-3)
- Eligibility Checklist (EC-1,2)
- Risk Assessment Form (RA-1-10)
- Enrollment form, if no informed consent provided

# Enrollment Visit for Russia & China, page 1

Participant ID:

Visit Date:

Visit Code: **1.0**

Target Study Date: **Day 0**

## Between Screening and Enrollment visits: (enter date completed next to staff initials)

- \_\_\_ Receive the participant's HIV test results.
- \_\_\_ Document results on **Local Lab Results Form** and store it for faxing after the enrollment visit.
- \_\_\_ Complete items 1,2,3, and 5 on the **Enrollment Form**.
- \_\_\_ Document in signed and dated chart note

## During the Enrollment Visit:

\_\_\_ Confirm participant identity and ID number.

\_\_\_ Review/update participant contact and locator information.

\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.

\_\_\_ Complete **Enrollment Form** with HIV test results.

\_\_\_ Deliver HIV test result and post-test counseling:

⇒ ***If HIV infection is confirmed*** by WB or IFA, the participant is ***ineligible***:

\_\_\_ Discontinue the study screening and enrollment process.

⇒ ***If HIV status is indeterminate*** (i.e., EIA is reactive and WB or IFA is indeterminate):

\_\_\_ Collect blood (one 10 ml purple top tube) for repeat EIA/ WB at the Local Lab (LL) for HIV testing and plasma processing and storage.

☞ *Log sample into LDMS.*

\_\_\_ Schedule post-test visit in 7-14 days.

\_\_\_ Repeat specimen collection, counseling, and testing procedures until HIV status is resolved.

***Document all visits in signed and dated chart notes.***

⇒ ***If HIV infection is ruled out*** (i.e., the EIA is not reactive or the WB/IFA is negative), the participant is ***eligible***:

\_\_\_ Schedule Month 3 Locator Contact and Month 6 Follow-up Pre-Test Visit.

\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 3 Contact.

## Enrollment Visit for Russia & China, page 2

Participant ID:

Visit Date:

Visit Code: **1.0**

Target Study Date: **Day 0**

\_\_\_\_\_ Refer to local health care, social services and/ or other providers if needed.

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Local Lab Results Form (LL-1)
- Enrollment Form (EN-1,2)

## Locator Contact (Month 3) for Russia & China

Participant ID:

Visit Date:

Visit Code: **2.0**

Target Study Date: **Month 3**

- The Month 3 Locator Contact is scheduled to take place three months from the participant's study enrollment date, however, it may take place any time between the three-month timepoint and the participant's Month 6 Follow-up Pre-Test Visit (scheduled 14 days prior to target date for Month 6 Follow-up Visit).
- The contact may take place via any modality the study site deems appropriate for its local study population.

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Confirm schedule for the Month 6 Follow-up Pre-Test Visit.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 6 Follow-up Pre-test visit.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Document the contact in a signed and dated chart note.

\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

- Participant Encounter Form (PE-1)

## Follow-up Pre-test Visit (Month 6) for Russia & China

Participant ID:	Visit Date:
Visit Code: <b>3.0</b>	Target Study Date: <b>Day 182</b>

- This Follow-up Visit is scheduled to take place 6 months from each participant's study enrollment date, however, the visits may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date.
- Visits that do not take place during this interval are treated as "interim visits" in which HIV counseling and testing should be provided, however the Risk Assessment should not be administered (see Interim Visit Checklist later in this section).

- \_\_\_\_\_ Confirm Participant identity and ID number.
- \_\_\_\_\_ Review elements of informed consent as needed.
- \_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.
- \_\_\_\_\_ Review/update locator information.
- \_\_\_\_\_ Administer the **Risk Assessment**.
  - ☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling by a staff member who has not previously provided HIV counseling to the participant.*
- \_\_\_\_\_ Provide HIV pre-test and risk reduction counseling.
  - ☞ *Counseling must be delivered **after** administration of the Risk Assessment.*
- \_\_\_\_\_ Collect blood (one 10 ml purple top tube) to deliver to Local Lab (LL) for HIV EIA/WB and storage.
  - ☞ *Log the sample into LDMS.*
- \_\_\_\_\_ Schedule the Follow-up Post-Test Visit to occur in 7-14 days (or earlier, if HIV test results are available).
- \_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study and/or HIV counseling, if needed, prior to the Follow-up Post-Test Visit.
- \_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.
- \_\_\_\_\_ Document the visit in a signed and dated chart note.
- \_\_\_\_\_ Complete the **Participant Encounter Form**.
- \_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Participant Encounter Form (PE-1)
- Risk Assessment (RA-1-10)

# Follow-up Post-Test Visit (Month 6) for Russia & China page 1

Participant ID: \_\_\_\_\_

Visit Date: \_\_\_\_\_

Visit Code: **4.0**

Target Study Date: **1 to 14 days after Pre-Test Visit**

## Between Pre-Test and Post-Test Visits (*enter date completed next to staff initials*):

- \_\_\_\_\_ Receive the participant's HIV test results.
- \_\_\_\_\_ Document results on **Local Lab Results Form** and store it for faxing after the 6 Month Post-Test Visit.
- \_\_\_\_\_ Document HIV result in signed and dated chart note

## During the Follow-up Post-Test visit:

\_\_\_\_\_ Confirm participant identity and Participant ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Deliver HIV test result and post-test counseling; refer participant to local healthcare, social service, and/or other providers and research studies.

⇒ ***If HIV infection is confirmed*** by WB or IFA:

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for confirmatory HIV WB and plasma processing and storage at the Local Lab (LL).

☞ *Log sample into LDMS.*

\_\_\_\_\_ Schedule appointment for participant to receive confirmatory test results.

*After confirmation of test*

\_\_\_\_\_ Discontinue the participant from the study.

\_\_\_\_\_ Complete **Termination Form**.

⇒ ***If HIV status is indeterminate*** (i.e., EIA is reactive and WB or IFA is indeterminate):

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for repeat EIA/ WB at the Local Lab (LL) for HIV testing and plasma processing and storage.

☞ *Log sample into LDMS.*

\_\_\_\_\_ Schedule post-test visit in 7-14 days (or earlier if HIV test results are available).

\_\_\_\_\_ Repeat specimen collection, counseling, and testing procedures until HIV status is resolved.

***Document all visits in signed and dated chart notes.***

⇒ ***If HIV infection is ruled out*** (i.e., the EIA is not reactive or the WB/IFA is negative):

\_\_\_\_\_ Schedule Month 9 locator contact and Month 12 Follow-up Pre-Test Visit.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 9 contact.

## Follow-up Post-Test Visit (Month 6) for Russia & China page 2

Participant ID:

Visit Date:

Visit Code: **4.0**

Target Study Date: **7-14 days after Pre-Test Visit**

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Complete the **Participant Encounter** Form.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

π Participant Encounter Form(PE-1)

π Local Lab Results Form (LL-1)

### Optional form (use if applicable):

π Termination Form (TM-1) after confirmatory visit

## Locator Contact (Month 9) for Russia & China

Participant ID:

Visit Date:

Visit Code: **5.0**

Target Study Date: **Month 9**

- The Month 9 Locator Contact is scheduled to take place three months from the participant's study enrollment date, however, it may take place any time between the nine-month timepoint and the participant's Month 12 Pre-Test Follow-up Visit (scheduled 14 days prior to target date for Month 12 Follow-up Visit).
- The contact may take place via any modality the study site deems appropriate for its local study population.

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Confirm schedule for the Month 12 Follow-up Pre-Test Visit.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed, prior to the Month 6 Follow-up Pre-test visit.

\_\_\_\_\_ Document the contact in a signed and dated chart note.

\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

### Forms required at this visit:

- Participant Encounter Form (PE-1)

## Follow-up Pre-test Visit (Month 12) for Russia & China

Participant ID:	Visit Date:
Visit Code: <b>6.0</b>	Target Study Date: <b>Day 365</b>

- This Follow-up Visit is targeted to take place 12 months from the participant's study enrollment date, however, the visits may take place any time within the period extending from 14 days prior to the target date to 30 days after the target date.
- Visits that **do not** take place during this interval are treated as "interim visits" and documented on the **Interim Visit Form** and the **Participant Encounter Form** (see Interim Visit Checklist later in this section).

- \_\_\_\_\_ Confirm Participant identity and ID number.
- \_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.
- \_\_\_\_\_ Review/update locator information.
- \_\_\_\_\_ Administer the **Risk Assessment**.  
☞ *The Risk Assessment must be administered **prior** to the delivery of HIV counseling by a staff member who has not previously provided HIV counseling to the participant..*
- \_\_\_\_\_ Provide HIV pre-test and risk reduction counseling.  
☞ *Counseling must be delivered **after** administration of the Risk Assessment.*
- \_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.
- \_\_\_\_\_ Collect blood (one 10 ml purple top tube) to deliver to Local Lab (LL) for HIV EIA/WB and plasma storage.  
☞ *Log sample into LDMS.*
- \_\_\_\_\_ Schedule the Follow-up Post-Test Visit to occur in 7-14 days.
- \_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study and/or HIV counseling, if needed, prior to the Follow-up Post-Test Visit.
- \_\_\_\_\_ Document the visit in a signed and dated chart note.
- \_\_\_\_\_ Complete the **Participant Encounter Form**.
- \_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Participant Encounter Form (PE-1)
- Risk Assessment (RA-1-10)

## Follow-up Post-Test Visit (Month 12) for Russia & China

Participant ID: \_\_\_\_\_

Visit Date: \_\_\_\_\_

Visit Code: **7.0**

Target Study Date: **Days 358-364**

**Between Pre-Test and Post-Test Visits (*enter date completed next to staff initials*):**

- \_\_\_\_\_ Receive the participant's HIV test results.
- \_\_\_\_\_ Document results on **Local Lab Results Form** and store it for faxing after the 12 Month Post-Test Visit.
- \_\_\_\_\_ Document HIV result in signed and dated chart note

**During the Follow-up Post-Test visit:**

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.

\_\_\_\_\_ Review/update participant contact and locator information.

\_\_\_\_\_ Deliver HIV test result and post-test counseling:

⇒ ***If HIV infection is confirmed***

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for confirmatory re-testing to deliver to Local Lab (LL) for HIV testing and plasma processing and storage.  
☞ *Log sample into LDMS.*

\_\_\_\_\_ Schedule appointment for participant to receive confirmatory test results.

\_\_\_\_\_ Discontinue the participant from the study.

⇒ ***If HIV status is indeterminate*** (i.e., EIA is reactive and WB or IFA is indeterminate):

\_\_\_\_\_ Collect blood (one 10 ml purple top tube) for confirmatory re-testing to deliver to Local Lab (LL) for HIV testing and plasma processing and storage.  
☞ *Log sample into LDMS.*

\_\_\_\_\_ Schedule post-test visit in 7-14 days (or earlier, if HIV test results are available).

\_\_\_\_\_ Repeat specimen collection, counseling, and testing procedures until HIV status is resolved.

⇒ ***If HIV infection is ruled out*** (i.e., the EIA is not reactive or the WB/IFA is negative):

\_\_\_\_\_ Obtain permission to contact the participant regarding future studies.

\_\_\_\_\_ Complete the **Termination Form**.

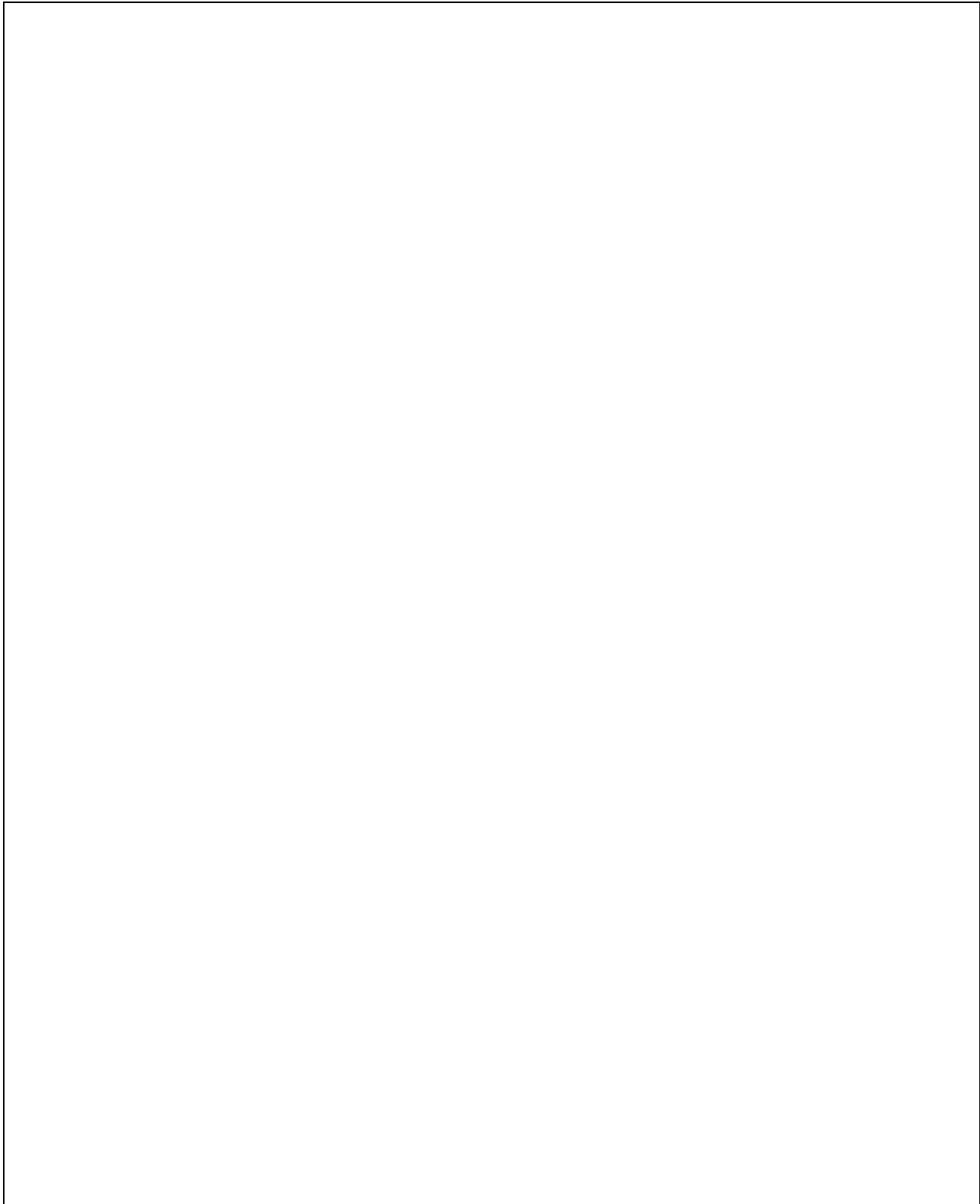
\_\_\_\_\_ Complete the **Participant Encounter Form**.

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

**Forms required at this visit:**

- Local Lab Result Form (LLR-1)
- Participant Encounter Form (PE-1)
- Termination Form (TM-1)



## Interim Contact/Visit for Russia & China

Participant ID:

Visit Code: x.1, x.2

Visit Date:

- Visit and Contacts are treated as “Interim Contact/Visit” when they do not take place during the targeted study visit window. They may be conducted at the participant request at any time during the study.
- The contact may take place via any modality that the study sites deems appropriate for the participant.

\_\_\_\_\_ Confirm participant identity and ID number.

\_\_\_\_\_ Determine reason for interim visit.

\_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the contact.

\_\_\_\_\_ Review/update locator information.

\_\_\_\_\_ Refer participant to local healthcare, social service, and/or other providers if needed.

\_\_\_\_\_ Reiterate study site contact information and instructions to contact the site for additional information about the study, HIV counseling, and/or HIV testing, if needed.

\_\_\_\_\_ Confirm schedule for the next scheduled contact/ visit.

\_\_\_\_\_ Document the visit in a signed and dated chart note.

\_\_\_\_\_ Review required data collection forms for accuracy and completeness and fax to SCHARP:

\_\_\_\_\_ Complete the **Participant Encounter Form**.

☞ *Provide interim HIV counseling and testing as needed in response to the participant's concerns and reports of potential exposure to HIV. Document all test results on a Local Lab Results Form.*

### Forms required at this visit:

- Participant Encounter Form (PE-1)

### Other forms, as applicable

- Comments Form (COM-1)
- Local Lab Form (LLR-1)

## Section 9. Participant Retention

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Study staff must make every effort to retain all enrolled study participants for the duration of the study. Successful retention begins with collection of exhaustive locator information from each study participant. It also relies on development and implementation of a comprehensive retention plan. Both of these components are described below.

### 9.1 Obtaining and Updating Locator Information

All study participants will be asked to provide locator information at their first study visit. Provision of "adequate" locator information is a study eligibility requirement. The HPTU must specify its definition of adequate locator information in a study retention plan (see Section 9.2).

The HPTU is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. The following is a list of potential locator items:

- Participant's name, alias, and/or nickname; social security number; driver's license state and number; home address; home phone number; cell phone number; pager number; work address; work phone number; fax number; e-mail address; daytime and night time hangouts.
- Name, address, telephone number, and/or other contact information for stable community contacts who typically know the whereabouts of the participant.

*Note: Although contact information for a participant's current primary partner will likely be useful, contact information for other contacts also should be collected, since it is possible that the participant could end his relationship with this partner during the course of the study.*

- Name, address, telephone number, and/or other contact information for the participant's health care provider, school or training program; social service case worker; drug counselor, rehabilitation provider, etc.
- Name, address, telephone number, and/or other contact information for support groups, shelters, food pantries, etc. frequented by the participant.

During the informed consent process and when collecting locator information, study participants must be informed that their locator sources will be contacted if study staff are unable to locate the participant directly. Study staff will negotiate with the participant how they will identify themselves when locator sources are contacted.

Study staff should view every participant contact as an opportunity to update the participant's locator information. When updating locator information, staff should actively review each item on the locator form to determine whether the information is still current (i.e., rather than simply asking "Has any of your information changed since your last visit?"). Staff also should probe for additional information that the participant was not able or willing to provide at previous visits.

### 9.2 Retention Plan

HPTU staff are responsible for establishing a retention plan for this study, and for updating the plan and retention efforts undertaken, if needed, to meet the 95% study retention goal. The retention plan — including a copy of the study locator form — should be stored with the “local study-specific SOPs”.

The retention plan should include comprehensive and detailed specification of time frames, procedures, and staff responsibility for identifying when scheduled contacts and study visits are due, reminding participants of their appointment dates, and taking action on missed contacts and visits.

Some additional tips for successful retention strategies are as follows:

- Work with community members to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
- Keep participants and community members up-to-date on study progress, to foster a sense of partnership and ownership of the study (through the use of participant newsletters, for example).
- Inform local service providers who interact with the local study population about the study, so that they also can express their support for it.
- Dedicate adequate staff time and effort to retention efforts.
- Emphasize the value of the participant’s involvement in the study during the study informed consent process and subsequently at follow-up visits.
- Develop and implement a tracking system to easily identify when participants’ scheduled visits and contacts are due. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled contacts and visits.
- Prepare a calendar of scheduled contacts and visits for each enrolled participant, based on his enrollment date (or offer a planner calendar as a participant incentive and note all scheduled visits and contacts in it). Note the dates of all scheduled visits and contacts in the participant’s file for easy reference.
- Schedule follow-up visits for the beginning of the allowable visit window (i.e., up to 14 days before the actual target date) to allow maximum time for re-contact and re-scheduling if needed.
- Always schedule the participants’ next contact and/ or visit before he/ she completes the prior contact or visit. Give the participant an appointment card with the scheduled contact or visit date and time noted.
- Follow-up on missed visits with an attempt to re-contact/ re-schedule within 24 hours (preferably on the same day). Continue these efforts per the local retention plan until contact is made.
- Keep locator information up-to-date and maintain thorough documentation of all efforts to contact the participant. Keep all this information in an organized manner, so that different staff members can easily review the information and contribute to re-contact efforts when necessary.
- Pay close attention to the allowable visit window (extending 14 days before and 30 days after the target date) and prioritize retention efforts for participants nearing the end of the window. Organize daily caseloads and work assignments based on these priorities.

- Make use of all information collected on the participant's locator form. Even if a locator source is not useful/ successful on one occasion, try it again later.
- Make use of all available contact methods (e.g. phone, mail, home visits, street outreach, newspapers, e-mail/ internet), Also make use of other available locator information sources, such as phone and post office directories and other public registries.
- Post outreach workers at other local service organizations utilized by the study population.
- Schedule parties and/ or other social events for participants.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
- For home and other community based efforts, if applicable and allowed by local regulations, utilize staff with phlebotomy training, so that specimens for HIV testing can be collected in the field.
- If a participant reports that he wishes to discontinue participation in the study, ask if he would be willing/ interested to continue having semiannual HIV testing, or at least a final study test at study month 12. If the participant refuses this level of involvement, explain that he is always welcome to come back if he wishes.

## **Section 10. Data Collection**

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To be inserted (from Stat Center)

## **Section 11. Study Reporting Requirements**

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To be provided by SCHARP

## **Section 12. Laboratory Procedures**

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To be provided by SCHARP

## **Section 13. Sample Tables**

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To be provided by SCHARP

